

INTRODUCTION

The 2007 legislative reforms introduced statutory price reductions (SPRs) (in sections 99ACB and 99ACD of the *National Health Act 1953* ('the Act')) to apply when the first bioequivalent or biosimilar brand listed on the Pharmaceutical Benefits Scheme (PBS).

Amendments to these provisions in 2018, arising out of a Strategic Agreement with Medicines Australia, allow a more flexible application of new brand SPRs, including through the introduction of instances of Ministerial discretion. The Act now provides an avenue for Sponsors¹ of drugs listed on the F1 formulary to list "new presentations" of existing listed PBS medicines in certain circumstances without being required to offer a lower price and triggering an SPR.

The new provisions are intended to enable Sponsors of F1 listed medicines to list new presentations of those medicines, subject to certain conditions, without necessarily triggering an SPR. Where the Minister has discretion not to apply an SPR, the exercise of that power is likely to take into account that the Government intends to encourage user-friendly presentations that support better health outcomes and/or quality of life, which might not be available when a medicine is first added to the PBS.

An extract from the legislation is at Appendix 1.

An extract from the Strategic Agreement with Medicines Australia, is at Appendix 2.

What is a "new presentation"?

The new provisions are intended to encourage innovation that contributes to better outcomes for patients. The Government does not intend to incentivise new formulations of existing drugs which will simply delay or reduce brand competition.

New presentations² of existing brands of pharmaceutical items include, for example:

- (a) a medicine presented as an auto-injector instead of the existing presentation which consists of a vial and a syringe;
- (b) a medicine which is presented as an effervescent tablet instead of the existing presentation which is a capsule; and
- (c) a medicine which is presented in an inhaler device that does not need to be primed before each dose, compared to an inhaler device that needs to be primed before each dose.

Changes to medicines which do not amount to new presentations include, for example, new flavours, shapes or colours.

¹ 'Sponsor' has the same meaning in this guidance material as Responsible Person. The term 'Sponsor' is used to align with the Pharmaceutical Benefits Advisory Committee Guidelines.

² The new presentations to which this guideline applies are presentations that can be considered bioequivalent to a currently listed pharmaceutical item for the purposes of the *National Health Act 1953*. See also Section 4.1 of the Procedure guidance for listing medicines on the Pharmaceutical Benefits Scheme for information on the evidence required for different types of new listing applications. <http://www.pbs.gov.au/industry/listing/procedure-guidance/files/procedure-guidance-listing-medicines-on-the-pbs.pdf>

The Minister's powers to make determinations to include new forms (under section 85(3)) or brands (under section 85(6)) and to agree prices (under section 85AB) are currently delegated to specified Departmental officers.

Whether a new pharmaceutical item is a new presentation of an existing item is a matter that will be considered by the Department before, or in conjunction with, the decision whether to agree the price and to determine the form and brand of the new item.

HOW TO APPLY FOR LISTING

Step 1 - You must make a submission to the PBAC to list the new pharmaceutical item and follow the processes for listing as set out in the PBAC Guidelines.

Step 2 - This will depend on how long the *drug* in the existing listed brand has been listed on the PBS, and the date on which the Sponsor proposes the new pharmaceutical item be added to the PBS.

Noting that Sponsors listing new presentations can only avoid an SPR if the new listing occurs within a specified time period after the date the existing drug was declared to be a pharmaceutical benefit, Sponsors are encouraged to apply sufficiently in advance of the proposed listing date.

A. If the proposed listing date is within 5 years of the drug being listed on the PBS then:

- The Sponsor must make a separate application to the Department asking that the Department recognise the new item as a new presentation.

The information in that application should include:

- a) the date that the drug in the pharmaceutical item was first PBS listed;
- b) a statement that the company is the Sponsor for both the existing listed item and the new item; and
- c) an explanation, and evidence (if applicable), as to why the new item is a new presentation.

Sponsors must send the application to PBSSPR@health.gov.au at the same time as the submission to PBAC.

What next?

If the item is a new presentation:

- The Sponsor will be notified within three weeks of the conclusion of the PBAC meeting.
- The new item and the existing item will both remain in F1 until the drug no longer meets the F1 criteria.
- Sponsors must make a formal price offer with the same Approved Ex Manufacturer Price (AEMP) as the existing listed item to proceed with the new listing.

If the item is not a new presentation:

- The Department will notify the Sponsor within three weeks of the conclusion of the PBAC meeting of why the new item is not a new presentation within the meaning of the Act.
- Sponsors will be given an opportunity to provide further information to the Department before a final assessment is made.

- If the item is not a new presentation, the listing can only proceed if the Sponsor offers a lower price in accordance with sections 99ACB and 99ACD of the Act.

B. If the proposed listing date is between 5 to 10 years after the drug was listed on the PBS:

- Sponsors must ask:
 - (1) the Department to recognise the new item as a new presentation; and
 - (2) the Minister to exercise the discretion not to apply the SPR and not to move the drug from F1 to F2.

The information in the application to the Department and Minister should include:

- a) the date that the drug in the pharmaceutical item was first PBS listed;
- b) a statement that the company is the Sponsor for both the existing listed brand and the new item;
- c) an explanation, and evidence (if applicable) as to why the new item is a new presentation; and
- d) an explanation as to why the Ministerial discretion should be exercised, setting out any matters that the Sponsor considers are relevant to the decision.

Sponsors must send this application to PBSSPR@health.gov.au at the same time as submitting an application to the PBAC.

Please note that even if a new item is a new presentation, the Minister still has to consider whether or not to trigger the SPR and move the drug to F2.

What next?

If the item is a new presentation, it will then be assessed for Ministerial discretion.

If the item is not a new presentation:

- The Department will notify the Sponsor within three weeks of the conclusion of the PBAC meeting of why the new item is not a new presentation within the meaning of the Act.
- Sponsors will be given an opportunity to provide further information to the Department before a final assessment is made.
- If the item is not a new presentation, the listing can only proceed if the Sponsor offers a lower price in accordance with sections 99ACB and 99ACD of the Act.

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

The Act states that the Minister may consider:

- a) Any advice given by the PBAC;
- b) Any information provided by the Sponsor; and
- c) Any other matter the Minister considers relevant.

Some (but not all) of the other matters that the Minister considers relevant may include:

- the pricing history of the medicine;
- clinical aspects, including but not limited to whether the medicine is clinically needed on the PBS and whether the new presentation provides advantages for patients;

- the potential impact of the listing on future brand competition (and therefore PBS expenditure) in relation to the drug; and
- other financial impacts on the PBS if the discretion is exercised.

What next?

If the Minister decides to exercise the discretion not to apply the SPR:

- (a) The Department will notify the Sponsor of the decision within six³ weeks of the conclusion of the PBAC meeting.
- (b) The Sponsor will need to make a formal price offer with the same AEMP as the existing listing for the new listing to proceed.
- (c) The Minister (or delegate) will include the brand of pharmaceutical item in a Notifiable Instrument published on the Federal Register of Legislation and the drug will remain in F1 until whichever of the following events occurs first:
 - A new brand of the same pharmaceutical item is listed by a different Sponsor;
 - The drug in the pharmaceutical item no longer satisfies the F1 criteria; or
 - The tenth anniversary of the drug in the pharmaceutical item being on F1 is reached.
 If one of these events occur, the drug will move from F1 to F2 and the applicable SPR will apply.

If the indicative Ministerial decision is not to exercise the discretion:

- (d) The Department will notify the Sponsor of the outcome of its request for Ministerial discretion, and brief reasons why the Minister is not inclined to exercise the discretion, within six weeks⁴ of the publication of the PBAC outcomes.
- (e) Sponsors will be given an opportunity to provide further information to the Department before the Minister makes a final decision about whether to exercise the discretion.
- (f) If the Minister's final decision is not to exercise the discretion, the listing can only proceed if the Sponsor offers a lower price in accordance with sections 99ACB and 99ACD of the Act.

C. If it is after 10 years of the existing drug listing on the PBS:

- No exemptions apply. The Sponsor will need to offer a lower AEMP in accordance with sections 99ACB and 99ACD of the Act and the new item will cause the drug to be moved to F2 and the SPR to apply.

³ Noting this may be longer if (a) the Department's initial assessment is that the new item is not a new presentation, but that assessment is changed after the Sponsor provides further information or (b) the Minister elects to exercise the discretion personally.

⁴ Noting that this may be longer if the Minister elects to exercise the discretion personally.

Appendix 1 - LEGISLATION

The Act sets out the legislative basis for the Minister's discretionary power.

99ACB 16% price reduction for new 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% or 16% 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% or 16% 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% or 16% administrative price reduction has applied.
- (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 (1);
 - (ii) subsection 99ACF(1) or (2) because of item 1 of the table in section 99ACF;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), subsection (1) is taken not to have applied in relation to a brand of a pharmaceutical item in some cases: see section 99AEI.

- (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.

...

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).

99ACD 16% price reduction for new 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% or 16% 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% or 16% 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% or 16% administrative price reduction has applied.
- (2) This section does not apply in relation to the new brand of the trigger combination item if subsection (1) or section 99ACE 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, subsection (1) is taken not to have applied in relation to a brand of a pharmaceutical item in some cases: see section 99AEI.

- (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.

...

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).

5. Savings measures from new price policies

5.1 F1 Statutory Price Reductions

- 5.1.1 The Commonwealth will seek amendments to the act to:
- (a) extend the current one-off 5 per cent Statutory Price Reduction that applies to brands of pharmaceutical items on the F1 formulary once the drug has been listed on the PBS for 5 years, to include new reduction dates on 1 April 2021 and 1 April 2022;
 - (b) apply a further one-off Statutory Price Reduction of 10 per cent to brands of pharmaceutical items on the F1 formulary once the drug has been listed on the PBS for at least 10 years; and
 - (c) apply an additional one-off 5 per cent Statutory Price Reduction to brands of pharmaceutical items on the F1 formulary once the drug has been listed on the PBS for at least 15 years.
- 5.1.2 The one-off 10 per cent Statutory Price Reductions described in clause 1.1.1(b) are intended to initially apply on 1 June 2018 (and will be applied on each subsequent 1 April up to and including 1 April 2021) to each brand of pharmaceutical item with a drug on the F1 formulary once the drug has been listed on the PBS for 10 years on or prior to that reduction day.
- 5.1.3 The additional one-off 5 per cent Statutory Price Reductions described in clause 1.1.1(c) are intended to initially apply on 1 June 2018 (and will be applied on each subsequent 1 April up to and including 1 April 2021) to each brand of pharmaceutical item with a drug on the F1 formulary once the drug has been listed on the PBS for 15 years on or prior to that reduction day.
- 5.1.4 The intent of clauses 1.1.1(b) and 1.1.1(c) is that brands of pharmaceutical items that have been listed on the PBS for fifteen years or more as of 1 June 2018 will receive a one-off 10 per cent Statutory Price Reduction followed by a one-off 5 per cent Statutory Price Reduction on the same day.

5.2 Price reductions applicable at the entry of first new brand of a pharmaceutical item

The Commonwealth will seek amendments to the act to increase, from 16 per cent to 25 per cent, the Statutory Price Reduction applicable at the entry of the first new brand of a pharmaceutical item (**First New Brand**). The amendments to the Act described in this clause 5.2 are intended to commence on 1 October 2018, and will apply until the end of the Term. Following the end of the Term, the Statutory Price Reduction applying due to the entry of the First New Brand will revert to 16%.

5.3 Effective prices

- 5.3.1 Only reductions in the effective price of a medicine will be calculated for the purpose of the process described in clause 5.8.
- 5.3.2 This means that for the purpose of determining eligibility for discretion to not apply a Statutory Price Reduction (or to reduce a Statutory Price Reduction), a change in the published price that does not impact the effective price is not included.

5.4 Indications

- 5.4.1 Where drugs in brands of pharmaceutical item have received amended listings (for example, listing of new indications) following their first listing and remain in the F1 formulary, any 5 per cent (whether at 5 years or 15 years since listing on the PBS) or 10 per cent Price Reductions will continue to be calculated from the date on which the drug in that brand of pharmaceutical item was first listed on the PBS. The 5 per cent or 10 per cent Price Reductions will be applied to the price of the brands of pharmaceutical item as at the relevant reduction day when the drug has been listed on the PBS for 5 or 10 or 15 years and is on the F1 formulary, as applicable.
- 5.4.2 Where a new indication is added that results in the introduction of a weighted price for the drug, or a reduction in weighted price, this reduction will be excluded for the purposes of determining eligibility for the discretion to not apply Statutory Price Reductions described in clause 5.8.

5.5 Reference pricing of 5% or 10% Statutory Price Reductions

- 5.5.1 Where a 5 per cent (whether at 5 years or 15 years since listing on the PBS) or 10 per cent Statutory Price Reduction has been applied to a brand of pharmaceutical item containing a drug (**Reduced Drug**), pharmaceutical items containing other drugs which may be linked to the Reduced Drug for pricing purposes will not be reference priced against the Reduced Drug in respect of the 5 per cent or 10 per cent Statutory Price Reduction for the Reduced Drug.
- 5.5.2 Clause 5.5.1 does not prevent the application of other reference pricing changes to the Reduced Drug and other related drugs that are not related to a F1 Statutory Price Reduction.

5.6 Combination items

- 5.6.1 Where a drug on the single brand combination drug list has a component drug that is not PBS listed, the applicable F1 Statutory Price Reduction will be applied to that component drug on the same day it would have otherwise applied had the component drug been listed on the PBS on the same day as the combination item (for 5 years, 10 years or 15 years, as applicable).
- 5.6.2 Clause 5.5.1 does not prevent F1 Statutory Price Reductions being applied to component drugs being flowed on to combination items on the single brand combination drugs list.
- 5.6.3 For the purposes of clause 5.8, flow on price reductions to combination items will be accounted for in the discretion applied at the time of anniversary Statutory Price Reductions and when a new combination brand lists.

5.7 F1 price reductions effect on new listings

- 5.7.1 Subject to the remainder of this clause 5.7, new listing applications can request a price adjustment where:
- (a) The new drug will be listed on the PBS in F1; or
 - (b) The drug in F1 has its listing on the PBS extended to a new consumer population or with changes in its PBS restriction,
- on a cost-minimisation basis, by comparison with a medicine on the F1 formulary that has already taken a 5 per cent (whether at 5 or 15 years since listing) or 10 per cent Statutory Price Reduction (**Existing Items**).

- 5.7.2 At the request of the applicant, the listing medicine will not have the 5 per cent or 10 per cent Statutory Price Reduction which has been applied to the existing items used to calculate the listing medicine's price when it:
- (a) is listed on the PBS; or
 - (b) has its listing on the PBS extended.
- 5.7.3 The processes described in clauses 5.7.1 and 5.7.2 are not intended to limit the requirement in the Act that the Minister must agree or determine the price at which a drug in F1 is listed on the PBS or has its listing on the PBS extended.
- 5.7.4 The processes described in clauses 5.7.1 and 5.7.2 are intended to only apply where the PBAC determined comparator is in F1 and has been subject to either of the 5 per cent Statutory Price Reductions (whether at 5 years and/or at 15 years since listing) or a 10 per cent Statutory Price Reduction. The PBAC will continue to consider medicines against the appropriate comparator in accordance with PBAC guidelines and regardless of the comparator's formulary.
- 5.7.5 Where a medicine's listing price has been agreed or determined in accordance with the processes described in clauses 5.7.1 and 5.7.2, it is the intention that such medicines will be subject to an administrative Price Reduction at the end of the Term. The Price Reduction of the medicine at the end of the Term will be equivalent to the percentage by which the PBS listing price, or extended listing price, of that medicine exceeded the Existing Item's price at the time of the medicine's listing on the PBS, or extension of listing on the PBS, except that any Price Reduction of the medicine at the end of the Term should be reduced to reflect any Statutory Price Reductions in respect of the medicine that occurred during the Term.
- 5.7.6 The process for, and basis upon which, the Price Reduction described in clause 5.7.5 will be achieved will be agreed between the Commonwealth and the relevant responsible person at the time of the listing, or extension of the listing, of the medicine. This may include the Minister requiring the relevant responsible person to enter into a deed of agreement with the Commonwealth to achieve this outcome, which should include how price reductions taken during the term of the deed of agreement will be managed at the end of the Term.

5.8 Discretion to apply Statutory Price Reductions

- 5.8.1 The amendments to the Act described in clause 5.8.3 are intended to allow the Minister the discretion to not apply a Statutory Price Reduction (or to reduce a Statutory Price Reduction) where a medicine has already been subject to disproportionately large price decline since listing.
- 5.8.2 Without limiting the Minister's discretion under the Act, the intention is that the medicines described in clause 5.8.3:
- (a) that have already taken a price reduction since 1 January 2016 (**Start Date**) that is less than the full applicable Statutory Price Reduction, will not be subject to the full Statutory Price Reductions and will only be subject to partial Statutory Price Reductions calculated by subtracting the earlier Price Reductions (expressed in dollars) from the applicable Statutory Price Reduction (expressed in dollars); or
 - (b) that have already had a larger Price Reduction since the Start Date (expressed in dollars) than would arise under the applicable Statutory Price Reduction

(expressed in dollars) will not be subject to the applicable Statutory Price Reduction.

- 5.8.3 The Commonwealth will seek amendments to the Act to allow the Minister the discretion to not apply a Statutory Price Reduction, or to apply a lower Statutory Price Reduction, in circumstances where brands of pharmaceutical items have since the Start Date:
- (a) already taken a Price Reduction as a result of the application of the Reference Pricing Policy;
 - (b) triggered a reduction under the Reference Pricing Policy resulting in a Price Reduction for other medicines; or
 - (c) already taken an administrative price reduction as a result of the application of existing pricing policies.
- 5.8.4 At the time of the application of the Statutory Price Reduction applicable at the 5, 10 or 15 year anniversary since listing, the calculation will be the Statutory Price Reduction level minus the total price reductions taken prior to that anniversary. If the total price reductions are greater than the Statutory Price Reduction otherwise due, the relevant Statutory Price Reduction will not occur.
- 5.8.5 At the time of the application of the Statutory Price Reduction arising due to the entry of the First New Brand as defined in clause 5.2 (**Relevant Reduction**), previous Price Reductions for the medicine will be taken into account as follows:
- (a) If the previous Price Reductions are equivalent to 40 per cent or more of the original price of the medicine, the Relevant Reduction will not occur;
 - (b) If the previous Price Reductions are equivalent to between 15 and 40 per cent of the original price of the medicine, the Relevant Reduction is to be calculated as a dollar figure equal to 40 per cent of the original price of the medicine less the total Price Reductions, expressed in dollars, in relation to that medicine since listing such that the overall reduction does not exceed 40 per cent of the original price of the medicine; and
 - (c) If the previous Price Reductions are equivalent to 15 per cent or less of the original price of the medicine, then the Relevant Reduction will still be the full 25 per cent Statutory Price Reduction.

5.9 New presentations

- 5.9.1 The Commonwealth will seek amendments to the Act⁵ so that for drugs on the F1 formulary, where the same responsible person lists a new presentation of the drug:
- (a) Prior to, or on, the fifth anniversary of listing, the new presentation will not be defined as a 'new brand' for the purposes of sections 99ACB or 99ACD of the Act;
 - (b) From the fifth anniversary to the tenth anniversary of listing, the new presentation may, at the discretion of the minister, be defined as a 'new brand' for the purposes of sections 99ACB or 99ACD of the Act, as applicable; and
 - (c) On and from the tenth anniversary of the listing, this new presentation will be a 'new brand' for the purposes of sections 99ACB or 99ACD of the Act, as applicable.

⁵ The parties acknowledge that the arrangements described in this clause 5.9 may be implemented in the Act without changes being made to the sections of the Act specified in this clause 5.9.

- 5.9.2 In exercising the discretion referred to in clause 5.9.1(b), the minister may rely on advice from the PBAC and other relevant considerations including provision of required information from the responsible person.

5.10 Clarification in respect of arrangements

Nothing in this clause 5 is intended to limit:

- 5.10.1 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;
- 5.10.2 The operation of Departmental processes that enable responsible persons to seek increases or decreases in the price of medicines; or
- 5.10.3 The operation of Departmental processes that enable responsible persons to apply for exemption from reductions in the price of pharmaceutical items resulting from the application of Statutory Price Reductions. For the avoidance of doubt, the Department will continue to consider exemption applications from responsible persons, for example where the viability of continued supply may be compromised by price reductions.