

DEED

BETWEEN

THE COMMONWEALTH OF AUSTRALIA

AND

COMPANY

IN RELATION TO

SHARING THE COSTS OF THE

COMMONWEALTH SUBSIDY FOR

THE SUPPLY OF **[DRUG]**

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COMMERCIAL IN CONFIDENCE

DEED

IN RELATION TO SHARING THE COSTS OF THE COMMONWEALTH SUBSIDY FOR THE SUPPLY OF [DRUG]

Parties

This deed is made between and binds the following parties:

1. **Commonwealth of Australia** represented by the Department of Health ABN 83 605 426 759 (**Commonwealth**); and
2. **[Company]** ABN [number] ACN [number] of [address] (the **Company**).

Context

This deed is made in the following context:

- A. Under the *National Health Act 1953* (Cth), the *Veterans' Entitlements Act 1986* (Cth), the *Military Rehabilitation and Compensation Act 2004* (Cth) and the *Australian Participants in British Nuclear Tests (Treatment) Act 2006* (Cth), the Commonwealth subsidises the supply of certain drugs and medicinal preparations.
- B. **[To be completed]**

Operative provisions

The parties agree as follows:

1. Interpretation

1.1. Definitions

- 1.1.1. Unless the contrary intention appears, a term in bold type has the meaning shown opposite it:

Act	means the <i>National Health Act 1953</i> (Cth);
Advisers	means a party's agents, contractors (including subcontractors), consultants or advisers (including legal advisers) engaged in, or in relation to, the performance or management of this deed;
AEST and AEDT	means Australian eastern standard time and Australian eastern daylight time, respectively;
agreed price	has the meaning given in s.84(1);
Business Day	in relation to the doing of any action in a place, means a weekday other than a public holiday in that place;
claimed price	has the meaning given in s.84(1);
combination item	has the meaning given in s.84(1);

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Commencement Date	[To be completed]
Commonwealth Expenditure	means for each Month, the total Subsidy paid by the Commonwealth in relation to the supply of the Drug, during that Month (calculated by reference to the number of Processed Prescriptions);
Commonwealth Payment	means, for each Year, the total Subsidy paid by the Commonwealth (less any amount paid or payable to the Commonwealth under a special pricing arrangement) in relation to the supply during that Year (calculated by reference to the number of Processed Prescriptions) of: a. the Drug; and b. subject to clause 3.4, any New Drug;
Confidential Information	means the information listed in Attachment A;
Department	means the Commonwealth Department of Health or its successors;
Determined Interest Rate	means the interest rate which is 3% above the market rate for 10-year Treasury bonds at the time interest is payable; <i>Note - the Treasury Bond rate can be obtained by contacting the Reserve Bank of Australia.</i>
determined price	has the meaning given in s.84(1);
Drug	means any pharmaceutical benefit supplied by the Company (including any combination item) that has the drug or medicinal preparation known as [DRUG] irrespective of the brand name, form or manner of administration (including any new brand name, form or manner of administration determined after the Commencement Date that may be Subsidised);
GST	has the meaning given in the <i>A New Tax System (Goods and Services Tax) Act 1999</i> (Cth);
Minister	means the Minister with responsibility for administering the Act;
Month	means: a. in relation to the first Month, the period from the Commencement Date until and including the last day of the calendar month in which the Commencement Date falls; and b. for each subsequent Month, the period from the first day of the calendar month until and including the last day of the calendar month;

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New Drug	means any pharmaceutical benefit notified by the Department in accordance with clause 3.4;
Part	means a part of the Act;
PBAC	means the Pharmaceutical Benefits Advisory Committee, which is established under s.100A;
pharmaceutical benefit	has the meaning given in s.84(1) and includes any repatriation pharmaceutical benefit as defined in s.84(1);
Price Ex Manufacturer	means the price ex manufacturer as specified in the Schedule of Pharmaceutical Benefits as updated from time to time;
Price Variation	means any change to the amount payable by the Commonwealth for the supply of the Drug, including a change resulting from: <ul style="list-style-type: none">a. the agreed price, determined price or claimed price being varied in accordance with Division 3A, 3B or 3C of Part VII;b. the agreed price, determined price or claimed price being varied for any other reason (including because of a Reference Pricing change);c. a determination under s.98B(1) being varied in any way (including by a replacement instrument);d. a determination under s.98C(1) being varied in any way (including by a replacement instrument);e. a determination under s.99(4) being varied in any way (including by a replacement instrument); orf. a variation to the amount of the co-payment payable by the patient for the supply of the Drug;
Processed Prescription	means a pharmaceutical benefit in relation to which a Subsidy is validly paid as reported by the Department;
Reference Pricing	means the methodology referred to as reference pricing used by the Department to recommend prices;
responsible person	has the meaning given in s.84(1);
s.	means a section of the Act;
Schedule of Pharmaceutical Benefits	means the document titled 'Schedule of Pharmaceutical Benefits' or its equivalent and/or any supplements to that Schedule, published by the Department and updated from time to time; <i>Note - some item codes for drugs or medicinal preparations may only be listed in supplements to the Schedule of Pharmaceutical Benefits (or equivalent).</i>

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State	means each State of Australia;
Subsidisation Cap	means the limit of the Commonwealth Payment in each Year, as detailed in clause 3.2.3;
Subsidy	means any payment made by the Commonwealth in respect of the supply of a pharmaceutical benefit; Subsidisation or Subsidised have equivalent meanings;
Territory	means each of the Australian Capital Territory and the Northern Territory;
Term	[To be completed]; and
Year	[To be completed]

1.2. Interpretation

- 1.2.1. In this deed, unless the contrary intention appears:
- words in the singular include the plural and vice versa;
 - clause headings are inserted for convenient reference only and have no effect in limiting or extending the language of provisions to which they refer;
 - words importing a person include a partnership and a body, whether incorporated or otherwise;
 - all references to dollars are to Australian dollars;
 - a reference to any provision in legislation or to any legislative instrument includes any amendment of that provision or instrument or replacement instrument;
 - where any word or phrase is given a defined meaning, any other part of speech or other grammatical form in respect of that word or phrase has a corresponding meaning; and
 - a reference to writing means any representation of words, figures or symbols, whether or not in a visible form.
- 1.2.2. For the avoidance of doubt, a reference to 'supply' of the Drug or a pharmaceutical benefit in this deed includes supply under an arrangement made under s.100(1).

1.3. Guidance on construction of this deed

- 1.3.1. This deed records the entire agreement between the parties in relation to its subject matter.
- 1.3.2. No variation of this deed is binding unless it is agreed in writing and signed by the parties.
- 1.3.3. Any reading down or severance of a particular provision does not affect the other provisions of this deed.

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1.3.4. This deed is to be construed in accordance with the laws of the Australian Capital Territory.

1.4. Acknowledgement

1.4.1. The Company acknowledges that:

- a. this deed is made pursuant to s.85E; and
- b. nothing in this deed in any way limits the operation of the Act or affects or fetters any function or power of the Minister, the PBAC, or any other person or body under the Act.

2. Operation of the deed

2.1. Commencement

2.1.1. Subject to clause 2.1.2, this deed commences operation on the Commencement Date.

2.1.2. [To be completed]

2.2. Continued operation

2.2.1. Subject to clause 7.2, this deed continues in force notwithstanding any:

- a. variations to the Act, instruments, declarations or determinations made under the Act; or
 - b. decisions made under the Act,
- that may affect the operation of this deed.

3. Reimburse the Commonwealth

3.1. Rebate

3.1.1. The Company will rebate the Commonwealth for each Month, an amount which is calculated in accordance with the following formula:

[insert agreed formula]

3.2. Reimbursement

3.2.1. In addition to clause 3.1, if the Commonwealth Payment for any Year exceeds the Subsidisation Cap in that Year, the Company agrees to reimburse the Commonwealth in accordance with the following formula:

[insert agreed formula]

3.2.2. For the purposes of this deed, the 'Drug's share of the market during the Year' (MS) shall be calculated by applying the following formula:

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$$\text{MS} = \frac{\text{that part of the Commonwealth Payment that relates to the supply of the Drug during that Year}}{\text{the total Commonwealth Payment in that Year}}$$

Note: Where there are no New Drugs during a Year, MS will equal 1. It is possible for there to be more than one 'New Drug' at any time.

3.2.3. For the purposes of this deed, each Year's Subsidisation Caps are:

Year 1: [insert Subsidisation Cap]

Year 2: [insert Subsidisation Cap]

Year 3: [insert Subsidisation Cap]

Year 4: [insert Subsidisation Cap]

3.2.4. The Company undertakes not to misrepresent:

- a. the rebate formula in clause 3.1.1 or the amount to be rebated in accordance with that formula; or
- b. the reimbursement formula in clause 3.2.1 or the amount to be reimbursed in accordance with that formula.

3.3. Subsidisation Caps amended if stocks are exhausted or there is a failure to supply

3.3.1. If, in any Year and for any reason:

- a. stocks of the Drug in Australia are exhausted for a period of 10 or more Business Days, whether consecutive or in total; and/or
- b. the Commonwealth forms the opinion, acting reasonably, that the Company has failed to adequately supply the Drug in any State or Territory,

the Subsidisation Cap in that Year will be reduced in accordance with the following formula:

$$\frac{\text{A}}{\text{B}} \times \text{C}$$

where:

- A** means the number of days per Year when the Drug was available for dispensing, being:
- i. the number of days in the Year less the number of days during which stocks of the Drug were exhausted; and/or
 - ii. the number of days in the Year less the number of days between the date on which the Company first fails to supply the Drug to a given

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State or Territory and the date upon which the Company resumes supplying the Drug to that given State or Territory;

B means the number of days in the Year; and

C means the Subsidisation Cap.

3.4. New Drugs

3.4.1. The Commonwealth may at any time notify the Company in writing that a pharmaceutical benefit will be a New Drug for the purposes of this deed, subject to any limitations contained in the notice.

3.4.2. The notice issued under clause 3.4.1 must define the New Drug and the date from which it will be a New Drug.

3.4.3. The notice issued under clause 3.4.1 may define the New Drug by reference to some or all of the following:

- a. the drug or medicinal preparation it contains;
- b. a brand it may be supplied under;
- c. a form in which it may be supplied;
- d. a manner in which it may be administered; or
- e. the circumstances in which it may be prescribed.

4. Payments

4.1. Invoices

4.1.1. In this clause:

EOFY Month means a Month which begins on 1 June; and

EOFY Month Invoice means an invoice for the EOFY Month.

4.1.2. Subject to clause 4.1.3, after the end of each Month, the Commonwealth will provide the Company with a properly rendered invoice and supporting information to enable the Company to validate the calculation of the amount payable under clause 3.1.

4.1.3. The Commonwealth will provide the Company with an EOFY Month Invoice for each EOFY Month during or before the EOFY Month. The amount of an EOFY Month Invoice will be an amount determined by the Department based on amounts payable under clause 3.1 in previous Months. The Commonwealth will provide:

- a. at the time an EOFY Month Invoice is issued, information regarding the basis upon which the amount of the EOFY Month Invoice was determined; and
- b. after the end of an EOFY Month, the supporting information relating to the supply of the Drug during the EOFY Month to enable the Company to

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validate the calculation of the amount payable under clause 3.1 in relation to the EOFY Month.

- 4.1.4. If clause 3.2 applies, the Commonwealth will:
- a. notify the Company of that event; and
 - b. provide the Company with a properly rendered invoice and supporting information to enable the Company to validate the calculation of the amount payable under clause 3.2.

4.2. Supporting information

4.2.1. For the purposes of clause 4.1, '**supporting information**' means information regarding the number of Processed Prescriptions for the Drug (and any New Drug) reported by the Department relevant to the calculation of the rebate under clause 3.1 or the reimbursement under clause 3.2. Subject to clauses 4.2.2 and 4.2.3, this supporting information is final and determinative.

- 4.2.2. If the Commonwealth becomes aware that:
- a. there may be an error in the supporting information provided with an invoice under clause 4.1; or
 - b. the amount of an EOFY Month Invoice does not reflect the calculation of the rebate payable in accordance with clause 3.1,

it must notify the Company in writing within 20 Business Days of becoming aware of the potential error.

- 4.2.3. If the Company believes that:
- a. an error exists in the supporting information provided with an invoice under clause 4.1; or
 - b. the amount of an EOFY Month Invoice does not reflect the calculation of the rebate payable in accordance with clause 3.1,

it must notify the Commonwealth in writing and provide details of the error within 20 Business Days of becoming aware of the error.

4.2.4. Where the Commonwealth issues a notice under clause 4.2.2 or receives a notice under clause 4.2.3 (**error notice**), the Commonwealth will promptly review the supporting information to determine whether there is an error and if so what, if any, impact the error has had on the operation of this deed. Where the review is not completed within 20 Business Days of the error notice, the Commonwealth will notify the Company that the review is not completed and provide the Company with an estimate of the time it will take for the review to be completed. Once the review is completed, the Commonwealth will notify the Company of its determination which will be final.

4.2.5. If as a result of the review the Commonwealth determines that an error exists in the supporting information or that the amount of an EOFY Month Invoice does not reflect the calculation of the rebate payable in accordance with clause 3.1

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and as a result of the error an invoice has been issued under clause 4.1 (**original invoice**) for the incorrect amount, where the original invoice has:

- a. not already been paid by the Company, the Commonwealth will cancel the original invoice and issue a replacement invoice for the correct amount; or
- b. already been paid by the Company and the error resulted in:
 - i. an overpayment by the Company - the Commonwealth will refund the amount of the overpayment to the Company within 20 Business Days of the date on which the Commonwealth gives notification of its determination or advise the Company that the Company may set off the amount of the overpayment against the next invoice issued under clause 4.1; or
 - ii. an underpayment by the Company - the Commonwealth will issue an additional invoice to the Company for the amount of the underpayment or advise the Company that the underpayment will be incorporated in the amount due under the next invoice issued under clause 4.1.

4.2.6. If the Commonwealth is required to pay an amount to the Company under clause 4.2.5.b.i then no interest is payable by the Commonwealth to the Company on the amount to be paid.

4.2.7. If the Company is required to pay an underpayment to the Commonwealth under clause 4.2.5.b.ii then, subject to clause 4.3, no interest is payable by the Company to the Commonwealth on the amount to be paid.

4.2.8. The Company must pay the amount invoiced under clause 4.1 to the Commonwealth without any reduction, set-off (subject to clause 4.2.5.b.i) or counterclaim, within 20 Business Days of the date of the invoice (**due date**), unless the Commonwealth issues a replacement invoice under clause 4.2.5.a prior to the due date. The Company must pay the amount set out in any replacement invoice issued under clause 4.2.5.a or additional invoice issued under clause 4.2.5.b.ii within 20 Business Days of the date of the invoice.

4.3. **Late payment**

4.3.1. The Company must pay interest, at the Determined Interest Rate, on any amount payable by it which has not been paid to the Commonwealth within the period specified in clause 4.2.8.

4.3.2. Any outstanding amount payable by the Company, including interest, which has not been paid by the Company when required to be paid constitutes a debt due to the Commonwealth which is recoverable by it at any time without notice.

4.4. **GST**

4.4.1. Unless otherwise indicated, all consideration for any supply made under this deed is exclusive of any GST imposed on the supply.

4.4.2. Subject to this clause, if one party (**supplier**) makes a taxable supply under this deed to the other party (**recipient**), the recipient on receipt of a tax invoice from

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the supplier must pay without set-off an additional amount to the supplier equal to the GST imposed on the supply in question.

- 4.4.3. No party may claim or retain from the other party any amount in relation to a supply made under this deed for which the first party can obtain an input tax credit or decreasing adjustment.

5. Confidential Information

5.1. No disclosure of Confidential Information

- 5.1.1. Subject to clause 5.2.1, a party must not, without the prior written consent of the other party, disclose any Confidential Information of the other party to a third party.

5.2. Exceptions

- 5.2.1. The obligations on the parties under this clause 5 will not be taken to have been breached to the extent that Confidential Information:
- a. is disclosed by a party to its Advisers or employees (including any employee of any related body corporate within the meaning of section 9 of the *Corporations Act 2001* (Cth)) solely in order to comply with obligations, or to exercise rights, under this deed;
 - b. is disclosed to a party's internal management personnel, solely to enable effective management or auditing of deed-related activities;
 - c. is disclosed by the Department to the responsible Minister;
 - d. is disclosed by the Department, in response to a request by a House or a Committee of the Parliament of the Commonwealth;
 - e. is disclosed by the Department to a court, tribunal or other legally constituted enquiry or for the purposes of any alternative dispute resolution process;
 - f. is shared within the Department, or within another Australian government agency, including the PBAC, where this serves the Commonwealth's legitimate interests;
 - g. is otherwise required by law to be disclosed;
 - h. is disclosed by the Commonwealth to ensure the proper administration of the Pharmaceutical Benefits Scheme including the negotiation or administration of any existing or future risk sharing deed or the addition of New Drugs; or
 - i. is in the public domain otherwise than due to a breach of this clause.
- 5.2.2. If the Company intends to disclose the Confidential Information of the Commonwealth under clause 5.2.1.a to an Adviser, the Company must:

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- a. notify the receiving person that the information is Confidential Information; and
 - b. not provide the information unless the receiving person agrees to use the information only for the purpose for which it has been given to the receiving person.
- 5.2.3. Prior to the Company disclosing the Confidential Information of the Commonwealth under clause 5.2.1.g, the Company must advise the Commonwealth of:
- a. the person to whom the Confidential Information of the Commonwealth is to be disclosed; and
 - b. the information to be disclosed.

5.3. Survivorship

- 5.3.1. The obligations under this clause continue, notwithstanding the expiration or termination of this deed.

6. General

6.1. Company's acknowledgment

- 6.1.1. Without limiting the operation of clauses 1.4.1.b and 2.2, the Company acknowledges that:
 - a. nothing in this deed:
 - i. prevents the application of any Price Variation to any form of the Drug; or
 - ii. otherwise limits the application of the Act, or fetters the power of any person or body to effect a Price Variation for any form of the Drug; and
 - b. this deed continues without modification, notwithstanding any Price Variation.

6.2. Dispute resolution

- 6.2.1. If a dispute arises between the parties in respect of any matters under this deed (except clauses 4.1 and 4.2), the parties agree that, before taking any other action in respect of the dispute, the dispute will be dealt with in accordance with this clause.

Note - this clause 6.2 applies to disputes arising between the parties in respect of matters under this deed and not to disputes arising under the Act.

- 6.2.2. Either party may give written notice to the other party setting out the nature and details of the dispute.
- 6.2.3. A notice given under clause 6.2.2 is a "dispute notice".

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- 6.2.4. Senior representatives of the parties must seek, in good faith, to resolve the dispute by direct negotiation between them, within 20 Business Days after service of a dispute notice.
- 6.2.5. The parties must continue to perform all their obligations under this deed pending the resolution of any dispute.
- 6.2.6. Nothing in this clause prevents a party from seeking urgent interlocutory relief from a court.
- 6.2.7. This clause survives the expiration or termination of this deed.

6.3. Merger or sale

- 6.3.1. If the Company:
 - a. is subject to a merger, takeover, re-organisation or any other arrangement which results in it ceasing to supply the Drug in Australia; or
 - b. sells or otherwise disposes of its interest in the Drug to another company, it must:
 - c. notify the Commonwealth of that event prior to its occurrence; and
 - d. provide the Commonwealth with enough detail of the event to allow the Commonwealth to determine the action it requires.
- 6.3.2. If it receives notice under clause 6.3.1, the Commonwealth may, in its absolute discretion, notify the Company that the Company is to, and the Company must:
 - a. procure the novation of this deed to the relevant successor company; or
 - b. procure the relevant successor company to enter into a new deed with the Commonwealth on terms acceptable to the Commonwealth.
- 6.3.3. Unless the parties agree otherwise, upon the date specified in the novation or new deed as being the date on which the successor company's obligations will begin, the Company is released from its obligations under this deed.

7. Continued operation and termination

7.1. Continued operation of deed

- 7.1.1. During the period commencing 6 months prior to end of the Term (**the negotiation period**), the Commonwealth and the Company agree to negotiate in good faith the terms of a new deed for the sharing of costs in relation to the Subsidisation of supply of the Drug following the end of the Term.
- 7.1.2. If the Commonwealth and the Company are unable to agree the terms of a new deed during the negotiation period in accordance with clause 7.1.1, the deed will continue to operate on the same terms following the end of the Term (applying the Subsidisation Cap for [insert final Year]) until:

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- a. the Commonwealth and the Company enter into a new deed for the sharing of costs in relation to the Subsidisation of supply of the Drug; or
- b. the deed is terminated in accordance with clause 7.2.

7.2. Termination of the deed

7.2.1. This deed will terminate:

- a. immediately, if supply of the Drug ceases to be Subsidised; or
- b. at the time agreed, upon mutual written agreement of the parties.

7.2.2. Termination of this deed does not affect:

- a. the rights and obligations in clauses 3 and 4 in relation to the Year in which the deed is terminated; or
- b. any liability which accrues before the date of termination.

7.2.3. If this deed is terminated before the end of a Month or Year (including where this deed has continued to operate pursuant to clause 7.1.2), despite any other provision in this deed:

- a. the relevant Month will be the period from the end of the previous Month to the date that the deed is terminated; and
- b. the relevant Year will be the period from the end of the previous Year to the date that the deed is terminated and the Subsidisation Cap for that relevant Year will be reduced proportionate to the period of time that has elapsed in the relevant Year.

8. Notices

8.1. Format and delivery

8.1.1. A notice, request or other communication (**notice**) must be in writing and delivered by hand, sent by pre-paid post or transmitted electronically to the address set out in clause 8.2.

8.1.2. Subject to clause 8.1.3, a notice is deemed to be received:

- a. if delivered by hand – upon delivery to the relevant address;
- b. if sent by post – upon the expiration of 2 Business Days after the date on which it was sent; and
- c. if transmitted electronically – upon actual receipt by the addressee.

8.1.3. A notice received:

- a. after 5.00 pm (AEST or AEDT, as applicable) on a Business Day; or
- b. on a day that is not a Business Day,

is deemed to be received on the next Business Day.

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8.2. Address

8.2.1. A notice must be addressed:

a. if given by the Company to the Commonwealth, to:

The Assistant Secretary
Pricing and Policy Branch

By hand:

Sirius House
23 Furzer Street
PHILLIP ACT 2606

By mail:

MDP 900 GPO Box 9848
CANBERRA ACT 2601

or as otherwise notified by the Commonwealth; or

b. if given by the Commonwealth to the Company, to [any person who is a responsible person under the Act for the Drug]:

By hand:

[insert]

By mail:

[insert]

or as otherwise notified by the Company.

9. Counterparts

9.1. Counterparts

9.1.1. This deed may be executed in any number of counterparts. All counterparts, taken together, constitute one instrument. A party may execute this deed by signing any counterpart.

EXECUTED as a deed.

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This deed is made on the.....day of.....

SIGNED SEALED AND DELIVERED for
and on behalf of the **COMMONWEALTH
OF AUSTRALIA** by:

Name of signatory

Signature

In the presence of:

Name of witness

Signature of witness

SIGNED SEALED AND DELIVERED for
and on behalf of **[COMPANY]** by:

Authorised Signatory
Signatory's Name

Authorised Signatory
Signatory's Name

Print Name
Director

Print Name
Director

Position

Position

ATTACHMENT A - CONFIDENTIAL INFORMATION

A. The Commonwealth's Confidential Information

- A.1.1. Any amount reimbursed by the Company to the Commonwealth under clause 3 and the Subsidisation Caps.
- A.1.2. Any information about special pricing arrangements relating to New Drugs.

B. The Company's Confidential Information

- B.1.1. Any amount reimbursed by the Company to the Commonwealth under clause 3 and the Subsidisation Caps.
- B.1.2. The rebate formula contained in clause 3.1.

COMPANY NAME