Australian Government

Department of Health

Strategic Agreement

Commonwealth of Australia
and

Generic Medicines Industry Association Pty Ltd
trading as Generic and Biosimilar Medicines Association

Contents

Strategic Agreement

Parties

Name	**The Honourable Greg Hunt MP, Minister for Health and Aged Care** on behalf of the **Commonwealth of Australia**
Short name	**Commonwealth**

Name	**Generic Medicines Industry Association Pty Ltd** ACN 096 009 540 trading as **Generic and Biosimilar Medicines Association**
Short name	**GBMA**

Recitals

A. This Agreement reflects the common intention of the Commonwealth and GBMA that Australians have access to the right medicines when they need them. The parties agree that this access is underpinned by secure medicines supply delivered at an efficient cost to the Australian taxpayer. The generic and biosimilar medicines industry is key to the achievement of these objectives as integral suppliers of life saving and life changing medicines in Australia subsidised through the Pharmaceutical Benefits Scheme (**PBS**).

B. The package of reforms in this Agreement has been designed closely with industry, recognising that medicines are essential to life for many Australians and that the community rightly expects to be able to access medicines when they are needed. These reforms comprise a balanced package of incentives designed to support the medicines industry to manage supply chain risks to meet Australians' expectations, while ensuring PBS subsidy represents value for money for the Australian taxpayer. The reforms are intended to direct Commonwealth investment through the PBS towards medicines supply chains to reduce the impact of global medicine shortages on Australian patients.

C. This Agreement is underpinned by the shared principles of:

C.1 stewardship of the health system, particularly the PBS, and a shared responsibility for its ongoing sustainability;

C.2 stability and certainty for a strong generic and biosimilar medicines sector and reliable supply of medicines to Australians that advance health outcomes for patients, including recognition of the role that a predictable and stable PBS plays in encouraging new generic and biosimilar medicines;

C.3 partnership in the delivery of the National Medicines Policy;

C.4 transparency, predictability, and efficiency of processes for listing medicines on the PBS;

C.5 integrity of Australia's world class health system, including patient safety and high value clinical care; and

C.6 acknowledgement of the value of the generic and biosimilar pharmaceutical industry and the medicines sector in ensuring a healthy Australia for a vibrant economic recovery.

D. The package of investment and incentives in this Agreement seeks to create the right conditions for the medicines industry in Australia to thrive, and includes measures to reduce barriers to market entry for new competitors and incentivise companies to maintain broad portfolios of medicines in Australia. This will support choice for Australian prescribers and patients.

E. This Agreement also contains measures identified by the parties that will improve the efficiency of the PBS, and ensure that the Australian taxpayer pays fair market prices for medicines throughout the patent and post-patent lifecycle.

1. Definitions

1.1 In this Agreement, unless the contrary intention appears:

12.5% Price Reduction means a 12.5% price reduction referred to in, or previously applied under, Division 3A of Part VII of the Act.

14.5% Price Reduction means a price reduction of the kind described in Item 6 of the table in subsection 99ACF(1) of the Act (as at 30 June 2022).

16% Price Reduction means a 16% price reduction referred to in, or previously applied under, Division 3A of Part VII of the Act.

25% Price Reduction means a 25% price reduction referred to in, or previously applied under, Division 3A of Part VII of the Act.

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

Agreement means this 2021 Strategic Agreement between the Commonwealth and GBMA.

Approved Ex-Manufacturer Price or **AEMP** has the meaning given to the term 'approved ex-manufacturer price' in subsection 84(1) of the Act.

Bill means the bill or bills that will bring about the legislative changes required to implement the legislated measures described in this Agreement.

Biosimilar Brand means a Listed Brand that is a biosimilar version of a reference biologic.[1]

Business Day means a day other than a Saturday, Sunday or public holiday in the Australian Capital Territory.

Combination Item has the meaning given to the term 'combination item' in subsection 84(1) of the Act.

Control has the meaning given to the term 'control' in section 50AA of the *Corporations Act 2001* (Cth).

Data Collection Period has the meaning given to the term 'data collection period' in section 99ADBA of the Act.

Department means:

(a) the Department of Health; or

(b) any successor department or agency of the Commonwealth having responsibility for the administration of Part VII of the Act.

Drug is on F1 has the meaning given to the term 'drug is on F1' in section 84AC of the Act.

Drug is on F2 has the meaning given to the term 'drug is on F2' in section 84AC of the Act.

[1] There may be more than one Biosimilar Brand with respect to the same reference biologic.

Effective Price[2] means, in respect of a Listed Brand that is subject to a deed entered into under section 85E of the Act (**Deed**), the payment made by the Commonwealth in respect of the supply of that Listed Brand less any:

(a) rebates or reimbursement payable to the Commonwealth under the Deed; and

(b) fees and mark ups,

for that Listed Brand.

First New Brand means the new brand described in sections 99ACB and 99ACD of the Act.

Floor Price has the meaning given in clause 3.5.

Joint Oversight Committee means the committee described in clause 5.

Listed Brand has the meaning given to the term 'listed brand' in subsection 84(1) of the Act.

Listed Drug has the meaning given to the term 'listed drug' in subsection 84(1) of the Act.

Minister means the Minister who administers the Act.

Multi-branded Drug means a drug or medicinal preparation with more than one Listed Brand for which the Responsible Person is not the same as, or is not a Related Body Corporate of, the Responsible Person for another Listed Brand of a Pharmaceutical Item that includes that drug or medicinal preparation.

Originator Brand has the meaning given to the term 'originator brand' in section 99ADB of the Act.

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

Pharmaceutical Benefit has the meaning given to the term 'pharmaceutical benefit' in subsection 84(1) of the Act.

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

Pharmaceutical Item has the meaning given to the term 'pharmaceutical item' in subsection 84(1) of the Act.

Poisons Standard means the instrument made under paragraph 52D(2)(b) of the *Therapeutic Goods Act 1989* (Cth).

Price Disclosure means the price disclosure arrangements in Division 3B of Part VII of the Act, and any related arrangements in the Regulations.

Price Disclosure Cycle means a Data Collection Period plus its associated calculation period resulting in the Minister making a determination of a Weighted Average Disclosed Price under subsection 99ADB(4) of the Act.

[2] For the purposes of this Agreement, a Listed Brand will not have an Effective Price where it is not the subject of a deed entered into under section 85E of the Act.

Price Reduction means a reduction (including Statutory Price Reductions or price reductions that occur administratively):

(a) where the Listed Brand has an Effective Price at the relevant time, to the Effective Price of the Listed Brand; or

(b) where the Listed Brand does not have an Effective Price at the relevant time, to the Approved Ex-Manufacturer Price of the Listed Brand.

Reference Pricing Policy means the policy that links the prices of drugs in the F1 formulary, or on the single brand combination drug list, that the PBAC advises to be of similar safety and efficacy.

Regulations means the *National Health (Pharmaceutical Benefits) Regulations 2017* (Cth).

Related Bodies Corporate has the meaning given to the term 'related bodies corporate' in section 50 of the *Corporations Act 2001* (Cth) and **Related Body Corporate** has a corresponding meaning.

Responsible Person has the meaning given to the term 'responsible person' in subsection 84(1) of the Act.

Single Branded Drug means a drug or medicinal preparation that is not a Multi-branded Drug.

Statutory Price Reduction or **SPR** means a price reduction applying to a Listed Brand of a Pharmaceutical Item under Division 3A of Part VII of the Act.

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

Weighted Average Disclosed Price or **WADP** has the meaning given to the term 'weighted average disclosed price' in subsection 99ADB(1) of the Act.

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

2. Term

2.1 Term of Agreement

This Agreement commences on the date of this Agreement and, subject to clause 2.2, will expire on 30 June 2027.

2.2 Condition precedent to commencement of Agreement

2.2.1 The measures described in this Agreement that require amendments to the Act or other legislation will not commence until the passage of the Bill through the Australian Parliament in the form required to implement them in full, unless this condition is waived (in whole or in part) by the Commonwealth following consultation with GBMA.

2.2.2 The Commonwealth and GBMA agree to use their respective best endeavours to ensure the passage of the Bill through the Australian Parliament.

2.2.3 If, at any time, the parties consider that the Bill is unlikely to pass the Australian Parliament in the form required to satisfy the condition in clause 2.2.1, the parties will consult with each other in relation to alternative arrangements aimed at achieving the outcomes intended by the measures that have not commenced.

2.2.4 If the condition in clause 2.2.1 is not satisfied or waived by the Commonwealth in whole or in part, this Agreement ceases except where the parties agree otherwise in writing.

2.2.5 If the condition in clause 2.2.1 is waived in whole or in part, any subsequent satisfaction of the condition does not operate to extend the Term, unless the parties agree otherwise in writing.

2.3 End of last Agreement

The Strategic Agreement between the parties dated 24 May 2015 (as extended) will end on the date of this Agreement.

3. Measures to support patient access and sustainability

3.1 Overview of implementation of measures

3.1.1 Where necessary, the Commonwealth will seek amendments to the Act and the Regulations to implement the measures described in this clause 3 from 1 July 2022.

3.1.2 The security of supply measures described in this clause 3 reflect the parties' intention to improve the operation of the PBS for the purposes of achieving reliable supply of medicines for Australian patients. It is intended that, on balance, the cost of these proposed measures[3] will be no more than what would have been the cost of continuing the existing 30% Price Disclosure threshold from 1 July 2022, when it would have otherwise ceased.

3.2 Price competition

3.2.1 The Commonwealth is aware that:

(a) certain Single Branded Drugs that should be treated as interchangeable (as specified by the PBAC) with other drugs that are, or have become, Multi-branded Drugs may be sold at discounted prices below their AEMP, or with incentives, in competition with those Multi-branded Drugs; and

[3] Excluding any measures or arrangements of the kind described in clauses 3.7, 3.8 and 3.9.

(b) any discounting below the AEMP or provision of incentives where Single Branded Drugs should be treated as interchangeable (as specified by the PBAC) with Multi-branded Drugs jeopardises supply of those Multi-branded Drugs.

3.2.2 Recognising the risk described in clause 3.2.1, GBMA acknowledges and agrees that the Commonwealth will seek to negotiate an outcome with the Responsible Person for the Single Branded Drug to address that risk.

3.2.3 To support the security of supply measures outlined in this Agreement and greater visibility of stockholdings and market practices in Australia, the parties agree that the Commonwealth will seek amendments to the Act and Regulations from 1 July 2022 so that, for Multi-branded Drugs, information with respect to supplies to public hospitals will be taken into account for the purposes of calculating the WADP after the 7th Price Disclosure Cycle of the Multi-branded Drug.[4]

3.3 Early removal of Originator Brand

3.3.1 The parties agree that the Commonwealth will seek amendments to the Act and Regulations from 1 July 2022 so that where there has been no price reduction under Division 3B of Part VII of the Act during (or with respect to) the first three Price Disclosure Cycles for a Listed Drug with a particular manner of administration (**Relevant Drug**), the removal of Originator Brand information from the WADP calculation for the Relevant Drug will be brought forward to the 4th Price Disclosure Cycle of that Relevant Drug.

3.3.2 For clarity:

(a) following the changes provided for in clause 3.3.1, information provided about the Originator Brand will not be taken into account after 18 months (instead of after 30 months, as currently provided for in the Regulations); and

(b) nothing in this clause 3.3 is intended to remove or limit the existing arrangements for removal of the Originator Brand information from the WADP calculation for the Relevant Drug after 30 months where there has been a price reduction for the Relevant Drug under Division 3B of Part VII of the Act during (or with respect to) the first three Price Disclosure Cycles for the Relevant Drug.

3.4 Security of supply

3.4.1 Recognising the significant impact on patients where multi-branded medicines are unavailable, GBMA acknowledges and agrees that the Commonwealth will implement arrangements (including, where necessary, by amending the Act[5] and Regulations) under which:

(a) a modified version of the 30% Price Disclosure threshold as set out in clause 3.5 is continued from 1 July 2022;[6]

(b) a Floor Price is established for certain F2 medicines listed on the PBS on the basis set out in clause 3.5; and

(c) Responsible Persons for medicines with a Floor Price are required to hold a minimum level of stock of those medicines in Australia (as set out in clause 3.6) and provide details of stock holdings of those medicines (including the level of such stockholdings) when providing information for Price Disclosure for each month of the Data Collection Period.

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[4] That is, at the 8th Price Disclosure Cycle and onwards.
[5] If necessary, amendments may also be sought to the *National Health Amendment (Pharmaceutical Benefits—Budget and Other Measures) Act 2018* (Cth).
[6] Provided for under section 99ADH of the Act and due to cease on 30 June 2022.

3.4.2 The measures in clauses 3.5.3 to 3.5.6 (inclusive) and in clause 3.6 are not intended to apply to PBS medicines that are listed in Schedule 2 of the Poisons Standard.

3.5 Floor Price and 30% Price Disclosure threshold

3.5.1 GBMA acknowledges and agrees that the Commonwealth will seek amendments to the Act and Regulations to continue a modified version of the 30% Price Disclosure threshold on the following basis:

(a) the 30% Price Disclosure threshold will be reached after the later of:

(i) 7 Price Disclosure Cycles after the Drug is on F2; and

(ii) 5 Price Disclosure Cycles after the first Price Disclosure reduction;

(b) a minimum AEMP (**Floor Price**) would be set at:

(i) for Listed Brands with an AEMP on 1 August 2022 of $4 or less, the AEMP:

A) on 1 August 2022; or

B) after any subsequent price increase; or

(ii) for Listed Brands with an AEMP on 1 August 2022 of more than $4 for which the 30% Price Disclosure threshold has commenced, the AEMP of the Listed Brand once the 30% Price Disclosure threshold for that Listed Brand commenced.

3.5.2 It is intended that Listed Brands with a Floor Price:

(a) of $4 or less, will not be subject to Price Disclosure reductions; and

(b) of more than $4, will not be subject to Price Disclosure reductions unless there is discounting equal to or greater than:

(i) 30% in any Price Disclosure Cycle; or

(ii) 12.5%, on average, over 3 successive Price Disclosure Cycles without Price Disclosure reduction.

3.5.3 From the commencement of the Floor Prices (on or about 1 October 2022), it is also intended that for Price Disclosure purposes, any discounts and incentives for any Listed Brand of a Responsible Person (**Relevant Responsible Person**) with an AEMP of $4 or less will be apportioned instead to the AEMPs of any Listed Brands of the Relevant Responsible Person with an AEMP of more than $4. If the Relevant Responsible Person does not have any Listed Brands with an AEMP of more than $4, the Commonwealth may instead apportion the incentives or discounts (or both) to the Listed Brands with an AEMP of more than $4 of any Responsible Person that is a Related Body Corporate of the Relevant Responsible Person, or where that is not possible, such incentives or discounts (or both) may be apportioned to the Listed Brands with an AEMP of more than $4 of any Responsible Person who is under the same Control as the Relevant Responsible Person (if any).

3.5.4 It is intended that on 1 October 2022, Listed Brands that have an AEMP:

(a) below $2 as at that day will have their AEMP increased to $2.50; or

(b) between $2 and $3.50 as at that day will have their AEMPs increased by $0.50 up to a maximum AEMP of $3.50.

3.5.5 The Minister may from time to time agree to increase the price of a Listed Brand that is not covered by clause 3.5.4, and those Listed Brands will be subject to the 6 month stockholding requirement in clause 3.6 unless otherwise determined by the Minister.

3.5.6 Where AEMPs are increased under the measures set out in this clause 3.5 for Listed Brands that have a special patient contribution, the Commonwealth will seek amendments to the Act such that claimed prices for those Listed Brands will not be increased as a result of the once off measure described in clause 3.5.4, with the result that the special patient contribution for such Listed Brands will reduce accordingly. This may also be considered by the Minister if there are subsequent price increases of the kind contemplated in clause 3.5.5.

3.6 Stockholding requirement

3.6.1 By 1 July 2023, Responsible Persons for Listed Brands that have a Floor Price, will be required to hold a default minimum amount of stock of that Listed Brand in Australia, calculated by reference to the usual demand for the Listed Brand, as follows:

(a) where the Listed Brand has a drug and manner of administration that satisfies the requirements for the 30% Price Disclosure threshold, 4 months stockholding; or

(b) where the Listed Brand has received a price increase of the kind described in clause 3.5, 6 months stockholding,

unless a different amount is determined by the Minister for the relevant Pharmaceutical Item (following consultation with the impacted Responsible Persons) by reference to usual demand for the brands of that Pharmaceutical Item over a time period.

3.6.2 It is intended that the additional investment provided by the Commonwealth for Listed Brands with an AEMP of $4 or less to manage supply chain risk (as set out in this clause 3) will be used as such, and not be passed on by Responsible Persons as discounts and incentives. Accordingly, from 1 October 2022, any discounts and incentives provided for Listed Brands with an AEMP of $4 or less, as observed through Price Disclosure requirements, will become relevant to the exercise of the Minister's powers to list, or revoke PBS listings, for Responsible Persons who offer such discounts or incentives (or both) on the basis set out in clauses 3.6.6 and 3.6.7.

3.6.3 The parties will work together (including through the Joint Oversight Committee) to ensure the intended operation of clauses 3.6.2, 3.6.6 and 3.6.7 is communicated to the sector.

3.6.4 The Commonwealth will consult the medicines industry prior to 1 July 2023, and thereafter as considered necessary by the Commonwealth, regarding alternative appropriate stockholding amounts that may be suitable should the Minister wish to make a determination of the kind described in clause 3.6.1.

3.6.5 Medicines that are intended for the Australia market will be counted for the purposes of the stockholding requirement described in clause 3.6.1 when:

(a) the Responsible Person holds title to the stock; and

(b) where the stock is manufactured outside of Australia, the stock is in Australia.

3.6.6 The parties agree that the Commonwealth will seek amendments to the Act to make Listed Brands with a Floor Price subject to the following requirements:

(a) a requirement that the Responsible Person for a Listed Brand with a Floor Price to:

(i) notify the Minister if:

A) stock levels of that Listed Brand have fallen below the applicable stockholding requirement; or

B) it believes stock levels may fall below the applicable stockholding requirement; and

(ii) provide written reasons for the stock levels falling below the applicable stockholding requirement; and

(b) extension of existing consequences of failing to supply under Division 3C of Part VII of the Act to Listed Brands with a Floor Price where the applicable stockholding requirement is not met and to Listed Brands with an AEMP of $4 or less where the Responsible Person for that Listed Brand is offering discounts or incentives (or both) below its AEMP in respect of that Listed Brand. That is, in circumstances where Responsible Persons do not comply with applicable stockholding requirements or offer discounts or incentives (or both) below the AEMP, the Minister would have the same powers as exist under section 99AEH of the Act for when a Responsible Person fails to supply, including to:

(i) revoke the listing for the brand subject to the requirement;

(ii) revoke the listing for any brand supplied by the Responsible Person; and

(iii) refuse any request to list a brand made by the Responsible Person.

3.6.7 Amendments to the Act sought (as described in this clause 3.6) will include that where the powers referred to in clause 3.6.6(b) are exercised, the Minister is to take into account whether:

(a) a Responsible Person is consistently holding fewer stocks of Listed Brands than the required level;

(b) the Responsible Person is offering discounts or incentives (or both) in respect of such Listed Brands;

(c) other Responsible Persons for other Listed Brands of the same Pharmaceutical Item are maintaining required levels;

(d) the reasons provided by the Responsible Person satisfy the Minister that required stock levels will be consistently maintained in the future; and

(e) any other matters relevant to maintaining supply of PBS medicines that the Minister considers relevant.

3.7 Uptake of biosimilar medicines

Recognising that greater use of biosimilar medicines will be beneficial in supporting access to clinically and cost effective medicines for Australians, the Commonwealth and GBMA will consult regularly during the Term regarding further uptake drivers that may be implemented by the Commonwealth to increase the dispensing of Biosimilar Brands as more are included on the PBS.

3.8 Repurposing of medicines

GBMA acknowledges that the Department is conducting a public consultation that seeks to understand potential obstacles and incentives to the repurposing of prescription medicines. GBMA will, in good faith, work with the Commonwealth to advance, in a timely manner, potential regulatory and reimbursement policy options to advance the availability of treatments in Australia.

3.9 PBS listing of medicines approved under section 19A of *Therapeutic Goods Act 1989*

The Commonwealth and GBMA recognise:

3.9.1 the impacts on patients arising from medicines shortages; and

3.9.2 that when a shortage issue results in a PBS listed medicine being unavailable in Australia, sponsors of non-PBS listed brands may apply to temporarily list their brand on the PBS, if the brand has been approved under section 19A of the *Therapeutic Goods Act 1989* (Cth) (**TG Act**),

and agree to work with other relevant stakeholders (including the PBAC) during the Term in the establishment of a streamlined process for listing medicines on the PBS that have been approved under section 19A of the TG Act on the basis that, where the Minister determines that a medicine approved under section 19A of the TG Act will be listed on the PBS, the Minister may end such listing at or about the time the approval under section 19A of the TG Act ends.

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4. Statutory Price Reductions

4.1 Outline

4.1.1 As at the date of this Agreement, Division 3A of Part VII of the Act provides for Statutory Price Reductions.

4.1.2 The parties agree that the Commonwealth will seek amendments to the Act[7] to commence from 1 July 2022 to:

(a) continue or modify (or both) Statutory Price Reductions on the basis set out in clauses 4.2, 4.3 and 4.4.1;

(b) reflect the arrangements set out in clauses 4.5 and 4.6; and

(c) make consequential changes to Divisions 3A and 3B of Part VII of the Act to implement the modified Statutory Price Reductions and other arrangements described in this clause 4.

4.2 Amendments to Statutory Price Reductions

4.2.1 The percentage reductions for the Statutory Price Reductions in Table 1 that applied prior to this Agreement will be modified as per the new percentage under this Agreement set out in Table 1 and will apply on the corresponding reduction days specified in Table 1 during the Term.

4.2.2 The Statutory Price Reduction mechanisms described in this clause will apply until the end of the Term.

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[7] If necessary, amendments may also be sought to the *National Health Amendment (Pharmaceutical Benefits—Budget and Other Measures) Act 2018* (Cth).

Table 1: Amendments to SPRs

Section	Description	Percentage prior to this Agreement[8]	New percentage under this Agreement	Reduction day(s)
99ACHA	One off price reduction on 5th anniversary of the drug being a Listed Drug	5%	5%	1 April 2023 1 April 2024 1 April 2025 1 April 2026 1 April 2027
99ACJ	One off price reduction on tenth anniversary of drug being a Listed Drug	10%	5%	1 April 2023 1 April 2024 1 April 2025 1 April 2026 1 April 2027
99ACK	One off price reduction on 15th anniverary of drug being a Listed Drug (if before any first new brand price reduction)	5%	26.1%	1 April 2023 1 April 2024 1 April 2025 1 April 2026
			30%	1 April 2027
99ACB 99ACD 99ACE 99ACF 99ACH	First new brand price reduction (if before 15th anniversary of drug being a Listed Drug)	25% up to a maximum of 40% off the earliest of 1 January 2016 or date of listing AEMP until 30 June 2022. 16% thereafter	25% up to a maximum of 60% off the earliest of 1 January 2016 or date of listing AEMP[9]	The listing of the first new brand

4.3 Catch-up reductions

4.3.1 On 1 April 2023, a catch-up reduction of 5% will apply to Listed Brands that have a Listed Drug that has met its 10th anniversary of listing on the PBS between 1 May 2021 and 1 April 2022.

4.3.2 On 1 April 2023, a catch-up reduction will apply to all Listed Brands that have a Listed Drug that has been listed for 15 years or more, and have not taken a Price Disclosure reduction (under Division 3B of the Act), such that the sum of Statutory Price Reductions (including catch-ups) the Listed Brand has been subject to after these catch-up reductions, applied successively, will total 36.82%.[10] Examples of the catch-up percentages are set out in the Table at Appendix 1.

4.3.3 Listed Brands with a Listed Drug that move to the F2 formulary after 1 August 2022, and prior to the 15th anniversary of that Listed Drug being listed, will be subject to a 1.48% reduction on the 15th anniversary of that Listed Drug being listed if no Price Disclosure reduction has applied.

[8] Nothing in this Agreement modifies any Statutory Price Reduction already provided for in the Act, unless and until the Act is amended to do so.

[9] This will not limit application of the Commonwealth policy whereby the Commonwealth will seek a price from the responsible person for the first new brand that is not more than the Effective Price of the originator brand on 1 January 2016 or later date of listing reduced by 25%, subject to the 60% cap on Statutory Price Reductions specified in clause 4.4.

[10] For clarity, where a Listed Brand has already had a price reduction exceeding 36.82%, the price of such Listed Brands will not be increased under these catch-ups.

4.4 Cap on Statutory Price Reductions

4.4.1 Without limiting clauses 4.4.2 or 4.5.2 or the Minister's discretion under the Act, the Commonwealth will seek to amend the Act to provide that Statutory Price Reductions will not take Approved Ex-Manufacturer Price(s) for Listed Brands of Pharmaceutical Items below 40% of their Approved Ex-Manufacturer Price(s) on 1 January 2016 or later date of listing on the PBS.

4.4.2 Without limiting clause 4.5.2 or the Minister's discretion under the Act, the Commonwealth will continue its existing policy[11] for agreeing prices of the First New Brand where the originator brand of a Pharmaceutical Item (**Existing Brand**) has or had an Effective Price, subject to the new 60% cap. To list a First New Brand in this circumstance:

(a) the Responsible Person for the First New Brand will be expected to offer an Approved Ex-Manufacturer Price for the First New Brand that is not more than a price that is 25% lower than the Effective Price for the Existing Brand;

(b) where the Approved Ex-Manufacturer Price of the First New Brand that is 25% lower than the Effective Price of the Existing Brand would be below 40 per cent of the Effective Price of the Existing Brand on 1 January 2016 or later date of listing on the PBS, the Responsible Person for the First New Brand will be expected to offer an Approved Ex-Manufacturer Price for the First New Brand that is not more than 40% of the Effective Price of the Existing Brand on 1 January 2016 or later date of listing on the PBS; or

(c) where the Effective Price of the Existing Brand is already below 40% of the Effective Price on 1 January 2016 or later date of listing on the PBS, the Responsible Person for the First New Brand will be expected to offer an Approved Ex-Manufacturer Price that is equal to the current Effective Price of the Existing Brand.

4.4.3 By no later than July 2022 the Commonwealth will publish on the pbs.gov.au website a detailed statement of its First New Brand price reduction policy as updated as a result of this Agreement.[12]

4.5 Price reduction mechanism

4.5.1 The Commonwealth will seek to amend the Act to provide that all price reductions under Division 3A and Division 3B of the Act occur through a legislated mechanism without the need for the Minister and Responsible Person for the Listed Brand to enter into a new price agreement under section 85AD of the Act.

4.5.2 The Commonwealth will seek to amend the Act so that where a Listed Brand of a Pharmaceutical Item (**Existing Brand**) has an Effective Price, and the First New Brand of the Pharmaceutical Item that is bioequivalent or biosimilar to the Existing Brand (**New Brand**) is listed, the Approved Ex-Manufacturer Price of the Existing Brand will automatically adjust to be equal to the Approved Ex-Manufacturer Price of the New Brand without the need for the Minister and Responsible Person for the Existing Brand to enter into a new price agreement under section 85AD of the Act.

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[11] As at the date of this Agreement, it is Commonwealth policy that the Responsible Person for the First New Brand agree an Approved Ex-Manufacturer Price that is not more than the Effective Price of the existing brand reduced by 25%. As at the date of this Agreement, if the Effective Price reduced by 25% would be lower than 60% of the Effective Price of the Existing Brand on 1 January 2016 or later date of listing on the PBS, the Responsible Person for the First New Brand is expected to agree an AEMP not more than 60% of the effective price on 1 January 2016 or later date of listing on the PBS. Under this policy, if the Effective Price is already lower than 60% of the Effective Price of the Existing Brand on 1 January 2016 or later date of listing on the PBS, the Responsible Person for the First New Brand is expected to agree an AEMP equal to the Effective Price (i.e. no price reduction required). The responsible person for the First New Brand will be notified of the price expected by the Commonwealth prior to acceptance of a price offer.

[12] The detailed statement will address the matters set out in footnote 11 above, as updated under this Agreement.

Listed Brands that have the same drug and manner of administration as the New Brand, but are a different Pharmaceutical Item to the New Brand, will also have their Approved Ex-Manufacturer Price reduced by the same percentage reduction that applied to the Existing Brand upon the listing of the New Brand.

4.5.3 Amendments will be sought to the Act so that where a single ingredient Listed Drug that forms part of one or more Combination Items takes a price reduction under the Act, the Approved Ex-Manufacturer Price for the Combination Items containing that Listed Drug will be adjusted by legislated mechanism without the need for the Minister and Responsible Person for that Combination Item to enter into a new price agreement under section 85AD of the Act. This will be given effect through the formula at Appendix 2.

4.6 Ministerial discretion

4.6.1 During the Term, the Minister will continue to have the existing discretions to reduce or not apply Statutory Price Reductions under Division 3A of Part VII of the Act, and the Act will be amended to provide for Ministerial discretion for the new Statutory Price Reductions described in this clause 4, such that Ministerial discretion will be available for all Statutory Price Reductions in Division 3A of Part VII of the Act during the Term. For clarity, this includes the flow on price reductions referred to in clause 4.5. The procedure for flow on price reductions will ensure that the Responsible Person for a Listed Brand has an opportunity to apply for the exercise of Ministerial discretion before any reduction to the trigger item takes effect.

4.6.2 The Minister will continue to exercise the discretions to reduce or not apply Statutory Price Reductions having regard to the guidelines.

4.7 Clarification in respect of arrangements

4.7.1 Nothing in this Agreement is intended to limit:

(a) the ability of the Commonwealth or the Minister to accept or implement, and flow through Reference Pricing Policy based price reductions or price reductions as a result of a price offer by Responsible Persons; or

(b) the operation of Departmental processes that enable Responsible Persons to seek increases or decreases in the price of medicines.

4.7.2 Where a Drug is on F1 and has been subject to one or more amendments to its listing (for example, listing of new indications) after becoming a Listed Drug, any anniversary Statutory Price Reductions for Listed Brands that have that Listed Drug will continue to be calculated from the date on which the Listed Drug was first listed on the PBS, although the exercise of Ministerial discretion may be sought in respect of any such Statutory Price Reduction.

5. Agreement oversight

5.1 Consistent with the parties' intention to:

5.1.1 ensure the progress, and measure the outcomes, of the commitments made by the parties in this Agreement; and

5.1.2 facilitate ongoing discussions regarding the sustainability and viability of both the generic and biosimilar medicines sector and the PBS,

the operation of this Agreement will be monitored by the Department and GBMA via a Joint Oversight Committee.

5.2 Terms of reference for the Joint Oversight Committee will be developed by the Department in consultation with GBMA for agreement at the first meeting of the Joint Oversight Committee after 1 July 2022 and include:

5.2.1 streamlined governance and reporting arrangements ensuring no duplication with the Generic Medicines Working Group; and

5.2.2 reviewing the record of the savings derived through the measures described in this Agreement.

5.3 The parties agree that:

5.3.1 the Joint Oversight Committee is intended to enable the Commonwealth (represented by the Department) and GBMA to manage and monitor the implementation of this Agreement;

5.3.2 both parties will have equal representation on the Joint Oversight Committee, alternately chaired by a representative of the Department and a representative of GBMA;

5.3.3 both parties have shared responsibility for the workload of the Joint Oversight Committee and will allocate resources accordingly;

5.3.4 the Joint Oversight Committee will meet at least twice during each consecutive 12 month period during the Term from 1 July 2022; and

5.3.5 in the event that the Joint Oversight Committee is unable to reach consensus, issues will be resolved in accordance with clause 6.2.

6. General matters

6.1 Review of effectiveness of measures

6.1.1 By 1 July 2024 (or a later date agreed by the parties in writing), the parties will review the progress and outcomes of the measures described in this Agreement as at that time.

6.1.2 If, as a result of the review described in clause 6.1.1, either party considers that the measures described in this Agreement are not operating as intended, it may give written notice to the other party under this clause 6.1.2, and the parties will thereafter commence discussions in good faith to agree amendments to this Agreement (which may include proposed amendments to the Act) to be implemented during the remainder of the Term to deliver the outcomes as intended by this Agreement.

6.1.3 If the parties are unable to agree any required variation to this Agreement in writing within 3 months after the date a notice is given under clause 6.1.2, then either party may give the other party written notice of its intention to terminate this Agreement if a variation is not agreed within a further 21 days. If a notice is given under this clause 6.1.3 and a variation is not agreed within the required timeframe, the party issuing the notice may terminate this Agreement by giving written notice of termination to the other party at the conclusion of the further 21 days, with the effective date of termination to be the date of the notice of termination or such other date agreed by the parties in writing.

6.2 Issue resolution

6.2.1 For issues arising under this Agreement that cannot be resolved through the Joint Oversight Committee, but which do not result in notice being given pursuant to clause 6.1, the process for resolving issues is as follows:

(a) the party with the issue will send to the other party a notice setting out the nature of the issue; and

(b) the:

(i) Commonwealth representative specified in clause 6.6.1(a);and

(ii) GBMA representative specified in clause 6.6.1(b),

will then try to resolve the issue by direct negotiation.

6.2.2 If the issue is not resolved by direct negotiation under clause 6.2.1 within 40 Business Days from the date the notice referred to in clause 6.2.1(a) is given, either party may refer the matter for direct negotiation between the Minister and the Chairperson of the GBMA.

6.3 New agreement

The parties will use their best endeavours to ensure that negotiations for any new agreement to apply after expiry of this Agreement will commence no sooner than 12 months prior to the expiry of this Agreement.

6.4 Variation

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

6.5 Status of this document

6.5.1 Both parties acknowledge and agree that:

(a) it is their common intention to meet their commitments under this Agreement; and

(b) despite clause 6.5.1(a), nothing in this Agreement places a financial obligation on the Commonwealth or gives rise to an obligation on the Commonwealth to pay compensation, including during or after the end of the Term.

6.5.2 GBMA acknowledges and agrees that the Bill prepared in relation to implementing the measures described in this Agreement may not adopt the exact language used in this Agreement, and that modifications to certain language and principles set out in this Agreement may be required when drafting the Bill, provided that the Bill still allows the substance of the measures to be implemented.

6.5.3 To the extent of any inconsistency between this Agreement and the Act, the Act will prevail.

6.6 Notices

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

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

First Assistant Secretary
Technology Assessment and Access Division
Department of Health
Email: adriana.platona@health.gov.au

MDP 900
GPO Box 9848
CANBERRA ACT 2601,

or as otherwise notified by the Commonwealth; or

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

Chief Executive Officer
Generic Medicines Industry Association Pty Ltd ACN 096 009 540
Email: marnie.peterson@gbma.com.au

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

By hand to: Level 8, 121 Marcus Clarke Street, Canberra City ACT 2601,

or as otherwise notified by GBMA.

6.6.2 A notice is to be:

(a) signed by the person giving the notice and delivered by hand;

(b) signed by the person giving the notice and sent by pre-paid post; or

(c) transmitted electronically by the person giving the notice by email.

6.6.3 Communications take effect from the time they are received or taken to be received under clause 6.6.4 (whichever happens first) unless a later time is specified.

6.6.4 Communications are taken to be received:

(a) if delivered by hand, upon delivery;

(b) if sent by post, 6 days after posting; 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.

6.6.5 A notice received, or taken to be received under clause 6.6.4 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 in the place of receipt.

7. Interpretation

7.1 Words and headings

In this Agreement, unless expressed to the contrary:

7.1.1 words denoting the singular include the plural and vice versa;

7.1.2 the word 'includes' in any form is not a word of limitation;

7.1.3 where a word or phrase is defined, another part of speech or grammatical form of that word or phrase has a corresponding meaning;

7.1.4 headings and sub-headings are for ease of reference only and do not affect the interpretation of this Agreement; and

7.1.5 no rule of construction applies to the disadvantage of the person preparing this Agreement on the basis that it prepared or put forward this Agreement or any part of it.

7.2 Specific references

In this Agreement, unless expressed to the contrary, a reference to:

7.2.1 a decision, determination or action of the Minister includes a decision, determination or action of the Minister's delegate;

7.2.2 consulting on a matter, means seeking the views of the relevant other party or third party and is not an obligation to seek or obtain the agreement of any other person;

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

7.2.4 any legislation (including subordinate legislation) is to that legislation as amended, re-enacted or replaced and includes any subordinate legislation issued under it;

7.2.5 any document (such as a deed, agreement or other document) is to that document (or, if required by the context, to a part of it) as amended, novated, substituted or supplemented at any time;

7.2.6 writing includes writing in digital form;

7.2.7 'this Agreement' is to this Agreement as amended from time to time;

7.2.8 a clause, appendix, part, table or attachment is a reference to a clause, appendix, part, table or attachment in or to this Agreement;

7.2.9 to a 'person' includes an individual, a firm, a body corporate, a partnership, a joint venture, an unincorporated body or association, or any governmental, semi-governmental, administrative, fiscal, judicial or quasi-judicial body, department, commission, authority, tribunal, agency or entity; and

7.2.10 any body (**Original Body**) which no longer exists or has been reconstituted, renamed, replaced or whose powers or functions have been removed or transferred to another body or agency, is a reference to the body which most closely serves the purposes or objects of the Original Body.

Signing Page

Dated 6 September 2021

Signed by the **Honourable Greg Hunt MP, Minister for Health and Aged Care** on behalf of the **Commonwealth of Australia**)
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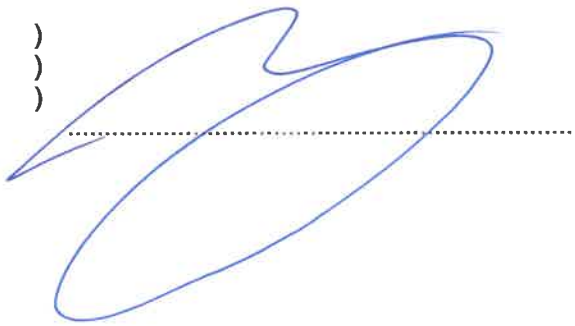

in the presence of:

Witness

DANIEL CHASTON

Name of witness

Signed for and on behalf of **Generic Medicines Industry Association Pty Ltd** ACN 096 009 540 by:)
)
)

Jane Halton AO PSM, Independent Chair

Dennis Bastas, Director

in the presence of:

Marnie Peterson, Chief Executive Officer & Secretary

Appendix 1

Examples of catch-up reductions for medicines listed for 15 years or more.

Example	Catch up criteria	Percentage catch-up
1	Drug is on F1 and achieved its 15th anniverary of being a Listed Drug on or prior to 1 April 2022	22.22%
2	Drug is on F2 and has taken: ▪ a 5% SPR on or about the 5th anniversary of it being a Listed Drug; and ▪ a 12.5% Price Reduction	23.99%
3	Drug is on F2 and has taken: ▪ a 5% SPR on or about the 5th anniversary of it being a Listed Drug; and ▪ a 16% Price Reduction	20.83%
4	Drug is on F2 and has taken: ▪ a 5% SPR on or about the 5th anniversary of it being a Listed Drug; ▪ a 14.5% Price Reduction on or about the 15th anniversary of it being a Listed Drug; and ▪ a 25% Price Reduction	Nil
5	Drug is on F2 and has taken: ▪ a 5% SPR on or about the 5th anniversary of it being a Listed Drug; ▪ a 10% SPR on or about the 10th anniversary of it being a Listed Drug; and ▪ a 25% Price Reduction	1.48%
6	Drug is on F2 and has taken a 25% Price Reduction	15.76%
7	Drug is on F2 and has taken: ▪ a 5% SPR on or about the 5th anniversary of it being a Listed Drug; and ▪ a 25% Price Reduction	11.33%
8	Drug is on F2 and has taken a 16% Price Reduction	24.79%
9	Drug is on F2 and has taken a 12.5% Price Reduction	27.79%
10	Drug is on F2 and has not taken any price reduction under either of Division 3A or Division 3B of Part VII of the Act	36.82%

Appendix 2

Formula for the purposes of clause 4.5.3 – Combination Items[13]

A. Where all component drugs are listed components

Where all its component drugs[14] are listed components, the new price of a single brand of a combination item that comes into force on the reduction day will be worked out as follows:

$$\left(\sum \text{listed component}_{AEMPs}\right) \times \frac{\text{brand of combination item}_{AEMP\ day\ before}}{\left(\sum \text{listed component}_{AEMPs\ day\ before}\right)}$$

B. Where one or more component drugs is not a listed component

Where one or more of its component drugs is not a listed component, the new price of a single brand of a combination item that comes into force on the reduction day will be worked out as follows:

$$\left(\left(\sum \text{listed component}_{AEMPs}\right) + \left(\text{non} - \text{listed component}_{price} \times (1 - Reduction\%)\right)\right) \times \frac{\text{Brand of combination item}_{AEMP\ day\ before}}{\left(\sum \text{component}_{AEMPs\ or\ Prices\ day\ before}\right)}$$

Where:

listed component means a pharmaceutical item that has a drug that is a component drug of a combination item on the reduction day. It can be a combination item itself (for example: combination item AB may be a component of combination item ABC[15]). Where multiple pharmaceutical items that have a drug that is a component drug of a combination item are subject to a price reduction on the same reduction day, the listed component is the pharmaceutical item that has the closest dose form strength and pricing quantity of the component drug to those available in the combination item.

listed component AEMP means the AEMP of any brand of the listed component on the reduction day adjusted where necessary so that the value attributed to the listed component in the combination item reflects any difference in dose form strength and pricing quantity in the combination item as compared to the amount in the listed component.

$\sum$**listed component** $_{\text{AEMPs}}$ means the sum of the listed component AEMPs.

$\sum$**listed component** $_{\text{AEMPs day before}}$ means the sum of the listed component AEMPs on the day before the reduction day.

brand of combination item $_{\text{AEMP day before}}$ means the AEMP for any brand of the combination item on the day before the reduction day.

$\sum$**component** $_{\text{AEMPs or prices day before}}$ means the sum of listed component AEMPs.

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[13] This drafting is intended to reflect the common understanding of the parties about how, generally, the legislated mechanism will calculate combination flow-on reductions. Legislative drafters may modify the language when preparing the required amendments to the Act.

[14] It may be necessary or desirable to modify the definitions of 'listed component drug' and 'component drug' in subsection 99ACA(1) to align with this drafting. This will be a matter for the legislative drafters.

[15] For avoidance of doubt, a reduction to listed component A which causes a reduction to combination item AB will be counted only once when determining the reduction to combination item ABC.

non-listed component $_{Price}$ means the price of the non-listed component of the combination item worked out by subtracting the listed component AEMPs on the day before the reduction day from the AEMP of the combination item on the day before the reduction day. If the sum of listed component AEMPs is the same or greater than the AEMP of the combination item then the non-listed component price is $0.

reduction% means the applicable price reduction percentage for the listed component taking a price reduction.

reduction day has the meaning given in paragraph 99ACC(1)(d) of the Act or paragraph 99ADHB(1)(f) of the Act, as applicable.

price reduction means a price reduction applying to a pharmaceutical item under Division 3A or Division 3B of Part VII of the Act.