

# 1. Principal Supply Status for the Pharmaceutical

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## 1.1 Principal Supplier

- (a) Subject to:
  - (i) Pharmac's other rights under this Agreement in relation to the Pharmaceutical; and
  - (ii) this clause relating to the Alternative Brand Allowance,

Pharmac will not list another supplier's brand of the [Chemical] and Pharmac will not delist the Pharmaceutical, at any time during the Principal Supply Period.
- (b) This clause does not prohibit Pharmac from entering into negotiations or arrangements with, or inviting proposals from, other suppliers to be the principal supplier of any forms and strengths of the [Chemical], if such supply commences after the end of the Principal Supply Period.
- (c) You shall have Principal Supply Status during the Principal Supply Period, which shall be subject to the Alternative Brand Allowance, where other suppliers' brands of the [Chemical] may be subsidised in the community and/or purchased by Te Whatu Ora Hospitals.
- (d) You acknowledge and agree that any other suppliers' brands of the [Chemical] may be concurrently listed at any time during the First Transition Period and the Principal Supply Period and your rights under this Agreement do not extend to an exclusive listing of the [Chemical].
- (e) The Alternative Brand Allowance referred to in paragraphs (a) and (c) above is specified as a percentage of the Total [Chemical] Volume for the [Chemical], as set out in the column entitled "ABA Limit" in the table below:

| [Chemical] | ABA Limit |
|------------|-----------|
| [ ]        | [ ]%      |

## 1.2 Exceptions to Principal Supply Status

- (a) Pharmac may, from time to time during the Principal Supply Period or the First Transition Period, amend the Alternative Brand Allowance for the [Chemical] after consultation with a relevant medical adviser (being either the Ministry of Health, Public Health Agency, Te Whatu Ora, PTAC or its Specialist Advisory Committees), provided that Pharmac may only increase the Alternative Brand Allowance without your prior agreement if it has a direction to that effect from Medsafe or its successor, or a recommendation that it do so from PTAC or its Specialist Advisory Committees, based on a significant clinical issue.
- (b) Subject to clause 1.3 below, you acknowledge and agree that while you have Principal Supply Status:

- (i) other supplier brands of the [Chemical] may be subsidised in the community and/or purchased by Te Whatu Ora Hospitals, subject to the Alternative Brand Allowance; and
- (ii) without derogating from any other rights available to Pharmac or Te Whatu Ora under this Agreement or otherwise, if you fail to supply the Pharmaceutical in accordance with this Agreement at any time during the Principal Supply Period, then the Alternative Brand Allowance shall not apply and other supplier brands of the [Chemical] may be subsidised in the community and/or purchased for use in Te Whatu Ora Hospitals without limitation during that period of non-supply and any calculation performed in accordance with clause 1.3 below shall exclude that period of non-supply.

### 1.3 Principal Supply Status Monitoring

- (a) If you reasonably believe that the percentage usage of other suppliers' brands of the [Chemical] purchased for use exceeds the Alternative Brand Allowance during the Principal Supply Period, you may at any date after a [three (3) month] period following the End Date, request that Pharmac carry out calculations for that Principal Supply Period in accordance with the procedure set out in this clause 1.3, and Pharmac may, acting reasonably, agree to carry out such calculations, provided that if Pharmac refuses to carry out such calculations, it will provide you with the reasons for refusing to do so.
- (b) Within 30 Business Days of Pharmac accepting your request to carry out calculations in accordance with clause 1.3(a) above, Pharmac shall carry out the following calculation:
  - (i)  $(\text{Total Brand Allowance [Chemical] Volume} / \text{Total [Chemical] Volume}) \times 100 = \text{Brand Allowance Indicator};$
  - (ii)  $\text{Brand Allowance Indicator} - \text{Alternative Brand Allowance} = \text{Brand Differential}$
- (c) In the event the Brand Differential is a number greater than zero i.e. a positive amount, Pharmac shall carry out the following calculation:
  - (i)  $\text{Total [Chemical] Volume} / 100 = \text{Volume Multiplier};$
  - (ii)  $\text{Volume Multiplier} \times \text{Brand Differential} = \text{Eligible Volume};$
  - (iii)  $(\text{Eligible Volume} \times \$[ \quad ]) / 2 = \text{Brand Compensation}$
- (d) Pharmac will notify you in writing of any Brand Compensation payable or not in accordance with clauses 1.3(b) and (c) above and will provide you with the details of the relevant party or parties to be invoiced for any Brand Compensation payable. Following such notification to you from Pharmac, you may invoice the relevant party or parties for the Brand Compensation.
- (e) You acknowledge and agree that the data extracted from the records used by Pharmac are the best data and those records are the best records, for the purposes of carrying out the calculations.

- (f) You may, within 10 Business Days following notification of the outcome of the calculations in accordance with clause 1.3(d) above (the “**Calculation**”), notify Pharmac in writing that you dispute the particular Calculation and that you require an audit of that Calculation to be carried out. If you do give a notice to Pharmac under this clause within that 10-Business Day period, then the following provisions are to apply:
- (i) The audit is to be carried out by an independent person jointly approved by us or, if there is no agreement on a mutually acceptable person within 5 Business Days of the date of your notice under this clause, then by an independent person nominated for that purpose by the President for the time being of the Institute of Chartered Accountants of New Zealand.
  - (ii) The independent person is to audit the particular Calculation, which is disputed by you, based on all relevant electronic data which is extracted by Pharmac from the records maintained by it. For the avoidance of doubt, the independent person will have no right to inspect, review or have access to the written prescriptions on which the data extracted by Pharmac from those electronic records are based, nor any right to request copies of those written prescriptions.
  - (iii) In carrying out the audit, the independent person is to be considered as acting as an expert and not as an arbitrator.
  - (iv) The independent person will be required to complete the audit, and to provide us with a written determination in that regard, within 5 Business Days of receiving all the information required by the independent person to make a determination and, in any case, no later than 10 Business Days from the date of his or her acceptance of appointment or nomination under this clause, unless we agree otherwise. The independent person’s determination of the particular Calculation is to be final and binding on both of us.
  - (v) The costs incurred by the independent person in completing the audit are to be met by you, irrespective of the outcome of the audit.

#### **1.4 Withdrawal of Principal Supply Status**

- (a) Pharmac may withdraw Principal Supply Status in relation to the Pharmaceutical (in which case clauses 1.1 and 1.3 above will no longer apply), by written notice to you at any time during the Principal Supply Period or (in anticipation) during the First Transition Period in the event of a Supply Issue or in accordance with any advice from Medsafe or clinical advice, based on patient safety or any other clinical reasons.
- (b) Any withdrawal of Principal Supply Status is without prejudice to Pharmac’s rights under Annex 3, clauses 4.5 and 4.6.

#### **1.5 Suspension of Principal Supply Status**

- (a) Pharmac may suspend Principal Supply Status in relation to the Pharmaceutical, by written notice to you at any time during the Principal Supply Period or (in anticipation) during the First Transition Period in the event of a Supply Issue or in accordance with any advice from Medsafe or clinical advice, based on patient safety or any other clinical reasons.

- (b) Any suspension of Principal Supply Status is without prejudice to Pharmac's rights under Annex 3, clauses 4.5 and 4.6.
- (c) Pharmac may, at any time, in its sole discretion, notify you of the date on which the suspension of Principal Supply Status under this clause 1.5 ceases and on which date:
  - (i) Principal Supply Status is to be re-implemented in respect of the Pharmaceutical; or
  - (ii) Principal Supply Status is to be withdrawn in accordance with clause 1.4 above.

## 1.6 Subsidy and supply arrangements after the End Date

- (a) Subject to clause 1.6(b) and (c) below, the Pharmaceutical is to continue to be the subject of a listing agreement between you and Pharmac with effect from the End Date, and accordingly:
  - (i) you will cease to have Principal Supply Status for that Pharmaceutical;
  - (ii) the Pharmaceutical will remain listed in the Pharmaceutical Schedule subject to the terms in Annex 3;
  - (iii) you may increase the price ex-manufacturer (exclusive of GST) at which you sell or supply, or make available for supply or sale, by you, to Te Whatu Ora Hospitals, wholesalers and other such distributors, on giving Pharmac 12 months' written notice of that price increase. You may provide Pharmac with this written notice at any time after, but not before, the End Date, subject to sub-paragraphs (A) and (B) as follows:
    - (A) Pharmac reserves the right to consult on any price increases prior to determining whether to increase the subsidy for the Pharmaceutical to the new price notified under this paragraph (a)(iii);
    - (B) Where you increase the price at which you supply the Pharmaceutical under this paragraph (a)(iii), you will not subsequently increase the price at which you supply the Pharmaceutical for at least 12 months from the effective date of the price increase.
  - (iv) if Pharmac does not increase the subsidy for the Pharmaceutical to the new price notified under paragraph (a)(iii) above, you may withdraw the Pharmaceutical from supply on not less than 12 months' prior written notice;
  - (v) if Pharmac does increase the subsidy for the Pharmaceutical to the new price notified under paragraph (a)(iii) above, you may withdraw the Pharmaceutical from supply on not less than 2 years' prior written notice (except where the withdrawal is due to a Force Majeure Event); and
  - (vi) if at the time of providing notice under paragraph (a)(v) above, you advise Pharmac that you are required to purchase a significant quantity of extra

stock of the Pharmaceutical to enable you to continue to supply for the two-year period, and you advise Pharmac of the total cost of that stock, Pharmac will either:

- (A) use reasonable endeavours to enter into an agreement to reimburse you for stock that remains unsold at the end of that two-year period; or
  - (B) release you from your obligations to supply under this clause 1.6(a).
- (b) Pharmac may at its sole discretion, with effect from the End Date:
- (i) require that the Pharmaceutical does not continue to be the subject of a listing agreement, in which case Pharmac will give you written notice not less than 6 months prior to the End Date; and/or
  - (ii) apply any of the strategies under Pharmac's then current OPPs to the Pharmaceutical (including delisting the Pharmaceutical).
- (c) In the event Pharmac applies any of the strategies described in clause 1.6(b)(ii) above, you may withdraw the Pharmaceutical from supply on not less than 12 months' prior written notice. You may provide Pharmac with this written notice at any time after, but not before, the date that the particular strategy takes effect in the Pharmaceutical Schedule.

## 1.7 Termination and restrictions for clinical reasons

Pharmac reserves the right, but only after consultation with you and a relevant medical adviser (being either Medsafe, PTAC or its Specialist Advisory Committees), to:

- (a) terminate this Agreement at any time during the Principal Supply Period if the medical adviser determines for clinical reasons that it is no longer appropriate to have either:
  - (i) a principal supplier for all indications for which the Pharmaceutical has Principal Supply Status in the Pharmaceutical Schedule; or
  - (ii) the Pharmaceutical as the principal pharmaceutical for all indications for which the Pharmaceutical has Principal Supply Status in the Pharmaceutical Schedule; and/or
- (b) impose at any time during the Principal Supply Period restrictions on the prescribing or dispensing of the Pharmaceutical if those restrictions are necessary for clinical reasons.

## 1.8 Definitions

The following definitions apply to clauses 1.1 to 1.7:

**Alternative Brand Allowance** means the alternative brand allowance relating to the [Chemical], in relation to hospital and/or community supply, as indicated as a percentage amount of the Total [Chemical] Volume, in the column entitled "ABA Limit" in the table set out in clause 1.1(e) above;

**Brand Allowance Indicator** means the actual percentage of Brand Allowance [Chemical] subsidised in the community and/or purchased by Te Whatu Ora Hospitals relative to the Total [Chemical] Volume in the Principal Supply Period;

**Brand Allowance [Chemical]** means an alternative supplier's brand of the [Chemical]. For the avoidance of doubt, a Brand Allowance [Chemical] shall not be interpreted to be an Alternative Pharmaceutical for the purposes of this Agreement;

**Brand Compensation** means the compensation payable to you in accordance with clause 1.3(c) above;

**Brand Differential** means the difference between the Brand Allowance Indicator and the Alternative Brand Allowance;

**[Chemical]** means [ ];

**Eligible Volume** means the Volume Multiplier multiplied by the Brand Differential, being a volume of the [Chemical] eligible for Brand Compensation in [ ];

**End Date** means the last day of the Principal Supply Period;

**First Transition Period** means the period of [ ] calendar months commencing on the Listing Date (provided that Pharmac may reduce or extend this period at its discretion by giving notice to you);

**Principal Supplier** means you, being the principal supplier of the relevant [Chemical] in relation to community and/or hospital supply (subject to the Alternative Brand Allowance provisions);

**Principal Supply Period** means the period beginning on [ ] and ending on [ ];

**Principal Supply Status** means the status of being the Principal Supplier for community and/or hospital supply of the [Chemical] for the Principal Supply Period;

**Total Brand Allowance [Chemical] Volume** means the total volume of Brand Allowance [Chemicals] subsidised in the community and/or purchased by Te Whatu Ora Hospitals in the Principal Supply Period, specified in [ ];

**Total [Chemical] Volume** means the total volume of the [Chemical] (inclusive of Brand Allowance [Chemicals]) subsidised in the community and/or purchased by Te Whatu Ora Hospitals in the Principal Supply Period, specified in [ ]; and

**Volume Multiplier** means the Total [Chemical] Volume divided by one hundred (100) (which shall equate to 1% of the Total [Chemical] Volume), specified in [ ].