



Australian Government

Department of Health

MINISTERIAL DISCRETION GUIDANCE MATERIAL FOR STATUTORY PRICE REDUCTIONS

Introduction

The purpose of this Guidance Material is to assist an Authorised Representative who, on behalf of a Responsible Person, is considering making a request to the Minister for Health (or the Minister's delegate)¹, for the exercise of Ministerial Discretion in relation to Statutory Price Reductions (SPRs) that apply under Division 3A of Part VII of the *National Health Act 1953* (Cth) (**the Act**).

Information about SPRs that apply under Division 3A of Part VII of the Act is at [Appendix 1](#). For further information about SPRs please consult the relevant sections in the Act and the [Explanatory Memorandum](#). An extract from the Act for the Minister's discretionary powers in relation to SPRs is at [Appendix 2](#). An extract from the Strategic Agreement with Medicines Australia is at [Appendix 3](#).

This Material is intended to provide guidance on the types of information and the matters that may be considered relevant to the exercise of discretion. It should not be used as a basis for legal interpretation and is not intended to limit the Minister's powers conferred by the Act.

The Minister and the Australian Government accept no responsibility arising from use of, or reliance on, this document.

Ministerial Discretion

The Act provides for Ministerial Discretion powers to reduce or not apply SPRs under Division 3A of Part VII of the Act by notifiable instrument.

Ministerial Discretion ensures that the prices of important Pharmaceutical Benefits Scheme (PBS) listed medicines will not be allowed to be reduced below what is needed to secure supply for Australian patients.

¹ All references to the Minister are also a reference, if applicable, to the Minister's delegate.

Statutory Price Reductions that Allow for Ministerial Discretion

The Act provides for Ministerial Discretion powers to reduce or not apply SPRs under Division 3A of Part VII of the Act ([Table 1](#)).

Table 1: Statutory Price Reductions that allow for Ministerial Discretion

Type of SPR	Description	Section/s of the Act
Anniversary price reductions	Anniversary reductions apply to F1 medicines on the fifth, tenth and fifteenth anniversary of a drug being listed on the PBS. Refer to Appendix 1, Part 1 .	99ACHB, 99ACJA, 99ACKA, 99ACKB and 99ACF Refer to Appendix 2, Part 1 .
First new brand reductions	A statutory price reduction is applied to existing PBS-listed products when the first new brand (the trigger item) that is bioequivalent or biosimilar and has the same manner of administration as an existing item lists on the PBS. The reduction that applies is 25% off the current AEMP, or a reduction to bring the price to 60% off the earliest of the 1 January 2016 or the date of listing AEMP. All related brands that have the same drug and manner of administration as the trigger item, will also have their AEMPs reduced by the same percentage reduction. Refer to Appendix 1, Part 2 .	99ACB, 99ACD and 99ACR Refer to Appendix 2, Part 2
Catch-up price reductions	On 1 April 2023, catch-up price reductions will apply to brands of any drugs that have been listed on the PBS for fifteen years or more and have not taken a price disclosure reduction. The size of catch-up price reductions will vary depending on previous SPRs that have applied to the pharmaceutical item and will be up to a maximum of 36.82%. Refer to Appendix 1, Part 3 .	99ACN Refer to Appendix 2, Part 3 .
Combination flow-on price reductions	From 1 July 2022, SPRs automatically “flow-on” to combination items. This occurs by reducing a combination item where a listed component in the combination item is subject to a SPR. Refer to Appendix 1, Part 4 .	99ACC and 99ADHB Refer to Appendix 2, Part 4 .
New presentations (5 – 10 years)	Where there is a “new presentation” ² of an existing medicine that has been listed on the PBS for 5 to 10 years, the Responsible Person can apply for Ministerial Discretion to not apply first new brand reductions for the purposes of section 99ACB and 99ACD of the Act. Refer to Appendix 1, Part 5 .	99ACBA and 99ACEA Refer to Appendix 2, Part 5 .

² Refer to the New Presentation guidance material for more information about making a new presentation request - <https://www.pbs.gov.au/industry/pricing/ministerial-discretion/New-Presentation-Ministerial-Discretion-Guidance.pdf>

What will be considered when making a decision to exercise discretion?

Guidance is provided on the types of information and the matters that might be considered relevant to the exercise of discretion in cases where a Responsible Person would like to request not to apply, or to reduce the amount of the SPRs outlined in [Table 1](#). This guidance is not intended to limit the Minister's powers conferred by the Act.

The Minister **must** take into account what the Approved Ex-Manufacturer Price (**AEMP**) would otherwise be if they do not exercise discretion (i.e., what the new price would be if the full reduction applied) and **may** take into account any other matter that they consider relevant.

Other matters that the Minister may consider relevant may include:

- 1. The pricing history of the medicine**, including, but not limited to, whether:
 - a) the medicine has taken significant price reductions since 1 January 2016
 - b) the medicine has taken significant price reductions as a result of actions of the Responsible Person (such as through self-initiated price reductions to list new indications), or of the actions of other Responsible Persons (such as through a reference pricing exercise)
 - c) the medicine has previously been granted Ministerial Discretion
 - d) the medicine has previously been subject to a price increase.

- 2. Clinical and viability aspects of the medicine**, including but not limited to, whether:
 - a) the medicine is clinically needed³ on the PBS, taking into consideration factors such as:
 - i. if the medicine is identified on the World Health Organization's Model Lists of Essential Medicines
 - ii. any new or existing advice from the PBAC or clinical experts
 - iii. if there is a therapeutic alternative available on the PBS
 - iv. if there are other available brands of the medicine on the PBS
 - v. whether the therapeutic alternatives and/or other available brands will be able to meet market demand.
 - b) a further reduction to the price will:
 - i. impact the viability⁴ of continued PBS supply; and
 - ii. lead to the medicine being de-listed from the PBS if discretion is not granted.

- 3. Financial impacts**, including:
 - a) The financial impact on the PBS if discretion is granted
 - b) The financial impact on the PBS if the medicine was delisted
 - c) The financial impacts on consumers if discretion is granted
 - d) The financial impacts on consumers if the medicine is delisted.

³ Where required, clinical advice will be sought to determine clinical need, such as from a medical advisor or the Pharmaceutical Benefits Advisory Committee (PBAC).

⁴ Refers to any impacts a price reduction may have on a company's ability to continue supplying the product and/or operating in Australia.

Note: it is not necessary for all matters listed above to be addressed in a request for Ministerial Discretion nor is it necessary for the Minister to consider all of these matters when deciding whether or not to exercise discretion. It remains open to Responsible Persons to submit any other reasons why discretion should be exercised, where that matter is not listed above.

Making a request

The request must be made through the Health Products Portal (**HPP**) under ‘list management service requests’ which includes completing cost of goods information. Requests are cost recovered and current fees are listed on the [PBS website](#).

Provision of additional material that is relevant to the request is not a requirement but may assist in determining whether discretion should be exercised. Examples of additional material that may be relevant include, but are not limited to:

Additional material relating to clinical need:

- PBAC or clinical advice;
- evidence of the medicine’s place in the clinical pathway, such as if it is used in patients who have failed prior treatments; and
- whether the medicine is for a specific and/or vulnerable patient community.

Additional material relating to viability:

- the Responsible Person’s plans for the listing should discretion not be granted;
- cost of goods information outlining where a reduction may take the price below this amount;
- commercial and fiscal viability including economies of scale, gross margins of the Listed Brand, and the impact on the company’s domestic and/or global revenue;
- available information on historical shortages or discontinuations of brands of the pharmaceutical item; and
- whether following de-listing because of non-viability, target patient groups would have the capacity to pay for the medicine.

Other material:

- availability and prices of alternative brands, products and treatments;
- prices of items when supplied privately in Australia and in comparable overseas markets; and
- reliability of information provided by the Responsible Person including certification by independent third party.

The Department has responsibility for managing all aspects of requests made to the Minister. The Department will provide the Minister with the submission together with a summary of the request and a recommendation in relation to the exercise of discretion. All submissions will be treated as commercial-in-confidence. Giving false or misleading information is a serious offence.

Application timeframes

1. 1 April 2023 reductions (catch-up reductions and anniversary reductions)

A list of medicines subject to reductions occurring on 1 April 2023 (catch-up reductions and anniversary reductions), and the indicative AEMP, will be made available on the PBS website on 1 July 2022 (refer to [Table 2](#)).

Combination items that contain a component item that is subject to a catch-up or anniversary reduction will be subject to a flow-on price reduction on the same date ([Refer to Appendix 1, Part 4](#)). Combination items are subject to the same Ministerial Discretion timeframes outlined in [Table 2](#).

Table 2: Ministerial Discretion application timeframes for 1 April 2023 reductions

Date	Milestone
1 Jul 2022	Publication of indicative list of medicines subject to 1 April 2023 reductions
	Ministerial Discretion applications open
29 Jul 2022	Closing date for Ministerial Discretion applications
10 Oct 2022	Indicative Ministerial Discretion outcomes ⁵
25 Oct 2022	Closing date for sponsors to submit additional information
15 Nov 2022	Sponsors notified of final Ministerial Discretion outcomes
15 Jan 2023	Closing date for delisting request (1 April 2023) ⁶
1 Apr 2023	Reduction Day

2. Anniversary price reductions occurring from 1 April 2024

A list of medicines subject to anniversary price reductions, and the indicative AEMP, will be made available on the PBS website from 1 August in the previous year before the 1 April reduction date (refer to [Table 3](#)). The closing date for Ministerial Discretion applications for anniversary price reductions is 11 September in the previous year before the 1 April reduction date (refer to [Table 3](#)).

Combination items that contain a component item that is subject to an anniversary reduction will be subject to a flow-on price reduction on the same date ([Refer to Appendix 1, Part 4](#)). Combination items are subject to the same Ministerial Discretion timeframes outlined in [Table 3](#).

⁵ Responsible Persons will be provided with opportunity to submit further information.

⁶ Some delist requests may require PBAC consideration therefore a 1 April 2023 delist date cannot be guaranteed.

Table 3: Ministerial Discretion application timeframes for anniversary price reductions

MD application close	Indicative MD outcome	Additional information due	Final MD outcome	Closing date for delist requests ¹	Reduction date
<i>30 business days</i>	<i>30 business days</i>	<i>10 business days</i>	<i>20 business days</i>	<i>24 business days</i>	<i>~77 business days</i>
11 Sept 2023	23 Oct 2023	6 Nov 2023	4 Dec 2023	15 Jan 2024	1 Apr 2024
11 Sept 2024	23 Oct 2024	6 Nov 2024	4 Dec 2024	15 Jan 2025	1 Apr 2025
11 Sept 2025	23 Oct 2025	6 Nov 2025	4 Dec 2025	15 Jan 2026	1 Apr 2026
11 Sept 2026	23 Oct 2026	6 Nov 2026	4 Dec 2026	15 Jan 2027	1 Apr 2027

¹Some delist requests may require PBAC consideration therefore a 1 April 2023 delist date cannot be guaranteed.

Note: business days indicate the amount of time available for each party to complete the activity.

3. First new brand reductions

Responsible Persons of originator medicines subject to first new brand reductions will be notified within five business days from the Department receiving the application to list the new brand. In some instances where the medicine is subject to a Deed of Agreement it may not be possible to notify the new AEMP within five business days. In these instances, Responsible Persons will be notified that an application has been received within five business days and will be notified of the new AEMP as soon as possible. The closing date for Ministerial Discretion applications will be 15 business days after the closing date for Responsible Persons to submit a new brand application (refer to [Table 4](#)).

Combination items that contain a component item that is subject to the first new brand reduction will be subject to the flow-on price reduction on the same date ([Refer to Appendix 1, Part 4](#)). Combination items are subject to the same Ministerial Discretion timeframes outlined in [Table 4](#).

Table 4: Ministerial Discretion application timeframes for First New Brand reductions

FNB application close	Originator notification	MD application close	Indicative MD outcome	Additional information due	Final MD outcome ¹	Reduction date
	<i>5 business days</i>	<i>10 business days</i>	<i>20 business days</i>	<i>5 business days</i>	<i>10 business days</i>	
1 Feb 2023	7 Feb 2023	21 Feb 2023	21 Mar 2023	28 Mar 2023	11 Apr 2023	1 Jun 2023
31 Mar 2023	11 Apr 2023	26 Apr 2023	17 May 2023	24 May 2023	7 Jun 2023	1 Aug 2023
1 Jun 2023	8 Jun 2023	22 Jun 2023	20 Jul 2023	27 Jul 2023	10 Aug 2023	1 Oct 2023

¹ Late delisting requests may be considered for a delist on the reduction date following notification of the final MD.

Note: business days indicate the amount of time available for each party to complete the activity.

4. New presentations (5 – 10 years)

Listing a “new presentation”⁷ of an existing medicine that has been listed on the PBS for 5 to 10 years allows the Responsible Person to apply for Ministerial Discretion to not apply [first new brand reductions](#) for the purposes of section 99ACB and 99ACD of the Act.

Table 5: Ministerial Discretion application timeframes for new presentations (5-10 years)

Submit intent to apply	Submit pricing offer package	MD closing date	MD indicative outcome	Additional information due	MD final outcome	Requested listing date
	<i>5 business days</i>	<i>10 business days</i>	<i>20 business days</i>	<i>5 business days</i>	<i>10 business days</i>	
1 Feb 2023	7 Feb 2023	21 Feb 2023	21 Mar 2023	28 Mar 2023	11 Apr 2023	1 Jun 2023
31 Mar 2023	11 Apr 2023	26 Apr 2023	17 May 2023	24 May 2023	7 Jun 2023	1 Aug 2023
1 Jun 2023	8 Jun 2023	22 Jun 2023	20 Jul 2023	27 Jul 2023	10 Aug 2023	1 Oct 2023

Note: business days indicate the amount of time available for each party to complete the activity.

⁷ Refer to the New Presentation guidance material for more information about making a new presentation request - <https://www.pbs.gov.au/industry/pricing/ministerial-discretion/New-Presentation-Ministerial-Discretion-Guidance.pdf>

Outcome of request

The Department will, in accordance with the timeframes outlined above:

- a) notify the Responsible Person of the indicative decision via the HPP
- b) where the indicative Ministerial decision is not to exercise the discretion, a summary of reasons will be provided and the Responsible Person will be given an opportunity to provide further information to the Department (via the HPP) before the Minister makes a final decision about whether to exercise the discretion
- c) notify the Responsible Person of the final outcome.

Where Ministerial discretion is exercised, the outcome will also be published on the Federal Register of Legislation in a Notifiable Instrument, as required by the legislation, before the reduction day.

If Ministerial Discretion is not exercised

The following options remain available to the Responsible Person through the HPP:

- a) Request a price increase
- b) Request a Brand Price Premium
- c) Request the product to be delisted from the PBS.

APPENDIX 1: Background on Statutory Price Reductions

1. Anniversary Price Reductions (5, 10, 15 year)

- Under section 99ACF of the Act, the Minister can exercise Ministerial Discretion in relation to the anniversary reductions which occur depending on the length of time a medicine has been listed on the Pharmaceutical Benefits Scheme (PBS).
- The price reduction applied will be capped at 60 per cent off (or 40 per cent of) the Listed Brand's AEMP on 1 January 2016 or the AEMP at a later date of listing.
- [Table 6](#) outlines the anniversary price reductions that commence from 1 April 2023.

Table 6: Anniversary price reductions

Listing duration	Reduction that applies	Section/s of the Act	Price reduction days
At least 5 years but less than 10 years	5%	99ACHB	1 April 2023 1 April 2024 1 April 2025 1 April 2026 1 April 2027
At least 10 years but less than 15 years	5%	99ACJA	1 April 2023 1 April 2024 1 April 2025 1 April 2026 1 April 2027
15 years or more	26.1%	99ACKA	1 April 2023 1 April 2024 1 April 2025 1 April 2026
	30%	99ACKB	1 April 2027

2. First New Brand Reductions

- Under sections 99ACB, 99ACD and 99ACR of the Act a statutory price reduction is applied to existing PBS-listed products when the first new brand (the trigger item) that is bioequivalent or biosimilar and has the same manner of administration as an existing item lists on the PBS. The reduction that applies is 25% off the current AEMP, or a reduction to bring the price to 60% off the earliest of the 1 January 2016 or the date of listing AEMP. Refer to [Table 7](#).
- All brands that have the same drug and manner of administration as the trigger item, will also have their AEMPs reduced by the same percentage reduction.
- The price reduction applied will be capped at 60 per cent off (or 40 per cent of) the Listed Brand's AEMP on 1 January 2016 or the AEMP at a later date of listing.
- Where the existing brand has an effective price, please refer to clause [9.4.2 of the Strategic Agreement](#).
- Refer to the First New Brand Policy that will be available on the PBS website from 1 July 2022 for more detailed information.

Table 7: First new brand reductions

Reduction off AEMP since 1 January 2016 or later date of listing	Reduction that applies to both the existing and new brand
60 % or more	0%
>35% and <60%	Reduced price is equal to 40% of the 1 January 2016 or date of listing AEMP.
<35%	25%

3. Catch-Up Reductions

- On 1 April 2023, catch-up price reductions will apply in accordance with section 99ACN of the Act to brands of any drugs that have been listed on the PBS for fifteen years or more that have not taken a price disclosure reduction.
- The size of catch-up price reductions will vary depending on previous statutory price reductions and will be up to a maximum of 36.82%. The catch-up reductions will be calculated in accordance with the formula outlined in section [99ACN\(2\)](#) of the Act.
- The price reduction applied will be capped at 60 per cent off the Listed Brand’s AEMP on 1 January 2016 or the AEMP at a later date of listing.

4. Combination Flow-on Reductions

- A combination item is a pharmaceutical item that has a drug that contains at least two other drugs, at least one of which is listed on the PBS.
- Under sections 99ACC and 99ADHB of the Act, statutory price reductions “flow-on” to combination items.
- Under section 99ACC of the Act, on the reduction day⁸, the AEMP of the **single** brand of the combination is reduced in accordance with section 65A of the Regulation⁹ (refer to [Appendix 4](#)).
- Under section 99ADHB of the Act, on the reduction day, the AEMP of the **existing** brand of the combination item is reduced in accordance with section 85A¹⁰ the regulations (refer to [Appendix 4](#)).

⁸ Sections 65A and 85A, as inserted by Schedule 1 to the *National Health (Pharmaceutical Benefits) Amendment (2021 Measures No. 1) Regulations 2021*, apply in relation to reduction days occurring on or after 1 July 2022.

⁹ National Health Act 1953 National Health (Pharmaceutical Benefits) Amendment (2021 Measures No. 1) Regulations 2021

¹⁰ National Health Act 1953 National Health (Pharmaceutical Benefits) Amendment (2021 Measures No. 1) Regulations 2021

5. New Presentations of medicines that have been PBS listed for 5 – 10 years

- “New presentation” provisions under the Act (sections 99ACBA, and 99ACEA) provide an avenue for Responsible Persons of existing brands of listed pharmaceutical items, to list new presentations of those medicines¹¹.
- This is intended to encourage innovation that contributes to better outcomes for patients and not to incentivise new formulations of existing drugs which will simply delay or reduce brand competition.
- If a proposed listing date is within 5 years of the drug being listed on the PBS, the Responsible Person must make an application to the Department asking that the Department recognise the new item as a new presentation.
- If the proposed listing date is between 5 to 10 years after the drug was listed on the PBS, listing a “new presentation” of an existing listed PBS medicine would enable the Responsible Person to apply for Ministerial Discretion to not apply [first new brand reductions](#) for the purposes of section 99ACB, and 99ACD. In this case the Responsible Person must request:
 - (1) the Department to recognise the new item as a new presentation¹²; and
 - (2) the Minister to exercise the discretion not to apply the SPR and not to move the drug from F1 to F2.
- A new presentation that is listed within 5 years of the initial PBS listing will not be defined as a new brand for the purposes of sections 99ACB or 99ACD of the Act. For example, if drug X has been listed on the PBS within 5 years, recognising drug X as new presentation would entail **not** triggering any price reduction under sections 99ACB, and 99ACD of the Act.
- Recognising a new item with a proposed PBS listing date of 5 to 10 years as a new presentation does not necessarily require the Minister to not trigger the SPR; the Minister would still have to consider whether or not to apply [first new brand reductions](#) for the purposes of section 99ACB, and 99ACD for the new presentation.

¹¹ To apply for a new presentation listing, refer to <https://www.pbs.gov.au/industry/pricing/ministerial-discretion/New-Presentation-Ministerial-Discretion-Guidance.pdf>

¹² To apply for a new presentation listing, refer to <https://www.pbs.gov.au/industry/pricing/ministerial-discretion/New-Presentation-Ministerial-Discretion-Guidance.pdf>

APPENDIX 2: Excerpts from the *National Health Act 1953* (Cth)

1. Anniversary price reductions

99ACHB 5% statutory price reduction for drugs on F1—fifth anniversary

- (1) This section applies to a brand of a pharmaceutical item on a 5% price reduction day if:
 - (a) the drug in the pharmaceutical item is on F1 on the 5% price reduction day; and
 - (b) the 5% price reduction day is on or after the fifth anniversary of the drug being a listed drug; and
 - (c) subsection 99ACR(4) has not applied to the brand of the pharmaceutical item; and
 - (d) on or before the 5% price reduction day, the approved ex-manufacturer price of the brand of the pharmaceutical item has not been reduced:
 - (i) under subsection 99ACF(1) or (2); or
 - (ii) because of repealed section 99ACE or repealed section 99ACH; or
 - (iii) under section 99ACQ; or
 - (iv) under subsection 99ACR(3).
- (2) In this section, each of the following is a *5% price reduction day*:
 - (a) 1 April 2023;
 - (b) 1 April 2024;
 - (c) 1 April 2025;
 - (d) 1 April 2026;
 - (e) 1 April 2027.

99ACJA 5% statutory price reduction for drugs on F1—tenth anniversary

- (1) This section applies to a brand of a pharmaceutical item on a 5% price reduction day if:
 - (a) the drug in the pharmaceutical item is on F1 on the 5% price reduction day; and
 - (b) the 5% price reduction day is on or after the tenth anniversary of the drug being a listed drug; and
 - (c) the approved ex-manufacturer price of the brand of the pharmaceutical item has not been previously reduced under subsection 99ACF(1) or (2) because of:
 - (i) item 3 in the table in section 99ACF; or
 - (ii) item 3A in the table in section 99ACF; or
 - (iii) item 5 in the table in section 99ACF;
 - (iv) item 7 in the table in section 99ACF; and
 - (d) subsection 99ACR(4) has not applied to the brand of the pharmaceutical item; and
 - (e) on or before the 5% price reduction day, the approved ex-manufacturer price of the brand of the pharmaceutical item has not previously been reduced:
 - (i) because of repealed section 99ACE or repealed section 99ACH; or
 - (ii) under section 99ACQ; or
 - (iii) under subsection 99ACR(3).
- (2) In this section, each of the following is a *5% price reduction day*:
 - (a) 1 April 2023;
 - (b) 1 April 2024;
 - (c) 1 April 2025;
 - (d) 1 April 2026;

(e) 1 April 2027.

99ACKA 26.1% statutory price reduction for certain drugs—15th anniversary

- (1) This section applies to a brand of a pharmaceutical item on a 26.1% price reduction day if:
- (a) the 26.1% price reduction day is on or after the 15th anniversary of the drug in the pharmaceutical item being a listed drug; and
 - (b) the approved ex-manufacturer price of the brand of the pharmaceutical item has not been previously reduced under subsection 99ACF(1) or (2) because of:
 - (i) item 4 in the table in section 99ACF; or
 - (ii) item 4A in the table in section 99ACF; or
 - (iii) item 6 in the table in section 99ACF; or
 - (iv) item 8 in the table in section 99ACF; and
 - (c) the approved ex-manufacturer price of the brand of the pharmaceutical item has not been previously reduced on or before the 26.1% reduction day:
 - (i) because of section 99ACB or 99ACD; or
 - (ii) because of repealed section 99ACE or repealed section 99ACH; or
 - (iii) under section 99ACQ; or
 - (iv) under subsection 99ACR(3); and
 - (d) subsection 99ACR(4) has not applied to the brand of the pharmaceutical item on or before the 26.1% price reduction day; and
 - (e) the pharmaceutical item is not an exempt item.

Note: See also section 99ACG..

- (2) In this section, each of the following is a **26.1% price reduction day**:
- (a) 1 April 2023;
 - (b) 1 April 2024;
 - (c) 1 April 2025;
 - (d) 1 April 2026.

99ACKB 30% statutory price reduction for certain drugs—15th anniversary

- (1) This section applies to a brand of a pharmaceutical item on the 30% price reduction day if:
- (a) the 30% price reduction day is on or after the 15th anniversary of the drug in the pharmaceutical item being a listed drug; and
 - (b) the approved ex-manufacturer price of the brand of the pharmaceutical item has not been previously reduced under subsection 99ACF(1) or (2) because of:
 - (i) item 4 in the table in section 99ACF; or
 - (ii) item 4A in the table in section 99ACF; or
 - (iii) item 6 in the table in section 99ACF; or
 - (iv) item 8 in the table in section 99ACF; and
 - (c) the approved ex-manufacturer price of the brand of the pharmaceutical item has not been reduced on or before the 30% reduction day:
 - (i) because of section 99ACB or 99ACD; or
 - (ii) because of repealed section 99ACE or repealed section 99ACH; or
 - (iii) under section 99ACQ; or
 - (iv) under subsection 99ACR(3); and

- (d) subsection 99ACR(4) has not applied to the brand of the pharmaceutical item on or before the 30% price reduction day; and
- (e) the pharmaceutical item is not an exempt item.

Note: See also section 99ACG.

- (2) In this section, the **30% price reduction day** is 1 April 2027.

99ACF Statutory price reductions

Reduction equal to percentage etc.

- (1) Subject to sections 99ACG and 99ADHC, if:
 - (a) a section or subsection referred to in column 2 of the table in this subsection applies to a listed brand of a pharmaceutical item on a day specified in the section or subsection (the **reduction day**); and
 - (b) subsection (2) does not apply to the listed brand of the pharmaceutical item on the reduction day; and
 - (c) on the day before the reduction day, an approved ex-manufacturer price was, or one or more claimed prices were, in force for the listed brand of the pharmaceutical item;

then, subject to subsections (1A), (2A) and (3), the approved ex-manufacturer price is, and (if applicable) each of the claimed prices are, taken to be reduced, on the reduction day, by the percentage or method specified in column 3 of the table for the section or subsection referred to in column 2.

Statutory price reductions table		
Item	Section or subsection	Percentage or method
2	99ACHA	5%
2A	99ACHB	5%
3	99ACJ	10%
3A	99ACJA	5%
4	99ACK	5%
4A	99ACKA	26.1%
4B	99ACKB	30%
5	99ACL(1)	10%
6	99ACL(2)	(a) first, 10%; and (b) second, using the price worked out under paragraph (a), by 5%
7	99ACM	5%
8	99ACN	The percentage referred to in paragraph 99ACN(1)(c)
9	99ACP	1.48%

Note: Subsection (1) does not apply if there is no determination under subsection 85(6) in respect of the pharmaceutical item in force on the specified day (whether or not the determination was revoked following a request by the Responsible Person for the pharmaceutical item).

Reduction cap

- (1A) If:

- (a) the approved ex-manufacturer price of a listed brand of a pharmaceutical item is to be reduced under subsection (1) because of an item in the table in subsection (1); and
 - (b) apart from this subsection, the reduced approved ex-manufacturer price would be less than the amount (the *capped price*) equal to:
 - (i) 40% of the approved ex-manufacturer price of a listed brand of the pharmaceutical item on 1 January 2016; or
 - (ii) if subparagraph (i) does not apply—40% of the original approved ex-manufacturer price of the first listed brand of the pharmaceutical item;
 the approved ex-manufacturer price of the listed brand of the pharmaceutical item is taken to be reduced under subsection (1) because of that item to an amount equal to the capped price.
- (1B) If the approved ex-manufacturer price mentioned in subparagraph (1A)(b)(i) or (ii) is by reference to a different pricing quantity than the pricing quantity on the reduction day, the approved ex-manufacturer price mentioned in that subparagraph is taken to be the amount that the approved ex-manufacturer price would have been had the pricing quantity been the same as the pricing quantity on the reduction day.

Reduction more than percentage

- (2) This subsection applies if:
- (a) a section or subsection referred to in column 2 of the table in subsection (1) applies to a listed brand of a pharmaceutical item on a reduction day; and
 - (b) subject to subsection (2A), on the reduction day, the approved ex manufacturer price of the listed brand of the pharmaceutical item does not exceed:
 - (i) the approved ex manufacturer price of the brand of the pharmaceutical item in force on the day before the reduction day, reduced by more than the percentage or method specified in column 3 of the table for the section or subsection referred to in column 2; or
 - (ii) if subsection (1A) would have applied to the brand of the pharmaceutical item if paragraph (1)(b) were disregarded—the capped price of the brand of the pharmaceutical item that would be worked under subsection (1A) if paragraph (1)(b) were disregarded; and
 - (c) if, on the day before the reduction day and on the reduction day, a determination under subsection 85B(3) was in force in relation to a particular pack quantity of the listed brand of the pharmaceutical item—the claimed price for that pack quantity of the brand of the pharmaceutical item does not exceed the claimed price for the same pack quantity of the brand of the pharmaceutical item in force on the day before the reduction day, reduced by more than the percentage or method specified in column 3 of the table for the section or subsection referred to in column 2.

Apportioning if pricing quantity changes

- (2A) If the pricing quantity of the listed brand of the pharmaceutical item on the day before the reduction day is different from the pricing quantity of the listed brand of the pharmaceutical item on the reduction day, then, for the purposes of subsection (1) and paragraph (2)(b), the approved ex-manufacturer price of the listed brand of the pharmaceutical item on the day before the reduction day is taken to be the amount worked out as follows:

$$\frac{\text{AEMP1}}{\text{PQ1}} \times \text{PQ2}$$

where:

AEMPI means the amount that was the approved ex-manufacturer price of the listed brand of the pharmaceutical item on the day before the reduction day.

PQ1 means the pricing quantity of the listed brand of the pharmaceutical item on the day before the reduction day.

PQ2 means the pricing quantity of the listed brand of the pharmaceutical item on the reduction day.

Ministerial discretion not to apply, or to reduce, statutory price reduction

- (3) In relation to a listed brand of a pharmaceutical item, the Minister may, by notifiable instrument, determine that:
- (a) the approved ex-manufacturer price is, or (if applicable) one or more claimed prices are, not to be reduced under a provision mentioned in an item of the table in subsection (1) (the **specified provision**) in relation to a particular reduction day; or
 - (b) the approved ex-manufacturer price is, or (if applicable) one or more of the claimed prices are, to be reduced by a lower percentage than would otherwise apply under a provision mentioned in an item of the table in subsection (1) (the **specified provision**) in relation to a particular reduction day.
- (3A) In making a determination in relation to the application of an item of the table in subsection (1):
- (a) the Minister must take into account what the approved ex-manufacturer price, and (if applicable) each of the claimed prices, of the listed brand of the pharmaceutical item would otherwise be under this section in relation to the particular reduction day if a determination were not made; and
 - (b) the Minister may take into account any other matter that the Minister considers relevant.
- (3B) If the Minister makes a determination in relation to a specified provision, the approved ex-manufacturer price is, and (if applicable) each of the claimed prices are, not to be further reduced under that specified provision on any reduction day that occurs after the reduction day specified in the determination made under subsection (3).

Section does not limit Minister's powers

- (4) This section does not limit the Minister's powers, on or after the reduction day, to make:
- (a) further price agreements; or
 - (b) further determinations under section 85B;
- for the listed brand of the pharmaceutical item.

2. First new brand reductions

99ACB First new brand price reductions for brands of pharmaceutical items that are not combination items

When section applies to new brands

- (1) Subject to subsections (2), (3), (3A) and (3B), this section applies to a brand (the ***new brand***) of a pharmaceutical item (the ***trigger item***) that is not a combination item if:
 - (a) a determination under subsection 85(6) comes into force in relation to the new brand of the trigger item on a day (the ***determination day***); and
 - (b) on the day before the determination day, the new brand of the trigger item was not a listed brand of the trigger item; and
 - (c) on the day before the determination day:
 - (i) a brand (the ***existing brand***) of a pharmaceutical item (the ***existing item***) was a listed brand of the existing item; and
 - (ii) the new brand of the trigger item is bioequivalent or biosimilar to the existing brand of the existing item; and
 - (iii) the trigger item and existing item have the same drug and manner of administration.

Note: For the purposes of paragraph (c), the new brand and the existing brand may be the same brand, or the trigger item and the existing item may be the same pharmaceutical item.

Circumstances in which section does not apply

- (2) This section does not apply in relation to the new brand of the trigger item if:
 - (a) the trigger item is in a class of pharmaceutical items to which a 12.5%, 16% or 25% administrative price reduction has applied; or
 - (b) another pharmaceutical item that has the same drug and manner of administration as the new brand of the trigger item is in a class of pharmaceutical items to which a 12.5%, 16% or 25% administrative price reduction has applied; or
 - (c) if the drug that is in the trigger item is in a therapeutic group—a pharmaceutical item that:
 - (i) has another drug that is in that group; and
 - (ii) has the same manner of administration as the new brand of the trigger item; is in a class of pharmaceutical items to which a 12.5%, 16% or 25% administrative price reduction has applied; or
 - (d) on the day before the determination day:
 - (i) the approved ex-manufacturer price of a listed brand of the existing item on 1 January 2016; or
 - (ii) if subparagraph (i) does not apply—the original approved ex-manufacturer price of the first listed brand of the existing item; has, by virtue of previous price reductions, been reduced by 60% or more.
- (2A) If the approved ex-manufacturer price mentioned in subparagraph (2)(d)(i) or (ii) is by reference to a different pricing quantity than the pricing quantity on the day before the determination day, the approved ex-manufacturer price mentioned in that subparagraph is taken to be the amount that the approved ex-manufacturer price would have been had the pricing quantity been the same as the pricing quantity on the day before the determination day.
- (3) This section does not apply in relation to the new brand of the trigger item if:

- (a) any of the following has applied:
 - (i) subsection (5) or (5A);
 - (ia) a determination under paragraph (6A)(b);
 - (ib) subsection 99ACF(1) or (2) because of item 4A, 4B or 8 in the table in subsection 99ACF(1);
 - (ii) subsection 99ACF(1) or (2) because of repealed section 99ACH;
 - (iii) repealed subsection 99ACF(2AB) or (2AC);
 - (iv) section 99ACQ;
 - (v) subsection 99ACR(3) or (4);

in relation to:

- (b) the new brand, or another listed brand, of the trigger item; or
- (c) a listed brand of another pharmaceutical item that has the same drug and manner of administration as the new brand of the trigger item; or
- (d) if the drug that is in the trigger item is in a therapeutic group—a listed brand of a pharmaceutical item that:
 - (i) has another drug that is in that group; and
 - (ii) has the same manner of administration as the new brand of the trigger item.

Note: For the purposes of subparagraph (a)(i), subsections (5) and (5A) of this section are taken not to have applied in relation to a brand of a pharmaceutical item in some cases: see section 99AEI and subsection (6B) of this section.

- (3A) This section does not apply in relation to the new brand of the trigger item if:
 - (a) the new brand of the trigger item is a new presentation of an existing listed brand of a pharmaceutical item; and
 - (b) the determination day in relation to the new brand of the trigger item is on or before the fifth anniversary of the drug in the pharmaceutical item being on F1; and
 - (c) the Responsible Person for the new brand of the trigger item is the same person as the Responsible Person for the existing listed brand of the pharmaceutical item; and
 - (d) either of the following apply:
 - (i) there is not another brand of the pharmaceutical item that has the drug that is a listed brand;
 - (ii) the drug is not on F2.
- (3B) This section does not apply in relation to the new brand of the trigger item if:
 - (a) the new brand of the trigger item is a new presentation of an existing listed brand of a pharmaceutical item; and
 - (b) the Minister has made a determination under section 99ACBA in relation to the new brand of the trigger item; and
 - (c) the determination under section 99ACBA has not ceased to have effect.

First new brand price reduction

- (4) The Minister:
 - (a) may, under section 85AD, make a price agreement for the new brand of the trigger item; and
 - (b) must not make a determination under section 85B in relation to the new brand of the trigger item.
- (4A) If, on the day before the determination day:
 - (a) the approved ex-manufacturer price of a listed brand of the existing item on 1 January 2016; or

(b) if paragraph (a) does not apply—the original approved ex-manufacturer price of the first listed brand of the existing item;

has, by virtue of previous price reductions, been reduced by:

(c) 35% or less, subsection (5) applies; and

(d) more than 35% but less than 60%, subsection (5A) applies.

Note: If previous price reductions have been 60% or more, see paragraph (2)(d).

- (4B) If the approved ex-manufacturer price mentioned in paragraph (4A)(a) or (b) is by reference to a different pricing quantity than the pricing quantity on the day before the determination day, the approved ex-manufacturer price mentioned in that paragraph is taken to be the amount that the approved ex-manufacturer price would have been had the pricing quantity been the same as the pricing quantity on the day before the determination day.
- (5) Subject to subsections (6) and (6A), the agreed price of the new brand of the trigger item that comes into force on the determination day must not exceed the approved ex-manufacturer price, on the day before the determination day, of the existing brand of the existing item, reduced by 25%.
- (5A) Subject to subsections (6) and (6A), the agreed price of the new brand of the trigger item that comes into force on the determination day must not exceed:
- (a) 40% of the approved ex-manufacturer price of a listed brand of the existing item on 1 January 2016; or
- (b) if paragraph (a) does not apply—40% of the original approved ex-manufacturer price of the first listed brand of the existing item.
- (5B) If the approved ex-manufacturer price mentioned in paragraph (5A)(a) or (b) is by reference to a different pricing quantity than the pricing quantity on the day before the determination day, the approved ex-manufacturer price mentioned in that paragraph is taken to be the amount that the approved ex-manufacturer price would have been had the pricing quantity been the same as the pricing quantity on the day before the determination day.

Apportioning if pricing quantity changes

- (6) If the pricing quantity of the existing brand of the existing item on the day before the determination day is different from the pricing quantity of the existing brand of the existing item on the determination day, then, for the purposes of subsections (5) and (5A), the approved ex-manufacturer price of the existing brand of the existing item on the day before the determination day is taken to be the amount worked out as follows:

$$\frac{AEMP1}{PQ1} \times PQ2$$

where:

AEMP1 means the amount that was the approved ex-manufacturer price of the existing brand of the existing item on the day before the determination day.

PQ1 means the pricing quantity of the existing brand of the existing item on the day before the determination day.

PQ2 means the pricing quantity of the existing brand of the existing item on the determination day.

Ministerial discretion not to apply, or to reduce, statutory price reduction

- (6A) The Minister may, by notifiable instrument, determine that:
- (a) the agreed price of the new brand of the trigger item that comes into force on the determination day is to be equal to the approved ex-manufacturer price, on the day before the determination day, of the existing brand of the existing item; or
 - (b) the agreed price of the new brand of the trigger item that comes into force on the determination day must not exceed the approved ex-manufacturer price, on the day before the determination day, of the existing brand of the existing item, reduced by a lower percentage than would otherwise result from the operation of subsection (5) or (5A) in relation to the determination day.
- (6B) If the Minister makes a determination under paragraph (6A)(a), subsections (5) and (5A) are taken not to have applied to the trigger item.
- (6C) In making a determination under subsection (6A):
- (a) the Minister must take into account what the agreed price of the new brand of the trigger item would otherwise be under this section in relation to the particular determination day if a determination were not made; and
 - (b) the Minister may take into account any other matter that the Minister considers relevant.

Section does not limit Minister's powers

- (7) This section does not limit the Minister's powers, after the determination day, to make:
- (a) further price agreements; or
 - (b) determinations under section 85B;
- for the new brand of the trigger item.

99ACD First new brand price reductions for brands of combination items

When section applies to new brands

- (1) Subject to subsections (1A), (2) and (3), this section applies to a brand (the ***new brand***) of a pharmaceutical item (the ***trigger combination item***) that is a combination item if:
- (a) a determination under subsection 85(6) comes into force in relation to the new brand of the trigger combination item on a day (the ***determination day***); and
 - (b) on the day before the determination day, the new brand of the trigger combination item was not a listed brand of the trigger combination item; and
 - (c) on the day before the determination day:
 - (i) a brand (the ***existing brand***) of a pharmaceutical item (the ***existing item***) was a listed brand of the existing item; and
 - (ii) the new brand of the trigger combination item is bioequivalent or biosimilar to the existing brand of the existing item; and
 - (iii) the drug in the trigger combination item and existing item contain the same component drugs; and
 - (iv) the trigger combination item and the existing item have the same manner of administration.

Note: For the purposes of paragraph (c), the new brand and the existing brand may be the same brand, or the trigger combination item and the existing item may be the same pharmaceutical item.

Circumstances in which section does not apply to new brands

- (1A) This section does not apply in relation to the new brand of the trigger combination item if:
- (a) the trigger combination item is in a class of pharmaceutical items to which a 12.5%, 16% or 25% administrative price reduction has applied; or
 - (b) another combination item that has the same drug and manner of administration as the new brand of the trigger combination item is in a class of pharmaceutical items to which a 12.5%, 16% or 25% administrative price reduction has applied; or
 - (c) if the drug in the trigger combination item is in a therapeutic group—a combination item that:
 - (i) has another drug that is in that group; and
 - (ii) has the same manner of administration as the new brand of the trigger combination item;is in a class of pharmaceutical items to which a 12.5%, 16% or 25% administrative price reduction has applied; or
 - (d) on the day before the determination day:
 - (i) the approved ex-manufacturer price of a listed brand of the existing item on 1 January 2016; or
 - (ii) if subparagraph (i) does not apply—the original approved ex-manufacturer price of the first listed brand of the existing item;has, by virtue of previous price reductions, been reduced by 60% or more.
- (1B) If the approved ex-manufacturer price mentioned in subparagraph (1A)(d)(i) or (ii) is by reference to a different pricing quantity than the pricing quantity on the day before the determination day, the approved ex-manufacturer price mentioned in that subparagraph is taken to be the amount that the approved ex-manufacturer price would have been had the pricing quantity been the same as the pricing quantity on the day before the determination day.
- (2) This section does not apply in relation to the new brand of the trigger combination item if a listed provision (see subsection (2A)) has applied in relation to:
- (a) the new brand, or another listed brand, of the trigger combination item; or
 - (b) a brand of another combination item that:
 - (i) has a drug that contains the same component drugs as the new brand of the trigger combination item; and
 - (ii) has the same manner of administration as the new brand of the trigger combination item; or
 - (c) if the drug in the trigger combination item is in a therapeutic group—a combination item that:
 - (i) has another drug that is in that group; and
 - (ii) has the same manner of administration as the new brand of the trigger combination item.

Note: For the purposes of this subsection, subsections (5) and (5A) of this section are taken not to have applied in relation to a brand of a pharmaceutical item in some cases: see section 99AEI and subsection (7B) of this section.

- (2A) For the purposes of subsection (2), ***listed provision*** means:
- (a) subsection (5) or (5A); or
 - (b) a determination under paragraph (7A)(b); or
 - (c) subsection 99ACF(1) or (2) because of item 4A, 4B or 8 in the table in subsection 99ACF(1); or

- (d) section 99ACQ; or
 - (e) subsection 99ACR(3) or (4); or
 - (f) repealed section 99ACE.
- (3) This section does not apply in relation to the new brand of the trigger combination item if:
- (a) all of the following apply:
 - (i) the new brand of the trigger combination item is a new presentation of an existing listed brand of a pharmaceutical item;
 - (ii) a declaration under subsection 85(2) is in force in relation to the drug in the pharmaceutical item;
 - (iii) the determination day in relation to the new brand of the trigger combination item is on or before the fifth anniversary of the declaration under subsection 85(2) being made;
 - (iv) the Responsible Person for the new brand of the trigger combination item is the same as the Responsible Person for the existing listed brand of the pharmaceutical item;
 - (v) the drug is not on F2; or
 - (b) all of the following apply:
 - (i) the new brand of the trigger combination item is a new presentation of an existing listed brand of a pharmaceutical item;
 - (ii) the Minister has made a determination under section 99ACEA in relation to the new brand of the trigger combination item;
 - (iii) the determination under section 99ACEA has not ceased to have effect.

First new brand price reduction

- (4) The Minister:
- (a) may, under a price agreement, agree an agreed price for the new brand of the trigger combination item that comes into force on the determination day; and
 - (b) must not make a determination under section 85B for the new brand of the trigger combination item.
- (4A) If, on the day before the determination day:
- (a) the approved ex-manufacturer price of a listed brand of the existing item on 1 January 2016; or
 - (b) if paragraph (a) does not apply—the original approved ex-manufacturer price of the first listed brand of the existing item;
- has, by virtue of previous price reductions, been reduced by:
- (c) 35% or less, subsection (5) applies; and
 - (d) more than 35% but less than 60%, subsection (5A) applies.
- Note: If previous price reductions have been 60% or more, see paragraph (1A)(d).
- (4B) If the approved ex-manufacturer price mentioned in paragraph (4A)(a) or (b) is by reference to a different pricing quantity than the pricing quantity on the day before the determination day, the approved ex-manufacturer price mentioned in that paragraph is taken to be the amount that the approved ex-manufacturer price would have been had the pricing quantity been the same as the pricing quantity on the day before the determination day.
- (5) Subject to subsections (7) and (7A), the agreed price of the new brand of the trigger combination item that comes into force on the determination day must not exceed the

approved ex-manufacturer price, on the day before the determination day, of the existing brand of the existing item, reduced by 25%.

- (5A) Subject to subsections (7) and (7A), the agreed price of the new brand of the trigger combination item that comes into force on the determination day must not exceed:
- (a) 40% of the approved ex-manufacturer price of a listed brand of the existing item on 1 January 2016; or
 - (b) if paragraph (a) does not apply—40% of the original approved ex-manufacturer price of the first listed brand of the existing item.
- (5B) If the approved ex-manufacturer price mentioned in paragraph (5A)(a) or (b) is by reference to a different pricing quantity than the pricing quantity on the day before the determination day, the approved ex-manufacturer price mentioned in that paragraph is taken to be the amount that the approved ex-manufacturer price would have been had the pricing quantity been the same as the pricing quantity on the day before the determination day.

Apportioning if pricing quantity changes

- (7) If the pricing quantity of the existing brand of the existing item on the day before the determination day is different from the pricing quantity of the existing brand of the existing item on the determination day, then, for the purposes of subsections (5) and (5A), the approved ex-manufacturer price of the existing brand of the existing item on the day before the determination day is taken to be the amount worked out as follows:

$$\frac{AEMP1}{PQ1} \times PQ2$$

where:

AEMP1 means the amount that was the approved ex-manufacturer price of the existing brand of the existing item on the day before the determination day.

PQ1 means the pricing quantity of the existing brand of the existing item on the day before the determination day.

PQ2 means the pricing quantity of the existing brand of the existing item on the determination day.

Ministerial discretion not to apply, or to reduce, statutory price reduction

- (7A) The Minister may, by notifiable instrument, determine that:
- (a) the agreed price of the new brand of the trigger combination item that comes into force on the determination day is to be equal to the approved ex-manufacturer price, on the day before the determination day, of the existing brand of the existing item; or
 - (b) the agreed price of the new brand of the trigger combination item that comes into force on the determination day must not exceed the approved ex-manufacturer price, on the day before the determination day, of the existing brand of the existing item, reduced by a lower percentage than would otherwise result from the operation of subsection (5) or (5A) in relation to the determination day.
- (7B) If the Minister makes a determination under paragraph (7A)(a), subsections (5) and (5A) are taken not to have applied to the trigger combination item.
- (7C) In making a determination under subsection (7A) :

- (a) the Minister must take into account what the agreed price of the new brand of the trigger combination item would otherwise be under this section in relation to the particular determination day if a determination were not made; and
- (b) the Minister may take into account any other matter that the Minister considers relevant.

Section does not limit Minister's powers

- (8) This section does not limit the Minister's powers, after the determination day, to make:
 - (a) further price agreements; or
 - (b) determinations under section 85B;
 for the new brand of the trigger combination item.

99ACR Flow-on of first new brand price reductions to related brands

- (1) This section applies to a brand (the *related brand*) of a pharmaceutical item (a *related item*) mentioned in subsection (2) if:
 - (a) subsection 99ACB(5) or (5A) or 99ACD(5) or (5A) has applied to the agreed price for a brand (the *new brand*) of a pharmaceutical item (the *new item*); and
 - (b) that price comes into force on a day (the *reduction day*); and
 - (c) on the day before the reduction day, the related brand of the related item was a listed brand of the related item; and
 - (d) the related item is not an exempt item.

Note: See also section 99ACG.

- (2) For the purposes of this section, a related brand of a related item is any of the following:
 - (a) a listed brand of another pharmaceutical item that has the same drug and manner of administration as the new item;
 - (b) if the drug in the new item is in a therapeutic group—a listed brand of a pharmaceutical item that:
 - (i) has another drug that is in that group; and
 - (ii) has the same manner of administration as the new brand of the new item.
- (3) Subject to subsections (4) and (6), on the reduction day, the approved ex-manufacturer price, and (if applicable) the claimed price, of the related brand of the related item is taken to be reduced by a percentage equal to the percentage by which the agreed price for the new brand was reduced as a result of the application of the subsection mentioned in paragraph (1)(a).
- (4) Subsection (3) does not apply to the related brand of the related item if:
 - (a) on the reduction day, the approved ex-manufacturer price of the related brand of the related item does not exceed the approved ex-manufacturer price of the related brand of the related item in force on the day before the reduction day, reduced by more than the percentage required under subsection (3); and
 - (b) if there is an applicable claimed price of the related brand of the related item—on the reduction day, the claimed price of the related brand of the related item does not exceed the claimed price of the related brand of the related item in force on the day before the reduction day, reduced by more than the percentage required under subsection (3).

Apportioning if pricing quantity changes

- (5) If the pricing quantity of the related brand of the related item on the day before the reduction day is different from the pricing quantity of the related brand of the related item on the reduction day, then, for the purposes of subsection (3) and paragraph (4)(a), the approved ex-manufacturer price of the related brand of the related item on the day before the reduction day is taken to be the amount worked out using the following formula:

$$\frac{AEMP1}{PQ1} \times PQ2$$

where:

AEMP1 means the amount that was the approved ex-manufacturer price of the related brand of the related item on the day before the reduction day.

PQ1 means the pricing quantity of the related brand of the related item on the day before the reduction day.

PQ2 means the pricing quantity of the related brand of the related item on the reduction day.

Ministerial discretion not to apply, or to reduce, flow-on price reduction

- (6) In relation to the related brand of the related item, the Minister may, by notifiable instrument, determine that:
- (a) the approved ex-manufacturer price, and (if applicable) the claimed price, is not to be reduced under subsection (3) in relation to a particular reduction day; or
 - (b) the approved ex-manufacturer price, and (if applicable) the claimed price, is to be reduced by a lower percentage than would otherwise apply under subsection (3) in relation to a particular reduction day.
- (7) If the Minister makes a determination under paragraph (6)(a), subsection (3) is taken not to have applied to the related brand of the related item.
- (8) In making a determination under subsection (6):
- (a) the Minister must take into account what the approved ex-manufacturer price, and (if applicable) the claimed price, of the related brand of the related item would otherwise be under this section in relation to the particular reduction day if a determination were not made; and
 - (b) the Minister may take into account any other matter the Minister thinks is relevant.

Section does not limit Minister's powers

- (9) This section does not limit the Minister's powers, on or after the reduction day, to make:
- (a) further price agreements; or
 - (b) determinations under section 85B;
- for the related brand of the related item.

3. Catch-up price reductions

99ACN Catch-up price reduction for certain drugs—15th anniversary

- (1) This section applies to a brand of a pharmaceutical item on the catch-up price reduction day if:
 - (a) the 15th anniversary of the drug in the pharmaceutical item being a listed drug was on or before 1 April 2022; and
 - (b) the pharmaceutical item is not an exempt item; and
 - (c) on the catch-up price reduction day, the percentage worked out using the formula in subsection (2) is greater than zero.

Note: See also section 99ACG.

- (2) The formula mentioned in paragraph (1)(c) is:

$$100\% - \frac{63.18\%}{\text{Product of differential percentages}}$$

where:

product of differential percentages means:

- (a) if there has been only one previous price reduction under this Division—the differential percentage for that price reduction; or
- (b) if there have been 2 or more previous price reductions under this Division—the product of the differential percentages for those previous price reductions; or
- (c) if there have not been any previous price reductions under this Division—100%.

Note 1: The effect of the formula is that, following the application of the price reduction which applies as a result of this section and item 8 of the table in section 99ACF(1), the cumulative impact of price reductions under this Division, applied successively, will be 36.82%. For example, if the brand of the pharmaceutical item has been subject to a 5% previous price reduction under this Division followed by a 16% previous price reduction under this Division, the product of the differential percentages will be $(100\% - 5\%) \times (100\% - 16\%) = 79.80\%$, and the percentage worked out using the formula will be $100\% - 63.18\%/79.80\% = 20.83\%$.

Note 2: For rounding of the percentage worked out using the formula, see subsection (5).

- (3) For the purposes of this section, ***previous price reduction under this Division*** has the meaning given by section 99ACNA.
- (4) For the purposes of this section, the ***differential percentage*** for a previous price reduction under this Division means the difference between 100% and the previous price reduction under this Division.
- (5) The percentage worked out using the formula in subsection (2) is to be calculated to 2 decimal places (rounding up if the third decimal place is 5 or more).
- (6) In this section, the ***catch-up price reduction day*** is 1 April 2023.

99ACNA Catch-up price reduction for certain drugs—meaning of *previous price reduction under this Division*

- (1) For the purposes of the application of section 99ACN to a brand (the ***relevant brand***) of a pharmaceutical item, ***previous price reduction under this Division*** means:

- (a) a reduction, on or before the catch-up price reduction day, in the approved ex-manufacturer price of the relevant brand or another brand of the pharmaceutical item under this Division (expressed as a percentage) (other than a reduction attributable to section 99ACN); or
 - (b) in the case of a reduction, on or before the catch-up price reduction day, in the approved ex-manufacturer price of the relevant brand or another brand of the pharmaceutical item under subsection 99ACF (2)—the reduction in the approved ex-manufacturer price of the relevant brand or the other brand of the pharmaceutical item (expressed as a percentage) that would have occurred under subsection 99ACF (1) if paragraph (b) of that subsection were disregarded; or
 - (c) in the case of a reduction, on or before the catch-up price reduction day, in the approved ex-manufacturer price of the relevant brand or another brand of the pharmaceutical item under subsection 99ACR (4)—the reduction in the approved ex-manufacturer price of the relevant brand or the other brand of the pharmaceutical item (expressed as a percentage) that would have occurred under subsection 99ACR (3) if subsection 99ACR(4) did not apply; or
 - (d) a 12.5% administrative price reduction that applied, on or before the catch-up price reduction day, to the relevant brand or another brand of the pharmaceutical item.
- (2) For the purposes of this section:
- (a) a reduction in the agreed price of a brand of the pharmaceutical item is taken to be a reduction in the approved ex-manufacturer price of the brand of the pharmaceutical item; and
 - (b) a reduction in the determined price of a brand of the pharmaceutical item is taken to be a reduction in the approved ex-manufacturer price of the brand of the pharmaceutical item; and
 - (c) a reduction before 1 October 2012 in the approved price to pharmacists (within the meaning of this Part as it stood before 1 October 2012) of a brand of the pharmaceutical item is taken to be a reduction in the approved ex-manufacturer price of the brand of the pharmaceutical item.
- (3) A reference in this section to the approved ex-manufacturer price of a brand of a pharmaceutical item being reduced under subsection 99ACR (4) is to be read as a reference to that subsection applying to the brand of the pharmaceutical item.
- (4) A reference in this section to this Division includes this Division as in force at any time before the commencement of this section.
- (5) In this section, the *catch-up price reduction day* is 1 April 2023.

4. Combination flow-on price reductions

99ACC Price reductions for single brands of combination items

When section applies

- (1) This section applies if:
 - (a) subsection 85AB(5) applies to the drug in a combination item; and
 - (b) there is only one listed brand (the **single brand**) of the combination item; and
 - (c) there is an approved ex-manufacturer price for the single brand of the combination item; and
 - (d) any of the following apply:
 - (i) if the drug in the combination item contains only one listed component drug—that listed component drug becomes subject to a statutory price reduction on a day (the **reduction day**); or
 - (ii) if the drug in the combination item contains 2 or more listed component drugs—one of the listed component drugs becomes subject to a statutory price reduction on a day (the **reduction day**); or
 - (iii) if the drug in the combination item contains 2 or more listed component drugs—2 or more of the listed component drugs become subject to a statutory price reduction on the same day (the **reduction day**); and
 - (e) on the reduction day, or on the day before that day, no listed brand of another combination item that has a drug that contains the same component drugs as the combination item:
 - (i) is bioequivalent or biosimilar to the single brand of the combination item; and
 - (ii) has the same manner of administration as the single brand of the combination item.

Price reduction

- (2) Subject to subsections (5A), (5C) and (5E), on the reduction day, the approved ex-manufacturer price of the single brand of the combination item is taken to be reduced in accordance with a method prescribed by the regulations.
- (3) Different methods may be prescribed by the regulations for different classes of combination items.
- (4) Subsection (3) does not limit subsection 33(3A) of the *Acts Interpretation Act 1901*.
- (5) Subject to subsections (5A) and (5C), if the approved ex-manufacturer price of the single brand of the combination item is reduced under subsection (2), then, on the reduction day, the claimed price (if any) of the single brand of the combination item is taken to be reduced by a percentage equal to the percentage by which the approved ex-manufacturer price of the single brand of the combination item is reduced under subsection (2).

Reduction cap

- (5A) If:
 - (a) the approved ex-manufacturer price of the single brand of the combination item is to be reduced under subsection (2); and

(b) apart from this subsection, the reduced approved ex-manufacturer price would be less than the amount (the *capped price*) equal to:

- (i) 40% of the approved ex-manufacturer price of a listed brand of the combination item on 1 January 2016; or
- (ii) if subparagraph (i) does not apply—40% of the original approved ex-manufacturer price of the first listed brand of the combination item;

the approved ex-manufacturer price of the single brand of the combination item is taken to be reduced under subsection (2) to an amount equal to the capped price.

(5B) If the approved ex-manufacturer price mentioned in subparagraph (5A)(b)(i) or (ii) is by reference to a different pricing quantity than the pricing quantity on the reduction day, the approved ex-manufacturer price mentioned in that subparagraph is taken to be the amount that the approved ex-manufacturer price would have been had the pricing quantity been the same as the pricing quantity on the reduction day.

Ministerial discretion not to apply, or to reduce, statutory price reduction

(5C) In relation to the single brand of the combination item, the Minister may, by notifiable instrument, determine that:

- (a) the approved ex-manufacturer price, and (if applicable) the claimed price, is not to be reduced under subsection (2) or (5), as the case requires, in relation to a particular reduction day; or
- (b) the approved ex-manufacturer price, and (if applicable) the claimed price, is to be reduced by a lower percentage than would otherwise apply under subsection (2) or (5), as the case requires, in relation to a particular reduction day.

(5D) In making a determination under subsection (5C):

- (a) the Minister must take into account what the approved ex-manufacturer price, and (if applicable) the claimed price, of the single brand of the combination item would otherwise be under this section in relation to the particular reduction day if a determination were not made; and
- (b) the Minister may take into account:
 - (i) any advice given to the Minister under subsection 101(4AC) in relation to the combination item; and
 - (ii) any other matter the Minister thinks is relevant.

(5E) If the Minister makes a determination under subsection (5C), the approved ex-manufacturer price of the single brand of the combination item is not to be further reduced under this section on any reduction day that occurs after the reduction day specified in the determination made under subsection (5C).

Section does not limit Minister's powers

(5F) This section does not limit the Minister's powers, on or after the reduction day, to make:

- (a) further price agreements; or
- (b) determinations under section 85B;

for the single brand of the combination item.

Subject to statutory price reduction etc.

(6) The following provisions have effect:

- (a) a listed component drug contained in a drug in a combination item becomes *subject to statutory price reduction* if section 99ACB or 99ACQ or subsection 99ACR(3)

or (4) or section 99ADH, has applied to a listed brand of a pharmaceutical item that:

- (i) has the listed component drug; and
 - (ii) has the same manner of administration as the combination item;
- (b) whichever provision mentioned in paragraph (a) applied, that provision applies to the listed component drug contained in the drug in the combination item in the same way as that provision applies to the listed brand of the pharmaceutical item that:
- (i) has the listed component drug; and
 - (ii) has the same manner of administration as the combination item;
- (c) a listed component drug contained in a drug in a combination item becomes **subject to statutory price reduction** if subsection 99ACF(1) or (2) because of an item in the table in section 99ACF has applied to a listed brand of a pharmaceutical item that has the listed component drug;
- (d) whichever provision mentioned in paragraph (c) applied, that provision applies to the listed component drug contained in the drug in the combination item in the same way as that provision applies to the listed brand of the pharmaceutical item that has the listed component drug.

Modified meaning of the same manner of administration

- (7) For the purposes of subsection (6), a combination item whose drug contains a listed component drug has the same manner of administration as another pharmaceutical item that has (or whose drug contains) the listed component drug if the manner of administration set out in a determination under subsection 85(5) for the combination item, to the extent that the manner of administration relates to the listed component drug:
- (a) if the other pharmaceutical item is not a combination item—is the same as the manner of administration set out in a determination under subsection 85(5) for the other pharmaceutical item; or
 - (b) if the other pharmaceutical item is another combination item—is the same as the manner of administration set out in a determination under subsection 85(5) for the other combination item, to the extent that the manner of administration relates to the listed component drug.

99ADHB Flow on price reductions for brands of combination items

When section applies

- (1) This section applies if:
- (a) there is an approved ex-manufacturer price (the **existing price**) in force for a brand (the **existing brand**) of a combination item; and
 - (b) the combination item is not an exempt item; and
 - (c) the combination item has a drug on F2; and
 - (d) a brand of a pharmaceutical item (the **non-combination item**) that is not a combination item has a drug (the **common drug**) that is in the combination item; and
 - (e) the combination item has the same manner of administration as the non-combination item; and
 - (f) on a day (the **reduction day**) after the day the existing price came into force for the existing brand of the combination item, section 99ADH applied to the brand of the non-combination item.

Note: The meaning of *the same manner of administration* is modified for the purposes of this section by subsection (7).

Price reduction

- (2) Subject to subsections (6) and (6B), on the reduction day, the approved ex-manufacturer price of the existing brand of the combination item is taken to be reduced in accordance with a method prescribed by the regulations.
- (3) Different methods may be prescribed by the regulations for different classes of combination items.
- (4) Subsection (3) does not limit subsection 33(3A) of the *Acts Interpretation Act 1901*.
- (5) Subject to subsection (6), if the approved ex-manufacturer price of the existing brand of the combination item is reduced under subsection (2), then, on the reduction day, the claimed price (if any) of the existing brand of the combination item is taken to be reduced by a percentage equal to the percentage by which the approved ex-manufacturer price of the existing brand of the combination item is reduced under subsection (2).

Ministerial discretion not to apply, or to reduce, statutory price reduction

- (6) In relation to the existing brand of the combination item, the Minister may, by notifiable instrument, determine that:
 - (a) the approved ex-manufacturer price, and (if applicable) the claimed price, is not to be reduced under subsection (2) or (5), as the case requires, in relation to a particular reduction day; or
 - (b) the approved ex-manufacturer price, and (if applicable) the claimed price, is to be reduced by a lower percentage than would otherwise apply under subsection (2) or (5), as the case requires, in relation to a particular reduction day.
- (6A) In making a determination under subsection (6):
 - (a) the Minister must take into account what the approved ex-manufacturer price, and (if applicable) the claimed price, of the existing brand of the combination item would otherwise be under this section in relation to the particular reduction day if a determination were not made; and
 - (b) the Minister may take into account:
 - (i) any advice given to the Minister under subsection 101(4AC) in relation to the combination item; and
 - (ii) any other matter the Minister thinks is relevant.
- (6B) If the Minister makes a determination under subsection (6), the approved ex-manufacturer price of the existing brand of the combination item is not to be further reduced under this section on any reduction day that occurs after the reduction day specified in the determination made under subsection (6).

Section does not limit Minister's powers

- (6C) This section does not limit the Minister's powers, on or after the reduction day, to make:
 - (a) further price agreements; or
 - (b) determinations under section 85B;for the existing brand of the combination item.

Modified meaning of the same manner of administration

- (7) For the purposes of this section, the existing brand of the combination item has the same manner of administration as a pharmaceutical item that is not a combination item (the ***non-combination item***) if the manner of administration set out in a determination under subsection 85(5) for the combination item, to the extent that the manner of administration relates to the common drug, is the same as the manner of administration set out in a determination under subsection 85(5) for the non-combination item.

Section does not limit Minister's powers

- (13) This section does not limit the Minister's powers, after the reduction day, to make further price agreements or determinations under section 85B in relation to the existing brand of the combination item.

5. New presentation (5 – 10 years)

99ACBA Ministerial determination—brand of pharmaceutical item that is not a combination item is not a new brand

- (1) If:
 - (a) a brand of a pharmaceutical item (the *trigger item*) is not a combination item; and
 - (b) the brand of the trigger item:
 - (i) is not a listed brand of the trigger item; and
 - (ii) is a new presentation of an existing listed brand of a pharmaceutical item; and
 - (c) the Minister is satisfied that the determination day in relation to the brand of the trigger item is to be after the fifth anniversary, and before the tenth anniversary, of the drug in the pharmaceutical item being on F1;the Minister may determine, by notifiable instrument, that the brand of the trigger item is not a new brand for the purposes of section 99ACB.
- (2) If the Minister makes a determination under this section in relation to the brand of the trigger item, it must be made before the determination day in relation to the brand of the trigger item.
- (3) In making a determination, the Minister may have regard to:
 - (a) any advice given by the Pharmaceutical Benefits Advisory Committee; and
 - (b) any information provided by the Responsible Person for the brand of the trigger item; and
 - (c) any other matter that the Minister considers relevant.
- (4) A determination made under this section ceases to have effect on whichever is the earliest of the following:
 - (a) the day that another brand of the pharmaceutical item becomes a listed brand;
 - (b) the day that the drug in the pharmaceutical item does not satisfy all of the criteria for F1;
 - (c) the tenth anniversary of the drug in the pharmaceutical item being on F1.
- (5) In this section:

determination day has the same meaning as in paragraph 99ACB(1)(a).

99ACEA Ministerial determination—brand of pharmaceutical item that is a combination item is not a new brand

- (1) If:
 - (a) a brand of a pharmaceutical item (the *trigger combination item*) is a combination item; and
 - (b) the brand of the trigger combination item is a new presentation of an existing listed brand of a pharmaceutical item; and
 - (c) a declaration under subsection 85(2) is in force in relation to the drug in the pharmaceutical item; and
 - (d) the Minister is satisfied that the determination day in relation to the brand of the trigger combination item is after the fifth anniversary, and before the tenth anniversary, of the declaration under subsection 85(2) being made;

the Minister may determine, by notifiable instrument, that the brand of the trigger combination item is not a new brand for the purposes of section 99ACD.

- (2) If the Minister makes a determination under this section in relation to the brand of the trigger combination item, it must be made before the determination day in relation to the brand of the trigger combination item.
- (3) In making a determination, the Minister may have regard to:
 - (a) any advice given by the Pharmaceutical Benefits Advisory Committee; and
 - (b) any information provided by the Responsible Person for the brand of the trigger combination item; and
 - (c) any other matter that the Minister considers relevant.
- (4) A determination made under this section ceases to have effect on whichever is the earliest of the following:
 - (a) the tenth anniversary of the declaration under subsection 85(2) being made;
 - (b) the day that the drug is on F2.
- (5) In this section:

determination day has the same meaning as in paragraph 99ACD(1)(a).

APPENDIX 3: Excerpts from the Strategic Agreement with Medicines Australia

9. Statutory Price Reductions

9.1 Outline

- 9.1.1 As at the date of this Agreement, Division 3A of Part VII of the Act provides for Statutory Price Reductions.
- 9.1.2 The parties agree that the Commonwealth will seek amendments to the Act¹³ to commence from 1 July 2022 to:
- (a) continue or modify (or both) Statutory Price Reductions on the basis set out in clauses 9.2, 9.3 and 9.4.1;
 - (b) reflect the arrangements set out in clauses 9.5 and 9.6; 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 9.

9.2 Amendments to Statutory Price Reductions

- 9.2.1 The percentage reductions for the Statutory Price Reductions in Table 2 that applied prior to this Agreement will be modified as per the new percentage under this Agreement set out in Table 2 and will apply on the corresponding reduction days specified in Table 2 during the Term.
- 9.2.2 The Statutory Price Reduction mechanisms described in this clause will apply until the end of the Term.

Table 2: Amendments to SPRs

Section	Description	Percentage prior to this Agreement ¹⁴	New percentage under this Agreement	Reduction day(s)
99ACHA	One off price reduction on 5 th 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 10 th anniversary of drug being a Listed Drug	10%	5%	1 April 2023 1 April 2024 1 April 2025 1 April 2026 1 April 2027

¹³ If necessary, amendments may also be sought to the *National Health Amendment (Pharmaceutical Benefits—Budget and Other Measures) Act 2018* (Cth).

¹⁴ 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.

Section	Description	Percentage prior to this Agreement ¹⁴	New percentage under this Agreement	Reduction day(s)
99ACK	One off price reduction on 15 th anniversary 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 15 th 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 ¹⁵ ,	The listing of the first new brand

9.3 Catch-up reductions

- 9.3.1 On 1 April 2023, a catch-up reduction of 5% will apply to Listed Brands that have a Listed Drug that has had its 10th anniversary of listing on the PBS between 1 May 2021 and 1 April 2022.
- 9.3.2 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%.¹⁶ Examples of the catch-up percentages are set out in the Table at Appendix 1.
- 9.3.3 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.

9.4 Cap on Statutory Price Reductions

- 9.4.1 Without limiting clauses 9.4.2 or 9.5.2 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.

¹⁵ 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 9.4.

¹⁶ 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.

9.4.2 Without limiting clause 9.5.2 or the Minister’s discretion under the Act, the Commonwealth will continue its existing policy¹⁷ 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% 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.

9.4.3 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.¹⁸

9.5 Price reduction mechanism

9.5.1 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.

9.5.2 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

¹⁷ 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.

¹⁸ The detailed statement will address the matters set out in footnote 17 above, as updated under this Agreement.

Responsible Person for the Existing Brand to enter into a new price agreement under section 85AD of the Act. 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.

- 9.5.3 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.

9.6 Ministerial discretion

- 9.6.1 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 9, 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 9.5. 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.
- 9.6.2 The Minister will continue to exercise the discretions to reduce or not apply Statutory Price Reductions having regard to the Ministerial Discretion Guidance Material (as updated from time to time in consultation with relevant stakeholders, including Medicines Australia).

9.7 Clarification in respect of arrangements

- 9.7.1 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.
- 9.7.2 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.

APPENDIX 4: Excerpts from the *National Health (Pharmaceutical Benefits) Amendment (2021 Measures No. 1) Regulations 2021 (Cth)*

65A Price reductions for single brands of combination items

- (1) This section sets out, for the purposes of subsection 99ACC(2) of the Act, the method for calculating the reduced approved ex-manufacturer price of a single brand of a combination item on the reduction day mentioned in that subsection.
- (2) The reduced approved ex-manufacturer price of the brand of the combination item is the amount worked out by the following formula:

$$\text{reduction day component AEMPs} \times \frac{\text{day before combination item AEMP}}{\text{day before component AEMPs}}$$

where:

day before combination item AEMP means the approved ex-manufacturer price of the brand of the combination item on the day before the reduction day.

day before component AEMPs means the sum of:

- (a) the approved ex-manufacturer prices, on the day before the reduction day, of any one brand of each of the listed component items, adjusted in accordance with subsection (3); and
- (b) if the combination item includes one or more component drugs that are not listed component drugs—the non-listed component price.

listed component item, for each listed component drug contained in the combination item, means the pharmaceutical item that has:

- (a) the listed component drug; and
- (b) the same manner of administration as the combination item as referred to in subsection 99ACC(7) of the Act; and
- (c) subject to subsection (4) of this section, the smallest difference in the total quantity or amount of the listed component drug contained in the quantity or number of units in the pricing quantity of any one brand of the pharmaceutical item compared to the total quantity or amount of the listed component drug in the pricing quantity of the brand of the combination item.

non-listed component price means the day before combination item AEMP reduced (but not below zero) by the day before component AEMPs.

reduction day component AEMPs means the sum of:

- (a) the approved ex-manufacturer prices, on the reduction day, of any one brand of each of the listed component items, adjusted in accordance with subsection (3); and
- (b) if the combination item includes one or more component drugs that are not listed component drugs—the non-listed component price multiplied by the differential reduction percentage.

differential reduction percentage means the difference between 100% and the percentage (or average percentage) by which the approved ex-manufacturer price of any one brand of each listed component item in the combination item has been reduced under a provision mentioned in subsection 99ACC(6) of the Act on the reduction day.

- (3) For the purposes of the definition of *day before component AEMPs* in subsection (2), adjust the approved ex-manufacturer price of a brand of a listed component item so that the value attributed to the listed component drug in the combination item reflects:
 - (a) any difference in quantity or amount; and
 - (b) any difference in pricing quantity;
 of the listed component drug in the listed component item.
- (4) For the purposes of paragraph (c) of the definition of *listed component item* in subsection (2), if there is more than one pharmaceutical item that has the smallest difference as referred to in that paragraph, the pharmaceutical item that results in the largest reduction under this section to the approved ex-manufacturer price of the brand of the combination item is taken to be the listed component item for the purposes of this section.

85A Flow on price reductions for brands of combination items

- (1) This section sets out, for the purposes of subsection 99ADHB(2) of the Act, the method for calculating the reduced approved ex-manufacturer price of an existing brand of a combination item on the reduction day mentioned in that subsection.
- (2) The reduced approved ex-manufacturer price of the brand of the combination item is the amount worked out by the following formula:

$$\text{reduction day component AEMPs} \times \frac{\text{day before combination item AEMP}}{\text{day before component AEMPs}}$$

where:

component drug, in relation to a drug in a combination item, means a drug or medicinal preparation that is contained in that drug.

day before combination item AEMP means the approved ex-manufacturer price of the brand of the combination item on the day before the reduction day.

day before component AEMPs means the sum of:

- (a) the approved ex-manufacturer prices, on the day before the reduction day, of any one brand of each of the listed component items, adjusted in accordance with subsection (3); and
- (b) if the combination item includes one or more component drugs that are not listed component drugs—the non-listed component price.

listed component drug means a component drug in relation to which a declaration under subsection 85(2) is in force.

listed component item, for each listed component drug that is in the combination item and in a non-combination item as mentioned in paragraph 99ADHB(1)(d) of the Act, means the pharmaceutical item that has:

- (a) the same listed component drug as the non-combination item; and
- (b) the same manner of administration as the combination item as referred to in subsection 99ADHB(7) of the Act; and
- (c) subject to subsection (4) of this section, the smallest difference in the total quantity or amount of the listed component drug contained in the quantity or number of units in the pricing quantity of any one brand of the pharmaceutical item compared

to the total quantity or amount of the listed component drug in the pricing quantity of the brand of the combination item.

non-listed component price means the day before combination item AEMP reduced (but not below zero) by the day before component AEMPs.

reduction day component AEMPs means the sum of:

- (a) the approved ex-manufacturer prices, on the reduction day, of any one brand of each of the listed component items, adjusted in accordance with subsection (3); and
- (b) if the combination item includes one or more component drugs that are not listed component drugs—the non-listed component price multiplied by the differential reduction percentage.

differential reduction percentage means the difference between 100% and the percentage (or average percentage) by which the approved ex-manufacturer price of any one brand of each listed component item in the combination item has been reduced under a provision in Division 3A of Part VII of the Act on the reduction day.

- (3) For the purposes of the definition of ***day before component AEMPs*** in subsection (2), adjust the approved ex-manufacturer price of a brand of a listed component item so that the value attributed to the listed component drug in the combination item reflects:
 - (a) any difference in quantity or amount; and
 - (b) any difference in pricing quantity;of the listed component drug in the listed component item.
- (4) For the purposes of paragraph (c) of the definition of ***listed component item*** in subsection (2), if there is more than one pharmaceutical item that has the smallest difference as referred to in that paragraph, the pharmaceutical item that results in the largest reduction under this section to the approved ex-manufacturer price of any one brand of the combination item is taken to be the listed component item for the purposes of this section.