Appendix 1

Provisional Agreement between PHARMAC and Mundipharma New Zealand Limited

PHARMAC
Pharmaceutical Management Agency

Level 14, Cigna House,
40 Mercer Street, PO Box 10-254,
Wellington 6001, New Zealand
Phone 64 - 4 - 460 4990
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www.pharmac.govt.nz

17 May 2005

Chandra Selvadurai
Co-Chief Executive Officer
Pharmaco NZ Ltd as agent for Mundipharma New Zealand Limited
PO Box 4079
AUCKLAND

Dear Chandra

TERMS OF LISTING OF OXYCODONE HYDROCHLORIDE ON THE PHARMACEUTICAL SCHEDULE

PHARMAC agrees to:

- list in Section B of the Pharmaceutical Schedule, with effect from (or, in the case of 5 mg controlled-release tablets, no earlier than) 1 August 2005, the pharmaceutical oxycodone hydrochloride (under the brand name **OxyContin**), as supplied by you in the form and strengths set out in Annex One;

- list in Section B of the Pharmaceutical Schedule, with effect from 1 August 2005, the pharmaceutical oxycodone hydrochloride (under the brand name **OxyNorm**), as supplied by you in the form and strengths set out in Annex One;

- list in Section H of the Pharmaceutical Schedule, with effect from (or, in the case of 5 mg controlled-release tablets, no earlier than) 1 August 2005, the pharmaceutical oxycodone hydrochloride (under the brand name **OxyContin**), as supplied by you in the form and strengths set out in Annex One; and

- list in Section H of the Pharmaceutical Schedule, with effect from 1 August 2005, the pharmaceutical oxycodone hydrochloride (under the brand name **OxyNorm**), as supplied by you in the form and strengths set out in Annex One,

on the terms set out in this letter and the attached Annexes (together forming this "**Agreement**").

In this Agreement:

- "**Funder**", being a term used in this Agreement in relation to the subsidising of community pharmaceuticals, means the body or bodies responsible, pursuant to the New Zealand Public Health and Disability Act 2000, for the funding of pharmaceuticals listed in Sections A to G of the Pharmaceutical Schedule (which may be one or more District Health Boards and/or the Ministry of Health) and their successors;

- "**Pharmaceutical**" means the pharmaceuticals described in Annex One, in the forms and strengths set out in Annex One;

- "**Section B**" means the relevant section or sections of the Pharmaceutical Schedule relating to community pharmaceuticals;

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

- for a community Pharmaceutical that is subsidised by the Funder, references to the "listing" of a pharmaceutical are to the listing of that pharmaceutical on the Pharmaceutical Schedule (and references to "list", "listed", "delist", "delisted", and "delisting" are to be interpreted accordingly); and

- for a hospital Pharmaceutical that can be purchased by DHB Hospitals, references to the "listing" of a Pharmaceutical are to the listing of that Pharmaceutical in Section H of the Pharmaceutical Schedule and are deemed to include any written notification by PHARMAC of that Pharmaceutical being the subject of a national supply contract negotiated by PHARMAC on behalf of DHBs, where such written notification is in advance of the actual listing of that Pharmaceutical in Section H of the Pharmaceutical Schedule (and references to "list", "listed", "delist", "delisted", and "delisting" are to be interpreted accordingly).

Annexes

- Annex One describes each Pharmaceutical.

- Annex Two specifies the price at which each Pharmaceutical:

  - listed in Section B of the Pharmaceutical Schedule is to be supplied, or made available for supply, by you to wholesalers and other such distributors, and at which that Pharmaceutical is to be subsidised by the Funder, unless another price is determined under Annex Three (A) or Annex Four; and

  - listed in Section H of the Pharmaceutical Schedule is to be supplied or sold, or made available for supply or sale, by you to, at a DHB's discretion, any Designated Delivery Points, or Contract Manufacturers (expressly for the purpose of compounding), and at which that Pharmaceutical can be purchased by DHB Hospitals, unless another price is determined under Annex Three (B) or Annex Four.

- Annex Three (A) specifies the standard terms of listing for each Pharmaceutical listed in Section B of the Pharmaceutical Schedule.

- Annex Three (B) specifies the standard terms of listing for each Pharmaceutical listed in Section H of the Pharmaceutical Schedule.

- Annex Three (A) and Annex Three (B) apply independently and exclusively of each other to the relevant Pharmaceutical, according to whether community or hospital supply is being referred to.

- Annex Four specifies the special terms of listing for each Pharmaceutical.

- The special terms in Annex Four are to prevail if they conflict with any other terms of this Agreement.

Acceptance

To confirm your acceptance of this Agreement, please sign and return the attached copy to PHARMAC by 12 pm on 27 May 2005.

Yours faithfully

Wayne McNee
Chief Executive

Signed and agreed by Mundipharma New Zealand Limited by:

C Hentzsch

Name: DR. C. HENTZSCH

Position: GENERAL MANAGER

Date: 20-5-05

ANNEX ONE

The Pharmaceutical means each of the following pharmaceuticals, individually or collectively, according to the context:

Table One: New listing in Section B of the Pharmaceutical Schedule

Pharmaceutical	*Brand*	*Form*	*Strength*	*Pack Size*
Oxycodone hydrochloride	OxyContin	Controlled-release tablets	5mg	20
Oxycodone hydrochloride	OxyContin	Controlled-release tablets	10mg	20
Oxycodone hydrochloride	OxyContin	Controlled-release tablets	20mg	20
Oxycodone hydrochloride	OxyContin	Controlled-release tablets	40mg	20
Oxycodone hydrochloride	OxyContin	Controlled-release tablets	80mg	20
Oxycodone hydrochloride	OxyNorm	Capsules	5mg	20
Oxycodone hydrochloride	OxyNorm	Capsules	10mg	20
Oxycodone hydrochloride	OxyNorm	Capsules	20mg	20

Table Two: New listing in Section H of the Pharmaceutical Schedule

Pharmaceutical	*Brand*	*Form*	*Strength*	*Pack Size*
Oxycodone hydrochloride	OxyContin	Controlled-release tablets	5mg	20
Oxycodone hydrochloride	OxyContin	Controlled-release tablets	10mg	20
Oxycodone hydrochloride	OxyContin	Controlled-release tablets	20mg	20
Oxycodone hydrochloride	OxyContin	Controlled-release tablets	40mg	20
Oxycodone hydrochloride	OxyContin	Controlled-release tablets	80mg	20
Oxycodone hydrochloride	OxyNorm	Capsules	5mg	20
Oxycodone hydrochloride	OxyNorm	Capsules	10mg	20
Oxycodone hydrochloride	OxyNorm	Capsules	20mg	20

For the purposes of this Agreement:

"**OxyContin C5**" applies to the 5 mg per controlled-release tablet form of oxycodone hydrochloride in the pack size referred to in Table One above in relation to community supply;

"**OxyContin C10**" applies to the 10 mg per controlled-release tablet form of oxycodone hydrochloride in the pack size referred to in Table One above in relation to community supply;

"**OxyContin C20**" applies to the 20 mg per controlled-release tablet form of oxycodone hydrochloride in the pack size referred to in Table One above in relation to community supply;

"**OxyContin C40**" applies to the 40 mg per controlled-release tablet form of oxycodone hydrochloride in the pack size referred to in Table One above in relation to community supply;

"**OxyContin C80**" applies to the 80 mg per controlled-release tablet form of oxycodone hydrochloride in the pack size referred to in Table One above in relation to community supply;

"**OxyNorm C5**" applies to the 5 mg per capsule form of oxycodone hydrochloride in the pack size referred to in Table One above in relation to community supply;

"**OxyNorm C10**" applies to the 10 mg per capsule form of oxycodone hydrochloride in the pack size referred to in Table One above in relation to community supply;

"OxyNorm C20" applies to the 20 mg per capsule form of oxycodone hydrochloride in the pack size referred to in Table One above in relation to community supply;

"OxyContin H5" applies to the 5 mg per controlled-release tablet form of oxycodone hydrochloride in the pack size referred to in Table Two above in relation to hospital supply;

"OxyContin H10" applies to the 10 mg per controlled-release tablet form of oxycodone hydrochloride in the pack size referred to in Table Two above in relation to hospital supply;

"OxyContin H20" applies to the 20 mg per controlled-release tablet form of oxycodone hydrochloride in the pack size referred to in Table Two above in relation to hospital supply;

"OxyContin H40" applies to the 40 mg per controlled-release tablet form of oxycodone hydrochloride in the pack size referred to in Table Two above in relation to hospital supply;

"OxyContin H80" applies to the 80 mg per controlled-release tablet form of oxycodone hydrochloride in the pack size referred to in Table Two above in relation to hospital supply;

"OxyNorm H5" applies to the 5 mg per capsule form of oxycodone hydrochloride in the pack size referred to in Table Two above in relation to hospital supply;

"OxyNorm H10" applies to the 10 mg per capsule form of oxycodone hydrochloride in the pack size referred to in Table Two above in relation to hospital supply; and

"OxyNorm H20" applies to the 20 mg per capsule form of oxycodone hydrochloride in the pack size referred to in Table Two above in relation to hospital supply.

ANNEX TWO

Price of Pharmaceutical

Presentation of Pharmaceutical	*Price (Exclusive of GST) ($NZ)*
OxyContin C5	7.51
OxyContin C10	11.14
OxyContin C20	18.93
OxyContin C40	33.29
OxyContin C80	58.03
OxyNorm C5	2.83
OxyNorm C10	5.58
OxyNorm C20	9.77
OxyContin H5	7.51
OxyContin H10	11.14
OxyContin H20	18.93
OxyContin H40	33.29
OxyContin H80	58.03
OxyNorm H5	2.83
OxyNorm H10	5.58
OxyNorm H20	9.77

ANNEX THREE (A)

General Terms of Listing on Pharmaceutical Schedule

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 Operating Policies and Procedures ("**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;

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

(vi) any action taken by PHARMAC pursuant to its OPPs may impact on the listing of a Pharmaceutical.

(b) PHARMAC agrees not to apply, amend or update its OPPs in order to avoid any of PHARMAC's obligations under Annex Four of this Agreement.

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

3. **Reference Price Reduction.** If the reference price of the therapeutic sub-group in which a Pharmaceutical is listed is reduced for any reason, then:

(a) the subsidy payable by the Funder for that Pharmaceutical is to be reduced, with immediate effect, to an amount equal to the new reference price; and

(b) the Pharmaceutical Schedule is to be amended accordingly.

In those circumstances, you may either:

(c) continue to supply that Pharmaceutical at the price it was supplied by you immediately before the subsidy was reduced; or

(d) reduce the price at which that Pharmaceutical is supplied by you.

4. **Supply Price.** The price at which a Pharmaceutical is supplied by you must not exceed the price set out in Annex Two and, for the avoidance of doubt, if it does exceed the price set out in Annex Two that is a breach of the Agreement.

5. **Warranty that Not Less Than Cost Price.** You warrant that the price at which you are required to supply a Pharmaceutical under this Agreement is greater than the cost price of that Pharmaceutical (including, without limitation, the costs of manufacturing that Pharmaceutical and of supplying it to you for supply in New Zealand).

6. **Continuity of Supply.**

(a) You must supply, and continue to supply, the Pharmaceutical(s) on the terms set out in, and in accordance with, this Agreement.

(b) You warrant that you have entered into contractual and other arrangements to the extent necessary to ensure that you meet your obligations under paragraph (a) above. You therefore acknowledge that any failure to meet these obligations that is attributable (without limitation) to:

(i) any failure on the part of a person in the relevant Pharmaceutical supply chain; or

(ii) any act or omission by a related entity of yours,

is not considered by PHARMAC to be a reason outside your control for the purposes of clauses 7 and 8 below.

7. **Indemnity for Failure to Supply.**

(a) You must notify PHARMAC in writing as soon as you have reasonable cause to believe that you will fail to supply a Pharmaceutical on the terms set out in, and in accordance with, this Agreement.

(b) You agree to indemnify the Funder if for any reason you fail to supply a Pharmaceutical on the terms set out in, and in accordance with, this Agreement (other than for reasons PHARMAC considers to be wholly outside your control), and (only in the case of any non-supply of a Pharmaceutical) if PHARMAC considers that such failure will result in the requirements of any patients under their prescriptions for the Pharmaceutical not being met. This indemnity covers all additional costs (including costs relating to securing and/or subsidising, or increasing the subsidy for, a pharmaceutical of similar therapeutic effect to that Pharmaceutical, or increasing the subsidy for a Pharmaceutical, additional dispensing fees, and all actual legal expenses) incurred by the Funder (or by PHARMAC on its behalf) as a result of your failure to supply that Pharmaceutical in accordance with this Agreement.

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

8. **Liquidated Damages.**

(a) If you fail to supply a Pharmaceutical on the terms set out in, and in accordance with, this Agreement (other than for reasons that PHARMAC considers to be wholly outside your control), and (only in the case of any non-supply of a Pharmaceutical) if PHARMAC considers that such failure will result in the requirements of any patients under their prescriptions for the Pharmaceutical not being met, and:

(i) you have not notified PHARMAC under clause 7(a) of Annex Three (A), then in addition to your obligations under clause 7(b) of Annex Three (A), you must pay to PHARMAC liquidated damages for the administrative, operational and/or loss of opportunity costs incurred by PHARMAC as a result of your failure to supply in the amount of $25,000 (plus GST) per Pharmaceutical in respect of which you failed to notify PHARMAC; or

(ii) you have notified PHARMAC under clause 7(a) of Annex Three (A), then in addition to your obligations under clause 7(b) of Annex Three (A), you must pay to PHARMAC (on behalf of the Funder) liquidated damages, being a contribution towards the administrative, operational and/or loss of opportunity costs incurred by PHARMAC and the Funder as a result of your failure to supply, in the amount of $5,000 per Pharmaceutical in respect of which you notified PHARMAC.

(b) You acknowledge and agree that:

(i) subject to the fact that only a contribution is being sought where paragraph (a)(ii) above applies, the amounts of liquidated damages in this clause represent a reasonable estimate of the administrative, operational and the loss of opportunity 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, and do not, include any penalty element nor any amount for costs relating to securing and/or subsidising, or increasing the subsidy for, a pharmaceutical of a similar therapeutic effect to that Pharmaceutical, or increasing the subsidy for a Pharmaceutical, additional dispensing fees, and all actual legal expenses.

(c) All amounts referred to in this clause are plus GST (if any).

9. **Default Interest and Recovery Costs.** If payment of any amount required to be paid by you under clauses 7 or 8 of Annex Three (A) is not made by you, in full, by the due date for payment of that amount as notified to you in writing by PHARMAC, then:

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

(b) PHARMAC may take any action, including legal action, without first needing to implement the dispute resolution procedure contained in clause 16 below, to recover that amount and you agree to pay to PHARMAC actual enforcement costs incurred in relation to that action.

10. **PHARMAC's Rights Reserved.** If you fail to supply a Pharmaceutical on the terms set out in, and in accordance with, this Agreement (other than for reasons that PHARMAC considers to be

wholly outside your control), and the benefit of this Agreement to the Funder is substantially reduced as a result, then:

(a) without limiting PHARMAC's rights or your liabilities and obligations under clauses 7 and 8 of Annex Three (A), PHARMAC may enter into negotiations, and alternative supply arrangements, with other suppliers for the supply of a pharmaceutical of similar therapeutic effect to that Pharmaceutical; and

(b) PHARMAC may, on 30 days' written notice to you, delist that Pharmaceutical, provided that if you have failed to supply that Pharmaceutical on the terms set out in, and in accordance with, this Agreement on more than one occasion then PHARMAC may delist that Pharmaceutical without needing to provide 30 days' written notice to you.

Subject to paragraph (b) above, PHARMAC will not delist a Pharmaceutical under this clause if, within the 30 day notice period, you recommence supply of that Pharmaceutical, on the terms set out in, and in accordance with, this Agreement.

11. **Consents.** You warrant that you have, and will maintain, all consents (including Ministry of Health market approval) necessary for you to supply a Pharmaceutical in New Zealand for the treatment of each indication for which it is subsidised (each a "**Consent**"). If you are required by the Minister or Ministry of Health or any other New Zealand governmental authority to recall a Pharmaceutical or withdraw a Pharmaceutical from supply, whether temporarily or otherwise, that will be deemed to be a failure to hold a Consent. If a Consent is not held by you or is withdrawn, or a Pharmaceutical is no longer approved for the treatment of an indication for which it is subsidised then:

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

(b) you acknowledge and agree that the provisions of clauses 7 and 8 of Annex Three (A) are to apply.

12. **Changed Medicine Notification.** If the Ministry of Health approves a changed medicine notification for a Pharmaceutical, or for a variant of a Pharmaceutical:

(a) you must immediately notify PHARMAC; and

(b) PHARMAC may review:

(i) the listing of, and subsidy payable for, the Pharmaceutical; and

(ii) whether the Funder will subsidise a variant of that Pharmaceutical.

13. **Confidentiality.** Information relating to the terms of this Agreement, or any other information exchanged during negotiation of this Agreement or otherwise, that is agreed in writing by both of us as being confidential ("**Confidential Information**") is confidential to us and our employees, legal advisers and other consultants (including the Pharmacology and Therapeutics Advisory Committee and its sub-committees) and Funder employees (if applicable). 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 the course of consultation on this Agreement; or

(c) in publicly notifying any approval by the PHARMAC Board of this Agreement; or

(d) 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 (d) 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 (d) above, Confidential Information must not be disclosed by either of us (or by our employees, legal advisers and other consultants) unless:

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

(f) 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:

(g) generalised aggregated information regarding the Pharmaceutical(s) that does not identify you, or that cannot reasonably be expected to identify you, is not Confidential Information and PHARMAC may use and publish such information as it sees fit;

(h) information released by PHARMAC in accordance with paragraphs (a) to (d) 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.

14. **Consultation.** This Agreement is conditional on:

(a) PHARMAC completing all consultation it considers necessary or appropriate (including consultation under its Operating Policies and Procedures); and

(b) following consultation, approval of its terms by PHARMAC's Board (or by PHARMAC's chief executive under delegated authority pursuant to section 61 of the New Zealand Public Health and Disability Act 2000, where applicable).

You may withdraw from this Agreement, or negotiate with PHARMAC to amend its terms, if consultation or a decision of PHARMAC's Board results in a material change to the terms of this Agreement.

15. **Litigation Support.** If this Agreement or its terms (including the basis on which a Pharmaceutical is listed):

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

(b) result in PHARMAC being made a party to 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.

16. **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.

(e) Pending resolution of the dispute, this Agreement will remain in full effect without prejudicing our respective rights and remedies (including PHARMAC's rights under clause 1 of this Annex).

17. **No Derogation.** The express provision of a remedy for, or consequence of, failure to comply with any term of this Agreement does not derogate from any other legal right or remedy available to PHARMAC under this Agreement or otherwise in respect of such breach.

18. **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.

19. **Entire Agreement.** This Agreement:

(a) is the entire agreement between us regarding the terms on which the Pharmaceutical(s) is/are listed in Section B of the Pharmaceutical Schedule; and

(b) supersedes and extinguishes all prior agreements and understandings between us regarding the Pharmaceutical(s).

20. **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 which

(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.

21. **Contracts Privity.**

(a) For the purposes of the Contracts (Privity) Act 1982, we both acknowledge that your obligations in this Agreement constitute promises which confer or are intended to confer a benefit on the Funder and related persons, and are enforceable at the suit of the Funder and any such persons.

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

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

22. **No Reliance.** You acknowledge that you have entered into this Agreement in reliance on your own knowledge, skill and independent advice, and not in reliance on any representations made, or any information made available to you, by PHARMAC.

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

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

25. **Governing Law.** This Agreement is governed by New Zealand law.

26. **Jurisdiction.** We each submit to the exclusive jurisdiction of the New Zealand courts.

ANNEX THREE (B)

General Terms of Listing in Section H of the Pharmaceutical Schedule

1. Definitions. In this Annex Three (B) and, as applicable, in Annex Four:

"Alternative Pharmaceutical" means an alternative brand of a Pharmaceutical that HPAC or PTAC and its sub-committees considers to be an acceptable substitute for that Pharmaceutical;

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

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

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

(a) a delivery point agreed between you and the relevant DHB Hospital, to which delivery point you must supply the Pharmaceutical directly in accordance with any applicable delivery terms and conditions as at the date of this Agreement, or that are subsequently agreed between you and that DHB Hospital; and/or

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

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

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

"Hospital Pharmaceuticals Supplement" means the supplement that clarifies the application of PHARMAC's Operating Policies and Procedures in respect of hospital pharmaceuticals;

"HPAC" means the Hospital Pharmaceutical Advisory Committee;

"Pharmacode" means the unique six or seven digit identifier assigned to a Pharmaceutical and notified to you by the Pharmacy Guild;

"Potential Out-of-Stock Event" means:

(a) your stock of a Pharmaceutical falls below the average volume of stock of that Pharmaceutical required to supply the entire New Zealand DHB Hospital market for that Pharmaceutical for any given two month period;

(b) your stock of a Pharmaceutical falls below two-thirds of your most recent three months' total Unit sales of that Pharmaceutical; or

(c) your forecast of sales demand in respect of the next two-month period is greater than your stock of a Pharmaceutical;

"Price" means the price (exclusive of GST) at which a Pharmaceutical is to be sold and supplied, or made available for sale and supply, by you to, at a DHB Hospital's discretion, any Designated Delivery Points and/or Contract Manufacturers (expressly for the purpose of compounding);

"PTAC" means the Pharmacology and Therapeutics Advisory Committee;

"Unit" means an individual unit of a Pharmaceutical (e.g. tablet, 1ml of an oral liquid, ampoule, syringe); and

"Unit Price" means the relevant Price specified for a pack of a Pharmaceutical 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 Pharmaceutical.

2. **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 Operating Policies and Procedures, as supplemented by the Hospital Pharmaceuticals Supplement ("OPPs"), which provide guidance on the way in which PHARMAC carries out its statutory responsibilities in relation to the management of the Pharmaceutical Schedule;

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

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

(A) listing new pharmaceuticals;

(B) changing guidelines or restrictions on the purchasing of listed pharmaceuticals;

(C) changing the market dynamics for pharmaceuticals as a result of PHARMAC adopting one of the strategies set out in the OPPs;

(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 Annex Four of this Agreement.

3. **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 a Pharmaceutical.

4. **Supply Price.** The Price at which each Pharmaceutical is supplied by you must not exceed the Price set out in Annex Two.

5. **Warranty that Not Less Than Cost Price.** You warrant that the Price at which you are required to supply each Pharmaceutical under this Agreement is greater than the cost price of that Pharmaceutical (including, without limitation, the costs of manufacturing that Pharmaceutical and of supplying it to you for supply in New Zealand).

6. **Continuity of Supply.** You are to supply each Pharmaceutical in accordance with this Agreement to, at a DHB Hospital's discretion, any Designated Delivery Points, and/or Contract Manufacturers (expressly for the purpose of compounding).

7. **Notification of Potential Out-of-Stock Event and supply of Alternative Pharmaceutical.**

(a) You must:

(i) notify PHARMAC in writing as soon as you have reasonable cause to believe that you will fail to supply a Pharmaceutical in accordance with this Agreement;

(ii) where possible, notify PHARMAC and the relevant DHB Hospitals if at any time a Potential Out-of-Stock Event occurs.

(b) If you fail to supply a Pharmaceutical in accordance with this Agreement for more than 1 business day to any DHB Hospital, then:

(i) you must use your best endeavours to procure, within what the relevant DHB Hospitals consider to be a reasonable period of time, an Alternative Pharmaceutical for supply to, at a DHB Hospital's discretion, any Designated Delivery Points, and/or Contract Manufacturers (expressly for the purpose of compounding) at the Price; and

(ii) if you fail to procure an Alternative Pharmaceutical at the Price in accordance with sub-clause (i) above (other than for reasons that PHARMAC considers to be wholly outside your control) then, at PHARMAC's option:

(A) you must pay to all relevant DHB Hospitals any additional costs incurred by such DHB Hospitals as a result of the purchase of the Alternative Pharmaceutical; or

(B) PHARMAC may implement an arrangement with another supplier to supply an Alternative Pharmaceutical (including an arrangement for back-up supply), and you must pay to all relevant DHB Hospitals any additional costs incurred by such DHB Hospitals as a result of the purchase of the Alternative Pharmaceutical.

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

8. **Liquidated Damages.**

(a) If you fail to supply a Pharmaceutical in accordance with this Agreement (other than for reasons that PHARMAC considers to be wholly outside your control), whether as a result of your inability to meet demand for supply of that Pharmaceutical, your withdrawal of that Pharmaceutical from supply, any failure to have and maintain a Consent as specified in clause 9 below, or a Pharmaceutical being recalled in accordance with clause 12 of Annex Three (B), or for any other reason, and:

(i) you have not notified PHARMAC and the relevant DHB Hospitals under clause 7 of Annex Three (B), then in addition to your obligations under clause 7(b)(i) and (ii) of Annex Three (B), you must pay to PHARMAC (on behalf of DHB Hospitals) liquidated damages for the administrative and/or operational costs incurred by PHARMAC and DHB Hospitals as a result of your failure to supply in the amount of $50,000 per Pharmaceutical in respect of which you failed to notify PHARMAC; or

(ii) you have notified PHARMAC and the relevant DHB Hospitals under clause 7 of Annex Three (B), then in addition to your obligations under clause 7(b)(i) and (ii) of Annex Three (B), you must pay to PHARMAC (on behalf of DHB Hospitals) liquidated damages for the administrative and/or operational costs incurred by PHARMAC and DHB Hospitals as a result of your failure to supply in the amount of $5,000 per Pharmaceutical in respect of which you notified PHARMAC.

(b) You acknowledge and agree that:

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

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

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

(c) Where you notify PHARMAC under clause 7 above of a Potential Out-of-Stock Event, PHARMAC agrees to recover as liquidated damages under clause 8(a)(ii) of this Annex Three (B) only the amounts specified in clause 8(a)(ii), which represent only a portion of PHARMAC's and DHB Hospitals' costs actually incurred.

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

9. **Consents.** You warrant that you have and will maintain all consents (including Ministry of Health market approval) necessary for you to supply each Pharmaceutical in New Zealand for the treatment of any indication specified for that Pharmaceutical in its listing in Section H of the Pharmaceutical Schedule (each a "**Consent**). If a Consent is not held by you or is withdrawn, or a Pharmaceutical is no longer approved for the treatment of any indication for which it is listed in Section H of the Pharmaceutical Schedule then:

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

(b) you acknowledge and agree that the provisions of clauses 7 and 8 of Annex Three (B) are to apply.

10. **Changed Medicine Notification.** If the Ministry of Health approves a changed medicine notification for a Pharmaceutical, or for a variant of a Pharmaceutical:

(a) you must immediately notify PHARMAC; and

(b) PHARMAC may review:

(i) the terms of listing of that Pharmaceutical; and

(ii) the extent to which DHB Hospitals may purchase a variant of that Pharmaceutical.

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

12. **Pharmaceutical Recall.**

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

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

(c) If you fail to provide replacement Pharmaceuticals to DHB Hospitals in accordance with paragraph (b) above, then the provisions of clause 7(b) of this Annex Three (B) are to apply, provided that if clause 7(b)(ii)(B) applies and if PHARMAC is also unable to secure the supply of an Alternative Pharmaceutical within what the relevant DHB Hospitals consider to be a reasonable period of time, then DHB Hospitals may purchase an Alternative Pharmaceutical elsewhere and any additional costs incurred by DHB Hospitals in purchasing such Alternative Pharmaceuticals must be met by you on demand by PHARMAC or the DHB Hospitals and will be recoverable from you as a debt due to the DHB Hospitals.

(d) In the event that a Pharmaceutical is recalled as contemplated by paragraph (a) above, you must immediately refund to DHB Hospitals all money paid by them to you for or on account of that Pharmaceutical and such money will be recoverable from you as a debt due to DHB Hospitals, unless you have provided a replacement Pharmaceutical to DHB Hospitals' satisfaction.

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

13. **Shelf-life of Pharmaceutical.**

(a) You will not supply a Pharmaceutical if:

(i) the remaining shelf-life of that Pharmaceutical is less than 6 months; or

(ii) where the total shelf-life of that Pharmaceutical is less than 6 months, the remaining shelf-life is less than 75% of that Pharmaceutical's total shelf-life,

without prior agreement from the relevant DHB Hospital.

(b) If you have an agreement with the relevant DHB Hospital to supply a Pharmaceutical, where the total shelf-life of that Pharmaceutical is less than 6 months and the remaining shelf-life is less than 75% of that Pharmaceutical's total shelf-life, and that DHB Hospital does not use that Pharmaceutical before its expiry or use-by date, 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.

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

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

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

(b) source the Pharmaceutical or a pharmaceutical that is the same brand as the Pharmaceutical from any overseas manufacturer, supplier or distributor, and air-freighting

that stock to New Zealand (for which the relevant DHB Hospital will meet all reasonable costs) for supply, either under Medsafe's explicit consent to import, sell or distribute the Pharmaceutical or under Section 29 of the Medicines Act 1981, to DHB Hospitals.

15. **Confidentiality.** Information relating to the terms of this Agreement, or any other information exchanged during negotiation of this Agreement or otherwise, that is agreed in writing by both of us as being confidential ("**Confidential Information**") is confidential to us and our employees, legal advisers and other consultants (including HPAC, PTAC and its sub-committees), the Ministry of Health and DHBs (if applicable). 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 the course of consultation on this Agreement; or

(c) in publicly notifying any approval by the PHARMAC Board of this Agreement; or

(d) 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 (d) 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 (d) above, Confidential Information must not be disclosed by either of us (or by our employees, legal advisers and other consultants) unless:

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

(f) 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:

(g) generalised aggregated information regarding the Pharmaceuticals that does not identify you, or that cannot reasonably be expected to identify you, is not Confidential Information and PHARMAC may use and publish such information as it sees fit;

(h) information released by PHARMAC in accordance with paragraphs (a) to (d) 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.

16. **Access to Price and Volume Data.**

(a) You acknowledge that PHARMAC and its agents will require access to price and volume data held by you and DHB Hospitals in respect of each 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 clause 15 of Annex Three (B) regarding confidential information, you agree that where the circumstances in this clause apply, a DHB Hospital may provide PHARMAC and its agents with any price and

volume data held by that DHB Hospital in respect of a Pharmaceutical covered by this Agreement and PHARMAC and its agents may provide such data to DHBs.

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

17. **Invoicing and Payment.** Where the Designated Delivery Point to which you directly supply a Pharmaceutical is a DHB Hospital:

(a) you are to invoice the particular DHB Hospital at the end of each month, but no later than the second business day following the month to which the invoice in respect of the Pharmaceutical relates, specifying for the Pharmaceutical supplied during that month:

(i) your delivery note reference number;

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

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

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

(A) DHB's item codes;

(B) quantity of the Pharmaceutical supplied;

(C) price of the Pharmaceutical;

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

(v) any other information that DHB Hospital requires you to supply;

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

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

(ii) on the 20th day of the month following the month to which the invoice for the Pharmaceutical relates, or, if the 20th day of the month is not a business day, then on the next business day following the 20th of the month;

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

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

(e) this clause 17 confers a benefit on (and is enforceable by) DHB Hospitals in accordance with the Contracts (Privity) Act 1982.

18. **Consultation.** This Agreement is conditional on:

(a) PHARMAC completing all consultation it considers necessary or appropriate (including consultation under its Operating Policies and Procedures); and

(b) following consultation, approval of its terms by PHARMAC's Board of Directors (or by PHARMAC's chief executive under delegated authority pursuant to section 61 of the New Zealand Public Health and Disability Act 2000, where applicable).

You may withdraw from this Agreement, or negotiate with PHARMAC to amend its terms, if consultation or a decision of PHARMAC's Board results in a material change to the terms of this Agreement.

19. **Litigation Support.** If this Agreement or its terms (including the basis on which a 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.

20. **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.

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

For the avoidance of doubt you acknowledge and agree that PHARMAC may elect to involve any relevant District Health Board in any part, or all, of the above procedure.

21. **No Derogation.** For the avoidance of doubt, the express provision of a remedy for, or consequence of, breach of any term of this Agreement does not derogate from any other legal right or remedy available to PHARMAC under this Agreement or otherwise in respect of such breach.

22. **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.

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

24. **Entire Agreement.** This Agreement:

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

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

25. **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 which

    (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.

26. **Contracts Privity.**

    (a) For the purposes of the Contracts (Privity) Act 1982, we both acknowledge that your obligations in this Agreement constitute promises which confer or are intended to confer a benefit on DHB Hospitals and related persons, and are enforceable at the suit of any such DHB Hospitals or persons.

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

27. **No Reliance.** You acknowledge that you have entered into this Agreement in reliance on your own knowledge, skill and independent advice, and not in reliance on any representations made, or any information made available to you, by PHARMAC.

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

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

30. **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.

31. **Governing Law.** This Agreement is governed by New Zealand law.

32. **Jurisdiction.** We each submit to the exclusive jurisdiction of the New Zealand courts.

ANNEX FOUR

Special Terms of Listing

1. **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, 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; and

      (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.

2. **PHARMAC's Rights Reserved Regarding Patient Safety.** Notwithstanding any other provision of this Agreement, and without prejudice to any other of PHARMAC's legal rights and remedies, whether under this Agreement or otherwise, PHARMAC reserves the right at any time to take any action in relation to the listing of a Pharmaceutical, or the basis on which it is listed, including (without limitation):

   (a) changing or imposing restrictions on the prescribing or dispensing of a Pharmaceutical;

   (b) delisting a Pharmaceutical;

   (c) terminating the Agreement; and/or

   (d) any other action that PHARMAC decides, in its sole discretion, is necessary or appropriate,

   without your agreement, in accordance with any direction from Medsafe, or recommendation from PTAC, or relevant PTAC sub-committee, based on patient safety.

3. **Single Agreement.** This Agreement is a single agreement encompassing all of the Pharmaceuticals listed in Annex One and does not operate as a separate agreement for each Pharmaceutical, provided that this does not limit PHARMAC's rights under clause 1 of Annex Three (A) or clause 2 of Annex Three (B) to take actions in respect of a particular Pharmaceutical or Pharmaceuticals. For the avoidance of doubt, if PHARMAC takes any such action this does not terminate the Agreement.

4. **Liquidated Damages.**

   (a) Sub-clauses (i) and (ii) of clause 8(a) of Annex Three (A) are deleted and replaced with the following:

      (i) you have not notified PHARMAC under clause 7(a) of Annex Three (A), then in addition to your obligations under clause 7(b) of Annex Three (A), you must pay to PHARMAC (for the benefit of PHARMAC and the Funder) liquidated damages for the administrative, operational and/or loss of opportunity costs incurred by PHARMAC and the Funder as a result of your failure to supply in the amount of $25,000 per Pharmaceutical in respect of which you failed to notify PHARMAC; or

(ii) you have notified PHARMAC under clause 7(a) of Annex Three (A), then in addition to your obligations under clause 7(b) of Annex Three (A), you must pay to PHARMAC (for the benefit of PHARMAC and the Funder) liquidated damages, being a contribution towards the administrative, operational and/or loss of opportunity costs incurred by PHARMAC and the Funder as a result of your failure to supply, in the amount of $5,000 per Pharmaceutical in respect of which you notified PHARMAC.

(b) Sub-clauses (i) and (ii) of clause 8(a) of Annex Three (B) are deleted and replaced with the following:

(i) you have not notified PHARMAC and the relevant DHB Hospitals under clause 7 of Annex Three (B), then in addition to your obligations under clause 7(b)(i) and (ii) of Annex Three (B), you must pay to PHARMAC (for the benefit of PHARMAC and DHB Hospitals) liquidated damages for the administrative and/or operational costs incurred by PHARMAC and DHB Hospitals as a result of your failure to supply in the amount of $50,000 per Pharmaceutical in respect of which you failed to notify PHARMAC; or

(ii) you have notified PHARMAC and the relevant DHB Hospitals under clause 7 of Annex Three (B), then in addition to your obligations under clause 7(b)(i) and (ii) of Annex Three (B), you must pay to PHARMAC (for the benefit of PHARMAC and DHB Hospitals) liquidated damages for the administrative and/or operational costs incurred by PHARMAC and DHB Hospitals as a result of your failure to supply in the amount of $5,000 per Pharmaceutical in respect of which you notified PHARMAC.

5. **Definitions.** The definition of "Crown Direction" in clause 1 of Annex Three (B) is deleted and replaced with the following:

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

6. **Consultation.**

(a) Clause 14(b) of Annex Three (A) is deleted and replaced with the following:

(b) following consultation, approval of its terms by PHARMAC's Board (or by PHARMAC's chief executive under delegated authority pursuant to section 73 of the Crown Entities Act 2004, where applicable).

(b) Clause 18(b) of Annex Three (B) is deleted and replaced with the following:

(b) following consultation, approval of its terms by PHARMAC's Board of Directors (or by PHARMAC's chief executive under delegated authority pursuant to section 73 of the Crown Entities Act 2004, where applicable).

7. **Approval and Listing of OxyContin C5 and OxyContin H5**

(a) You agree that you will use your best endeavours to:

(i) obtain market approval for OxyContin C5 and OxyContin H5 under the Medicines Act 1981; and

(ii) obtain any other necessary Consents (as defined in clause 11 of Annex Three (A) and clause 9 of Annex Three (B), respectively) for OxyContin C5 and OxyContin H5,

as soon as reasonably practicable, and in any case, no later than 1 August 2006.

(b) PHARMAC agrees to list OxyContin C5 in Section B of the Pharmaceutical Schedule at the price and subsidy ex-manufacturer (exclusive of GST) specified in the table in Annex Two, and on the terms set out in this Agreement, as soon as practicable following notification to PHARMAC that you have obtained market approval and any other Consents under paragraph (a) for OxyContin C5, provided that this will be no earlier than 1 August 2005. You acknowledge and agree that PHARMAC's obligation to list OxyContin C5

under this paragraph (b) expires on 1 August 2006, unless extended by PHARMAC in its absolute discretion.

(c) PHARMAC agrees to list OxyContin H5 in Section H of the Pharmaceutical Schedule and at the price ex-manufacturer (exclusive of GST) specified in the table in Annex Two, and on the terms set out in this Agreement, as soon as practicable following notification to PHARMAC that you have obtained market approval and any other Consents under paragraph (a) for OxyContin H5, provided that this will be no earlier than 1 August 2005. You acknowledge and agree that PHARMAC's obligation to list OxyContin H5 under this paragraph (c) expires on 1 August 2006, unless extended by PHARMAC in its absolute discretion.

(d) For the avoidance of doubt:

(i) you must supply OxyContin C5 and OxyContin H5, on the terms set out in this Agreement, from the date OxyContin C5 and OxyContin H5 are listed under this clause 7; and

(ii) this clause 7 does not override clauses 1, 3 or 4 of Annex Three (A) or clauses 2 or 4 of Annex Three (B).