Australian Government

Strategic Agreement

Commonwealth of Australia
and

Medicines Australia Limited
ACN 126 990 001

Contents

Strategic Agreement

Dated 2017

Parties

Name	**The Honourable Greg Hunt MP Minister For Health and Minister For Sport** on behalf of the **Commonwealth of Australia**
Short name	**Commonwealth**

Name	**Medicines Australia Limited ACN 126 990 001**
Address	Level 1, 16 Napier Close, Deakin in the Australian Capital Territory
Short name	**Medicines Australia**

Background

A. The innovator medicines sector provides medicines that are an essential component of the Pharmaceutical Benefits Scheme and both parties are committed to a viable innovator medicines sector in Australia.

B. The Commonwealth and Medicines Australia have a common interest in:

B.1 ongoing, timely and reliable access for Australians to new, innovative medicines that provide clinical benefits to the population;

B.2 a sustainable PBS that can meet the current and future needs of Australians; and

B.3 maintaining a responsible and viable medicines industry.

C. The PBS Medicines Package 2017 (**Package**) is intended to support the National Medicines Policy and appropriately balance the need to:

C.1 ensure patients can continue to have timely access to PBS subsidised medicines that are necessary to improve the health of the community;

C.2 promote and improve the quality use of medicines;

C.3 ensure a cost effective and sustainable PBS; and

C.4 support the viability of the sectors that support the PBS, including the innovator medicines sector.

D. The parties acknowledge:

D.1 the PBS reforms that were part of the 2015 PBS Access and Sustainability Package (including those given effect through the *National Health Amendment (Pharmaceutical Benefits) Act 2015* (Cth)), which have brought about (or are in the

process of bringing about) estimated gross PBS savings of $6.6 billion over 5 years; and

D.2 that the additional PBS reforms comprising the Package (as described in this Agreement) are further measures directed at PBS access and sustainability.

E. In entering this Agreement, the parties:

E.1 affirm the current fundamental architecture of the PBS, including separation of the F1 and F2 formularies under the Act; and

E.2 recognise that the purpose of the PBS reforms described in paragraph D is to ensure the predictability, timeliness and stability of the PBS in relation to innovative medicines.

1. Definitions and interpretation

1.1 In this Agreement, unless the contrary intention appears:

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

Agreement means this Strategic Agreement.

AMWG means the Access to Medicines Working Group.

Bill means the National Health Amendment (Pharmaceutical Benefits) Bill 2017 or such other bill(s) that will bring about the legislative changes required to implement the Package.

Business Day means a day other than:

(a) a Saturday, Sunday or public holiday in the Australian Capital Territory; and

(b) a day during the Department's shutdown period between Christmas Day and New Year's Day.

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

Exempt Price Reduction means a price reduction occurring where:

(a) a weighted price has been ascribed to, or there is a change in the weighted price of, a brand of pharmaceutical item following an amendment to the listing of the pharmaceutical item (including additional or extended indication) that is a result of increased patient population; or

(b) there is no reduction in the effective price for a brand of pharmaceutical item due to the operation of a deed of agreement in place with the Commonwealth.

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

Joint Oversight Committee means the committee established under clause 11.2.

Minister means the Minister who administers the Act.

Package has the meaning given in paragraph C of the Background and summarised in clause 4.2.

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

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

Price Reduction means a reduction to the approved ex-manufacturer price for a brand of pharmaceutical item listed on the Schedule (including Statutory Price Reductions or price reductions that occur administratively), other than Exempt Price Reductions.

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

Schedule means the Schedule of Pharmaceutical Benefits published by the Commonwealth from time to time in relation to the PBS.

Statutory Price Reduction means a reduction to the approved ex-manufacturer price for a brand of pharmaceutical item listed on the Schedule which is required to take effect due to the operation of the Act.

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

TGA means the Therapeutic Goods Administration that forms part of the Department.

1.2 In this Agreement, unless the contrary intention appears:

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

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

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

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

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

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

1.2.7 a reference to a 'person' includes an individual, a firm, a body corporate, a partnership, a joint venture, an unincorporated body or association, or any Government Agency; and

1.2.8 the words 'includes' or 'including' are not terms of limitation.

2. Term

2.1 Term of Agreement

Subject to clause 2.2, this Agreement commences on the date of this Agreement and expires on 30 June 2022.

2.2 Conditions precedent to commencement of Agreement

2.2.1 The measures contained in clause 5 and sub-clause 9.1 and any other measures that require amendments to the Act will not commence until the passage of the Bill through the Australian Parliament in a form that will enable the achievement of the Package, unless this condition is waived (in whole or in part) by the Commonwealth following consultation with Medicines Australia.

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

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

2.2.4 If the condition in clause 2.2.1 is not satisfied or waived in whole or in part, and the parties agree that it will not be able to be satisfied, this Agreement ceases except where the parties agree otherwise in writing.

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

3. Consultation

3.1 The Commonwealth will consult with relevant stakeholders, in particular Medicines Australia, so that this Agreement is implemented in a manner that supports the objectives of the National Medicines Policy while limiting unintended consequences, including through safeguards and exemptions as determined by the Commonwealth. Representatives of the Commonwealth will meet with Medicines Australia to undertake such consultations, including through the Joint Oversight Committee.

3.2 The Joint Oversight Committee (as further described in clause 11.2) will be established to enable the parties to manage and monitor the implementation of this Agreement.

3.3 The Commonwealth undertakes not to pursue during the Term any additional policies or measures aimed at generating medicine price based savings from the F1 or F2 formularies or related PBS changes that may impact on the innovative medicines sector without first consulting with Medicines Australia at the earliest opportunity in relation to the intended scope and impact of such future policies or measures.

3.4 Nothing in this Agreement obliges the Commonwealth to consult with Medicines Australia in relation to the pricing of individual medicines.

4. PBS Medicines Package 2017

4.1 The Package is a comprehensive set of interlinked initiatives, comprising both savings and investments, designed to support ongoing, timely and reliable consumer access to medicines and the financial sustainability of the PBS.

4.2 Particular reforms within the Package comprise:

4.2.1 changes to the price of medicines in the F1 formulary for the Term as described in clause 5 and summarised as follows:

(a) extending the current F1 formulary 5 per cent Statutory Price Reduction to include reduction dates in April 2021 and April 2022;

(b) from 1 June 2018, applying an additional 10 per cent Statutory Price Reduction to brands of pharmaceutical items with a drug on the F1 formulary that have been listed on the PBS for 10 years or more; and

(c) from 1 June 2018, applying an additional 5 per cent Statutory Price Reduction to brands of pharmaceutical items with a drug on the F1 formulary that have been listed on the PBS for 15 years or more;

4.2.2 from 1 October 2018, and for the duration of the Term, an increase in the Statutory Price Reduction applicable on PBS listing of the first new brand of a pharmaceutical item from 16 per cent to 25 per cent (as described in clause 5.2);

4.2.3 investment in a national consumer-centric electronic system that includes an electronic prescribing (e-Prescribing) system (as described in clause 7);

4.2.4 from 1 July 2017, and on a case-by-case basis for particular medicines, introducing biosimilar uptake drivers (as described in clause 8);

4.2.5 from 1 April 2018, introducing changes to price disclosure for drugs under certain conditions (as described in clause 9.1) to better ensure the sustainability of supply;

4.2.6 from 1 July 2017, the reserving of savings arising from this Agreement in the contingency reserve to be allocated to new and amended PBS listings of medicines (as described in clause 6); and

4.2.7 policy commitments from the Commonwealth contained in this Agreement to provide greater certainty in relation to important issues in pharmaceutical pricing and listing (as described in clauses 5, 9 and 10).

4.3 The measures in the Package are expected to represent gross savings to the Budget of approximately $1.8 billion over the five years of this Agreement (excluding implementation costs).

4.4 The parties acknowledge that certain measures in the Package are contingent upon the passage of the Bill through the Australian Parliament.

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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 5.1.1(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 5.1.1(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 5.1.1(b) and 5.1.1(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 the 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 items 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 Act[1] 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.

5.9.2 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

[1] 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.

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.

6. Future PBS listings funding

6.1 Reserved savings

6.1.1 The parties recognise that PBS expenditure is likely to grow as a result of new and amended listings and continuing growth in demand for access to medicines.

6.1.2 The Commonwealth will, as a part of this Agreement, record savings accrued from this Agreement in the contingency reserve to support investment in new and amended listings of medicines (including supply chain costs associated with the supply of these listings), in order to maintain the Commonwealth's commitment to list positive recommendations of the PBAC. These savings are not intended to limit, and should support, the Australian Government's commitment to implement all new and amended listings recommended by the PBAC.

6.1.3 The parties agree that the reserved savings will include savings arising from measures in this Agreement, and potential other savings determined by the Minister that are as yet unidentified (such as savings derived from reference pricing).

6.1.4 The allocation of savings generated by the measures described in this Agreement does not limit the ability for the Commonwealth to determine cost offsets from alternative sources or include additional funding in the savings reserved in the contingency reserve, irrespective of the remaining reserved savings.

6.2 Review of the reserved savings

6.2.1 It is intended that the reserved savings arising during the Term will be available to be drawn down from the contingency reserve at any time over the full Term for new and amended PBS listings.

6.2.2 The role of the Joint Oversight Committee in relation to the reserved savings will be to:

(a) review the costs of the PBS annual expenditure and variations to expenditure at least twice a year, with an aggregated overview of the extent to which the PBS reserved savings have been required; and

(b) review the effectiveness and sustainability of the reserved savings and explore opportunities for additional investments, re-investments and expansion of the amount of savings reserved after two years of operation, at 1 July 2019.

6.2.3 Prior to the end of the Term, the parties will review the reserved savings approach in the context of discussions regarding a new agreement.

7. e-Prescribing

7.1 The Commonwealth intends to implement enhancements to electronic systems for prescribing, dispensing and capturing data for PBS medicines, including the development of a national consumer-centric e-Prescribing system in consultation with relevant stakeholders including Medicines Australia.

7.2 Such e-Prescribing arrangements are intended to:

7.2.1 support consistent approaches across prescribing and dispensing software packages that produce default prescriptions by applying international non-proprietary names[2] (or a similar medicines naming methodology determined by the Minister), while still preserving prescriber choice;

7.2.2 improve PBS data analytic capabilities with expanded PBS core data elements, making provision where appropriate for sponsor access to relevant de-identified data in a timely manner directly from the available Departmental systems, subject to any legal requirements;

7.2.3 explore capacity in software for enhanced notification on shortages and deletions;

7.2.4 recognise the importance of pharmacovigilance principles and reporting, including the adoption of naming conventions and where needed, notifications to prescribers; and

7.2.5 improve real-time reporting, recording and monitoring of controlled drugs, including provision of relevant information to prescribers and dispensers by means of the national Electronic Recording and Reporting of Controlled Drugs system.

8. Biosimilar medicines

8.1 The Commonwealth intends to implement policy changes during the Term that will promote the greater use of biosimilar medicines in Australia, in consultation with relevant stakeholders including Medicines Australia.

8.2 Such changes are intended to apply to new PBS listings only, and should complement the existing education and awareness campaign and building prescriber confidence. The changes are intended to reflect the following three principles:

8.2.1 the greater use of biosimilars is beneficial for supporting access to clinically and cost effective medicines in Australia;

8.2.2 the policy approaches described in clause 8.3 below, which are intended as biosimilar uptake drivers, will be considered by the PBAC on a case by case basis, with regard to the evidence for, and context of the particular medicine and the clinical setting in which it will be used; and

8.2.3 that physicians will retain, in consultation with their patient, prescriber choice.

8.3 The parties acknowledge that the PBAC may, on a case by case basis when considering a biosimilar listing, recommend either or both of the following:

8.3.1 a different prescribing process for biosimilars and reference biologics through allowing a lower level of authority[3] to the biosimilar than exists for the reference biologic at the point of introduction of the biosimilar, which may be at commencement of therapy or continuation of therapy (or both); and

8.3.2 that for treatment naïve[4] patients only, the prescribing of the new biosimilar compared with the reference biologic is the preferred choice for these patients, which may be further reinforced in the prescribing software.

[2] As published by the World Health Organisation.
[3] 'authority' means the administrative arrangements that apply prior to prescribing certain PBS medicines.
[4] 'treatment naïve' means that the patient has not previously received this biologic molecule.

8.4 Nothing in this clause 8 is intended to:

8.4.1 remove or restrict physician choice;

8.4.2 change the conditions of listing for the existing reference biologic (or other existing biosimilars) at the time of new biosimilar listing;

8.4.3 change the functions of the PBAC; or

8.4.4 alter the equal opportunity for all sponsors to make applications for changes to their listing.

8.5 During the Term, the Joint Oversight Committee will assess the effectiveness of the measures described in clause 8.3 as biosimilar uptake drivers, the equitable application of these drivers, competitiveness, and the savings potential of biosimilars.

8.6 The Commonwealth will not implement additional measures directed at increasing biosimilar uptake during the Term without first:

8.6.1 consulting with Medicines Australia in accordance with clause 3.3; and

8.6.2 considering the outcome of any assessment undertaken by the Joint Oversight Committee under clause 8.5 as at that time.

9. Price certainty

9.1 Price disclosure reform

9.1.1 To ensure viability of medicines that have had originator brand data removed from price disclosure calculations, the Commonwealth will seek to amend the Act to increase the discounting threshold (after which a Price Reduction is applied) where a medicine has been subject to two price disclosure reduction days in respect of which originator brand data was excluded from the calculations. It is intended that the discounting threshold in these circumstances will increase from 10 per cent to 30 per cent.

9.1.2 Prices of medicines to which the 30 per cent discounting threshold applies will continue to be monitored by the Department through normal price disclosure data capture processes and the discounting threshold will revert to 10 per cent if a medicine has taken a reduction (with the 30 per cent discounting threshold) on two consecutive price disclosure reduction days.

9.2 Application of the Reference Pricing Policy

9.2.1 The Commonwealth will ensure that:

(a) where a reference pricing recommendation (following the application of the Reference Pricing Policy) lowers the price of a pharmaceutical item; and

(b) such a reference pricing decision results from a PBAC recommendation as to the price of another pharmaceutical item,

the notification of the intention to apply the Reference Pricing Policy will allow for no less than 20 Business Days for the responsible person for the impacted pharmaceutical item to respond to the initial request from the Department for a lower price offer.

9.2.2 The Commonwealth will consult with Medicines Australia during the Term to seek to implement measures aimed at increasing transparency, predictability and communication around the application of the Reference Pricing Policy.

9.3 Therapeutic groups

9.3.1 The Minister undertakes not to determine any new therapeutic groups under section 84AG of the Act during the Term.

9.3.2 The Commonwealth and Medicines Australia agree to work collaboratively during the Term to develop a new framework for potential therapeutic group formation, with an aim to:

a) set clear and transparent criteria for establishing therapeutic groups, including expert clinical advice through the PBAC, principles of pharmacological mechanisms of action and anatomical therapeutic chemical classifications;

b) establish means to determine clinically meaningful differences in efficacy and safety, including for sub-groups of populations;

c) define the trigger for establishing new therapeutic groups;

d) allow for greater flexibility in aligning prices through therapeutic groups than current arrangements, for example the parties may consider the possibility of maintaining relativities in pricing while recognising additional benefits of particular medicines for some patient populations and indications;

e) ensure a transparent process to allow stakeholder consultation in relation to the decision-making process around the establishment and maintenance of therapeutic groups; and

f) ensure that pricing differentials due to Statutory Price Reductions applying at different times for different medicines are maintained.

9.3.3 It is the intention of both parties not to form therapeutic groups to cover all products listed on a cost minimisation basis and that, once agreed, a future framework for therapeutic group formation would apply (after expiry of the Term) only to groups that meet the new agreed criteria.

9.4 Existing policies or measures

9.4.1 Notwithstanding clause 3.3, the Commonwealth may pursue measures and policies that were, as at the date of this Agreement:

a) already provided for in the Act; or

b) otherwise operative or announced.

9.4.2 Nothing in this Agreement limits the Commonwealth or the Department from undertaking negotiations with:

a) responsible persons in relation to flow on price reductions as a result of reference pricing; or

b) persons seeking to be responsible persons in relation to a pharmaceutical item, on or about the time a pharmaceutical item is listed on the PBS, including negotiations which are intended to, or do, result in price reductions.

10. Streamlined medicines listing processes

10.1 Availability of new medicines

It is the common intention of the parties that they work cooperatively during the Term to facilitate, consistent with the recommendations of the PBAC and the budget priorities of the Commonwealth, the availability of new medicines on the PBS as promptly as possible and at a cost individuals and the community can afford.

10.2 Cost recovery

During the Term, the Commonwealth and Medicines Australia will work to improve transparency and efficiency in PBS listing processes from initial applications and PBAC submissions through to final delisting of PBS listed medicines. This work will include revising the associated cost recovery arrangements with the objectives of:

10.2.1 improving the transparency and efficiency of the PBS listing process;

10.2.2 ensuring that the real costs of activity associated with different requests for listing or management of listings are recovered;

10.2.3 improving service standards; and

10.2.4 ensuring that PBS listings and list management activities comply with the government's policy for recovery of the costs of all regulatory activities from the entity seeking the activity.

10.3 PBS processes

10.3.1 During the Term, the Commonwealth and Medicines Australia will work to improve the efficiency, transparency and timeliness of the PBS listing processes by seeking to achieve the following:

(a) by July 2018, developing a revised pathways framework for approval by the Minister, to:

(i) focus resources on the more complex PBAC submissions and to streamline processes and costs associated with less complex PBAC submissions; and

(ii) following a review by PBAC and other stakeholders, possibly propose amendments to the PBAC meeting cycle;

(b) by July 2018, the doubling of access for sponsors to early advice by commencing a trial of increases in the timing and frequency of PBAC pre-submission meetings for complex submissions, aligned to the revised pathways for listing, where two pre-submission meetings are allowable within the 6 months prior to intended PBS application;

(c) facilitating the online submission of applications for the listing of medicines on the PBS;

(d) by the end of year 3 of the Term, reducing the time from PBAC recommendation to listing by an average of 2 months by:

(i) examining possible methods to reduce the time taken to finalise deeds of agreement;

(ii) examining possible methods to reduce the time taken to finalise restrictions; and

(iii) examining possible methods to reduce the time from finalisation of listing requirements to publication;

(e) targeting of a 50 per cent reduction in the number of resubmissions to the PBAC, including discussions regarding:

(i) formalising solution oriented processes for post-rejection discussions; and

(ii) the feasibility of establishing faster consideration of resubmissions, including alternative pathways, submission dates and PBAC consideration dates;

(f) during the Term, reviewing the alignment of PBAC meeting times and additional arrangements to navigate and align with amendments to regulatory processes arising from the Medicines and Medical Devices Review implementation, including and in particular, provisional TGA approvals; and

(g) through consultation, exploring other areas for improvement to PBS listing processes.

10.3.2 Any new agreed initiatives will be enacted through collaborative effort between the Department and Medicines Australia, recognising the important role of individual sponsors in supporting these goals.

10.3.3 The work described in clause 10.3.1 will be progressed and monitored by the Joint Oversight Committee.

11. Agreement oversight

11.1 Overview of oversight arrangements

With the intention of:

11.1.1 ensuring the progress, and measuring the outcomes, of the commitments made by the parties in this Agreement; and

11.1.2 facilitating ongoing discussions regarding the sustainability and viability of both the innovator medicines sector and the PBS,

the parties will form the Joint Oversight Committee described in clause 11.2 and continue the existing Access to Medicines Working Group referred to in clause 11.3. Medicines Australia will also be provided access to PBS data on the basis described in clause 11.4.

11.2 Joint Oversight Committee

11.2.1 During the first six months of the Term, the parties will establish a new joint oversight committee to enable the Commonwealth (represented by the Department) and Medicines Australia to manage and monitor the implementation of this Agreement.

11.2.2 Both parties will have equal representation on the Joint Oversight Committee, alternately chaired by a representative of the Department and a representative of Medicines Australia.

11.2.3 The Joint Oversight Committee will meet at least twice during each consecutive 12 month period during the Term (with the first 12 month period commencing on 1 July 2017).

11.2.4 The terms of reference and remaining governance arrangements for the Joint Oversight Committee will be developed by the Department in consultation with Medicines Australia and will be agreed at its first meeting. It is intended that the terms of reference will include:

(a) reviewing the record of the reserved savings derived through the measures described in this Agreement (see clause 6.2);

(b) identifying and discussing solutions for unintended consequences arising from measures within this Agreement, including:

(i) the extent of exemptions from Statutory Price Reductions sought and agreed by the Commonwealth including due to potential impacts on the viability of supply (see clause 5.10.3);

(ii) the impact and use of Agreement changes for medicines undergoing long term price disclosure (see clause 9.1);

(c) considering and agreeing details intended to guide sponsors in:

(i) applications for exemptions and applications of Statutory Price Reductions; and

(ii) contributing to achievement of the intended outcomes in 10.3.

(d) considering the effectiveness of measures relating to the application of Statutory Price Reductions (see clause 5);

(e) evaluating progress towards the implementation, and the effectiveness of, the e-Prescribing measures outlined in clause 7, including consistency of the software development with this Agreement;

(f) considering the effectiveness of biosimilar uptake driver measures, including the equitable application of these drivers, competitiveness, and savings potential of biosimilars (see clause 8);

(g) reporting on progress towards:

(i) enhancing PBS processes for efficiency, transparency and timeliness of PBS processes (see clauses 9.2 and 10.3); and

(ii) a new framework for therapeutic groups (see clause 9.3); and

(h) consideration of, and timing for negotiation of, any future agreement between the parties (see clause 12.2).

11.2.5 In the event that the Joint Operating Committee is unable to reach consensus, issues will be resolved in accordance with 12.1.

11.3 Access to Medicines Working Group

The parties will continue to consult with each other, through the AMWG to address:

11.3.1 issues currently being considered by the AMWG;

11.3.2 the new issue of comparator selection; and

11.3.3 where agreed by the Minister, other policy matters associated with the PBS.

11.4 Access to PBS data

To enable monitoring of the sustainability of the innovator medicines sector in Australia, the Commonwealth will progress work to enable Medicines Australia to access relevant information directly from the enterprise data warehouse operated by the Department once that enterprise data warehouse is available for use by parties outside the Commonwealth and for the remainder of the Term.

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12. General matters

12.1 Issue resolution

12.1.1 For issues that cannot be resolved through the Joint Oversight Committee, the process for resolving issues is as follows:

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

(b) the:

(i) Commonwealth representative specified in clause 12.5.1(a); and

(ii) Medicines Australia representative specified in clause 12.5.1(b),

will then try to resolve the issue by direct negotiation.

12.1.2 If the issue is not resolved by direct negotiation under clause 12.1.1 within 20 Business Days from the date the notice referred to in clause 12.1.1(a) is given, either party may refer the matter for direct negotiation between the Minister and the Chairperson of Medicines Australia.

12.2 New agreement

The parties will use their best endeavours to ensure that negotiations for any new agreement to apply after expiry of this Agreement will commence 12 months prior to the expiry of this Agreement.

12.3 Variation

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

12.4 Status of this document

Both parties acknowledge and agree that:

12.4.1 it is their common intention to meet their commitments under this Agreement; and

12.4.2 despite clause 12.4.1, nothing in this Agreement places a financial obligation on the Commonwealth or gives rise to an obligation on the Commonwealth to pay compensation, including during or after the end of the Term.

12.5 Notices

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

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

First Assistant Secretary
Pharmaceutical Benefits Division
Department of Health

MDP 903
GPO Box 9848
CANBERRA ACT 2601,

or as otherwise notified by the Commonwealth; or

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

Chief Executive Officer
Medicines Australia Limited ACN 126 990 001

Level 1, 16 Napier Close
Deakin ACT 2600,

or as otherwise notified by Medicines Australia.

12.5.2 A notice is to be:

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

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

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

12.5.3 Communications take effect from the time they are received or taken to be received under clause 12.5.4 (whichever happens first) unless a later time is specified.

12.5.4 Communications are taken to be received:

(a) if sent by post, 6 days after posting (or 10 days after posting if sent from one country to another);

(b) if sent by facsimile, at the time shown in the transmission report as the time that the whole facsimile was sent; or

(c) if sent by email;

(i) when the sender receives an automated message confirming delivery; or

(ii) four hours after the time sent (as recorded on the device from which the sender sent the email) unless the sender receives an automated message that the email has not been delivered,

whichever happens first.

12.5.5 A notice received, or taken to be received under clause 12.5.4 after 5.00 pm, or on a day that is not a business day in the place of receipt, is deemed to be effected on the next business day in the place of receipt.

Signing Page

Dated 27 April 2017

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

.....

in the presence of:

.....
Witness

ALEX. BEST
.....
Name of witness

Signed by Mr Wes Cook, Chairman, Medicines Australia on behalf of **Medicines Australia Limited ACN 126 990 001** by:

.....

In the presence of:

.....
Witness

M. CATLIN
.....
Name of witness