

5 June 2002

Dear District Health Board representatives

## **CONSULTATION RELATING TO THE NATIONAL HOSPITAL PHARMACEUTICAL STRATEGY**

*This letter contains:*

- *A draft list of pharmaceuticals used in hospitals for which PHARMAC proposes to seek national supply contracts (consultation responses due 31 July 2002).*
- *A draft hospital pharmaceutical tender document (consultation responses due 31 July 2002).*
- *A draft supplement to PHARMAC's operating policies and procedures (OPPs) (consultation due 5 July 2002).*
- *An invitation to attend a seminar on the National Hospital Pharmaceutical Strategy.*

Changes are proposed within these documents, which will impact upon your District Health Board (DHB). You are invited and encouraged to comment on any or all of these issues.

This document and its appendices are also available in electronic format on the PHARMAC website: [www.pharmac.govt.nz](http://www.pharmac.govt.nz). Additional copies can also be obtained by contacting Jessica Nisbet at PHARMAC on 0800 66 00 50 or emailing [jessica.nisbet@pharmac.govt.nz](mailto:jessica.nisbet@pharmac.govt.nz).

### ***The proposed national contracting process for hospital pharmaceuticals***

PHARMAC has developed a Hospital Product List containing pharmaceuticals including the top 90% of pharmaceutical expenditure for DHBs' hospitals, for which national contracts are sought. The list contains some pharmaceuticals that are still on patent and some for which generic competition already exists within New Zealand. Suppliers have been asked to submit proposals for any pharmaceuticals used within hospitals in anticipation of a national tender for hospital pharmaceuticals (the Tender). This process is referred to as the "Alternative Commercial Proposal (ACP) Process". Pharmaceuticals for which proposals are accepted or likely to be accepted by PHARMAC, and those which are known by PHARMAC to still be on patent, will be removed from the list before the Tender.

Contracts awarded in respect of pharmaceuticals for use in hospitals are likely to be similar to those awarded in the community with one key exception. Where market exclusivity is sought by the supplier (whether via an ACP or a tender bid), such rights to exclusivity will be subject to limits, within which DHBs will have the discretion to use alternative products. These provisions are referred to as the "Discretionary Variance (DV) Limits." If the DV Limit for 1mg prednisone tablets is 5% then 95% of the volume of 1mg prednisone tablets purchased by DHBs nationally should be that brand which has been awarded a national contract. Where the volumes of other brands purchased by DHBs nationally exceeded 5%, PHARMAC would endeavour to identify those DHBs whose use was contributing to the average and remind them of their contractual obligations.

The draft Hospital Pharmaceutical Tender Document is based on PHARMAC's existing community tender document and process. Some key features of the draft Hospital Pharmaceutical Tender Document are:

- **Hospital Supply Status** – This is the status awarded to the successful tenderer and its brand of the pharmaceutical. With the exception of purchasing DV Pharmaceuticals within the DV Limit, DHBs are required (once their current supply contracts for that chemical entity expire) to purchase the pharmaceutical with Hospital Supply Status during the first transition period and the Hospital Supply Period.

- **Term of the contract** – “Hospital Supply Status” awarded under the tender will be for a period until 30 June 2004 with provision to extend the period until 30 June 2005.
- **Price vs. subsidy** – Subsidies do not apply in the hospital sector. All national hospital pharmaceutical contracts, including the tender document, will specify a price (ex manufacturer, excluding GST), at which all DHBs’ hospitals will be able to purchase the pharmaceutical. Hospital prices will not automatically apply in the community sector.
- **Provision for supply to the community** – The draft Hospital Pharmaceutical Tender Document contains provision for PHARMAC to negotiate supply of the pharmaceutical at the agreed price for supply to community pharmacies. Where such agreement is reached, it is envisaged that the pharmaceutical would be fully subsidised at the agreed price.
- **Distribution arrangements** – Suppliers will supply the pharmaceutical to wholesalers and other distributors at the specified price. Where pharmaceuticals are supplied directly to DHBs’ hospitals, current distribution costs, if any, will continue to apply. (Refer to “*Potential Risks for DHBs*”)
- **DV Limits** – as previously explained.
- **Penalty for DV Limit breach** – The draft Hospital Pharmaceutical Tender Document contains provision for PHARMAC to seek compensation from DHBs for suppliers where a loss in market volume results from breach of the DV Limit. For more on this, refer to clause 2.6 of Schedule Five of the draft Tender Document and “*Potential Risks for DHBs*”.
- **Transitional arrangements** – The draft Hospital Pharmaceutical Tender Document contains provision for current contracts between suppliers and individual DHBs to be phased out before DV Limits will apply. (Refer to clause 1.9 of Schedule Two of the draft Tender Document)
- **Evaluation** – The process and matters for evaluation will be done at a national level using a variety of committees representing DHBs and Clinicians. Refer to Clause 5 of Schedule Three of the Tender Document and “*Proposed Evaluation Process*” for more information.
- **Section H of the Pharmaceutical Schedule** – Pharmaceuticals for which national contracts are awarded will be listed in Section H. Section H will also include details of the contract (e.g. DV Limits, pharmaceuticals covered within DV Limits etc). PHARMAC proposes to make Section H available to clinicians and pharmacists, including those who do not work within a hospital.

### ***Proposed Evaluation Process***

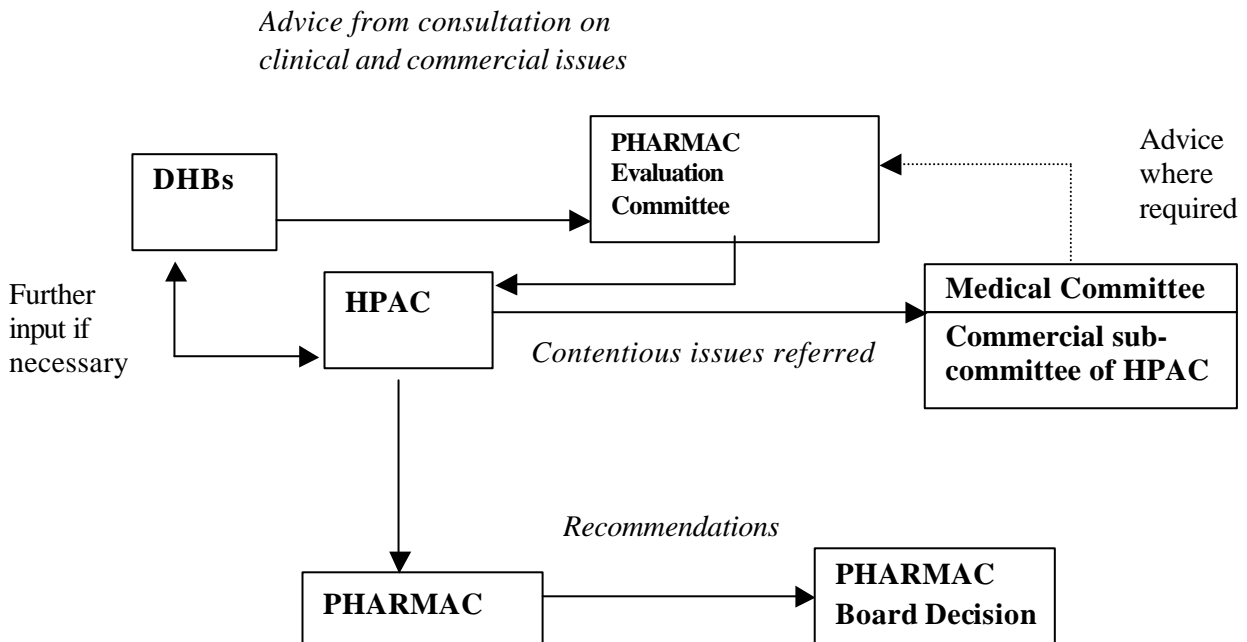
PHARMAC has attempted to develop an evaluation process that is both practical and ensures the concerns of all DHBs are considered. For this reason it is proposed that the bulk of the evaluation be done by a PHARMAC Hospital Evaluation Committee comprising 2-3 PHARMAC staff members and an independent observer. This evaluation could take into account the preferences of each individual DHB as collected via this consultation process. At this stage, PHARMAC would seek advice from a commercial sub-committee (2-3 members of the Hospital Pharmaceutical Advisory Committee (HPAC)) and/or a medical committee (which could, for example, be a sub-committee of PTAC comprising some HPAC members and some clinicians) if it considered there to be a need to.

It is envisaged that HPAC would then review the recommendations of the PHARMAC Hospital Evaluation Committee (seeking feedback from DHBs not involved in HPAC where necessary). Any issues that HPAC considered contentious would then be referred to the commercial sub-committee and/or medical committee.

Final recommendations would be taken to the PHARMAC Board who would decide, at its sole discretion, whether or not to accept each specific proposal.

Assessment of ACPs could follow a similar evaluation process. PHARMAC staff could undertake an initial evaluation; HPAC (or a sub-committee thereof) would then consider the proposal, which could be progressed to provisional agreement stage. The provisional agreement would then be consulted on with

the industry and DHBs as per PHARMAC's usual process. Following consultation, a recommendation would be made by PHARMAC staff to the Board. The main difficulty would be assessing the impact of complex proposals on DHBs. HPAC has recommended that proposals should only be assessed in respect of their net impact nationally (as opposed to the impact on individual DHBs).



### **Potential Risks for DHBs**

- **Distribution costs** - PHARMAC is concerned that DHBs might be exposed to a risk of higher distribution costs if national supply contracts for pharmaceuticals are based on cost ex manufacturer prices without consideration of distribution costs. An attempt was made to cover off this risk in the draft Tender Document but the provisions proved too complex and unwieldy. The approach now proposed is to accept bids/proposals based on a price (cost ex manufacturer) assuming the current logistics arrangements would apply. While this leaves those DHBs who do not purchase directly from suppliers potentially exposed to increased distribution costs, these costs can be monitored. If it becomes apparent that distribution costs are rising, the issue should be addressed via national logistics arrangements negotiated by PHARMAC.
- **Penalties for non-compliance with DV Limits** – The concept of contractual penalty provisions enforceable on DHBs for non-compliance with DV Limits was introduced in the *National Hospital Pharmaceutical Strategy (Feb 2002)*. Such provisions are still considered necessary to ensure that suppliers are sufficiently assured that they will obtain expected market share, to encourage competitive price bids. The provisions proposed by PHARMAC expose each non-compliant DHB to a minimum penalty of \$5,000 per line item involved in the breach. Enforcement of the provisions is contingent on:
  - (1) the ability of PHARMAC and/or suppliers to identify non-compliant DHBs and calculate the level of non-compliance; and
  - (2) the ability of PHARMAC to collect the payment required.

Without a national dataset of information about DHB pharmaceutical utilisation, it may be difficult to identify non-compliant DHBs and calculate the level of non-compliance. PHARMAC endeavours to establish a national database as this is viewed as being critical to the *National Hospital Pharmaceutical Strategy*. More information regarding this will be sent out in due course.

Possible mechanisms for collecting penalties include:

- withholding of rebates payable under contracts negotiated by PHARMAC via the ACP process;
- deducting the penalty from payments made to DHB via the Vote Health funding stream;
- payment to PHARMAC or the supplier on invoice; and/or
- obtaining a signed agreement between PHARMAC and DHBs in advance for DHBs to pay penalties endorsed by PHARMAC on invoice from the supplier.

### ***Feedback on national contracting process***

While feedback is welcome on any aspect of this document and its attachments, PHARMAC is seeking specific input from you on:

- The appropriate DV Limit for each pharmaceutical on the Hospital Pharmaceutical List. The HPAC has suggested DV Limits for some products. In these cases, and where no indicative DV Limit has been recommended, PHARMAC would welcome comment/suggestions on the appropriate DV Limit. Space has been provided on the list for you to write your comments. If you suggest that the DV Limit should be different from that proposed, please provide the rationale for such a change.
- Products where you would wish there to be back-up supply (BUS) contracts (i.e. pharmaceuticals where an out of stock occurrence would lead to serious clinical implications for patients stabilised on that medication such that it would be worth contracting for alternative stock to be held on reserve in case of an out of stock). Where a need for BUS contracts is indicated, PHARMAC will endeavour to secure such contracts to help reduce the risk of supply issues. Please indicate on the Hospital Pharmaceutical List (using the tick boxes provided) those products for which you would like PHARMAC to negotiate BUS contracts.
- Clinical and/or other issues affecting your DHB that you consider should be considered in PHARMAC's decision-making process. Where such considerations are consistent with the assessment criteria set out in section 6.4 of the *National Hospital Pharmaceutical Strategy (Feb 2002)*, PHARMAC will include them in its evaluation.
- The acceptability of the evaluation process and/or amendments and/or alternative processes.
- The acceptability of the level of risk associated with the proposed approach to distribution costs.
- The acceptability of provisions for penalties to be imposed on DHBs for non-compliance with DV Limits and the preferred mechanisms for obtaining penalty payments.

### ***Consultation on Supplement to OPPs***

On the whole PHARMAC's existing OPPs continue to apply to hospital pharmaceuticals. PHARMAC invites consultation on the attached draft supplement to the OPPs which clarifies the application of the OPPs to hospital pharmaceuticals and sets out any amendments and additions required.

### ***Consultation responses***

If you wish to address the above issues and provide any other comments you have on the draft Hospital Tender Document and/or the Tender List please send them to PHARMAC by 5pm, Wednesday 31 July 2002.

Please provide any comments you have on the draft supplement to the OPPs to PHARMAC by 5pm, Friday 5 July 2002.

The product list has been adapted, to allow for distribution and quick reporting of any issues by your colleagues. It would be useful if, once all consultation responses have been received from your

colleagues, you compile them and submit one response on behalf of you DHB, incorporating the views of all those you consider appropriate to provide feedback.

***Invitation to a Seminar***

PHARMAC will be holding a series of 1.5-2 hour seminars for DHB staff on the *National Hospital Pharmaceuticals Strategy* over the period 10-14 June during which further explanation of the Hospital Tender and ACP process will be provided. PHARMAC invites you or employees/colleagues to attend any of these seminars you would like to attend. If you wish to attend, please RSVP by 7 June to Jessica Nisbet (Email: [jessica.nisbet@pharmac.govt.nz](mailto:jessica.nisbet@pharmac.govt.nz)) indicating how many people from your organisation intend to be present and also which seminar you intend coming to.

Details of proposed seminars are as follows:

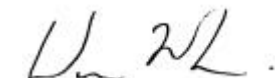
<b>Location</b>	<b>Date</b>	<b>Details</b>
Wellington	10 June 2002	12:30pm Small Lecture Theatre, Level D Wellington School of Medicine
Hamilton	12 June 2002	2pm Bryant Education Centre, Waikato Hospital
Auckland	13 June 2002	1:30pm 4 <sup>th</sup> Floor Lecture Theatre, Auckland Hospital
Napier	14 June 2002	2pm Education Centre, Hawke's Bay Hospital Hastings
Dunedin	17 June 2002	10:30am Room A, Fraser Building Cnr Cumberland and Hanover St Dunedin Hospital
Christchurch	17 June 2002	3:30pm Level 5, Princess Margaret Hospital Christchurch Hospital

***Contact details***

Meanwhile, if you have any questions about the Hospital Tender or ACP process, you should contact Matthew Perkins (DDI: +4 9167 504; Email: [matthew.perkins@pharmac.govt.nz](mailto:matthew.perkins@pharmac.govt.nz)) or Cristine Della Barca (DDI: +4 9167 514; Email: [cristine.dellabarca@pharmac.govt.nz](mailto:cristine.dellabarca@pharmac.govt.nz)) at PHARMAC.

We look forward to hearing from you.

Yours sincerely



Wayne McNee  
Chief Executive

Encl: Draft product list, draft hospital tender document, draft supplement to PHARMAC's Operating Policies and Procedures

**National Hospital Pharmaceutical Strategy**

**Consultation Documents**

**Appendix One**

**Draft Hospital Tender Document**

[Date]

Dear Supplier

## INVITATION TO TENDER – SUPPLY OF PHARMACEUTICALS TO DHB HOSPITALS

PHARMAC invites tenders for the supply of certain pharmaceuticals to DHB hospitals in New Zealand.

This invitation to tender incorporates the following schedules:

- (a) Schedule 1 sets out the definitions used in this invitation;
- (b) Schedule 2 specifies the pharmaceuticals for which you may submit a tender bid and/or a back supply proposal;
- (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 and/or a back-up supply proposal;
- (d) Schedule 4 sets out the forms you must use if you wish to submit a tender bid or a back-up supply proposal;
- (e) Schedule 5 sets out the terms that will apply if your tender bid is accepted;
- (f) Schedule 6 sets out indicative terms for the purposes of negotiating an agreement for back-up supply status between you and PHARMAC if PHARMAC wishes to accept your proposal for back-up hospital supply.

If you wish to submit a tender bid and/or a back-up supply proposal, you must submit it to PHARMAC no later than [**Time**] pm (New Zealand time) on [**Day**] [**Date**], 2002.

If you have any inquiries about this invitation you should contact Cristine Della Barca or Matthew Perkins at PHARMAC.

We look forward to receiving your tender.

Yours sincerely

Wayne McNee  
Chief Executive

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# Schedule 1: Definitions and interpretation

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## 1. Definitions

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In this Invitation:

**Aggregated Tender Bid** means a Tender Bid that is specified to be an Aggregated Tender Bid and that includes more than one Tender Item of the same Chemical Entity that PHARMAC is to consider in aggregate (but does not include aggregation within a single Tender Item);

**Agreement** means Schedule Five and includes, to the extent applicable, the other Schedules comprising the Invitation;

**Alternative Pharmaceutical** means an alternative brand of the Pharmaceutical that PHARMAC considers at its sole discretion to be an acceptable substitute for a Pharmaceutical;

**Back-up Supply Proposal** means a proposal for Back-up Supply Status for a particular Tender Item;

**Back-up Supply Status** means the status of being the back-up supplier of a particular Tender Item in the event that Hospital Supply Status for that Tender Item is suspended under clause 2.8 of Schedule Five;

**Back-up Supply Submission Form** means the form on which you must submit your Back-up Supply Proposal, and which is attached to the Offer Letter, as set out in Schedule Four;

**Chemical Entity** means any pharmaceutical that contains, and is described generically according to, the relevant active ingredient specified in Schedule Two;

**Confidential Information** means all information exchanged between us under this Invitation 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);

**Crown Direction** means any ministerial direction given to PHARMAC under section 65 of the New Zealand Public Health and Disability Act 2000;

**Deadline** means [*time*] pm, [*Day*], [*Date*], 2002 (New Zealand time);

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

**Direct Supply Requirements** means, for a DHB requiring a Tender Item to be supplied directly to its DHB Hospital(s), the direct supply terms and conditions that are agreed, from time to time, between you and the relevant DHB or any direct supply terms and conditions that are set out in a National Logistics Provider Agreement;

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

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**DV Limit** means the discretionary variance limit available to DHB Hospitals during the First Transition Period and the Hospital Supply Period in respect of patients whose exceptional needs require a DV Pharmaceutical to be prescribed and is to be expressed as a percentage of the total market volume of the relevant Chemical Entity, such total market volume being based on data available to PHARMAC, up to which a given DHB Hospital has the discretion to purchase DV Pharmaceuticals. The discretionary variance limit is to be set for DHB Hospitals nationally:

- (a) for the number of months during which the First Transition Period and/or the Hospital Supply Period applies during the period ending on 30 June 2003; and
- (b) for the respective 12 month periods ending on 30 June 2004 and 30 June 2005, as applicable;

**DV Pharmaceutical** means a pharmaceutical, being the same Chemical Entity as the Pharmaceutical, that does not have Hospital Supply Status and is listed as a DV Pharmaceutical in the then current Section H of the Pharmaceutical Schedule;

**End Date** means the last day of the Hospital Supply Period, being 30 June 2004 or, if applicable, the last day of the Renewed Term, being 30 June 2005;

**First Transition Period** means the period of two calendar months commencing on the date on which PHARMAC notifies the market that a Tender has been accepted for a Tender Item (or such later commencement date or other period as PHARMAC determines under clause 1.3 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 in Section H of the Pharmaceutical Schedule (which may be, without limitation, one or more District Health Boards and/or the Ministry of Health) and their successors;

**Hospital Evaluation Committee** means a committee established by PHARMAC to evaluate Tender Bids, taking into account such regulatory, legal, medical and other advice as it considers appropriate;

**Hospital Pharmaceuticals Supplement** means the supplement that clarifies the application of PHARMAC's OPPs in respect of hospital pharmaceuticals;

**Hospital Supply Period** means the period beginning on the day after the end of the First Transition Period and ending on 30 June 2004, or ending on 30 June 2005 if PHARMAC renews the Agreement for the Renewed Term;

**Hospital Supply Status** means the status of being the brand or the supplier of the relevant Pharmaceutical listed in Section H of the Pharmaceutical Schedule, subject to any DV Limit for that Pharmaceutical for the Hospital Supply Period;

**HPAC** means the Hospital Pharmaceutical Advisory Committee;

**IMM** means interchangeable multi-source medicine, as defined by the New Zealand Medicines and Medical Devices Safety Authority (**Medsafe**);

**Invitation** means this invitation to tender and includes the cover letter and each of the Schedules;

**National Logistics Provider Agreement** means any agreement between PHARMAC, on behalf of DHB Hospitals, and a provider of logistics services, for that provider to be a national logistics provider for the delivery of pharmaceuticals;

**Offer Letter** means the letter of offer to which your Tender Submission Form(s) and/or Back-up Supply Submission Form(s) must be attached, in the form set out in Schedule Four;

**OPPs** means PHARMAC's then current Operating Policies and Procedures, as amended by the Hospital Pharmaceuticals Supplement;

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

**Pharmacode** means the six or seven digit number assigned and notified to you by the Pharmacy Guild;

**Potential Out-of-Stock Event** means:

- (a) your stock of the Pharmaceutical falls below the average volume of stock of the Pharmaceutical required to supply the entire New Zealand market for the Pharmaceutical for any given two month period;
- (b) your stock of the Pharmaceutical falls below two-thirds of your most recent three months' total Unit sales of the Tender Item; or
- (c) your forecast of sales demand in respect of the next two-month period is greater than your stock of the Pharmaceutical;

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

- (i) wholesalers and other such distributors; or
- (ii) at a DHB's discretion, a DHB and its DHB Hospital directly, in accordance with the Direct Supply Requirements,

and at which the DHB is to purchase the Pharmaceutical, being:

- (iii) in relation to Hospital Supply Status, the price specified in your successful Tender Submission Form, unless there has been a subsequent price change in accordance with the terms of the Invitation, in which case the Price will be the price notified to you by PHARMAC upon acceptance of your Tender Bid; or
- (iv) in relation to Back-up Supply Status, the price agreed between you and PHARMAC in accordance with clause 8 of Schedule Three;

**PTAC** means the Pharmacology and Therapeutics Advisory Committee;

**Renewed Term** means the period of 12 months commencing on 1 July 2004 and ending on 30 June 2005;

**Second Transition Period** means the period of three calendar months beginning on the day after the end of the Hospital Supply Period;

**Section H** means the relevant section or sections of the Pharmaceutical Schedule relating to hospital pharmaceuticals;

**Tender Bid** means the Offer Letter together with the Tender Submission Form submitted for a particular Tender Item;

**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 and which is attached to the Offer Letter, as set out in Schedule Four;

**Transition Periods** collectively refers to the First and Second Transition Periods;

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

**Unit Price** means the relevant Price specified for 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 in Section H of the Pharmaceutical Schedule, the price and pack size specified in the most recent issue of Section H of the Pharmaceutical Schedule published prior to that Tender Item being de-listed).

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## 2. Interpretation

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In the construction of this Invitation, 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 Invitation;
- (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; and
- (g) headings in this Agreement are for convenience only and have no legal effect.

## Schedule 2: Products to be tendered

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### 1. Information about Tender Items

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#### 1.1 List of Tender Items

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

#### 1.2 Patents

- (a) Where possible, PHARMAC has identified Tender Items that it understands may be the subject of a patent that it believes is due to expire after the Deadline.
- (b) Where PHARMAC has been advised of the existence of a process patent prior to sending out this Invitation, it has shown this in the attached list by the use of a + symbol.
- (c) However, PHARMAC makes no representation as to the patent status of the Tender Items and accepts no liability for any patent infringement that might occur as a result of this tender process or PHARMAC's acceptance of a Tender Bid, including infringement of process patents.

#### 1.3 Market size

PHARMAC makes no representation as to the size of the market for any Tender Item. 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.

#### 1.4 Special terms

Where there are any special terms relating to a particular Tender Item, those terms are indicated in the column entitled "Comments" in the list.

#### 1.5 DV Limits

Where there is a DV Limit relating to a particular Tender Item, that limit is indicated as a percentage amount in the column entitled "DV Limit" in the list.

#### 1.6 Back-up supply

Where a ^ symbol is indicated, you may submit a Back-up Supply Proposal in accordance with clause 8.1 of Schedule Three.

#### 1.7 IMM status

Where a ✓ symbol is indicated, your brand of the relevant Chemical Entity for which you submit a bid must have or be expected to gain IMM status.

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## 1.8 Direct supply requirements

- (a) Where you supply a Tender Item directly to a DHB that supply is to be in accordance with the Direct Supply Requirements for the relevant DHB.
- (b) In the event that PHARMAC enters into a National Logistics Provider Agreement then the applicable parts of this Agreement in respect of logistics arrangements and the delivery of the Pharmaceutical including any Direct Supply Requirements agreed between you and the relevant DHB will be superseded by the National Logistics Provider Agreement to the maximum extent necessary to give full effect to the National Logistics Provider Agreement. Where there is any conflict between this clause and any other provisions in this Agreement, this clause will take precedence.

## 1.9 Current contract expiry

- (a) Where there are current DHB Hospital contracts relating to the supply of a particular Tender Item that will continue to exist for part or all of the Transition Periods or the Hospital Supply Period, the column entitled "DV Limit apply after" indicates in which calendar quarters the relevant DHB Hospital contracts are anticipated to expire by using the following symbols as applicable:
  - (i) Q103 means 1 January to 31 March 2003;
  - (ii) Q203 means 1 April to 30 June 2003;
  - (iii) Q303 means 1 July to 30 September 2003;
  - (iv) Q403 means 1 October to 31 December 2003;
  - (v) Q104 means 1 January to 31 March 2004;
  - (vi) Q204 means 1 April to 30 June 2004;
  - (vii) Q304 means 1 July to 30 September 2004;
  - (viii) Q404 means 1 October to 31 December 2004;
  - (ix) Q105 means 1 January to 31 March 2005;
  - (x) Q205 means 1 April to 30 June 2005;
  - (xi) Q305 means 1 July to 30 September 2005.
- (b) Notwithstanding paragraph (a) above, you acknowledge that the above contract expiry details are based on information that is outside PHARMAC's direct knowledge, such information being provided to PHARMAC, and PHARMAC makes no representation as to the actual expiry dates of current DHB Hospital contracts relating to the supply of a particular Tender Item. You acknowledge and agree that in submitting your Tender Bid you will rely on your own knowledge and independent advice or assessment of the anticipated or actual expiry dates for current DHB Hospital contracts relating to the supply of a particular Tender Item.

## 2. List of Products

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*[To be provided by PHARMAC.]*

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## Schedule 3: Tender Process

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### 1. General

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#### 1.1 Hospital Supply Period

Tender Bids are to be submitted on the basis that if your Tender Bid is accepted, you will have Hospital Supply Status for the particular Tender Item for the Hospital Supply Period.

#### 1.2 Renewed Term

Tender Bids are to be submitted on the basis that if your Tender Bid is accepted and PHARMAC in its sole discretion chooses to extend the Hospital Supply Period for the Renewed Term, you will have Hospital Supply Status for that Renewed Term for the particular Tender Item at the Price.

#### 1.3 Transition Periods

- (a) There will be two Transition Periods during which the successful tenderer's brand of the Tender Item is to be available for supply and purchased by DHB Hospitals.
- (b) The First Transition Period is intended to allow for an orderly transition to the arrangements that will apply during the Hospital Supply Period. PHARMAC may, in its sole discretion, determine a different commencement or end date for the First Transition Period, including where it considers that a different commencement or end date is necessary to ensure appropriate stock management or appropriate supply of the Tender Item.
- (c) During the First Transition Period DHB Hospitals are expected to use up existing stocks of DV Pharmaceuticals but may still purchase DV Pharmaceuticals provided that DHB Hospitals do not exceed the DV Limit for that Pharmaceutical.
- (d) The Second Transition Period is intended to allow for an orderly transition to any new arrangements following the end of the Hospital Supply Period.
- (e) During the Second Transition Period DHB Hospitals may purchase DV Pharmaceuticals without regard to any DV Limits.

#### 1.4 Contract

If PHARMAC (on behalf of the Funder) accepts your Tender Bid, then a contract on the terms and conditions set out in:

- (a) your Tender Bid (incorporating any variations as a result of negotiations or discussions under clause 1.5 of this Schedule); and
- (b) Schedule Five,

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.

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## 1.5 PHARMAC may initiate limited negotiations

- (a) Notwithstanding clause 2.5 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 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); or
  - (v) 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.
- (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 or any variation to that Tender Bid.

## 1.6 Supply to community

- (a) Tenders are to be submitted on the basis that if your Tender Bid is accepted, you will, if so requested by PHARMAC, supply the Pharmaceutical for use in the community as soon as practicable after such a request, and in any case no later than three months after that request:
  - (i) at a price that is equal to (or subject to your agreement, less than) the Price;
  - (ii) at PHARMAC's option, either:
    - (A) on the terms set out in Schedule Five, as applicable;
    - (B) on PHARMAC's standard terms of supply for pharmaceuticals used in the community (as recorded in the then current Annex Three of PHARMAC's standard contract template); and/or
    - (C) such other terms to be agreed between the parties;
  - (iii) in such quantities as are required for use in the community; and
  - (iv) for such period as PHARMAC, requires, which period will not extend beyond the End Date. For the avoidance of doubt, nothing in this clause prevents PHARMAC from implementing any arrangements (including a tender) in relation to the supply of the Tender Item for use in the community,

in which event PHARMAC will fully subsidise the Pharmaceutical at the price determined under sub-clause (i) above and will list the Pharmaceutical in the relevant section of the Pharmaceutical Schedule.

- (b) This clause confers a benefit on (and is enforceable by) the Funder in accordance with the Contracts (Privity) Act 1982.

## 1.7 Termination and amendment of Invitation

PHARMAC may:

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

## 2. Information about submitting a Tender Bid

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

### 2.3 Individual Tender Bids

You may submit more than one bid for a Tender Item (for example, you may submit separate bids for different pack sizes of a Tender Item) provided that each bid is submitted on a separate Tender Submission Form.

### 2.4 Aggregated Tender Bids

- (a) You may in addition to, or instead of, submitting a separate Tender Bid for each Tender Item, submit an Aggregated Tender Bid, provided that:
  - (i) each brand contained in an Aggregated Tender Bid is only a different form and strength of the same Chemical Entity; and
  - (ii) you may not aggregate within a single Tender Item.
- (b) Where a Tender Item includes different forms and strengths of a Chemical Entity or different entities and you bid for the whole Tender Item, that is not an Aggregated Tender Bid.

- (c) You must clearly indicate on your Tender Submission Form if your Tender Bid is an Aggregated Tender Bid.

## 2.5 No conditions

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

## 2.6 Separate offers

PHARMAC will treat each Tender Bid as a separate offer.

## 2.7 Tender Bid prices

You must:

- (a) submit, for each Tender Bid, in New Zealand dollars a single price in New Zealand dollars (exclusive of GST), which will be the price at which you will supply the Tender Item:
  - (i) to wholesalers and other distributors; and/or
  - (ii) directly to a DHB Hospital in accordance with the Direct Supply Requirements, if applicable;
- (b) not submit a Tender Bid that contains a price in foreign currency.

## 3. What to include in your Offer Letter and Tender Submission Form

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### 3.1 Compulsory use of Offer Letter and Tender Submission Form

- (a) You must submit your Tender Bid by completing and signing the Offer Letter and completing a separate Tender Submission Form for each Tender Item for which you wish to submit a bid.
- (b) An electronic version of these forms is available on disc from PHARMAC or on PHARMAC's website at <[www.pharmac.govt.nz](http://www.pharmac.govt.nz)>.

### 3.2 Information that must be supplied about you

In the Offer Letter, you must supply the following information about you:

- (a) your company structure;
- (b) your management and technical skills;
- (c) your financial resources;
- (d) your (or your supplier's) existing supply commitments;
- (e) your (or your supplier's) previous supply performance;

- (f) your quality assurance processes, where applicable;
- (g) your drug information and interaction support services; and
- (h) any other benefits to PHARMAC and DHB Hospitals in selecting you as the supplier of a Tender Item, including details of how you have added value to your customers' business in the past.

### 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) where the Tender Item is an injectable controlled drug, whether the ampoules or vials in which that drug is supplied are made of glass or plastic (our preferred option being glass);
- (c) the price in New Zealand dollars (exclusive of GST) at which you will supply the Tender Item to wholesalers and other distributors or directly to DHB Hospitals in accordance with the Direct Supply Requirements;
- (d) whether it has all necessary Consents (and if not, what the status of registration is);
- (e) whether it has IMM status, and if so, to which brand and presentation;
- (f) the approximate lead times for both initial and ongoing supply (on the basis of your assessment of the size of the market for the Tender Item);
- (g) the name and location of:
  - (i) the manufacturer(s) of the finished product (and name and location of the packaging site, if different); and
  - (ii) the manufacturer(s) of the active ingredients; and
  - (iii) alternative manufacturers of the finished product and active ingredients (if any); and
- (h) the Pharmacode for your brand of that Tender Item, if applicable.

### 3.4 PHARMAC may request further information

- (a) PHARMAC may request such further information as it considers necessary from or about you for the purposes of clarifying or evaluating your Tender Bid, including (but not limited to):
  - (i) information about your credit status;
  - (ii) information on the price of a Tender Item, but only where PHARMAC requires clarification to confirm the exact price being offered, or where PHARMAC initiates negotiations with you under clause 1.5 of this Schedule;

- (iii) where a Tender Item is a controlled drug, information about the form in which the Tender Item will be supplied, in which case you must supply that information within 10 business days of PHARMAC requesting the information; and
  - (iv) a sample pack or container of the Tender Item (and if you intend supplying it in a different form from that sample pack or container, information about the form in which it will be supplied), in which case you must supply that sample pack or container or information within 10 business days of PHARMAC requesting it.
- (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

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### 4.1 Submission of Tender Bids

As this tender is a closed tender, no Tender Bids will be opened until after the Deadline. Therefore, it is important that all Tender Bids (either as hard copies or electronic versions contained on a disc) must:

- (a) be contained in a sealed envelope marked "TENDER FOR THE SUPPLY OF CERTAIN PHARMACEUTICALS - COMMERCIAL IN CONFIDENCE", and, if you wish to be notified of the receipt of the Tender Bid immediately, the sealed envelope must have your return address stated clearly on the outside of the envelope and be marked "FOR IMMEDIATE NOTIFICATION OF RECEIPT"; and
- (b) be delivered in the specially marked envelope either in person, by courier or by post (**and not by facsimile or email**) to:

The Chief Executive  
c/- Legal Counsel  
Pharmaceutical Management Agency  
Level 1, Old Bank Chamber  
98 Customhouse Quay  
PO Box 10-254  
WELLINGTON

### 4.2 Key dates

Your Tender Bid must:

- (a) be received by PHARMAC no later than the Deadline; and
- (b) be irrevocable and remain open for acceptance by PHARMAC until, as applicable:
  - (i) **[Date]**;
  - (ii) the date specified for a Tender Item in Schedule Two (if any); or
  - (iii) if PHARMAC so requests at any time, such later date as you agree in writing.

## 5. Evaluation

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### 5.1 Process of evaluation

The Hospital 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 6.1(a) of this Schedule, and any non-conforming Tender Bids that are admitted for consideration under clause 6.1(b) of this Schedule.

### 5.2 Matters for evaluation

The matters to be taken into account by the Hospital 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 Hospital Evaluation Committee in its sole discretion. The matters taken into account by the Hospital Evaluation Committee will, however, include:

- (a) your ability to ensure continued availability of the Tender Item throughout the Hospital Supply Period and each of the Transition Periods, 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; and
  - (v) your quality assurance processes, where applicable;
- (b) the pack size of the Tender Item and the type of packaging including where that Tender Item is an injectable controlled drug, whether the ampoules or vials in which that drug is supplied are made of glass or plastic;
- (c) the price of the Tender Item;
- (d) the amount and timing of savings, including non-pharmaceutical savings accruing to the Funder or PHARMAC during the Hospital Supply Period;
- (e) either:
  - (i) evidence that you have obtained, and still have, market approval for your brand of the Tender Item, and all necessary Consents; or
  - (ii) evidence that will enable the Hospital Evaluation Committee to form a view on the likelihood and timing of your brand of the Tender Item gaining all necessary Consents;
- (f) whether your brand of the Tender Item has IMM status, or is likely to gain IMM status;
- (g) the name and location of the manufacturer of the finished and active ingredients of the Tender Item;

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- (h) your drug and interaction support services; and
- (i) any other benefits to the Funder of selecting you as the supplier of the Tender Item.

## 6. Conformity

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### 6.1 Conformity

- (a) PHARMAC may, in its sole discretion, check your Tender Bid for conformity with this Invitation. 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 received by the Deadline;
  - (ii) is submitted on the Tender Submission Form and attached to the Offer Letter;
  - (iii) has no conditions or qualifications attached;
  - (iv) includes all information required under clause 3.2, 3.3, and if applicable clause 3.4, of this Schedule; and
  - (v) otherwise complies, both as to form and substance, with the requirements of this Invitation.
- (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.

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## 7. Decision

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### 7.1 Decision on acceptance of Tender Bid

- (a) The Hospital Evaluation Committee will make a recommendation as to which Tender Bid should be accepted to PHARMAC's board of directors (or chief executive acting under delegated authority pursuant to section 61 of the New Zealand Public Health and Disability Act 2000, where applicable).
- (b) PHARMAC's board of directors (or chief executive, where applicable) will then have the sole discretion to decide whether or not to accept (on behalf of the Funder) a Tender Bid for any Tender Item.
- (c) PHARMAC's board of directors (or chief executive, where applicable):
  - (i) will use the decision criteria for hospital pharmaceuticals 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 Hospital Evaluation Committee.

## 7.2 Notification of acceptance

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

## 7.3 PHARMAC's rights reserved

- (a) PHARMAC reserves the right to accept or reject any Tender Bid, and is not obliged to give reasons for its decision.
- (b) While it is PHARMAC's current intention to enter into an agreement to award Hospital Supply Status for each Tender Item, PHARMAC will not in any circumstances be bound to accept any or all Tender Bids and, in particular, PHARMAC will not be bound to accept the lowest or any other Tender Bid for a Tender Item.
- (c) Acceptance only occurs if, and when, PHARMAC's board of directors (or chief executive, where applicable) resolves to accept a Tender Bid and this acceptance is notified to the successful tenderer.
- (d) PHARMAC may take any action, or do anything, that is incidental to the process described in this Invitation, except to the extent that such action is explicitly excluded in this Invitation.

## 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 1.4 of Schedule Three 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 chief executive, where applicable), and the contract referred to in clause 1.4 of Schedule Three, 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.

## 8. Additional terms for Back-up Supply Proposals

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### 8.1 Back-up Supply Proposals

- (a) Where a Tender Item is indicated in Schedule Two as being an item that may require a contract for Back-up Supply Status, then in addition to, or instead of, submitting a bid for Hospital Supply Status for that Tender Item, you may submit a proposal for Back-up Supply Status.
- (b) This request to submit a Back-up Supply Proposal is a request for proposals and is not an invitation to tender. Any such proposal you make is not an offer capable of being converted into a contract by PHARMAC's apparent acceptance and instead a separate agreement needs to be negotiated in accordance with the process outlined in clause 8.7 of Schedule Three.

### 8.2 Terms applicable to Back-up Supply Proposals

If you submit a proposal for Back-up Supply Status for a Tender Item the terms applicable to (and the process to be followed by PHARMAC for) a proposal for Back-up Supply Status are as follows:

- (a) Schedule One
- (b) Schedule Two;
- (c) clauses 1.1 (Hospital Supply Period), 1.2 (Renewed Term), 1.3 (Transition Periods), 1.6 (Supply to community) and 1.7 (Termination and amendment of Invitation) of Schedule Three;
- (d) clause 2 (Information about submitting a Tender Bid) of Schedule Three;
- (e) clause 3 (What to include in your Offer Letter and Tender Submission Form) of Schedule Three;
- (f) clause 4 (How to submit Tender Bid) of Schedule Three;
- (g) clause 5 (Evaluation) of Schedule Three;
- (h) clause 7 (Decision) of Schedule Three;
- (i) clause 9 (Dealing with information) of Schedule Three;
- (j) clause 10 (Miscellaneous) of Schedule Three;
- (k) Schedule Four;
- (l) Schedule Six (Standard back-up supply terms), subject to additional terms agreed between you and PHARMAC,

unless qualified by this clause 8, and all references in the above provisions to Tender Bids, Hospital Supply Status and Tender Submission Form shall be read as referring to Back-up Supply Proposals, Back-up Supply Status and Back-up Supply Submission Form, where applicable.

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### 8.3 Contract

If Back-up Supply Status is awarded to you by PHARMAC (on behalf of the Funder) it will be awarded on the terms agreed between us, being the standard back-up supply terms specified in Schedule Six of this Agreement, subject to any additional terms agreed between you and PHARMAC.

### 8.4 Consents must be held

You must only submit a Back-up Supply Proposal where your brand of the Tender Item has all necessary Consents.

### 8.5 Compulsory use of Offer Letter and Back-up Supply Submission Form

You must submit your Back-up Supply Proposal by completing a separate Back-up Supply Submission Form for each Tender Item for which you wish to submit a proposal and attaching that form to the Offer Letter.

### 8.6 Information that must be supplied about the Tender Item

In addition to the information to be supplied under clause 3.3 of this Schedule, you must:

- (a) supply details of the level of stock (in number of Units) and the shelf-life of the Tender Item that you will hold (whether in New Zealand or off-shore) during the Hospital Supply Period if your Back-up Supply Proposal is accepted;
- (b) specify the maximum lead time for supply of the Tender Item to the New Zealand market;
- (c) specify any terms and conditions proposed by you with respect to Unsold Stock; and
- (d) set out any other terms and conditions or information in relation to your Back-up Supply Proposal.

### 8.7 Negotiation

- (a) PHARMAC may, in its sole discretion, initiate negotiations or discussions with you and/or other suppliers in relation to Back-up Supply Proposals.
- (b) Negotiations are to proceed on the basis that the standard back-up supply terms specified in Schedule Six will apply and may be added to by the indicative terms specified in your Back-up Supply Proposal or any other terms, by agreement between you and PHARMAC.
- (c) PHARMAC may enter into a provisional agreement with you or any other supplier for Back-up Supply Status on whatever terms PHARMAC considers appropriate.
- (d) Any provisional agreement for Back-up Supply Status will be conditional on such consultation, if any, as PHARMAC considers appropriate, and on approval by PHARMAC's board of directors (or chief executive acting under delegated authority, where applicable) and otherwise in accordance with the process set out in clause 7 of this Schedule Three.

- (e) If you and PHARMAC are unable to reach a provisional agreement for Back-up Supply Status within what PHARMAC considers to be a reasonable time, PHARMAC may terminate negotiations with you and may continue or initiate negotiations for Back-up Supply Status with any other suppliers, as it sees fit.

## 8.8 Evaluation

In evaluating your Back-up Supply Proposal, the Hospital Evaluation Committee will not take into account the amount and timing of savings accruing to the Funder or PHARMAC during the Hospital Supply Period.

## 9. Dealing with information

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### 9.1 Confidentiality

Subject to clause 9.2 below, all Confidential Information is confidential to us and our employees, legal advisers and other consultants (including HPAC, PTAC and their sub-committees), the Ministry of Health 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) to (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) to (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.

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## 9.2 Use of information

Generalised aggregated information regarding your Tender Bid that does not identify you or that can not 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

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### 10.1 Costs

PHARMAC is not liable for any direct or indirect costs incurred, or loss 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 any Tender Item.

### 10.2 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).

### 10.3 No further liability

PHARMAC's liability (if any) under, or in relation to, the tendering process is limited to the obligations expressly contained in this Invitation, and no further private law liability exists in relation to the process.

### 10.4 No lobbying

- (a) You are not to initiate any communication with PHARMAC, the Minister of Health (or any Associate Ministers), the Ministry of Health, 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.

### 10.5 Enquiries

If you have any enquiries about this Invitation you should contact Cristine Della Barca or Matthew Perkins at PHARMAC. 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.

### 10.6 Jurisdiction and governing law

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

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# Schedule 4: Offer Letter, Tender Submission Form and Back-up Supply Submission Form

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## 1. Offer Letter

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<Insert today's date>

Chief Executive  
c/- Legal Counsel  
PHARMAC  
PO Box 10-254  
(or for courier delivery:  
Level 1, Old Bank Chambers  
98 Customhouse Quay)  
Wellington  
New Zealand

Dear Sir/Madam

### **Tender for the supply of certain pharmaceuticals - commercial in confidence**

In response to your invitation to tender dated <insert date>, we offer to provide the tender items specified in the attached form(s), in the presentations and strengths set out in the attached form(s), on the terms and conditions contained in the invitation.

Set out below (or, where applicable, attached to this offer letter) is further information in support of our tender bid.

- (a) information about our company structure:

- (b) information about our management and technical skills:

- (c) information about our financial resources:

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(d) information about our, or our supplier's, existing supply commitments:

--

(e) information about our, or our supplier's, previous supply performance:

--

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

--

(g) information about our drug information and interaction support services:

--

(h) information about any other benefits to the Funder in selecting us as the supplier of a Tender Item (including details of how we have added value to our customer's business in the past):

--

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

<b>Name</b>	
<b>Designation</b>	
<b>Address</b>	
<b>Phone</b>	
<b>Facsimile</b>	
<b>Email address</b>	

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

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**<Insert name>**  
**<Insert designation>**

Please find attached **<insert number>** Tender Submission Forms.

Please find attached **<insert number>** Back Up Supply Submission Forms (where applicable).

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## 2. Tender Submission Form

Note: You must submit separate forms for each Tender Item for which you wish to submit a Tender Bid (except in the case of an Aggregated Tender Bid) and attach all forms to the Offer Letter.

Supplier's name

Tender item	
Chemical name e.g., paracetamol	
Strength e.g., 500 mg	
Unit type (form/presentation) e.g., capsule and, where applicable, if an ampoule or vial of an injectable controlled drug is glass or plastic e.g., glass vial	
Product name (brand name)	
Pack size e.g., 30's	
Packaging type e.g., blister	
Pharmacode	

Pricing	
Pack price in \$NZ	

**(If Aggregated Tender Bid, please repeat the above tables as often as necessary in the same Tender Submission Form and clearly indicate that it is an Aggregated Tender Bid)**

Product approval status (please complete only one of the following three options)	
Date of market approval (please attach copy of Medsafe gazette notice)	
<b>OR</b> Date of submission of dossier (please attach confirmation from Medsafe that dossier has been submitted)	
<b>OR</b> Expected date of dossier submission to Medsafe	

Miscellaneous	
IMM status (if so, interchangeability with which brand and presentation)	
Approximate lead time for supply (on the basis of your assessment of the size of the market for the Tender Item)	

Name and location of manufacture	
Name and location of manufacturer(s) of finished product	
Name and location of packaging site (if different from above)	
Name and location of manufacturer(s) of active ingredients	
Alternative name and location of finished manufacturer(s) of finished product (if any)	
Alternative name and location of manufacturer(s) of active ingredients (if any)	

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### 3. Back-up Supply Submission Form

Note: You must submit separate forms for each Tender Item which is indicated in Schedule Two as being an item that may require a contract for Back-up Supply Status and for which you wish to submit a Back-up Supply Proposal and attach all forms to the Offer Letter.

Supplier's name

Tender item	
Chemical name e.g., paracetamol	
Strength e.g., 500 mg	
Unit type (form/presentation) e.g., capsule and, where applicable, whether an ampoule or vial of an injectable controlled drug is glass or plastic e.g., glass vial	
Product name (brand name)	
Pack size e.g., 30's	
Pack type e.g., blister	
Stock holding level (number of Units)	
Location of stock holding	
Expiry of stock	

DRAFT

Pricing	
Pack price in \$NZ	
Reimbursement price for unsold stock (if applicable)	

**(If aggregated Back-up Supply Proposal, please repeat the above tables as often as necessary in the same Back-up Supply Submission Form and clearly indicate that it is an aggregated Back-up Supply Proposal)**

Product approval status	
Date of market approval (please attach copy of Medsafe gazette notice)	

Miscellaneous	
IMM status (if so, to which brand)	
Approximately lead time for supply (once notification of an out of stock had occurred)	

Name and location of manufacture	
Name and location of manufacturer(s) of finished product	
Name and location of packaging site (if different from above)	
Name and location of manufacturer(s) of active ingredients	

Terms and conditions associated with Unsold Stock
<i>These details may be submitted as an attachment to the Back-up Supply Submission Form.</i>

**Any other terms and conditions of Back-up Supply Status, or related information**

*These details may be submitted as an attachment to the Back-up Supply Submission Form.*

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## Schedule 5: Contract terms

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### 1. General

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#### 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 prescribing and dispensing of listed pharmaceuticals;
    - (C) changing the subsidy levels 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; and
    - (E) delisting pharmaceuticals, or delisting all or part of a therapeutic group or sub-group; and
  - (vi) any action taken by PHARMAC pursuant to its OPPs may impact on the listing of each Pharmaceutical.
- (b) PHARMAC agrees not to apply, amend or update its OPPs in order to avoid any of PHARMAC's obligations under Schedule Five of this Agreement.

#### 1.2 Amendments to Pharmaceutical Schedule

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

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## 2. Effect of Hospital Supply Status

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### 2.1 Pricing arrangements

- (a) Subject to PHARMAC's other rights under this Agreement, during the First Transition Period and the Hospital Supply 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 wholesalers and other distributors, for supply to DHB Hospitals, or directly to DHB Hospitals at the Price.
- (b) Subject to PHARMAC's other rights under this Agreement in relation to the Pharmaceutical (including under clause 2.9 of this Schedule), the Pharmaceutical:
  - (i) is to continue to be listed, sold and purchased at the Price referred to in clauses 2.1(a)(i) and (ii) above during the Second Transition Period and beyond; and
  - (ii) is not to be delisted during the Second Transition Period.

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### 2.2 Second Transition Period

Subject to clause 2.1 of this Schedule you acknowledge and agree that DHB Hospitals may purchase DV Pharmaceuticals at any time within the Second Transition Period without any requirement to comply with the DV Limit.

### 2.3 Supplier for Hospital Supply Period

- (a) Subject to:
  - (i) PHARMAC's other rights under this Agreement in relation to the Pharmaceutical; and
  - (ii) clauses 2.5 and 2.6 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 Period, as the brand having Hospital Supply Status.

- (b) This clause does not prohibit PHARMAC (on behalf of the Funder) from entering into negotiations or arrangements with, or inviting tenders from, other suppliers to be the supplier of any forms and strengths of a Chemical Entity having a status equivalent to Hospital Supply Status, if such supply commences after the end of the Hospital Supply Period.

### 2.4 Renewal of Hospital Supply Period

PHARMAC may in its sole discretion extend the Hospital Supply Period for the Pharmaceutical for the Renewed Term. In that event your brand of the Pharmaceutical will be the brand having Hospital Supply Status on the same basis as under clause 2.3 above.

## 2.5 DV Limit

Subject to clauses 2.6 and 2.10 of this Schedule you acknowledge and agree that while you have Hospital Supply Status:

- (a) a DHB Hospital may purchase DV Pharmaceuticals at any time within the First Transition Period or Hospital Supply Period, provided that the DHB Hospital does not exceed the DV Limit for the relevant Pharmaceutical;
- (b) without derogating from any other rights available to PHARMAC or the Funder under this Agreement or otherwise if you are unable to supply the Pharmaceutical as required under this Agreement 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 2.6 below;
- (c) if a DHB's usage of any DV Pharmaceuticals, in percentage terms, reaches or exceeds the percentage at which the national DV Limit is set for the relevant Pharmaceutical, that DHB may negotiate with you to agree to vary the application of the DV Limit to the DHB in respect of particular patients with exceptional needs.

## 2.6 DV Limit Compliance

- (a) For the purposes of this clause 2.6:
  - (i) **"Relevant Period"** means:
    - (A) the initial period starting on the day that the First Transition Period begins up to and including 30 June 2003; or
    - (B) the period commencing on 1 July 2003 and ending on 30 June 2004; or
    - (C) if PHARMAC renews the term of the Hospital Supply Status for a Pharmaceutical in accordance with clause 1.2 of Schedule Three, the period commencing on 1 July 2004 and ending on 30 June 2005,

provided that for the purposes of carrying out the calculations in this clause 2.6 any calendar months that fall within those periods when:

- (D) there is any failure to supply the Pharmaceutical in accordance with this Agreement; and
- (E) any DHB's existing supply contract for a Chemical Entity that is the same as the Pharmaceutical remains current,

will be excluded. For the avoidance of doubt the compliance mechanisms under this clause 2.6 are not activated for any particular Pharmaceutical until all existing DHB supply contracts for a Chemical Entity that is the same as the Pharmaceutical have terminated;

- (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;**

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- (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 Chemical Entity purchased by DHB Hospitals, as calculated by PHARMAC, following your request in accordance with clause 2.6(b) below, on the basis of the electronic records used by it; and
- (iv) **"Total Pharmaceutical Volume"** means, for a particular Pharmaceutical in any Relevant Period, the total number of Units of the Pharmaceutical purchased by DHB Hospitals, as calculated by PHARMAC following your request in accordance with clause 2.6(b) below, on the basis of the electronic records used by it.
- (b) If you reasonably believe that an individual DHB's percentage usage of DV Pharmaceuticals exceeds the DV Limit percentage 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 2.6 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 PHARMAC will not unreasonably refuse to carry out such calculations where requested to do so if the relevant data is available to PHARMAC.
- (c) It is acknowledged, for the avoidance of doubt, that if the Actual National DV Limit Indicator is less than the DV Limit specified for the relevant Pharmaceutical in Schedule Two then, regardless of whether an individual DHB's percentage usage of DV Pharmaceuticals has exceeded the DV Limit percentage for that Pharmaceutical, PHARMAC will not take any further action.
- (d) If the Actual National DV Limit Indicator is greater than the DV Limit, PHARMAC will use all reasonable endeavours to identify which individual DHB's or DHBs' percentage usage of DV Pharmaceuticals have exceeded the 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 at an individual DHB level then you acknowledge that PHARMAC may not be able to calculate and obtain financial compensation for you under clause 2.6 (f)(ii). 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's percentage usage of DV Pharmaceuticals has exceeded the DV Limit percentage for that Pharmaceutical as a result of DV Pharmaceutical usage that has been agreed to by you in accordance with clause 2.5(c) 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 or DHBs identified in accordance with paragraph (d) above by:
- (i) using all reasonable endeavours to ensure that the relevant DHB complies with the DV Limit for that Pharmaceutical 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, requiring financial compensation (where PHARMAC is able to quantify this based on the information available to it) by that DHB for its contribution towards exceeding the DV Limit, being the greater amount of \$5,000 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 DV Pharmaceuticals Volume DHB<sub>x</sub> ÷ Total DV Pharmaceuticals Volume for Exceeding DHBs) x Total DV Pharmaceuticals Volume in Excess of DV Limit**

where:

**“Total DV Pharmaceuticals Volume DHB<sub>x</sub>”** means, for a particular Pharmaceutical in any Relevant Period, the total number of Units of all DV Pharmaceuticals of the relevant Chemical Entity purchased by the relevant DHB, as calculated by PHARMAC for such Relevant Period on the basis of the electronic records used by it;

**“Total DV Pharmaceuticals Volume for Exceeding DHBs”** means, for a particular Pharmaceutical in any Relevant Period, the total number of Units of all DV Pharmaceuticals of the relevant Chemical Entity purchased by all the DHBs identified by PHARMAC in accordance with paragraph (d) above as exceeding the DV Limit for that Relevant Period, as calculated by PHARMAC for such Relevant Period on the basis of 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 Chemical Entity purchased by DHB Hospitals in excess of the DV Limit for that Relevant Period, as calculated by PHARMAC on the basis of the electronic records used by it;

- (iii) PHARMAC will seek payment of any DV Limit compensation payable in accordance with clause 2.6(f)(ii) above from the relevant DHB, and will forward that sum to you as soon as reasonably practicable following receipt from the relevant DHB.
- (iv) If PHARMAC has not received the amount of any DV Limit compensation payable in accordance with clause 2.6(f)(ii) above from the DHB within 60 business days of notifying that DHB of the amount owing, then you may take such actions 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.

## 2.7 Withdrawal of Hospital Supply Status

- (a) PHARMAC may withdraw Hospital Supply Status in relation to your supply of the Pharmaceutical (in which case clauses 2.1, 2.2, 2.3, 2.4, 2.5 and 2.6 of this Schedule will no longer apply), by written notice to you at any time during the Hospital Supply Period if:
  - (i) you have failed to notify PHARMAC as required under clause 7.2 of this Schedule;

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- (ii) you are unable to supply the Pharmaceutical for a period of 30 days to any of the DHB Hospitals;
  - (iii) any Consent for the Pharmaceutical is withdrawn; or
  - (iv) you have failed to comply with clause 6 of this Schedule on more than one occasion.
- (b) Any withdrawal of Hospital Supply Status is without prejudice to PHARMAC's rights under clauses 7.3 and 7.4 of this Schedule.

## 2.8 Suspension of Hospital Supply Status

- (a) If, at any time, you are unable to meet demand for the Pharmaceutical, or you notify PHARMAC under clause 7.2 of this Schedule of a Potential Out-of-Stock Event, 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 without the requirement to comply with the DV Limit for the relevant Pharmaceutical;
- (b) Any suspension of Hospital Supply Status is without prejudice to PHARMAC's rights under clauses 7.3 and 7.4 of this Schedule.

## 2.9 Subsidy arrangements after the End Date

- (a) PHARMAC may at its sole discretion, with effect from the End Date:
- (i) require the Pharmaceutical to 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; or
  - (ii) apply any of the strategies under PHARMAC's then current OPPs to the Pharmaceutical (including delisting the Pharmaceutical after the Second Transition Period).
- (b) If the Pharmaceutical is to continue to be the subject of a listing agreement between you and PHARMAC under paragraph (a)(i) above, then:
- (i) you will cease to have Hospital Supply Status for that form and strength of the Chemical Entity; and
  - (ii) the Pharmaceutical will otherwise remain listed subject to the terms of this Agreement, as applicable, or on any such new terms as are agreed between us during the Second Transition Period or subsequently.

## 2.10 DHB Hospitals' current contracts

You acknowledge and agree that, during the Hospital Supply Period, some DHB Hospitals will not purchase the Pharmaceutical at the Price and are not required to comply with the DV Limit for the Pharmaceutical, or otherwise to give effect to your Hospital Supply Status, until the day following the date on which their current supply contract for that Chemical Entity expires.

### 3. Consents

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#### 3.1 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 an 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) you are to indemnify the Funder for any additional costs incurred by it (or by PHARMAC on its behalf) as a result of that withdrawal. This clause confers a benefit on (and is enforceable by) the Funder in accordance with the Contracts (Privity) Act 1982.

#### 3.2 Changed medicine notification

If the Ministry of Health approves any changed medicine notification for the Pharmaceutical, or for a variant of the Pharmaceutical:

- (a) you must immediately notify PHARMAC; and
- (b) PHARMAC may take such action as it considers appropriate in relation to that Pharmaceutical or variant of the Pharmaceutical including (but not limited to):
  - (i) withdrawing Hospital Supply Status for the Pharmaceutical; and
  - (ii) delisting the Pharmaceutical.

#### 3.3 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.

### 4. Price

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#### 4.1 Price change

You must change the price at which you supply the Pharmaceutical to wholesalers and other distributors and/or directly to DHB Hospitals to the Price with effect from the beginning of the First Transition Period.

#### 4.2 Supply price

During each of the First Transition Period, the Hospital Supply Period and the Second Transition Period, the price at which the Pharmaceutical is supplied by you to wholesalers and other distributors and/or directly to DHB Hospitals must not exceed the Price.

### 4.3 **Warranty that not less than cost price**

You warrant that the price 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).

## 5. **Emergency and disaster supply**

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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 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).

## 6. **Defective and short-dated Pharmaceuticals**

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### 6.1 **Pharmaceutical recall**

In the event that you are required by the Ministry of Health or any other authorities to recall your Pharmaceutical, you will notify PHARMAC and the relevant DHB Hospitals immediately you become aware of the need to recall any Pharmaceutical. You will use your best endeavours to provide replacement Pharmaceuticals to DHB Hospitals as soon as possible provided that the relevant DHB Hospital may purchase an Alternative Pharmaceutical elsewhere. Any reasonable additional costs incurred by the relevant DHB Hospital in purchasing such an Alternative Pharmaceutical will be met by you on demand by PHARMAC or the DHB Hospital and will be recoverable from you as a debt to PHARMAC or to the DHB Hospital, as applicable.

### 6.2 **Refund**

In the event that any Pharmaceutical is recalled as contemplated by clause 6.1 of this Schedule, you shall immediately refund to the relevant DHB Hospitals all money paid by them to you for or on account 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.

### 6.3 **Shelf-life of Pharmaceutical**

- (a) You will not deliver the Pharmaceutical if it has:
  - (i) a shelf-life of less than six months; or
  - (ii) less than 75% of time remaining until the Pharmaceutical's expiry or use-by date, whichever is the lesser, without prior agreement from the relevant DHB Hospital.

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- (b) If a Pharmaceutical that a DHB Hospital holds becomes short-dated (that is, has a shelf life of less than three months or has less than 50% of time remaining until the Pharmaceutical's expiry or use-by date, whichever is the lesser) due to fluctuations in patient use, the relevant DHB Hospital will advise you not less than 75 days before expiry of that Pharmaceutical and you agree to allow that DHB Hospital to return that Pharmaceutical to you and to provide that DHB Hospital with a credit for that Pharmaceutical.

## **7. Out-of-stock arrangements**

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### **7.1 Minimum stock-holding levels**

You must hold a minimum of two months' stock of the Pharmaceutical, having regard to the historical demand for those Pharmaceuticals and seasonality factors, and you must notify PHARMAC as soon as your stock-holding falls below this level.

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

- (a) You must notify PHARMAC in writing as soon as you have reasonable cause to believe that you will be unable to supply the Pharmaceutical and, in any event, you must notify PHARMAC if at any time a Potential Out-of-Stock Event occurs, in which case PHARMAC may suspend Hospital Supply Status in relation to your supply of the Pharmaceutical.
- (b) If a Potential Out-of-Stock Event occurs, then at PHARMAC's option:
- (i) PHARMAC may implement an arrangement with another supplier to supply an Alternative Pharmaceutical (including an arrangement for back-up supply); or
  - (ii) you must use your best endeavours to procure wholesalers and other such distributors to supply, as soon as practicable, an Alternative Pharmaceutical to DHB Hospitals at the Price, and if you are unable to do so you will pay to the Funder any additional costs incurred by the Funder as a result of the purchase price for the Alternative Pharmaceutical being higher than the Price.

### **7.3 General indemnity**

You agree to indemnify the Funder if you are unable to meet demand for supply of the Pharmaceutical (other than for reasons that PHARMAC considers to be outside your control) or you withdraw the Pharmaceutical from supply or if you fail to notify PHARMAC in accordance with clause 7.2 above. This indemnity:

- (a) covers all costs incurred by the Funder (or by PHARMAC on its behalf) as a result of your inability to meet supply demands or the withdrawal of the Pharmaceutical from supply that are additional to any costs specified in clause 7.4; and
- (b) confers a benefit on (and is enforceable by) the Funder in accordance with the Contracts Privity Act 1982.

### **7.4 Liquidated damages and specific indemnity**

- (a) If you fail to supply the Pharmaceutical (other than for reasons that PHARMAC considers to be outside your control) and:

- (i) you have not notified PHARMAC under clause 7.2 of this Schedule, then without prejudice to PHARMAC's rights under clause 7.3:
    - (A) you must pay to PHARMAC liquidated damages for the administrative and/or operational costs incurred by PHARMAC and the Funder as a result of your failure to supply in the amount of \$50,000 per Pharmaceutical; and
    - (B) you must indemnify the Funder or PHARMAC for all costs (if any) incurred in securing and purchasing an Alternative Pharmaceutical for the period you are unable to supply the Pharmaceutical, provided that such indemnity will not exceed a dollar amount equal to the Unit Price multiplied by the number of Units of the Tender Item estimated by PHARMAC as having been purchased by the Funder in the previous 12 months; and
    - (C) PHARMAC may withdraw Hospital Supply Status in relation to your supply of the Pharmaceutical under clause 2.5 of this Schedule; or
  - (ii) you have notified PHARMAC under clause 7.2 of this Schedule, then without prejudice to PHARMAC's rights under clause 7.3:
    - (A) you must pay to PHARMAC liquidated damages for the administrative and/or operational costs incurred by PHARMAC and the Funder as a result of your failure to supply in the amount of \$5,000 per Pharmaceutical; and
    - (B) you must indemnify the Funder or PHARMAC for all costs (if any) incurred in securing and purchasing an Alternative Pharmaceutical for the period you are unable to supply the Pharmaceutical, provided that such indemnity will not exceed a dollar amount equal to one quarter of the Unit Price multiplied by the number of Units of the Tender Item estimated by PHARMAC as having been purchased by the Funder in the previous 12 months; and
    - (C) if you are unable to supply the Pharmaceutical for more than 30 days, PHARMAC may withdraw Hospital Supply Status in relation to your supply of the Pharmaceutical under clause 2.5 of this Schedule.
- (b) If, having notified PHARMAC under clause 7.2 of this Schedule, you remain able to, and you continue to supply, the Pharmaceutical, or an Alternative Pharmaceutical in accordance with clause 7.2 (b)(ii) of this Schedule, 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 Funder has agreed to make a payment to that supplier to ensure continuity of supply, in which case you must indemnify the Funder or PHARMAC for that payment. Such indemnity will be limited to an amount of \$10,000.
- (c) You acknowledge and agree that:
- (i) the amounts of liquidated damages in this clause represent a reasonable estimate of the administrative and operational costs incurred by PHARMAC and the Funder (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 the Funder's previous experience; and
  - (ii) the amounts referred to as liquidated damages are not intended to include any penalty element nor any amount for costs relating to the securing of an Alternative Pharmaceutical, or the purchasing of an Alternative Pharmaceutical.

- (d) Where you notify PHARMAC under clause 7.2 above of a Potential Out-of-Stock Event, PHARMAC agrees to recover as liquidated damages under clause 7.4(a)(ii) of this Schedule only the amounts specified in paragraphs (a)(ii) and (b) of this clause, which represent only a portion of PHARMAC's and the Funder's costs actually incurred.
- (e) All amounts referred to in this clause are plus GST (if any).

## **8. Termination, restrictions and Crown Direction**

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### **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, HPAC, PTAC, or a sub-committee of HPAC or PTAC), to:

- (a) terminate this Agreement at any time during the Hospital Supply Period or the Transition Periods if the medical adviser determines for clinical reasons that it is no longer appropriate to have either:
  - (i) a supplier having Hospital Supply Status of that form and strength of the Chemical Entity; or
  - (ii) the Pharmaceutical as the brand having Hospital Supply Status; and/or
- (b) impose at any time during the Hospital Supply Period or the Transition Periods restrictions on the prescribing or dispensing of a Pharmaceutical if those restrictions are necessary for clinical reasons.

### **8.2 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 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.

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### 8.3 Termination following an audit

PHARMAC may terminate the Agreement, or impose restrictions on the prescribing or dispensing of a Pharmaceutical, at any time during the Hospital Supply Period or the Transition Periods, if you fail to remedy any area of non-compliance in accordance with clause 10(b) of this Schedule.

## 9. Guarantee

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- (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 7.3 and 7.4 of this Schedule including, without limitation, the payment of any sum payable under the indemnity contained in those clauses for any failure to supply the Pharmaceutical during the Hospital Supply Period.
- (b) The guarantor's liability under such a guarantee will be limited to a total of \$100,000 per Pharmaceutical for all claims made by PHARMAC under the guarantee.

## 10. Audit

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- (a) PHARMAC may, from time to time, review your records and any other information you hold that relates to this Agreement 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, 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 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 reasonably 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.
- (c) PHARMAC will take such steps as it considers appropriate to audit compliance by DHB Hospitals with the DV Limits and related requirements set out under this Agreement.

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## 11. Access by PHARMAC to price and volume data

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- (a) You acknowledge that PHARMAC will require access to price and volume data held by 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 7.1 and 7.2 of Schedule Three regarding confidential information, you agree that where the circumstances in this clause apply, a DHB Hospital may provide PHARMAC with any price and volume data held by that DHB Hospital in respect of a Pharmaceutical covered by this Agreement.

## 12. Miscellaneous

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### 12.1 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.

### 12.2 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.

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### 12.3 Advertising

You must not procure, or in any way participate or assist in, the publishing of any Advertisement that:

- (a) is aimed at consumers of pharmaceuticals; and
- (b) breaches any applicable:
  - (i) statute or regulation, including the Fair Trading Act 1986, Medicines Act 1981 and Medicines Regulations 1984; or
  - (ii) industry standard, including the Advertising Standards Authority Codes of Practice and the Researched Medicines Industry 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.

### 12.4 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.

### 12.5 Agreement paramount

Notwithstanding any of your terms of supply, whether recorded on your invoices or in credit arrangements entered into or elsewhere, this Agreement will be paramount and will apply to the exclusion of any of your terms or documentation.

### 12.6 Entire agreement

This Agreement and, to the extent applicable, the Invitation:

- (a) constitute the entire agreement between PHARMAC and you regarding the terms on which the Pharmaceutical is listed and purchased by DHB Hospitals; and
- (b) supersede and extinguish all prior agreements and understandings between us regarding the Pharmaceutical.

## 12.7 **Amendments**

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

## 12.8 **Assignment**

Except as otherwise provided in the Agreement, you will not permit any part of the 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.

## 12.9 **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.

## 12.10 **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: Back-up supply standard terms

### 1. Standard terms

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The following terms contained in clauses 2 to 4 of this Schedule Six are the standard terms that are to apply to a Pharmaceutical in respect of which PHARMAC awards Back-up Supply Status. You and PHARMAC may agree to any additional terms, such as the reimbursement of stock and stock-holding arrangements, as a result of any negotiations carried out in accordance with clause 8.7 of Schedule Three.

### 2. Definitions

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For the purposes of this Schedule only:

**Agreement** means this Schedule Six, subject to any additional terms agreed between you and PHARMAC; and

**Pharmaceutical** means the relevant Tender Item for which you have submitted, and PHARMAC has accepted, a Back-up Supply Proposal.

### 3. Application of Schedule Five terms

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The following terms in Schedule Five form part of this Agreement (incorporating any alterations or modifications necessary to give effect to those provisions in the context of this Schedule):

- (a) clause 1 (OPPs and amendments to the Pharmaceutical Schedule);
- (b) clause 3 (consents);
- (c) clause 4.2 (supply price);
- (d) clause 4.3 (warranty that not less than cost price);
- (e) clause 5 (emergency and disaster supply);
- (f) clause 6 (defective and short-dated pharmaceuticals);
- (g) clause 7.3 (general indemnity);
- (h) clause 8.2 (Crown direction);
- (i) clause 10 (audit);
- (j) clause 11 (access by PHARMAC to price and volume data); and
- (k) clause 12 (litigation support, dispute resolution, advertising, no waiver, agreement paramount, entire agreement, amendments, assignment, further assurances, and jurisdiction and governing law).

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#### 4. **Notification of need for Back-up Supply**

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At any time during the Hospital Supply Period, PHARMAC may notify you in writing that you are to supply the Pharmaceutical with effect from the date specified in the notice (which date will take into account the lead-time specified in your Back-up Supply Submission Form), in which case:

- (a) you must supply the Pharmaceutical to wholesalers and other distributors or DHB Hospitals, as applicable, at the Price from the date specified in the notice until PHARMAC advises you to stop supplying the Pharmaceutical;
- (b) you must advise PHARMAC of your stock levels of the Pharmaceutical on a weekly basis, and at such other times as requested by PHARMAC, during that period of supply.

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**Appendix Two**  
**Draft Product List**

## Draft Hospital Tender Product List

Chemical	Presentation	Strength	DV limit	Suggested DV	BUS?	Additional comments
<b>Abciximab</b>						
	Injection	10mg/5ml	0%	___%	<input type="checkbox"/>	_____
<b>Acetylcysteine</b>						
	Injection 10ml	200mg/ml	0%	___%	<input type="checkbox"/>	_____
<b>Acyclovir</b>						
	Injection	250mg	0%	___%	<input type="checkbox"/>	_____
	Injection	500mg	0%	___%	<input type="checkbox"/>	_____
	Oral liquid	200mg/5ml	0%	___%	<input type="checkbox"/>	_____
	Tablets	200mg	0%	___%	<input type="checkbox"/>	_____
	Tablets	400mg	0%	___%	<input type="checkbox"/>	_____
	Tablets	800mg	0%	___%	<input type="checkbox"/>	_____
<b>Adenosine</b>						
	Injection 2ml	3mg/ml	0%	___%	<input type="checkbox"/>	_____
<b>Adrenaline hydrochloride</b>						
	Injection 10ml	1-10000	0%	___%	<input type="checkbox"/>	_____
	Injection 1ml	1-1000	0%	___%	<input type="checkbox"/>	_____
<b>Alfentanil</b>						
	Injection 2ml	0.5mg/ml	0%	___%	<input type="checkbox"/>	_____
<b>Alprostadiol</b>						
	Injection	500mcg	0%	___%	<input type="checkbox"/>	_____
<b>Alteplase; recombinant tissue type plasminogen activator (rt-PA)</b>						
	Injection	20mg	0%	___%	<input type="checkbox"/>	_____
	Injection	50mg	0%	___%	<input type="checkbox"/>	_____
<b>Amiodarone hydrochloride</b>						
	Injection 3ml	50mg/ml	10%	___%	<input type="checkbox"/>	_____
	Tablets	100mg	10%	___%	<input type="checkbox"/>	_____
	Tablets	200mg	10%	___%	<input type="checkbox"/>	_____
<b>Amoxicillin trihydrate &amp; potassium clavulanate</b>						
	Tablet	625mg	0%	___%	<input type="checkbox"/>	_____
<b>Amoxicillin 125mg with clavulanic acid 31.25mg per 5 ml</b>						
	Granules for oral liquid		0%	___%	<input type="checkbox"/>	_____
<b>Amoxicillin 250mg with clavulanic acid 62.5mg per 5ml</b>						
	Granules for oral liquid		0%	___%	<input type="checkbox"/>	_____
<b>Amoxicillin 500mg with clavulanic acid 100mg</b>						
	Injection	1.2g	0%	___%	<input type="checkbox"/>	_____
	Injection	600mg	0%	___%	<input type="checkbox"/>	_____
<b>Amoxicillin sodium</b>						
	Injection	1g	0%	___%	<input type="checkbox"/>	_____
	Injection	250mg	0%	___%	<input type="checkbox"/>	_____
	Injection	500mg	0%	___%	<input type="checkbox"/>	_____
<b>Amoxicillin trihydrate</b>						
	Capsules	250mg	0%	___%	<input type="checkbox"/>	_____
	Capsules	500mg	0%	___%	<input type="checkbox"/>	_____
<b>Amphotericin B</b>						
	Injection	50mg	0%	___%	<input type="checkbox"/>	_____

Note: "Suggested DV" is the amount of variation for an alternative brand that is recommended for patients for whom a potential tender winner is clinically needed (if different from the DV limit indicated). "BUS?" is a tick-box option if you think Back Up Supply is necessary for this product.

Chemical	Presentation	Strength	DV limit	Suggested DV	BUS?	Additional comments
<b>Aprotinin</b>						
	Injection	500 000iu	0%	___%	<input type="checkbox"/>	_____
<b>Atorvastatin</b>						
	Tablets	10mg	0%	___%	<input type="checkbox"/>	_____
	Tablets	20mg	0%	___%	<input type="checkbox"/>	_____
	Tablets	40mg	0%	___%	<input type="checkbox"/>	_____
<b>Atracurium besylate</b>						
	Injection 2.5ml	10mg/ml	0%	___%	<input type="checkbox"/>	_____
	Injection 5ml	10mg/ml	0%	___%	<input type="checkbox"/>	_____
<b>BCG vaccine</b>						
	Injection		0%	___%	<input type="checkbox"/>	_____
<b>Benzylpenicillin sodium</b>						
	Injection	1.2g	0%	___%	<input type="checkbox"/>	_____
	Injection	600mg	0%	___%	<input type="checkbox"/>	_____
<b>Beractant</b>						
	Suspension	200mg/8ml	0%	___%	<input type="checkbox"/>	_____
<b>Bleomycin sulphate</b>						
	Injection	15iu	0%	___%	<input type="checkbox"/>	_____
<b>Bupivacaine 0.125% with fentanyl 2mcg/ml</b>						
	Epidural infusion		0%	___%	<input type="checkbox"/>	_____
	Prefilled Syringe		0%	___%	<input type="checkbox"/>	_____
<b>Bupivacaine hydrochloride</b>						
	Injection 100ml	0.125%	0%	___%	<input type="checkbox"/>	_____
	Injection 100ml	0.25%	0%	___%	<input type="checkbox"/>	_____
	Injection 10ml plain	0.5%	0%	___%	<input type="checkbox"/>	_____
	Injection 200ml	0.125%	0%	___%	<input type="checkbox"/>	_____
	Injection 20ml	0.25%	0%	___%	<input type="checkbox"/>	_____
	Injection 20ml	0.375%	0%	___%	<input type="checkbox"/>	_____
	Injection 20ml	0.5%	0%	___%	<input type="checkbox"/>	_____
	Injection 4ml isobaric or heavy	0.5%	0%	___%	<input type="checkbox"/>	_____
<b>Bupivacaine hydrochloride 0.25% with adrenaline 1-400 000</b>						
	Injection 10ml		0%	___%	<input type="checkbox"/>	_____
<b>Bupivacaine hydrochloride 0.5% with adrenaline 1-200 000</b>						
	Injection 10ml		0%	___%	<input type="checkbox"/>	_____
	Injection 20ml		0%	___%	<input type="checkbox"/>	_____
<b>Calcium carbonate</b>						
	Tablets	500mg	0%	___%	<input type="checkbox"/>	_____
<b>Calcium chloride</b>						
	Injection 10ml	10%	0%	___%	<input type="checkbox"/>	_____
<b>Calcium folinate</b>						
	Injection 5ml	10mg/ml	0%	___%	<input type="checkbox"/>	_____
	Tablets	15mg	0%	___%	<input type="checkbox"/>	_____
<b>Calcium gluconate</b>						
	Injection 10ml	10%	0%	___%	<input type="checkbox"/>	_____
<b>Capecitabine</b>						
	Tablets	150mg	0%	___%	<input type="checkbox"/>	_____
	Tablets	500mg	0%	___%	<input type="checkbox"/>	_____

Note: "Suggested DV" is the amount of variation for an alternative brand that is recommended for patients for whom a potential tender winner is clinically needed (if different from the DV limit indicated). "BUS?" is a tick-box option if you think Back Up Supply is necessary for this product.

**Chemical**

Presentation	Strength	DV limit	Suggested DV	BUS?	Additional comments
<b>Carboplatin</b>					
Injection 15ml	10mg/ml	0%	___%	<input type="checkbox"/>	_____
Injection 45ml	10mg/ml	0%	___%	<input type="checkbox"/>	_____
Injection 5ml	10mg/ml	0%	___%	<input type="checkbox"/>	_____
<b>Cefamandole naftate</b>					
Injection	1g	0%	___%	<input type="checkbox"/>	_____
Injection	500mg	0%	___%	<input type="checkbox"/>	_____
<b>Cefazolin sodium</b>					
Injection	1g	0%	___%	<input type="checkbox"/>	_____
Injection	500mg	0%	___%	<input type="checkbox"/>	_____
<b>Cefepime hydrochloride</b>					
Injection	1g	0%	___%	<input type="checkbox"/>	_____
Injection	2g	0%	___%	<input type="checkbox"/>	_____
Injection	500mg	0%	___%	<input type="checkbox"/>	_____
<b>Cefotaxime</b>					
Injection	1g	0%	___%	<input type="checkbox"/>	_____
Injection	2g	0%	___%	<input type="checkbox"/>	_____
Injection	500mg	0%	___%	<input type="checkbox"/>	_____
<b>Cefotetan</b>					
Injection	1g	0%	___%	<input type="checkbox"/>	_____
Injection	2g	0%	___%	<input type="checkbox"/>	_____
<b>Cefoxitin sodium</b>					
Injection	1g	0%	___%	<input type="checkbox"/>	_____
Injection	2g	0%	___%	<input type="checkbox"/>	_____
<b>Ceftazidime</b>					
Injection	1g	0%	___%	<input type="checkbox"/>	_____
Injection	2g	0%	___%	<input type="checkbox"/>	_____
Injection	500mg	0%	___%	<input type="checkbox"/>	_____
<b>Ceftriaxone sodium</b>					
Injection	1g	0%	___%	<input type="checkbox"/>	_____
Injection	250mg	0%	___%	<input type="checkbox"/>	_____
Injection	2g	0%	___%	<input type="checkbox"/>	_____
Injection	500mg	0%	___%	<input type="checkbox"/>	_____
<b>Cefuroxime axetil</b>					
Suspension	125mg/ml	0%	___%	<input type="checkbox"/>	_____
Tablets	125mg	0%	___%	<input type="checkbox"/>	_____
Tablets	250mg	0%	___%	<input type="checkbox"/>	_____
<b>Cefuroxime sodium</b>					
Injection as powder	1.5g	0%	___%	<input type="checkbox"/>	_____
Injection as powder	250mg	0%	___%	<input type="checkbox"/>	_____
Injection as powder	750mg	0%	___%	<input type="checkbox"/>	_____
<b>Cephazolin sodium</b>					
Injection 10ml	1g	0%	___%	<input type="checkbox"/>	_____
Injection 10ml	500mg	0%	___%	<input type="checkbox"/>	_____
<b>Charcoal activated 50g &amp; Sorbitol 70%</b>					
Liquid		0%	___%	<input type="checkbox"/>	_____

Note: "Suggested DV" is the amount of variation for an alternative brand that is recommended for patients for whom a potential tender win is clinically needed (if different from the DV limit indicated). "BUS?" is a tick-box option if you think Back Up Supply is necessary for this product.

**Chemical**

Presentation	Strength	DV limit	Suggested DV	BUS?	Additional comments
<b>Ciprofloxacin</b>					
Injection IV	2mg/ml	0%	___%	<input type="checkbox"/>	_____
Oral Suspension	10%	0%	___%	<input type="checkbox"/>	_____
Oral Suspension	5%	0%	___%	<input type="checkbox"/>	_____
Tablets	250mg	0%	___%	<input type="checkbox"/>	_____
Tablets	500mg	0%	___%	<input type="checkbox"/>	_____
Tablets	750mg	0%	___%	<input type="checkbox"/>	_____
<b>Clarithromycin</b>					
Injection IV	0.5g	0%	___%	<input type="checkbox"/>	_____
Tablets	250mg	0%	___%	<input type="checkbox"/>	_____
<b>Clindamycin hydrochloride</b>					
Capsules	150mg	0%	___%	<input type="checkbox"/>	_____
<b>Clindamycin phosphate</b>					
Injection 4ml	150mg/ml	0%	___%	<input type="checkbox"/>	_____
<b>Clopidogrel</b>					
Tablets	75mg	0%	___%	<input type="checkbox"/>	_____
<b>Clostridium Botulinum</b>					
Vials	500iu	0%	___%	<input type="checkbox"/>	_____
<b>Clozapine</b>					
Tablets	100mg	0%	___%	<input type="checkbox"/>	_____
Tablets	25mg	0%	___%	<input type="checkbox"/>	_____
<b>Cyclizine hydrochloride</b>					
Oral liquid	12.5mg/5ml	0%	___%	<input type="checkbox"/>	_____
Tablets	50mg	0%	___%	<input type="checkbox"/>	_____
<b>Cyclizine lactate</b>					
Injection 1ml	50mg/ml	0%	___%	<input type="checkbox"/>	_____
<b>Cyclophosphamide</b>					
Injection	1g	0%	___%	<input type="checkbox"/>	_____
Injection	500mg	0%	___%	<input type="checkbox"/>	_____
Tablets	50mg	0%	___%	<input type="checkbox"/>	_____
<b>Cyclosporin</b>					
Capsules	100mg	0%	___%	<input type="checkbox"/>	_____
Capsules	25mg	0%	___%	<input type="checkbox"/>	_____
Injection IV	250mg/5ml	0%	___%	<input type="checkbox"/>	_____
Oral liquid	100mg/ml	0%	___%	<input type="checkbox"/>	_____
<b>Cyproterone acetate</b>					
Tablets	50mg	0%	___%	<input type="checkbox"/>	_____
<b>Cytarabine</b>					
Injection 10ml	100mg/ml	0%	___%	<input type="checkbox"/>	_____
Injection 1ml	100mg/ml	0%	___%	<input type="checkbox"/>	_____
Injection 20ml	100mg/ml	0%	___%	<input type="checkbox"/>	_____

Note: "Suggested DV" is the amount of variation for an alternative brand that is recommended for patients for whom a potential tender winner is clinically needed (if different from the DV limit indicated). "BUS?" is a tick-box option if you think Back Up Supply is necessary for this product.

**Chemical**

Presentation	Strength	DV limit	Suggested DV	BUS?	Additional comments
<b>Dalteparin sodium</b>					
Injection	1000iu/0.4ml	0%	___%	<input type="checkbox"/>	_____
Injection	12500iu/0.5ml	0%	___%	<input type="checkbox"/>	_____
Injection	15000iu/0.6ml	0%	___%	<input type="checkbox"/>	_____
Injection	18000iu/0.72ml	0%	___%	<input type="checkbox"/>	_____
Injection	2500iu/0.2ml	0%	___%	<input type="checkbox"/>	_____
Injection	5000iu/0.2ml	0%	___%	<input type="checkbox"/>	_____
<b>Desflurane</b>					
Inhalation	100%	0%	___%	<input type="checkbox"/>	_____
<b>Dexamethasone</b>					
Tablets	4mg	0%	___%	<input type="checkbox"/>	_____
<b>Dexamethasone sodium phosphate</b>					
Injection 2ml	4mg/ml	0%	___%	<input type="checkbox"/>	_____
<b>Dinoprostone</b>					
Gel	1mg/2.5ml	0%	___%	<input type="checkbox"/>	_____
Gel	2mg/2.5ml	0%	___%	<input type="checkbox"/>	_____
<b>Disodium pamidronate</b>					
Injection	30mg	0%	___%	<input type="checkbox"/>	_____
Injection	90mg	0%	___%	<input type="checkbox"/>	_____
<b>Dobutamine hydrochloride</b>					
Injection 20ml	250mg/20ml	0%	___%	<input type="checkbox"/>	_____
<b>Docetaxel</b>					
Solution	80mg/2ml	0%	___%	<input type="checkbox"/>	_____
Vial	20mg/0.5ml	0%	___%	<input type="checkbox"/>	_____
<b>Dopamine hydrochloride</b>					
Injection 5ml	40mg/ml	0%	___%	<input type="checkbox"/>	_____
<b>Dornase</b>					
Injection	2.5mg	0%	___%	<input type="checkbox"/>	_____
<b>Doxorubicin hydrochloride</b>					
Injection	10mg	0%	___%	<input type="checkbox"/>	_____
Injection	50mg	0%	___%	<input type="checkbox"/>	_____
<b>Ephedrine sulphate</b>					
Injection 1ml	30mg/ml	0%	___%	<input type="checkbox"/>	_____
<b>Erythromycin</b>					
Tablets or capsules	250mg	0%	___%	<input type="checkbox"/>	_____
<b>Erythromycin ethyl succinate</b>					
Granules for oral liquid	200mg/5ml	0%	___%	<input type="checkbox"/>	_____
Granules for oral liquid	400mg/5ml	0%	___%	<input type="checkbox"/>	_____
Tablets	200mg	0%	___%	<input type="checkbox"/>	_____
Tablets	400mg	0%	___%	<input type="checkbox"/>	_____
<b>Erythromycin lactobionate</b>					
Injection	1g	0%	___%	<input type="checkbox"/>	_____
Injection	300mg	0%	___%	<input type="checkbox"/>	_____

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**Chemical**

Presentation	Strength	DV limit	Suggested DV	BUS?	Additional comments
<b>Erythropoietin</b>					
Injection 1ml	10 000iu/ml	0%	___%	<input type="checkbox"/>	_____
Injection 1ml	1000iu/ml	0%	___%	<input type="checkbox"/>	_____
Injection 1ml	2000iu/ml	0%	___%	<input type="checkbox"/>	_____
Injection 1ml	3000iu	0%	___%	<input type="checkbox"/>	_____
Injection 1ml	4000iu/ml	0%	___%	<input type="checkbox"/>	_____
Prefilled Syringe 0.3ml	3000iu/0.3ml	0%	___%	<input type="checkbox"/>	_____
Prefilled Syringe 0.4ml	4000iu/0.4ml	0%	___%	<input type="checkbox"/>	_____
Prefilled Syringe 0.5ml	2000iu/0.5ml	0%	___%	<input type="checkbox"/>	_____
<b>Fentanyl citrate</b>					
Injection 10ml	0.05mg/ml	0%	___%	<input type="checkbox"/>	_____
Injection 2ml	0.05mg/ml	0%	___%	<input type="checkbox"/>	_____
<b>Filgrastim G-CSF</b>					
Injection	300mcg	0%	___%	<input type="checkbox"/>	_____
<b>Flucloxacillin sodium</b>					
Capsules	250mg	0%	___%	<input type="checkbox"/>	_____
Capsules	500mg	0%	___%	<input type="checkbox"/>	_____
Granules for oral liquid	125mg/5ml	0%	___%	<input type="checkbox"/>	_____
Granules for oral liquid	250mg/5ml	0%	___%	<input type="checkbox"/>	_____
Injection	1g	0%	___%	<input type="checkbox"/>	_____
Injection	250mg	0%	___%	<input type="checkbox"/>	_____
Injection	500mg	0%	___%	<input type="checkbox"/>	_____
<b>Fluconazole</b>					
Capsules	150mg	0%	___%	<input type="checkbox"/>	_____
Capsules	200mg	0%	___%	<input type="checkbox"/>	_____
Capsules	50mg	0%	___%	<input type="checkbox"/>	_____
Injection IV 50ml	2mg/ml	0%	___%	<input type="checkbox"/>	_____
<b>Fludarabine phosphate</b>					
Injection	50mg	0%	___%	<input type="checkbox"/>	_____
<b>Fluticasone propionate</b>					
Dry Powder Inhaler	100mcg	0%	___%	<input type="checkbox"/>	_____
Dry Powder Inhaler	250mcg	0%	___%	<input type="checkbox"/>	_____
Dry Powder Inhaler	500mcg	0%	___%	<input type="checkbox"/>	_____
Dry Powder Inhaler	50mcg	0%	___%	<input type="checkbox"/>	_____
Metered Dose Inhaler	125mcg	0%	___%	<input type="checkbox"/>	_____
Metered Dose Inhaler	250mcg	0%	___%	<input type="checkbox"/>	_____
Metered Dose Inhaler	25mcg	0%	___%	<input type="checkbox"/>	_____
Metered Dose Inhaler	50mcg	0%	___%	<input type="checkbox"/>	_____
Nasal Spray Aqueous	0.05%	0%	___%	<input type="checkbox"/>	_____
Rotadisks	100mcg	0%	___%	<input type="checkbox"/>	_____
Rotadisks	250mcg	0%	___%	<input type="checkbox"/>	_____
Rotadisks	500mcg	0%	___%	<input type="checkbox"/>	_____
Rotadisks	50mcg	0%	___%	<input type="checkbox"/>	_____
<b>Follitropin</b>					
Injection	150iu	0%	___%	<input type="checkbox"/>	_____
Injection	75iu	0%	___%	<input type="checkbox"/>	_____

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**Chemical**

Presentation	Strength	DV limit	Suggested DV	BUS?	Additional comments
<b>Follitropin beta</b>					
Powder for Injection	100iu	0%	___%	<input type="checkbox"/>	_____
Powder for Injection	50iu	0%	___%	<input type="checkbox"/>	_____
<b>Gabapentin</b>					
Capsules	100mg	0%	___%	<input type="checkbox"/>	_____
Capsules	300mg	0%	___%	<input type="checkbox"/>	_____
Capsules	400mg	0%	___%	<input type="checkbox"/>	_____
<b>Ganciclovir</b>					
Capsules	250mg	0%	___%	<input type="checkbox"/>	_____
Injection IV	500mg	0%	___%	<input type="checkbox"/>	_____
<b>Gemcitabine Hydrochloride</b>					
Powder Vials for Injection	1g	0%	___%	<input type="checkbox"/>	_____
Powder Vials for Injection	200mg	0%	___%	<input type="checkbox"/>	_____
<b>Gentamicin sulphate</b>					
Injection 2ml	10mg/ml	0%	___%	<input type="checkbox"/>	_____
Injection 2ml	40mg/ml	0%	___%	<input type="checkbox"/>	_____
<b>Glyceryl trinitrate</b>					
Injection	50mg/10ml	0%	___%	<input type="checkbox"/>	_____
Injection 5ml	1mg/1ml	0%	___%	<input type="checkbox"/>	_____
Pump Spray	400mcg/dose	0%	___%	<input type="checkbox"/>	_____
Tablets	600mcg	0%	___%	<input type="checkbox"/>	_____
Transdermal delivery system	10mg	0%	___%	<input type="checkbox"/>	_____
Transdermal delivery system	5mg	0%	___%	<input type="checkbox"/>	_____
<b>Goserelin acetate</b>					
Injection	3.6mg	0%	___%	<input type="checkbox"/>	_____
Injection Subcutaneous	10.8mg	0%	___%	<input type="checkbox"/>	_____
<b>Haemaccel</b>					
Infusion		0%	___%	<input type="checkbox"/>	_____
<b>Heparin sodium</b>					
Injection 0.2ml	25 000iu/ml	0%	___%	<input type="checkbox"/>	_____
Injection 0.2ml	5000iu/ml	0%	___%	<input type="checkbox"/>	_____
Injection 0.5ml	10 000iu/ml	0%	___%	<input type="checkbox"/>	_____
Injection 1ml	1000iu/ml	0%	___%	<input type="checkbox"/>	_____
Injection 1ml	5000iu/ml	0%	___%	<input type="checkbox"/>	_____
Injection 35ml	1000iu/ml	0%	___%	<input type="checkbox"/>	_____
Injection 5ml	1000iu/ml	0%	___%	<input type="checkbox"/>	_____
Injection 5ml	100iu/ml	0%	___%	<input type="checkbox"/>	_____
Injection 5ml	10iu/ml	0%	___%	<input type="checkbox"/>	_____
Injection 5ml	25000iu/ml	0%	___%	<input type="checkbox"/>	_____
Injection 5ml	5000iu/ml	0%	___%	<input type="checkbox"/>	_____
<b>Heparinised saline</b>					
Injection	100iu/ml	0%	___%	<input type="checkbox"/>	_____
Injection	500iu/5ml	0%	___%	<input type="checkbox"/>	_____
Injection	50iu/5ml	0%	___%	<input type="checkbox"/>	_____
<b>Hyaluronidase</b>					
Injection	1500iu	0%	___%	<input type="checkbox"/>	_____

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**Chemical**

Presentation	Strength	DV limit	Suggested DV	BUS?	Additional comments
<b>Hydrocortisone sodium succinate</b>					
Injection 2ml	50mg/ml	5%	___%	<input type="checkbox"/>	_____
<b>Iloprost</b>					
Injection 0.5ml	0.1mg/ml	0%	___%	<input type="checkbox"/>	_____
<b>Imipenem 500mg with sodium cilastatin 500mg</b>					
Injection	500mg	0%	___%	<input type="checkbox"/>	_____
<b>Infliximab</b>					
Injection	100mg	0%	___%	<input type="checkbox"/>	_____
<b>Ipratropium bromide</b>					
Aerosol inhaler	20mcg/dose	0%	___%	<input type="checkbox"/>	_____
Aerosol inhaler	40mcg/dose	0%	___%	<input type="checkbox"/>	_____
Nebuliser solution 1ml	250mcg/ml	0%	___%	<input type="checkbox"/>	_____
Nebuliser solution 2ml	250mcg	0%	___%	<input type="checkbox"/>	_____
Nebuliser solution 2ml	500mcg	0%	___%	<input type="checkbox"/>	_____
<b>Irinotecan hydrochloride</b>					
Injection	100mg	0%	___%	<input type="checkbox"/>	_____
Injection	40mg/2ml	0%	___%	<input type="checkbox"/>	_____
<b>Isoflurane</b>					
Liquid	100%	0%	___%	<input type="checkbox"/>	_____
<b>Isotretinoin</b>					
Capsules	10mg	0%	___%	<input type="checkbox"/>	_____
Capsules	20mg	0%	___%	<input type="checkbox"/>	_____
<b>Ketamine hydrochloride</b>					
Injection	100mg/ml	0%	___%	<input type="checkbox"/>	_____
Injection	50mg/ml	0%	___%	<input type="checkbox"/>	_____
<b>Leuprorelin</b>					
Injection	1mg/0.2ml	0%	___%	<input type="checkbox"/>	_____
<b>Leuprorelin acetate</b>					
Injection	3.75mg	0%	___%	<input type="checkbox"/>	_____
<b>Lignocaine 1% with adrenaline 1:100000</b>					
Injection 5ml		0%	___%	<input type="checkbox"/>	_____
<b>Lignocaine 1% with adrenaline 1:200000</b>					
Injection 20ml		0%	___%	<input type="checkbox"/>	_____
<b>Lignocaine 2% with adrenaline 1:100000</b>					
Injection 2.2ml		0%	___%	<input type="checkbox"/>	_____
<b>Lignocaine 2% with adrenaline 1:200000</b>					
Injection 20ml		0%	___%	<input type="checkbox"/>	_____

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**Chemical**

Presentation	Strength	DV limit	Suggested DV	BUS?	Additional comments
<b>Lignocaine hydrochloride</b>					
Injection 100ml	2%	0%	___%	<input type="checkbox"/>	_____
Injection 10ml	10%	0%	___%	<input type="checkbox"/>	_____
Injection 20ml	0.5%	0%	___%	<input type="checkbox"/>	_____
Injection 20ml	1%	0%	___%	<input type="checkbox"/>	_____
Injection 20ml	10%	0%	___%	<input type="checkbox"/>	_____
Injection 20ml	2%	0%	___%	<input type="checkbox"/>	_____
Injection 2ml	1%	0%	___%	<input type="checkbox"/>	_____
Injection 2ml	2%	0%	___%	<input type="checkbox"/>	_____
Injection 50ml	1%	0%	___%	<input type="checkbox"/>	_____
Injection 50ml	2%	0%	___%	<input type="checkbox"/>	_____
Injection 5ml	0.5%	0%	___%	<input type="checkbox"/>	_____
Injection 5ml	1%	0%	___%	<input type="checkbox"/>	_____
Injection 5ml	10%	0%	___%	<input type="checkbox"/>	_____
Injection 5ml	2%	0%	___%	<input type="checkbox"/>	_____
Topical spray	10%	0%	___%	<input type="checkbox"/>	_____
<b>Lignocaine hydrochloride 2% with chlorhexidine gluconate 0.05%</b>					
Tube		0%	___%	<input type="checkbox"/>	_____
<b>Magnesium sulphate</b>					
Injection 5ml	49.3%	0%	___%	<input type="checkbox"/>	_____
<b>Meropenem</b>					
Injection	250mg	0%	___%	<input type="checkbox"/>	_____
Injection	500mg	0%	___%	<input type="checkbox"/>	_____
<b>Metaraminol tartrate</b>					
Injection 1ml	10mg/ml	0%	___%	<input type="checkbox"/>	_____
<b>Methotrexate</b>					
Injection 10ml	100mg/ml	0%	___%	<input type="checkbox"/>	_____
Injection 20ml	25mg/ml	0%	___%	<input type="checkbox"/>	_____
Injection 2ml	2.5mg/ml	0%	___%	<input type="checkbox"/>	_____
Injection 2ml	25mg/ml	0%	___%	<input type="checkbox"/>	_____
Injection 4ml	25mg/ml	0%	___%	<input type="checkbox"/>	_____
Tablets	10mg	0%	___%	<input type="checkbox"/>	_____
Tablets	2.5mg	0%	___%	<input type="checkbox"/>	_____
<b>Methylprednisolone acetate</b>					
Injection 1ml	20mg/ml	0%	___%	<input type="checkbox"/>	_____
Injection 1ml	40mg/ml	0%	___%	<input type="checkbox"/>	_____
Injection 2ml	40mg/ml	0%	___%	<input type="checkbox"/>	_____
Injection 5ml	20mg/ml	0%	___%	<input type="checkbox"/>	_____
Injection 5ml	40mg/ml	0%	___%	<input type="checkbox"/>	_____
<b>Methylprednisolone sodium succinate</b>					
Injection	1g	0%	___%	<input type="checkbox"/>	_____
Injection	2g	0%	___%	<input type="checkbox"/>	_____
Injection	500mg	0%	___%	<input type="checkbox"/>	_____
Injection 1ml	40mg/ml	0%	___%	<input type="checkbox"/>	_____

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**Chemical**

Presentation	Strength	DV limit	Suggested DV	BUS?	Additional comments
<b>Metoclopramide hydrochloride</b>					
Injection 2ml	5mg/ml	0%	___%	<input type="checkbox"/>	_____
Oral liquid	5mg/5ml	0%	___%	<input type="checkbox"/>	_____
Tablets	10mg	0%	___%	<input type="checkbox"/>	_____
<b>Metronidazole</b>					
Injection 100ml	500mg	0%	___%	<input type="checkbox"/>	_____
Suppositories	1g	0%	___%	<input type="checkbox"/>	_____
Suppositories	500mg	0%	___%	<input type="checkbox"/>	_____
Tablets	200mg	0%	___%	<input type="checkbox"/>	_____
Tablets	400mg	0%	___%	<input type="checkbox"/>	_____
<b>Midazolam</b>					
Injection 1ml	5mg/ml	0%	___%	<input type="checkbox"/>	_____
Injection 3ml	5mg/ml	0%	___%	<input type="checkbox"/>	_____
Injection 5ml	1mg/ml	0%	___%	<input type="checkbox"/>	_____
Tablets	7.5mg	0%	___%	<input type="checkbox"/>	_____
<b>Morphine hydrochloride</b>					
Oral liquid	10mg/ml	0%	___%	<input type="checkbox"/>	_____
Oral liquid	1mg/ml	0%	___%	<input type="checkbox"/>	_____
Oral liquid	2mg/ml	0%	___%	<input type="checkbox"/>	_____
Oral liquid	5mg/ml	0%	___%	<input type="checkbox"/>	_____
Powder		0%	___%	<input type="checkbox"/>	_____
Tablet	100mg	0%	___%	<input type="checkbox"/>	_____
Tablet	10mg	0%	___%	<input type="checkbox"/>	_____
Tablet	30mg	0%	___%	<input type="checkbox"/>	_____
Tablet	60mg	0%	___%	<input type="checkbox"/>	_____

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**Chemical**

Presentation	Strength	DV limit	Suggested DV	BUS?	Additional comments
<b>Morphine sulphate</b>					
Capsules long-acting	100mg	0%	___%	<input type="checkbox"/>	_____
Capsules long-acting	10mg	0%	___%	<input type="checkbox"/>	_____
Capsules long-acting	20mg	0%	___%	<input type="checkbox"/>	_____
Capsules long-acting	50mg	0%	___%	<input type="checkbox"/>	_____
Injection 1ml	10mg/ml	0%	___%	<input type="checkbox"/>	_____
Injection 1ml	15mg/ml	0%	___%	<input type="checkbox"/>	_____
Injection 1ml	2mg/ml	0%	___%	<input type="checkbox"/>	_____
Injection 1ml	30mg/ml	0%	___%	<input type="checkbox"/>	_____
Injection 1ml	5mg/ml	0%	___%	<input type="checkbox"/>	_____
Injection 30ml	1mg/ml	0%	___%	<input type="checkbox"/>	_____
Injection 30ml	2mg/ml	0%	___%	<input type="checkbox"/>	_____
Injection 4ml	30mg/ml	0%	___%	<input type="checkbox"/>	_____
Injection 50ml	1mg/ml	0%	___%	<input type="checkbox"/>	_____
Injection 5ml	10mg/ml	0%	___%	<input type="checkbox"/>	_____
Powder		0%	___%	<input type="checkbox"/>	_____
Suppositories	10mg	0%	___%	<input type="checkbox"/>	_____
Suppositories	20mg	0%	___%	<input type="checkbox"/>	_____
Suppositories	30mg	0%	___%	<input type="checkbox"/>	_____
Suppositories	5mg	0%	___%	<input type="checkbox"/>	_____
Tablets immediate release	10mg	0%	___%	<input type="checkbox"/>	_____
Tablets immediate release	20mg	0%	___%	<input type="checkbox"/>	_____
Tablets long acting	100mg	0%	___%	<input type="checkbox"/>	_____
Tablets long acting	10mg	0%	___%	<input type="checkbox"/>	_____
Tablets long acting	200mg	0%	___%	<input type="checkbox"/>	_____
Tablets long acting	30mg	0%	___%	<input type="checkbox"/>	_____
Tablets long acting	60mg	0%	___%	<input type="checkbox"/>	_____
<b>Morphine tartrate</b>					
Injection 1.5ml	80mg/ml	0%	___%	<input type="checkbox"/>	_____
Injection 5ml	80mg/ml	0%	___%	<input type="checkbox"/>	_____
<b>Mycophenolate Mofetil</b>					
Capsules	250mg	0%	___%	<input type="checkbox"/>	_____
<b>Naloxone hydrochloride</b>					
Injection 1ml	400mcg/ml	0%	___%	<input type="checkbox"/>	_____
<b>Nimodipine</b>					
Injection 50ml	200mcg/ml	0%	___%	<input type="checkbox"/>	_____
Tablets	30mg	0%	___%	<input type="checkbox"/>	_____
<b>Octreotide</b>					
Injection 1ml	100mcg/ml	0%	___%	<input type="checkbox"/>	_____
Injection 1ml	500mcg/ml	0%	___%	<input type="checkbox"/>	_____
Injection 1ml	50mcg/ml	0%	___%	<input type="checkbox"/>	_____

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**Chemical**

Presentation	Strength	DV limit	Suggested DV	BUS?	Additional comments
<b>Olanzapine</b>					
Tablets	10mg	0%	___%	<input type="checkbox"/>	_____
Tablets	2.5mg	0%	___%	<input type="checkbox"/>	_____
Tablets	5mg	0%	___%	<input type="checkbox"/>	_____
Wafer	10mg	0%	___%	<input type="checkbox"/>	_____
Wafer	5mg	0%	___%	<input type="checkbox"/>	_____
<b>Omeprazole</b>					
Capsules	10mg	0%	___%	<input type="checkbox"/>	_____
Capsules	20mg	0%	___%	<input type="checkbox"/>	_____
Capsules	40mg	0%	___%	<input type="checkbox"/>	_____
Injection	40mg	0%	___%	<input type="checkbox"/>	_____
<b>Ondansetron hydrochloride</b>					
Injection 2ml	4mg/2ml	0%	___%	<input type="checkbox"/>	_____
Injection 4ml	8mg/4ml	0%	___%	<input type="checkbox"/>	_____
Tablets	4mg	0%	___%	<input type="checkbox"/>	_____
Tablets	8mg	0%	___%	<input type="checkbox"/>	_____
Wafer	4mg	0%	___%	<input type="checkbox"/>	_____
Wafer	8mg	0%	___%	<input type="checkbox"/>	_____
<b>Oxytocin</b>					
Injection 1ml	10iu/ml	0%	___%	<input type="checkbox"/>	_____
Injection 1ml	5iu/ml	0%	___%	<input type="checkbox"/>	_____
<b>Paclitaxel</b>					
Injection	100mg	0%	___%	<input type="checkbox"/>	_____
Solution for infusion 5ml	6mg/ml	0%	___%	<input type="checkbox"/>	_____
<b>Pancuronium bromide</b>					
Injection 2ml	2mg/ml	0%	___%	<input type="checkbox"/>	_____
<b>Pantoprazole</b>					
Tablets	20mg	0%	___%	<input type="checkbox"/>	_____
Tablets	40mg	0%	___%	<input type="checkbox"/>	_____
<b>Paracetamol</b>					
Oral liquid	120mg/5ml	5%	___%	<input type="checkbox"/>	_____
Oral liquid	250mg/5ml	5%	___%	<input type="checkbox"/>	_____
Suppositories	125mg	5%	___%	<input type="checkbox"/>	_____
Suppositories	250mg	5%	___%	<input type="checkbox"/>	_____
Suppositories	500mg	5%	___%	<input type="checkbox"/>	_____
Tablets	500mg	5%	___%	<input type="checkbox"/>	_____
<b>Paroxetine hydrochloride</b>					
Tablets	20mg	0%	___%	<input type="checkbox"/>	_____
<b>Pentastarch</b>					
Injection IV 500ml	10%	0%	___%	<input type="checkbox"/>	_____
Injection IV 500ml	6%	0%	___%	<input type="checkbox"/>	_____

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**Chemical**

Presentation	Strength	DV limit	Suggested DV	BUS?	Additional comments
<b>Phenytoin sodium</b>					
Capsules	100mg	10%	___%	<input type="checkbox"/>	_____
Capsules	30mg	10%	___%	<input type="checkbox"/>	_____
Injection 2ml	50mg/ml	10%	___%	<input type="checkbox"/>	_____
Injection 5ml	50mg/ml	10%	___%	<input type="checkbox"/>	_____
Oral liquid	100mg/5ml	10%	___%	<input type="checkbox"/>	_____
Oral liquid	30mg/5ml	10%	___%	<input type="checkbox"/>	_____
Tablets	50mg	10%	___%	<input type="checkbox"/>	_____
<b>Piperacillin</b>					
Injection	1g	0%	___%	<input type="checkbox"/>	_____
Injection	2g	0%	___%	<input type="checkbox"/>	_____
Injection	4g	0%	___%	<input type="checkbox"/>	_____
<b>Piperacillin 2g with tazobactam 25mg</b>					
Injection	2.25g	0%	___%	<input type="checkbox"/>	_____
Injection	4.5g	0%	___%	<input type="checkbox"/>	_____
<b>Potassium chloride</b>					
Injection 10ml	150mg/ml	0%	___%	<input type="checkbox"/>	_____
Injection 10ml	75mg/ml	0%	___%	<input type="checkbox"/>	_____
Oral Solution	2mmol/ml	0%	___%	<input type="checkbox"/>	_____
Tablets long acting	600mg	0%	___%	<input type="checkbox"/>	_____
<b>Potassium dihydrogen phosphate</b>					
Injection 10ml	1mmol/ml	0%	___%	<input type="checkbox"/>	_____
<b>Potassium with chloride</b>					
Tablets effervescent		0%	___%	<input type="checkbox"/>	_____
<b>Prilocaine hydrochloride</b>					
Injection 50ml	0.5%	0%	___%	<input type="checkbox"/>	_____
Injection 5ml	1%	0%	___%	<input type="checkbox"/>	_____
Injection 5ml	2%	0%	___%	<input type="checkbox"/>	_____
<b>Prilocaine hydrochloride 3% with felypressin (octapressin)</b>					
Injection 2.2 ml		0%	___%	<input type="checkbox"/>	_____
<b>Propofol</b>					
Injection 100ml	10mg/ml	0%	___%	<input type="checkbox"/>	_____
Injection 100ml	20mg/ml	0%	___%	<input type="checkbox"/>	_____
Injection 20ml	10mg/ml	0%	___%	<input type="checkbox"/>	_____
Injection 20ml	20mg/ml	0%	___%	<input type="checkbox"/>	_____
Injection 50ml	10mg/ml	0%	___%	<input type="checkbox"/>	_____
<b>Quetiapine fumarate</b>					
Tablets	100mg	0%	___%	<input type="checkbox"/>	_____
Tablets	200mg	0%	___%	<input type="checkbox"/>	_____
Tablets	25mg	0%	___%	<input type="checkbox"/>	_____
<b>Remifentanyl</b>					
Vial	1mg	0%	___%	<input type="checkbox"/>	_____
Vial	2mg	0%	___%	<input type="checkbox"/>	_____
Vial	5mg	0%	___%	<input type="checkbox"/>	_____
<b>Reteplase</b>					
Powder For Reconstitution	10u	0%	___%	<input type="checkbox"/>	_____

Note: "Suggested DV" is the amount of variation for an alternative brand that is recommended for patients for whom a potential tender win is clinically needed (if different from the DV limit indicated). "BUS?" is a tick-box option if you think Back Up Supply is necessary for this product.

**Chemical**

Presentation	Strength	DV limit	Suggested DV	BUS?	Additional comments
<b>Risperidone</b>					
Oral Liquid	1mg/ml	0%	___%	<input type="checkbox"/>	_____
Tablets	0.5mg	0%	___%	<input type="checkbox"/>	_____
Tablets	1mg	0%	___%	<input type="checkbox"/>	_____
Tablets	2mg	0%	___%	<input type="checkbox"/>	_____
Tablets	3mg	0%	___%	<input type="checkbox"/>	_____
Tablets	4mg	0%	___%	<input type="checkbox"/>	_____
<b>Rituximab</b>					
Vials	100mg	0%	___%	<input type="checkbox"/>	_____
Vials	500mg	0%	___%	<input type="checkbox"/>	_____
<b>Rocuronium bromide</b>					
Injection 10ml	100mg/10ml	0%	___%	<input type="checkbox"/>	_____
Injection 5ml	50mg/5ml	0%	___%	<input type="checkbox"/>	_____
<b>Ropivacaine</b>					
Infusion	10mg/ml	0%	___%	<input type="checkbox"/>	_____
Infusion	2mg/ml	0%	___%	<input type="checkbox"/>	_____
Infusion	2mg/ml	0%	___%	<input type="checkbox"/>	_____
Infusion	7.5mg/ml	0%	___%	<input type="checkbox"/>	_____
<b>Ropivacaine 2mg/ml with fentanyl 2mcg/ml</b>					
Infusion		0%	___%	<input type="checkbox"/>	_____
<b>Salbutamol 100mcg with ipratropium bromide 20mcg</b>					
Aerosol inhaler		0%	___%	<input type="checkbox"/>	_____
Respules 2.5ml		0%	___%	<input type="checkbox"/>	_____
<b>Salbutamol 2.5mg with ipratropium bromide 2.5ml</b>					
Respules		0%	___%	<input type="checkbox"/>	_____
<b>Salbutamol sulphate</b>					
Aerosol inhaler	100mcg/dose	5%	___%	<input type="checkbox"/>	_____
Aerosol inhaler breath act.	100mcg/dose	5%	___%	<input type="checkbox"/>	_____
Injection 1ml	500mcg/ml	5%	___%	<input type="checkbox"/>	_____
Injection 5ml	1mg/ml	5%	___%	<input type="checkbox"/>	_____
Nebuliser solution 2.5ml	1mg/ml	5%	___%	<input type="checkbox"/>	_____
Nebuliser solution 2.5ml	2mg/ml	5%	___%	<input type="checkbox"/>	_____
Oral liquid	2mg/5ml	5%	___%	<input type="checkbox"/>	_____
Tablets long acting	4mg	5%	___%	<input type="checkbox"/>	_____
Tablets long acting	8mg	5%	___%	<input type="checkbox"/>	_____
<b>Sevoflurane</b>					
Inhalation Anaesthetic Liquid		0%	___%	<input type="checkbox"/>	_____
<b>Sodium chloride</b>					
Injection 100ml	0.9%	0%	___%	<input type="checkbox"/>	_____
Injection 10ml	0.9%	0%	___%	<input type="checkbox"/>	_____
Injection 10ml	20%	0%	___%	<input type="checkbox"/>	_____
Injection 20ml	0.9%	0%	___%	<input type="checkbox"/>	_____
Injection 2ml	0.9%	0%	___%	<input type="checkbox"/>	_____
Injection 50ml	0.9%	0%	___%	<input type="checkbox"/>	_____
Injection 5ml	0.9%	0%	___%	<input type="checkbox"/>	_____

Note: "Suggested DV" is the amount of variation for an alternative brand that is recommended for patients for whom a potential tender win is clinically needed (if different from the DV limit indicated). "BUS?" is a tick-box option if you think Back Up Supply is necessary for this product.

**Chemical**

Presentation	Strength	DV limit	Suggested DV	BUS?	Additional comments
<b>Sodium enoxaparin</b>					
Ampoule	20mg/ml	0%	___%	<input type="checkbox"/>	_____
Ampoule	40mg/ml	0%	___%	<input type="checkbox"/>	_____
Injection	100mg/ml	0%	___%	<input type="checkbox"/>	_____
Injection	120mg/ml	0%	___%	<input type="checkbox"/>	_____
Injection	60mg/ml	0%	___%	<input type="checkbox"/>	_____
Injection	80mg/ml	0%	___%	<input type="checkbox"/>	_____
<b>Sodium hyaluronate</b>					
Ophthalmic solution	10mg/ml	0%	___%	<input type="checkbox"/>	_____
Ophthalmic solution	12mg/ml	0%	___%	<input type="checkbox"/>	_____
Ophthalmic solution	14mg/ml	0%	___%	<input type="checkbox"/>	_____
Ophthalmic solution	16mg/ml	0%	___%	<input type="checkbox"/>	_____
Syringe 0.85ml	1%	0%	___%	<input type="checkbox"/>	_____
<b>Sodium phosphate</b>					
Injection Vials 5ml	15mmol/5ml	0%	___%	<input type="checkbox"/>	_____
<b>Sodium valproate</b>					
Injection 4ml	100mg/ml	5%	___%	<input type="checkbox"/>	_____
Oral liquid	200mg/5ml	5%	___%	<input type="checkbox"/>	_____
Oral Liquid Sugar Free	200mg/5ml	5%	___%	<input type="checkbox"/>	_____
Tablets crushable	100mg	5%	___%	<input type="checkbox"/>	_____
Tablets enteric coated	200mg	5%	___%	<input type="checkbox"/>	_____
Tablets enteric coated	500mg	5%	___%	<input type="checkbox"/>	_____
<b>Streptokinase</b>					
Injection	1 500 000iu	0%	___%	<input type="checkbox"/>	_____
Injection	250 000iu	0%	___%	<input type="checkbox"/>	_____
Injection	750 000iu	0%	___%	<input type="checkbox"/>	_____
<b>Tacrolimus</b>					
Capsules	1mg	0%	___%	<input type="checkbox"/>	_____
Capsules	5mg	0%	___%	<input type="checkbox"/>	_____
<b>Teicoplanin</b>					
Injection	400mg	0%	___%	<input type="checkbox"/>	_____
<b>Tirofiban hydrochloride</b>					
Injection 50ml	250mcg/ml	0%	___%	<input type="checkbox"/>	_____
<b>Tobramycin sulphate</b>					
Injection 1ml	40mg/ml	0%	___%	<input type="checkbox"/>	_____
Injection 2ml	10mg/ml	0%	___%	<input type="checkbox"/>	_____
Injection 2ml	40mg/ml	0%	___%	<input type="checkbox"/>	_____
<b>Tramadol hydrochloride</b>					
Capsules	50mg	10%	___%	<input type="checkbox"/>	_____
Injection 1ml	50mg/ml	0%	___%	<input type="checkbox"/>	_____
Injection 2ml	50mg/ml	0%	___%	<input type="checkbox"/>	_____
Tablets sustained release	100mg	10%	___%	<input type="checkbox"/>	_____
Tablets sustained release	150mg	10%	___%	<input type="checkbox"/>	_____
Tablets sustained release	200mg	10%	___%	<input type="checkbox"/>	_____

Note: "Suggested DV" is the amount of variation for an alternative brand that is recommended for patients for whom a potential tender winner is clinically needed (if different from the DV limit indicated). "BUS?" is a tick-box option if you think Back Up Supply is necessary for this product.

**Chemical**

Presentation	Strength	DV limit	Suggested DV	BUS?	Additional comments
<b>Tranexamic acid</b>					
Injection	100mg/ml	0%	___%	<input type="checkbox"/>	_____
Tablets	500mg	0%	___%	<input type="checkbox"/>	_____
<b>Tropisetron hydrochloride</b>					
Ampoules	2mg/2ml	0%	___%	<input type="checkbox"/>	_____
Ampoules	5mg/5ml	0%	___%	<input type="checkbox"/>	_____
Capsules	5mg	0%	___%	<input type="checkbox"/>	_____
<b>Vancomycin hydrochloride</b>					
Capsules	125mg	0%	___%	<input type="checkbox"/>	_____
Capsules	250mg	0%	___%	<input type="checkbox"/>	_____
Injection 10ml	50mg/ml	10%	___%	<input type="checkbox"/>	_____
<b>Vecuronium</b>					
Injection	10mg	0%	___%	<input type="checkbox"/>	_____
Injection	4mg	0%	___%	<input type="checkbox"/>	_____
<b>Water</b>					
Injection 100ml		0%	___%	<input type="checkbox"/>	_____
Injection 10ml		0%	___%	<input type="checkbox"/>	_____
Injection 20ml		0%	___%	<input type="checkbox"/>	_____
Injection 2ml		0%	___%	<input type="checkbox"/>	_____
Injection 5ml		0%	___%	<input type="checkbox"/>	_____
Irrigation		0%	___%	<input type="checkbox"/>	_____

Note: "Suggested DV" is the amount of variation for an alternative brand that is recommended for patients for whom a potential tender winner is clinically needed (if different from the DV limit indicated). "BUS?" is a tick-box option if you think Back Up Supply is necessary for this product.

**Attachment Three**

**Draft supplement to PHARMAC's Operating Policies and Procedures**

**HOSPITAL PHARMACEUTICALS SUPPLEMENT  
TO THE  
OPERATING POLICIES AND PROCEDURES  
OF THE  
PHARMACEUTICAL MANAGEMENT AGENCY  
("PHARMAC")**

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## 1. INTRODUCTION

This supplement clarifies the application of PHARMAC's Operating Policies and Procedures (**OPPs**) to hospital pharmaceuticals. It should be read in conjunction with the OPPs. This supplement follows the same clause numbering as in the OPPs and sets out any amendments or additions to a clause where necessary. Where reference to a clause in the OPPs is omitted from this supplement it continues to apply unamended.

### 1.1 PHARMAC's Objective

PHARMAC's objective remains the same.

### 1.2 PHARMAC's Role

PHARMAC's role has been extended to include managing the purchase of pharmaceuticals provided to patients for use while in hospital. This has arisen as a result of the Minister of Health authorising PHARMAC, under section 48(e) of the New Zealand Public Health and Disability Act 2000, to perform this function.

In addition to the role and activities set out in clause 1.2.1 of the OPPs, PHARMAC's role includes management of expenditure on pharmaceuticals used in DHB hospitals (or aspects thereof) and PHARMAC's activities may relate to the use of pharmaceuticals by DHB hospitals, in addition to subsidisation of pharmaceuticals used in the community.

The third sentence of clause 1.2.2 of the OPPs no longer applies. Hospital pharmaceuticals will be listed in a new section of the Pharmaceutical Schedule. The second sentence of clause 1.2.2 is, therefore, amended to reflect that the Schedule is a list of pharmaceuticals and related products (**pharmaceuticals**) that sets out:

- (a) the criteria for access to subsidy for community pharmaceuticals;
- (b) the level of subsidy; and
- (c) the national price applicable to the purchase of pharmaceuticals by DHB hospitals.

### 1.3 Operating Policies and Procedures

Clause 1.3.1 of the OPPs will now apply in relation to all pharmaceuticals funded by the Government, whether they are subsidised pharmaceuticals for use in the community or pharmaceuticals prescribed and supplied for use in DHB hospitals.

### 1.4 The Pharmacology and Therapeutics Advisory Committee (PTAC)

PHARMAC may obtain clinical advice from PTAC in relation to hospital pharmaceuticals. There may be additional specialist hospital representatives on PTAC subcommittees, or additional PTAC subcommittees, where PHARMAC considers this necessary.

## 1.5 Other Advisory Committees

- 1.5.2 The PHARMAC Board has established a Hospital Pharmaceuticals Advisory Committee (**HPAC**). This committee will be made up of representatives of the DHBs as nominated by the DHBs and appointed by the PHARMAC Board. Its role will include advising PHARMAC in relation to national purchasing strategies for hospital pharmaceuticals.

## 2. THE PHARMACEUTICAL SCHEDULE

### 2.1 Amendments to the Pharmaceutical Schedule

PHARMAC may amend the Pharmaceutical Schedule as it considers appropriate to implement national purchasing and other arrangements relating to the purchasing of hospital pharmaceuticals.

Possible amendments to the Schedule, in addition to those listed in clause 2.1 of the OPPs, include (but are not limited to):

- (a) the listing of pharmaceuticals that are subject to national contracts for supply to DHB hospitals;
- (b) publication of information or requirements relating to the implementation of such contracts (including in relation to pharmaceuticals that may be purchased by DHB hospitals other than those which are the subject of a national contract);
- (c) publication of information about applications in respect of hospital pharmaceuticals that are undergoing or have undergone assessment by PHARMAC and/or DHBs.

### 2.2 Decision Criteria

PHARMAC uses the criteria set out below, where applicable and giving such weight to each criterion as PHARMAC considers appropriate, to make decisions about proposed amendments to the Pharmaceutical Schedule. The decision criteria for hospital pharmaceuticals set out below are substantially the same as the decision criteria in clause 2.2 of the OPPs.

Where there are factors listed under a particular criterion PHARMAC may consider those factors, where applicable and giving such weight to each factor as it considers appropriate, in the course of applying that criterion. In doing so, PHARMAC will seek or use supporting information as it considers appropriate.

The criteria are as follows:

- (a) the health needs of all eligible people within New Zealand;
- (b) the particular health needs of Maori and Pacific peoples;
- (c) the availability and suitability of existing medicines, therapeutic medical devices and related products and related things, having regard (without limitation) to:

- other interventions (existing pharmaceuticals, medical interventions, therapeutic medical devices etc.) currently available to meet the health needs that would be met by the pharmaceutical;
  - other interventions that the pharmaceutical would be used in addition to or instead of;
  - any evidence that the pharmaceutical is more efficacious, more safe and/or clinically more acceptable to patients than the other interventions currently available to meet these health needs;
  - the clinical significance of any advantages identified above;
- (d) the availability and suitability of the pharmaceutical for use in hospitals, having regard (without limitation) to:
- the level of importance of having uninterrupted supply of the pharmaceutical;
  - the reliability of the supplier of the pharmaceutical in ensuring its availability;
  - other pharmaceuticals or other interventions that could be used in the event that the pharmaceutical was unavailable;
  - the suitability of the packaging and/or proposed pack size for the pharmaceutical;
  - the impact, if any, that the proposal would have on existing DHB supply contracts, to the extent that this can be ascertained by PHARMAC;
- (e) the clinical benefits and risks of pharmaceuticals;
- (f) the cost-effectiveness of meeting health needs by funding pharmaceuticals rather than using other publicly funded health and disability support services, having regard (without limitation) to:
- the cost-effectiveness of the pharmaceutical;
  - the effect that the use of the pharmaceutical would have on:
    - (i) the total cost of pharmaceuticals used in hospitals and/or the community;
    - (ii) the total cost of non-pharmaceutical hospital acquisitions;
    - (iii) staff costs in hospitals; and
    - (iv) other costs to DHBs;
- (g) the budgetary impact (in terms of the pharmaceutical budget and the Government's overall health budget) of any changes to the Pharmaceutical Schedule, having regard (without limitation) to:

- the impact the proposal has on total expenditure on pharmaceuticals;
- (h) the direct cost to health service users;
- (i) the Government's priorities for health funding, as set out in any objectives notified by the Crown to PHARMAC, or in PHARMAC's Funding Agreement, or elsewhere; and
- (j) such other criteria as PHARMAC thinks fit. PHARMAC will carry out appropriate consultation when it intends to take any such "other criteria" into account.

### **3. PHARMAC STRATEGIES**

#### **3.2 PHARMAC's Strategies**

The specific strategies that PHARMAC may adopt in relation to the management of hospital pharmaceuticals:

- (a) are as outlined in the *National Hospital Pharmaceutical Strategy (February 2002)*, as updated or amended from time to time, or in related documents or in any other strategy developed and notified by PHARMAC; and
- (b) may include strategies outlined in clause 3.2 of the OPPs, but do not include reference pricing (as defined in clause 3.3) unless, following consultation, PHARMAC subsequently decides to apply reference pricing in relation to certain groupings of pharmaceuticals.

### **4. PROCEDURE**

#### **4.1 General**

Clauses 4.1.1, 4.1.3 and 4.1.4 of the OPPs apply unamended to hospital pharmaceuticals. Clause 4.2.2 also applies, except that, as is already the case in relation to community pharmaceuticals, the process followed may differ from that set out in the flow diagram in clause 4.5 as an indicative guide. When amending the Pharmaceutical Schedule in relation to hospital pharmaceuticals PHARMAC may also obtain input from HPAC and such other committees or advisory groups as it considers necessary, in addition to obtaining input of the sort identified in the flow diagram in clause 4.5.

#### **4.2 Consultation**

Clause 4.2.1 of the OPPs applies to hospital pharmaceuticals, subject to the clarification in respect of clause 4.2.1(e) that PHARMAC generally envisages consulting on the adoption of a new strategy in the context of amending or updating the *National Hospital Pharmaceutical Strategy (February 2002)* from time to time, whether in subsequent versions of this document or in related documents.