



Australian Government

Strategic Agreement

Commonwealth of Australia
and

Generic Medicines Industry Association Pty Ltd

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Strategic Agreement

Dated 24th May 2015

Parties

Name	The Honourable Sussan Ley MP Minister For Health and Minister For Sport on behalf of the Commonwealth of Australia
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Short name	Commonwealth
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Name	Generic Medicines Industry Association Pty Ltd ACN 096 009 540
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Address	Level 3, 845 Pacific Highway, Chatswood in the State of New South Wales
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Short name	GMiA
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Background

- A. Generic medicines and biosimilars are an essential component of the Pharmaceutical Benefits Scheme.
- B. GMiA and the Commonwealth have a common interest in:
 - B.1 ongoing and reliable access for Australians to generic medicines and biosimilars;
 - B.2 a sustainable PBS that can meet the current and future needs of Australians; and
 - B.3 having a sustainable generic medicines sector.
- C. The Commonwealth recognises the contribution of the generic medicines sector in delivering the future sustainability of the PBS. The Commonwealth also recognises the significant level of savings consistently delivered from medicines in the F2 formulary through competition and the price disclosure mechanism.
- D. The PBS Access and Sustainability Package announced by the Australian Government in May 2015 (**Package**) seeks to establish pharmacy funding and medicines pricing arrangements and a range of sector improvements over five years. The Package is intended to support the National Medicines Policy and appropriately balance the need to:
 - D.1 ensure patients can continue to have access to PBS subsidised medicines that are necessary to maintain the health of the community;
 - D.2 promote and improve the quality use of medicines;
 - D.3 ensure a cost effective and sustainable PBS; and

- D.4 support the viability of the sectors that support the PBS, including the generics medicines sector.
- E. GMiA recognises that the reforms proposed as part of the Package, including as further described in this Agreement, are crucial for both PBS and generic medicines sector sustainability.

1. Definitions and interpretation

- 1.1 In this Agreement, unless the contrary intention appears:

Act means the *National Health Act 1953* (Cth).

Agreement means this Strategic Agreement.

Bill means the National Health Amendment (Pharmaceutical Benefits) Bill 2015.

Department means the Department of Health, and includes any successor department or agency of the Commonwealth having responsibility for the administration of Part VII of the Act.

Government Agency means any governmental, semi-governmental, administrative, fiscal, judicial or quasi-judicial body, department, commission, authority, tribunal, agency or entity.

Minister means the Minister who administers the Act.

Package has the meaning given in paragraph D of the Background.

PBAC means the Pharmaceutical Benefits Advisory Committee established under section 100A of the Act.

PBS means the Pharmaceutical Benefits Scheme established under Part VII of the Act.

Term means the term of this Agreement as set out in clause 2.

- 1.2 In this Agreement, unless the contrary intention appears:

1.2.1 a term (including a term that is not capitalised) that is given a particular meaning in Part VII of the Act, and is not defined otherwise in this Agreement, has the same meaning in this Agreement as it has in Part VII of the Act;

1.2.2 a reference to a statute, ordinance, code or other law includes regulations and other instruments under it and consolidations, amendments, re-enactments or replacements of any of them;

1.2.3 a reference to a section is a reference to a section of the Act;

1.2.4 a reference to a document (including this Agreement) includes any variation or replacement of it;

1.2.5 a reference to a clause, annexure or schedule is a reference to a clause in or annexure or schedule to this Agreement;

1.2.6 a reference to the singular includes the plural and vice versa;



- 1.2.7 a reference to a 'person' includes an individual, a firm, a body corporate, a partnership, a joint venture, an unincorporated body or association, or any Government Agency; and
- 1.2.8 the words 'includes' or 'including' are not terms of limitation.

2. Term

2.1 Term of Agreement

Subject to clause 2.2, this Agreement commences on the date of this Agreement and expires on 30 June 2020.

2.2 Conditions precedent to commencement of Agreement

- 2.2.1 Clauses 4, 5, 6 and 7 of this Agreement will not commence until the passage of the Bill through the Australian Parliament in a form that will enable the achievement of the maximum extent of the intended savings described clause 4, unless this condition is waived by the Commonwealth in its absolute discretion.
- 2.2.2 The Commonwealth and the GMiA agree to use their respective best endeavours to ensure that the condition in clause 2.2.1 is satisfied prior to 30 June 2015.
- 2.2.3 If the condition in clause 2.2.1 is not satisfied or waived by 30 June 2015, any subsequent satisfaction or waiver of those conditions will not result in an extension of this Agreement beyond 30 June 2020.

3. PBS Access and Sustainability Package

- 3.1 The Package is a comprehensive set of interlinked initiatives, comprising both savings and investments, designed to support ongoing consumer access to medicines and the financial sustainability of the PBS.
- 3.2 All participants in the PBS supply chain (including GMiA), as well as consumers, have roles to play under the Package.
- 3.3 Particular reforms within the Package include:
- 3.3.1 from 1 July 2015, an increase in the number of times a year that PBS medicine prices can change from three times to six times per year;
- 3.3.2 from 1 July 2015, the re-focussing of the Premium Free Dispensing Initiative to apply only where there is a brand premium;
- 3.3.3 from 1 July 2015 freezing of the indexation on CSO funding for a period of five years;
- 3.3.4 the substitution of biosimilar medicines at the pharmacy level based on clinical recommendations of the PBAC;
- 3.3.5 from 1 January 2016, ceasing Commonwealth subsidies for selected over-the-counter medicines by removing (delisting) them from the PBS, as recommended by the the PBAC;

- 3.3.6 from 1 January 2016, expanding the PBS early supply provision, 'Safety Net 20 Day rule', so that it applies to all PBS medicines where it is considered appropriate for the patient population, as recommended by the PBAC;
 - 3.3.7 from 1 April 2016, applying the component drug price disclosure arrangements under the Act to F2 combination medicines;
 - 3.3.8 from 1 April 2016, applying a one-off statutory price reduction of 5 per cent to all brands of pharmaceutical items on the F1 formulary after they have been listed on the PBS for at least five years;
 - 3.3.9 from 1 October 2015, removing the originator brand from the calculation of the weighted average disclosed price of medicines under the price disclosure arrangements in the Act for those medicines that have been listed on the F2 formulary for three years or more;
 - 3.3.10 from 1 July 2016, transferring the distribution of National Diabetes Services Scheme products from Diabetes Australia to pharmaceutical wholesalers through the existing CSO arrangements; and
 - 3.3.11 from 1 January 2016, permitting approved pharmacists to (but not obliging them to) discount the PBS patient co-payment by a maximum of \$1 per script.
- 3.4 The Package measures described in clause 3.3 are expected to represent savings to the Budget of approximately \$6.6 billion over the five years of this Agreement. Net of re-investment in various parts of the pharmacy and pharmaceuticals sectors, this represents savings of \$3.7 billion over the five years.
- 3.5 The measures in:
- 3.5.1 clauses 3.3.6, 3.3.7, 3.3.8, 3.3.9 and 3.3.11 are contingent upon the passage of the Bill through the Australian Parliament; and
 - 3.5.2 clauses 3.3.3 and 3.3.10 require the agreement and cooperation of other participants in the pharmacy supply chain.

4. Modification of price disclosure arrangements under the Act

- 4.1 Price disclosure arrangements for medicines which have been listed under the F2 formulary for three years or more will be accelerated through the removal of the originator brand as part of the calculation of the weighted average disclosed price (**WADP**) for medicines under the *National Health (Pharmaceutical Benefits) Regulations 1960*.
- 4.2 The originator brand will remain available on the PBS, but will only be subsidised up to the lower of either a new generic weighted average disclosed price, or the WADP.
- 4.3 These new arrangements will commence on 1 October 2015 with the first price disclosure reduction under the new policy not to occur before 1 October 2016. Removing the originator brand from the WADP calculation, which applies after the third year a medicine has been in price disclosure, will allow generic brands time to establish a market.
- 4.4 In implementing this measure, safeguards will be developed to protect certain potentially vulnerable markets.



5. Price policy changes for F2 formulary medicines

The Commonwealth undertakes not to pursue any further policy to generate price-related savings from the F2 formulary during the Term without consultation with the GMiA.

6. Biosimilar medicines

- 6.1 The PBAC has advised that its default position will be to recommend the 'a' flagging of all biosimilar medicines where clinical evidence does not provide a contrary view. It is anticipated that this will materially support take-up of biosimilar medicines through the PBS.
- 6.2 Should the PBAC consider that evidence for a biosimilar medicine does support a contrary view, the PBAC may not recommend 'a' flagging for selected biosimilar medicines.
- 6.3 In the event that the PBAC's default position does not result in the standard practice of 'a' flagging biosimilar medicines, other initiatives may be required to encourage uptake. Both parties commit to work together to identify and, with the approval of the Commonwealth, implement such initiatives.
- 6.4 It is recognised that some initiatives may require approval and no commitments can be made regarding approval by the Australian Government or the Australian Parliament.
- 6.5 Within a reasonable period after the commencement of this Agreement, the Commonwealth will launch a national campaign costing up to \$20 million over 3 years to increase the awareness, understanding and uptake of biosimilar medicines. The GMiA will work with the Commonwealth in the design and deployment of that campaign. Specific areas of engagement may include:
 - 6.5.1 campaign design;
 - 6.5.2 campaign development with input on themes, facts or detailed drafting;
 - 6.5.3 review of final campaign details; and
 - 6.5.4 campaign deployment and delivery.

7. Fair and equal market access for generic medicines

- 7.1 Part of the Package is an initiative to remove legislative restrictions around the patient contribution amounts for PBS medicines, to give community pharmacists the option to discount PBS patient co-payments by up to \$1. The Commonwealth anticipates this will support increased generic medicine uptake, based on discounting practices.
- 7.2 Part of the Package is an initiative to increase the number of dates on which the price of a PBS medicine can change from the current three dates per year, to six per year, on 1 February, 1 April, 1 June, 1 August, 1 October and 1 December. This will mean that some, first to market, generic brands of medicines will be able to list earlier than would be possible under the current arrangement.
- 7.3 Part of the Sixth Community Pharmacy Agreement (**6CPA**) is a reform to modify the application of the Premium Free Dispensing Initiative (**PFDI**) to better target its application to premium-free medicines. The Commonwealth anticipates this will support increased generic medicine uptake. Specifically, the Commonwealth intends the 6CPA to require the PFDI to be paid where the Commonwealth is satisfied that an eligible approved supplier has

dispensed a pack quantity of a listed brand of a pharmaceutical item (**Dispensed Medicine**) in all the following circumstances:

- 7.3.1 the Dispensed Medicine is Schedule equivalent to one or more other listed brands;
- 7.3.2 one or more pack quantities of the listed brands that are Schedule equivalent to the Dispensed Medicine has a special patient contribution;
- 7.3.3 the pack quantity of the Dispensed Medicine does not have a special patient contribution; and
- 7.3.4 before the addition of the PDFI, the Commonwealth price of the pack quantity of the Dispensed Medicine already exceeds the maximum PBS co-payment for the patient.

8. Sustainability of the generics medicines sector

- 8.1 Both parties will work together to identify and implement initiatives to support the ongoing sustainability of the generic medicines sector. This will be undertaken as part of a "sustainability initiative" between the Commonwealth and GMiA.
- 8.2 A working group will be established, comprising members of the Commonwealth and GMiA, and others as determined appropriate by agreement, to define and implement the sustainability initiative.
- 8.3 The working group will be chaired by a senior representative of the Commonwealth.
- 8.4 Upon its first meeting, to be scheduled after the commencement of this Agreement, the working group will establish terms of reference for agreement by the Minister, to guide its activities and focus. This first meeting will take place within three months after the commencement of this Agreement.
- 8.5 The working group may consider, as part of its activities, initiatives to further support uptake of the use of generic medicines through the PBS.
- 8.6 While parts of this initiative may require approval of the Australian Government, both parties will work together under this Agreement to proactively implement approved activities.
- 8.7 The GMiA acknowledges that any considerations and outcomes of the working group must be considered in the context of competing priorities of the Commonwealth at any point in time. This may impact decisions on how or when to implement certain agreed initiatives.
- 8.8 One role of the working group will be to monitor trends in, and drivers of, changes in the health and sustainability of the generic medicines sector including unsustainable pricing, medicines shortages, industry consolidation, and medicine de-listings. In response to these, both parties will take steps to investigate and identify solutions for any causative underlying policy issues, where and on a basis that both parties agree it is appropriate or necessary to do so.
- 8.9 The working group will also monitor any unintended consequences arising from the implementation of the savings measure outlined in clause 3.
- 8.10 Both parties will work with any other representative groups (as required) in a timely manner to implement any future changes to ensure sustainability of the generic medicines sector.

9. General matters

9.1 Issue resolution

Any issue arising from the operation of the Agreement will be resolved as follows:

- 9.1.1 the party with the issue will send to the other party a notice setting out the nature of the issue;
- 9.1.2 the Commonwealth representative specified in clause 9.4.1(a) and the GMiA representative specified in clause 9.4.1(b) will then try to resolve the issue by direct negotiation; and
- 9.1.3 if the issue is not so resolved by direct negotiation under clause 9.1.2 within 20 Business Days from the date the notice referred to in clause 9.1.1 is given, either party may refer the matter for direct negotiation between the Minister and the Chairperson of GMiA.

9.2 Variation

A provision of this Agreement may only be varied in writing, signed by GMiA and the Minister, or a delegate of the Minister.

9.3 Status of this document

Both parties acknowledge their common intention to meet their commitments under this Strategic Agreement. However nothing in this Strategic Agreement places a financial obligation on the Commonwealth or gives rise to an obligation on the Commonwealth to pay compensation during the Term or thereafter.

9.4 Notices

- 9.4.1 A notice under this Agreement is only effective if it is in writing, and dealt with as follows:

- (a) if given by GMiA to the Commonwealth - addressed to:

First Assistant Secretary
Pharmaceutical Benefits Division

MDP 61
GPO Box 9848
CANBERRA ACT 2601

or as otherwise notified by the Commonwealth; or

- (b) if given by the Commonwealth to GMiA - addressed to:

Chief Executive Officer
Generic Medicines Industry Association Pty Ltd

By mail to: PO Box 87, Deakin West ACT 2600

By hand to: Level 3, 845 Pacific Highway
Chatswood NSW 2067

or as otherwise notified by the GMiA.



- 9.4.2 A notice is to be:
- (a) signed by the person giving the notice and delivered by hand; or signed by the person giving the notice and sent by pre-paid post; or
 - (b) transmitted electronically by the person giving the notice by electronic mail or facsimile transmission.
- 9.4.3 Communications take effect from the time they are received or taken to be received under clause 9.4.4 (whichever happens first) unless a later time is specified.
- 9.4.4 Communications are taken to be received:
- (a) if sent by post, three days after posting (or seven days after posting if sent from one country to another); or
 - (b) if sent by fax, at the time shown in the transmission report as the time that the whole fax was sent; or
 - (c) if sent by email;
 - (i) when the sender receives an automated message confirming delivery; or
 - (ii) four hours after the time sent (as recorded on the device from which the sender sent the email) unless the sender receives an automated message that the email has not been delivered, whichever happens first.
- 9.4.5 A notice received, or taken to be received under clause 9.4.4 after 5.00 pm, or on a day that is not a Business Day in the place of receipt, is deemed to be effected on the next Business Day.



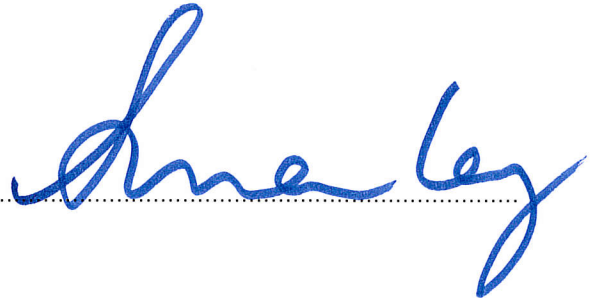
Signing Page

Dated 24th May 2015

**Signed by The Honourable Sussan Ley MP,
Minister For Health and Minister for Sport
on behalf of the Commonwealth of Australia**

in the presence of:

Witness

A blue ink signature of Sussan Ley, written in a cursive style, positioned above a horizontal dotted line.

**Signed for and on behalf of the Generic
Medicines Industry Association Pty Ltd by
its Chairman, Mark Crotty**

in the presence of:

Witness

A blue ink signature of Mark Crotty, written in a cursive style, positioned above a horizontal dotted line.