Agreement for the listing of Pharmaceutical(s) on the New Zealand Pharmaceutical Schedule

This Agreement specifies the terms on which the Pharmaceutical(s) specified in Annex 1 will be listed.

Parties

(1) Pharmaceutical Management Agency **(Pharmac)**; and

(2) Full legal name of supplier **(You)**

Pharmaceutical(s)

This Agreement relates to the following Pharmaceutical(s), more fully described in Annex 1:

Chemical Name 1 (Brand name X);

Chemical Name 2 (Brand name Y);

Annexes

Annex 1

- Describes the Pharmaceutical(s).
- Specifies the price at which the Pharmaceutical(s) are to be listed.
- Specifies the Listing Date of the Pharmaceutical(s).
- Specifies the minimum stock holding of the Pharmaceutical(s).

Annex 2

- Specifies the special terms of listing of the Pharmaceutical(s).

Annex 3

- Specifies the standard terms of listing of the Pharmaceutical(s).

Annex 4

- Specifies the definitions and principles of interpretation relevant to this Agreement.

Precedence

The special terms in Annex 2 are to prevail if those terms conflict or are inconsistent with any other terms of this Agreement.

Acceptance

Pharmac and you confirm acceptance of this Agreement by signing below:

_____

Pharmaceutical Management Agency (Pharmac)

Name:

Position:

Date:

_____

Full legal name of supplier

Name:

Position:

Date:

Annex 1: Pharmaceutical

Pharmaceutical	**Brand**	**Formulation**	**Pack Size**	**Price** (Exclusive of GST) ($NZ)	**Listing Date**	**Minimum Stock Holding**	**Community / Hospital / Both**

Annex 2: Special Terms

Annex 3: Standard Terms

1. Pharmac's Role

1.1 Rights and Responsibilities

(a) You acknowledge that:

(i) Pharmac is required to pursue its statutory objectives, carry out its statutory functions and otherwise comply with its statutory obligations;

(ii) Pharmac is subject to a range of legal and administrative 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 role and functions;

(iv) the actions which Pharmac may take under its OPPs include (without limitation):

(A) listing new pharmaceuticals;

(B) changing the terms on which a pharmaceutical is listed; and

(C) delisting pharmaceuticals or delisting part or all of a therapeutic group or sub-group; and

(v) any action taken by Pharmac pursuant to its OPPs may impact on the listing of the Pharmaceutical.

(b) Pharmac agrees not to apply, amend or update its OPPs in order to avoid any of Pharmac's obligations under Annex 2 of this Agreement.

(c) Pharmac may terminate or amend this Agreement at its sole discretion in the following circumstances:

(i) Pharmac is issued a Crown Direction;

(ii) in accordance with any advice from Medsafe or clinical advice, based on patient safety or any other clinical reasons;

(iii) a Supply Issue results in a failure to supply the Pharmaceutical;

(iv) any Consent or Market Approval is not held by you or is withdrawn for the Pharmaceutical;

(v) a Changed Medicine Notification is approved by Medsafe for the Pharmaceutical; or

(vi) the Pharmaceutical is delisted for any reason.

(d) In the event that:

(i) this Agreement is terminated (or notice of termination is given) or amended due to any of the circumstances set out in clause 1.1(c)(i) to (v), Pharmac reserves the right to delist, or suspend or amend the listing of, the Pharmaceutical; or

(ii) the Pharmaceutical is delisted, or has its listing suspended, for any reason then, unless this Agreement is terminated under clause 1.1(c)(vi), this Agreement shall continue in full force and effect until expiry or termination in accordance with its terms and such delisting or suspension shall not constitute or be construed as a repudiation or breach of the terms of this Agreement by Pharmac. You agree that you do not have, and you expressly waive, any rights, at law, including in equity or under statute, and particularly under Part 2, subpart 3 of the Contract and Commercial Law Act 2017 (Contractual remedies), to terminate this Agreement as a result of the delisting, or suspension of the listing, of the Pharmaceutical.

1.2 Amendments to Pharmaceutical Schedule

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

1.3 Conditions

(a) This Agreement is conditional on:

(i) Pharmac completing all consultation it considers necessary or appropriate; and

(ii) approval of its terms by Pharmac's board or its delegate.

(b) You may withdraw from this Agreement, or negotiate with Pharmac to amend its terms, if the consultation or a decision of Pharmac's board or its delegate described in clause 1.3(a) above results in a material change to the proposed listing of the Pharmaceutical.

1.4 Supplier Code of Conduct

You must comply with the New Zealand Government's Supplier Code of Conduct as amended or substituted from time to time.

2. Price and Payment

2.1 Price

(a) You must supply, or make available for supply, the Pharmaceutical, at the Price, to wholesalers, other such distributors and/or Health NZ Hospitals in accordance with this Agreement.

(b) The price at which the Pharmaceutical is supplied by you must not exceed the Price.

2.2 Invoicing and Payment

Where a Health NZ Hospital is to be invoiced for the Pharmaceutical:

(a) you are to invoice the particular Health NZ 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 Health NZ Hospital's purchase order reference number (if applicable);

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

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

(A) Health NZ Hospital'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

(E) any other information that the Health NZ Hospital requires you to supply;

(b) provided that the Pharmaceutical has been supplied in accordance with this Agreement, and the particular Health NZ Hospital receives an invoice in accordance with clause 2.2(a) above, payment by the Health NZ Hospital to you of the amount required to be paid is expected to occur:

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

(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 day of the month;

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

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

3. Reporting

3.1 Information

(a) You agree to provide any information related to the Pharmaceutical and its listing that Pharmac reasonably requests, in such manner and timeframe as Pharmac reasonably requests.

(b) In particular, and without limiting the generality of clause 3.1(a) above, you:

(i) acknowledge that Pharmac requires the provision of Unique Product Identifiers in order to implement the listing of each Pharmaceutical and you agree to obtain and notify Pharmac of the Unique Product Identifiers of each Pharmaceutical no later than 10 Business Days following your acceptance of this Agreement, unless that Pharmaceutical is already listed;

(ii) agree that in the event that you supply an Alternative Pharmaceutical in accordance with this Agreement, or in the event of a Changed Medicine Notification for a Pharmaceutical, you must notify Pharmac of any changed Unique Product Identifiers (or advise if there is no change) as soon as practicable;

(iii) acknowledge that in the event the listing of the Pharmaceutical includes special authority criteria or any other access criteria, you must, for the duration that the Pharmaceutical is listed:

(A) notify Pharmac in the event the Data Sheet is amended in a manner which, when considered in the context of any current special authority criteria or other current access criteria, could impact on patient safety; and

(B) provide Pharmac with a summary of the amendment to the Data Sheet as set out in clause 3.1(b)(iii)(A) above;

Following the notification in clause 3.1(b)(iii)(A) Pharmac reserves the right at its sole discretion to amend the special authority criteria or any other access criteria for the Pharmaceutical based on patient safety;

(iv) acknowledge that Pharmac may require stock reports and batch details held by you for the Pharmaceutical and you agree to provide all such stock reports and batch details to Pharmac upon request;

(v) acknowledge that Pharmac may require price and volume data held by you relating to sales of the Pharmaceutical and you agree to provide all such price and volume data to Pharmac upon request; and

(vi) agree that Health NZ may provide Pharmac and its agents with any price and volume data held by Health NZ in respect of the Pharmaceutical, and Pharmac may share any price and volume data held by Pharmac with Health NZ.

3.2 Supply Issues Reporting

(a) You must send a Supply Issues Report to Pharmac in accordance with clause 4.3(a)(ii) of this Agreement or otherwise at Pharmac's request.

(b) The Supply Issues Report must be provided to Pharmac in any form notified by Pharmac to you. Unless notified otherwise, the Supply Issues Report must include the following information:

(i) average usage of the Pharmaceutical in New Zealand;

(ii) quantity of Pharmaceutical stock:

(A) held by you (or on your behalf) in New Zealand;

(B) held by you (or on your behalf) in other international markets, and available for supply in New Zealand; and

(C) held by wholesalers in New Zealand;

(iii) reason for the Supply Issue;

(iv) when the Supply Issue occurred;

(v) expected delivery dates of the Pharmaceutical to New Zealand;

(vi) expected date of authorised release into the New Zealand market (including the date on which the Pharmaceutical is expected to be available for supply) and any applicable supporting evidence, for example export and import licences or other official authorisations and customs formalities necessary for the exportation and importation of the Pharmaceutical;

(vii) the estimated duration of the Supply Issue; and

(viii) any steps that you have taken or will take to mitigate the risk that you may fail to supply a Pharmaceutical.

(c) You acknowledge that Pharmac may wish to engage with you in respect of any steps that you advise Pharmac of under clause 3.2(b)(viii) above or any other steps that may be required to mitigate the risk that you may fail to supply the Pharmaceutical, and you agree that you will engage and cooperate with Pharmac in relation to all such actual and proposed mitigation activities.

4. Supply Obligations and Managing Supply Issues

4.1 Stock Holdings

The minimum stock holding of the Pharmaceutical that must be held by you (or on your behalf) in New Zealand and available for supply is set out in Annex 1.

4.2 Continuity of Supply

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

(b) You warrant that you have entered into all contractual and other arrangements to the extent necessary, including licence and supply agreements with third parties, to ensure that you will meet all of your obligations under clause 4.2(a) above and this Agreement generally.

4.3 Notification

(a) You must:

(i) notify Pharmac as soon as you become aware of a Supply Issue; and

(ii) send a Supply Issues Report to Pharmac within 2 Business Days of becoming aware of a Supply Issue.

(b) In the event that you consider (acting reasonably) that any circumstances or events may result in a Supply Issue you must notify Pharmac in writing as soon as practicable, including (but not limited to) any of the following circumstances:

(i) you plan any changes to your supply chain, for example but not limited to a change in manufacturing site, in respect of the Pharmaceutical;

(ii) you plan any changes to your ordering or delivery systems;

(iii) you plan to re-structure your organisation; or

(iv) you plan to change the presentation of the Pharmaceutical, including the brand name, pack size, packaging and strength.

(c) After giving Pharmac notice in accordance with clauses 4.3(a)(i) and/or 4.3(b), you must comply with all reasonable requests by Pharmac in respect of steps that may be required to mitigate the risk that you may fail to supply the Pharmaceutical.

4.4 Managing Supply Issues

(a) In addition to your obligations set out in clause 4.3 you must comply with the obligations set out in this clause 4.4.

(b) In the event of:

(i) a decision or notification by Medsafe or any other authorities to recall the Pharmaceutical; or

(ii) the withdrawal of any Consent or Market Approval for the Pharmaceutical,

you must use your best endeavours to engage and co-operate with Medsafe and any other relevant authorities and must, at all times, meet all your regulatory obligations.

(c) In the event a Supply Issue actually results in a failure to supply, or you have reason to believe may cause you to fail to supply, the Pharmaceutical in accordance with the terms of this Agreement, then:

(i) subject to the prior written consent of Pharmac, you must use your best endeavours to procure, within what Pharmac considers to be a reasonable period of time, an Alternative Pharmaceutical for supply to:

(A) wholesalers and other such distributors; and

(B) any Health NZ Hospital,

at the Price; and

(ii) if you fail to procure an Alternative Pharmaceutical at the Price and within the timeframe in accordance with clause 4.4(c)(i) above then 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 Pharmac any additional costs, fees and/or expenses incurred by Health NZ or Pharmac as a result of the purchase of the Alternative Pharmaceutical over and above the costs that would have been incurred by Pharmac had you supplied the Pharmaceutical.

(d) In the event Pharmac receives information that indicates that you may fail to supply a Pharmaceutical in accordance with this Agreement (whether you notify Pharmac under this Agreement or otherwise), you agree that Pharmac may inform other interested parties who may be impacted, including providing other suppliers with sufficient information to allow those suppliers to adequately prepare for a potential change in demand.

4.5 Indemnity

You agree to indemnify Pharmac and Health NZ (as applicable) for any damages, liability, loss, cost (operational or otherwise) or expense awarded against, incurred or suffered by Pharmac and/or Health NZ as a result of or arising from a Supply Issue (other than a Supply Issue resulting directly from a Force Majeure Event). This indemnity shall be deemed to indemnify Pharmac and Health NZ for all additional costs, including all costs incurred by Pharmac and/or Health NZ as a result of the purchase of the Alternative Pharmaceutical that are additional to any costs specified in clause 4.6.

4.6 Liquidated Damages

(a) Subject to clause 4.6(c) and clause 4.6(d), for each and every Supply Issue which actually results in a failure to supply the Pharmaceutical (other than a Supply Issue resulting directly from a Force Majeure Event) you must pay to Pharmac liquidated damages (plus GST (if any)) of $50,000 to cover Pharmac's administrative and/or operational costs.

(b) You acknowledge that Pharmac's right to claim the full liquidated damages amount specified in clause 4.6(a) in these circumstances reflects Pharmac's legitimate interests in securing delivery of the Pharmaceutical by the relevant date and in accordance with the terms of this Agreement and is proportionate to those interests during the period, and in the circumstances, in which the liquidated damages are payable under this clause 4.6.

(c) Liquidated damages are payable where you have not:

(i) notified Pharmac under and in accordance with clause 4.3; and/or

(ii) complied with all reasonable requests by Pharmac in respect of steps that may be required to mitigate the risk that you may fail to supply the Pharmaceutical.

(d) Pharmac may, in its sole discretion, require you to pay less than the amount specified as liquidated damages in clause 4.6(a) if Pharmac is satisfied that the actual costs in the circumstances are less than this amount.

4.7 Interest

If payment of any amount required to be paid by you under clauses 4.5 or 4.6 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 Default Interest Rate, 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 does not limit any other right or remedy of Pharmac; and

(b) Pharmac may take any action, including legal action, without first needing to implement the dispute resolution procedure contained in clause 5.5, to recover that unpaid amount and you agree to pay to Pharmac actual enforcement costs incurred in relation to that action.

5. General Obligations

5.1 Shelf-life of Pharmaceutical

You will not supply the Pharmaceutical:

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

(b) 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 written agreement from Pharmac or the applicable Health NZ Hospital.

5.2 Consents

(a) Prior to the Listing Date you must obtain:

(i) Market Approval for the Pharmaceutical;

(ii) any Consent required for the supply of the Pharmaceutical; and

(iii) any other Consent Pharmac requires you to have or hold.

(b) You must maintain Market Approval and any other Consent specified in clauses 5.2(a)(ii) and 5.2(a)(iii) for the Pharmaceutical for the duration the Pharmaceutical is listed.

5.3 Health and Safety

Where delivery of the Pharmaceutical (or provision of any related services described in this Agreement) occurs within the facilities of a Health NZ Hospital, you and your Personnel will comply with all relevant health and safety requirements, including:

(a) the Health and Safety at Work Act 2015 and all regulations made under that Act; and

(b) any policies and procedures communicated to you by the Health NZ Hospital.

5.4 Confidentiality

(a) Confidential Information is confidential to you, Pharmac, Health NZ and those parties' respective Personnel (as applicable).

(b) You acknowledge that Pharmac may be required to disclose Confidential Information in accordance with:

(i) the Official Information Act 1982; and

(ii) any other legal and administrative obligations,

and you consent to such disclosure.

(c) Pharmac may consult with you, and will act in good faith, before deciding at its sole discretion whether to disclose Confidential Information for the purposes stated in clause 5.4(b) above.

(d) Confidential Information must not be disclosed by you, Pharmac, Health NZ or those parties' respective Personnel unless:

(i) the information is publicly available or enters the public domain through no fault of the applicable parties; or

(ii) the disclosure is:

(A) required or permitted for the purposes of this Agreement;

(B) required or permitted by law; or

(C) agreed to between the applicable parties.

5.5 Dispute Resolution

If there is a dispute between you and Pharmac arising out of, or in connection with, this Agreement, neither of the parties 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) You and Pharmac will endeavour, in good faith, to resolve the dispute referred to in the notice by using informal dispute resolution techniques.

(c) If you and Pharmac have not resolved the dispute within 14 days after the date notice of a dispute was given, the parties may agree that the dispute is to be:

(i) mediated according to the standard mediation agreement of the Resolution Institute (a body corporate incorporated in Australia and registered as an overseas company in New Zealand), and the Chair of the Resolution Institute (or the Chair's nominee) will select the mediator and determine the mediator's remuneration, if you and Pharmac are unable to agree on such matters; or

(ii) submitted to arbitration in accordance with the Arbitration Act 1996, with such arbitration being conducted by a single arbitrator to be agreed on by the parties or, failing agreement, the Chair of the Resolution Institute (or the Chair's nominee) will select the arbitrator.

(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 the parties' respective rights and remedies (including Pharmac's rights under its OPPs).

5.6 Litigation Support

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

(a) give rise to proceedings being issued, or any claim being made, against Pharmac; or

(b) results in Pharmac being made a party to any proceedings issued, or claim made, by a third party,

you will give Pharmac all assistance it reasonably requires for the purpose of the handling of any negotiations and/or litigation related to those proceedings or any claim.

6. General Terms

6.1 No Derogation

The express provision of a remedy for, or consequence of, breach of any term of this Agreement does not derogate from, or limit, any other legal right or remedy available to Pharmac under this Agreement or otherwise in respect of such breach.

6.2 No Waiver

A failure or delay by either you or Pharmac 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.

6.3 Remedies Cumulative

Except as is expressly stated otherwise in this Agreement:

(a) the rights, powers and remedies provided in this Agreement are cumulative and are not exclusive of any rights, powers or remedies provided by law or under this Agreement; and

(b) the exercise of any of the rights, powers and remedies provided in this Agreement will not prejudice the exercise of any other right, power or remedy under this Agreement or existing at law.

6.4 Entire Agreement

This Agreement:

(a) is the entire agreement between you and Pharmac regarding the terms on which the Pharmaceutical is listed; and

(b) supersedes and extinguishes all prior agreements and understandings between you and Pharmac, and between you and Health NZ, and any prior agreements and understandings originally entered into between you and district health boards (as applicable), regarding the Pharmaceutical and the subject matter contained herein.

6.5 Advertising

You must ensure that any Advertisement aimed at consumers of the Pharmaceutical does not breach any applicable statute, regulation or industry standard, including the Advertising Standards Authority Codes of Practice and the Medicines New Zealand Code of Practice.

6.6 Contracts Privity

(a) You and Pharmac acknowledge that your obligations in this Agreement constitute promises and obligations which confer or are intended to confer a benefit on Health NZ and related persons, and are enforceable by Health NZ and any such persons pursuant to Part 2, subpart 1 of the Contract and Commercial Law Act 2017 (Contractual Privity).

(b) Except as expressly provided in clause 6.6(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) 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 Health NZ.

6.7 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.

6.8 Amendments

Amendments to this Agreement must be in writing.

6.9 Assignment

You will not permit this Agreement, or any part of this Agreement, to be transferred or assigned (either directly or due to a change of 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.

6.10 Further Assurances

You and Pharmac agree to execute any further documents and do any further acts as may be reasonably necessary from time to time to give effect to the terms and intentions of this Agreement.

6.11 Specific Performance

You acknowledge that in the event of any breach or threatened breach of this Agreement by you, damages may not be an adequate remedy and Pharmac may seek specific performance of the terms of this Agreement or injunctive relief or any other similar remedy, in addition to any other rights, powers or remedies provided under this Agreement or by law (including equity).

6.12 Agreement Prevails

Where any of your terms of supply, for example on invoices or any purchase orders, conflict or are inconsistent with any of the terms of this Agreement, the terms of this Agreement will prevail.

6.13 Governing Law and Jurisdiction

This Agreement is governed by New Zealand law and each party submits to the exclusive jurisdiction of the New Zealand courts.

Annex 4: Definitions and Interpretation

1. Definitions

In this Agreement:

Advertisement means any advertisement as defined in the Medicines Act 1981;

Agreement means this agreement, including all Annexures;

Alternative Pharmaceutical means an alternative Pharmaceutical that Pharmac has expressly agreed in writing constitutes an acceptable substitute for that Pharmaceutical;

Business Day means a day of the week, which excludes Saturday, Sunday, and national public holidays in New Zealand. A Business Day starts at 8.30am and ends at 5pm;

Changed Medicine Notification means a notification provided by you, in accordance with the Medicines Act 1981, to the Director-General of Health, of a planned material change to the Pharmaceutical, and the reasons for the change;

Confidential Information means information relating to the terms of this Agreement that is agreed in writing by you and Pharmac as being confidential, but excludes:

(a) information regarding the Pharmaceutical that does not identify you, or that cannot reasonably be expected to identify you, and you agree that such information is not Confidential Information and that Pharmac may use and publish such information; and

(b) information released by Pharmac in accordance with clause 5.4 of Annex 3 of this Agreement, and you agree that such information ceases to be Confidential Information and that Pharmac may release that information again at any time in future without consulting with you or obtaining your prior agreement;

Consent means registrations, consents, permits, licences and authorisations, whether statutory or otherwise;

Crown Direction means any direction given to Pharmac under statutory authority;

Data Sheet means the Pharmaceutical data sheet published by Medsafe on your behalf;

Default Interest Rate means the base rate of ASB Bank Limited plus 5% per annum;

Force Majeure Event means any cause preventing the affected party from performing any or all of its obligations under this Agreement which arises from or is attributable to acts, events, omissions or accidents beyond the reasonable control of the affected party, which:

(a) was not reasonably foreseeable;

(b) could not have been avoided or mitigated through the exercise of good industry practice and due care, skill and diligence; and

(c) was not caused by the affected party, its affiliates, officers, Personnel or suppliers,

but does not include any lack of finance or financial means or any changes in market conditions;

Health NZ means Health New Zealand, a Crown agent established under section 11 of the Pae Ora (Healthy Futures) Act 2022;

Health NZ Hospital means a hospital operated by Health NZ;

Listing Date means the date on which Pharmac will list, or amend the listing of (as applicable), the Pharmaceutical as recorded in Annex 1 of this Agreement or otherwise determined in accordance with this Agreement;

Market Approval means regulatory approval for sale and marketing in New Zealand;

Medsafe means the business unit within the Ministry of Health that has responsibilities in relation to the safety of medicines and medical devices used and supplied in New Zealand;

New Zealand Government's Supplier Code of Conduct means the New Zealand Government's supplier code of conduct (as updated from time to time);

OPPs means Pharmac's Operating Policies and Procedures (as updated from time to time);

Personnel means all individuals engaged by the relevant party, including the parties' employees, contractors, representatives, legal advisors, clinical advisors and other consultants;

Pharmaceutical means each pharmaceutical described in Annex 1, in the form(s) and strength(s) set out in Annex 1;

Pharmaceutical Schedule means the schedule listing all the medicines funded for New Zealanders (as updated from time to time);

Price means the price (exclusive of GST) of the Pharmaceutical recorded in Annex 1;

Supply Issue means an event which may result, or has resulted, in a failure to supply the Pharmaceutical in accordance with this Agreement, including but not limited to:

(a) your stock of the Pharmaceutical held by you in New Zealand falls below the minimum stock holding recorded in Annex 1;

(b) you recall (or have reason to believe you may recall), or are (or have reason to believe you may be) required by Medsafe or any other authorities to recall, the Pharmaceutical;

(c) any Consent or Market Approval, required in accordance with clause 5.2 of Annex 3 is withdrawn, revoked, suspended or withheld;

(d) you become aware of any issue that may impact on your ability to fulfil any orders for the Pharmaceutical;

(e) you plan to withdraw the Pharmaceutical from supply; and/or

(f) you fail to supply (or have reason to believe you may fail to supply) the Pharmaceutical from the Listing Date;

Supply Issues Report means a report provided by you to Pharmac in accordance with clause 3.2 of Annex 3 of this Agreement; and

Unique Product Identifiers means for each Pharmaceutical:

(a) the 'CTPP', which is the Containered Trade Product Pack SNOMED CT code, which is the unique identifier that describes the packaged, branded product and the container it is dispensed in, as used within the New Zealand Medicines Terminology;

(b) the ‘GTIN’ (if available), which is the Global Trade Item Number for a Pharmaceutical;

(c) the ‘Pharmacode’, which is the unique identifier assigned to a Pharmaceutical and notified to you by the Pharmacy Guild; and

(d) the ‘Supplier Code’, which is the unique product identifier assigned by you to the Pharmaceutical, if applicable.

2. Interpretation

In this Agreement, unless the context requires otherwise:

(a) references to **“Health NZ”** encompass Health NZ Hospitals;

(b) references to **“Health NZ Hospitals”** may reflect that certain operational matters can in practice occur at a local hospital level notwithstanding that Health NZ Hospitals are part of, and not separate legal entities from, Health NZ;

(c) references to clauses are to clauses in this Agreement;

(d) the headings to clauses will be ignored in construing this Agreement;

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

(f) any organisations (including government agencies) referenced in this Agreement include their successors;

(g) a reference to any statute includes that statute, and regulations made under it, as amended from time to time;

(h) a reference to any statute includes any statute passed in substitution for that statute;

(i) an obligation not to do anything includes an obligation not to suffer, permit or cause that thing to be done;

(j) derivatives of any defined word or term have a corresponding meaning;

(k) all references to dollars are references to New Zealand dollars unless provided otherwise;

(l) “including” and similar words do not imply any limitation;

(m) references to **“you”** include any third parties acting on your behalf, including sub-contractors;

(n) 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);

(o) the terms set out in this Agreement specify the terms of listing for each Pharmaceutical and the terms apply independently to each Pharmaceutical in Annex 1; and

(p) none of the terms are to be construed against a party by reason of the fact that that term was first proposed or was drafted by that party.