



Australian Government

Department of Health

Amended and Restated Sixth Community Pharmacy Agreement

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

The Pharmacy Guild of Australia

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Amended and Restated Sixth Community Pharmacy Agreement

Amended and Restated as at 1 July 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	The Pharmacy Guild of Australia (ABN 84 519 669 143)
Address	Level 2, 15 National Circuit, Barton in the Australian Capital Territory
Short name	Guild

Background

- A. This Agreement is the Sixth Community Pharmacy Agreement entered into by the Minister for Health (acting on behalf of the Commonwealth of Australia) and the Pharmacy Guild of Australia for the purposes of section 98BAA of the *National Health Act 1953* (Cth) and for related purposes.
- B. Community pharmacy is an integral part of the Australian health care system through its role in the delivery of the PBS and related services.
- C. The parties have a common interest in:
- C.1 promoting the sustainability, efficiency and cost-effectiveness of the PBS within the broader context of health reform;
 - C.2 ensuring that community resources are appropriately directed across the health system; and
 - C.3 supporting the sustainability and viability of an effective community pharmacy sector.
- D. The PBS Access and Sustainability Package referred to in this Agreement seeks to establish pharmacy funding and medicines pricing arrangements and a range of sector improvements over 5 years to achieve the outcomes referred to in paragraph C above. The Package is intended to support the National Medicines Policy and appropriately balance the need to:
- D.1 ensure consumers can continue to have access to new and innovative PBS subsidised medicines at an affordable price that are necessary to maintain the health of the community;
 - D.2 promote and improve the quality use of medicines; and

- D.3 ensure a cost-effective and sustainable PBS.
- E. The parties recognise that the purpose of the Package is to ensure longer term access to, and sustainability of, the PBS.
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1. Definitions

1.1 In this Agreement, unless the contrary intention appears:

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

2017 Bill means the National Health Amendment (Pharmaceutical Benefits) Bill 2017.

5CPA means the Fifth Community Pharmacy Agreement between the Commonwealth and the Guild dated 3 May 2010.

ACC means the Agreement Consultative Committee established under clause 5 of the 5CPA.

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

Additional AHI Fee means in relation to a Financial Year, the fee specified in Table 4, subject to any adjustment in accordance with clause 4.5.3.

Additional AHI Fee Cap has the meaning given in clause 4.5.2.

Admixed Ready-Prepared Pharmaceutical Benefit means an admixture of ready-prepared ingredients as specified in a determination made by the Minister under subsection 98C(1)(b) of the Act (as at the date of this Agreement being determination No. PB 119 of 2008).

Agreement means this Sixth Community Pharmacy Agreement.

AHI Fee means the administration, handling and infrastructure fee specified in Table 3.

approved ex-manufacturer price has the meaning given in Part VII of the Act.

approved pharmacist has the meaning given in Part VII of the Act.

approved supplier has the meaning given in Part VII of the Act.

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

Commonwealth price means the price for a pharmaceutical benefit of a particular quantity or number of units as set out in the Determination.

Community Pharmacy Programmes has the meaning given in clause 6 and **CPP** has the same meaning.

Compact means the document at Appendix D.

CSO means the Community Service Obligation Funding Pool which is described in clause 5.1.

dangerous drug has the meaning given in the Determination.

Department means:

- (a) the Department of Health; or
- (b) any successor department or agency of the Commonwealth having responsibility for the administration of Part VII of the Act.

Department Representative means:

- (a) the person from time to time holding or acting in the position of First Assistant Secretary, Pharmaceutical Benefits Division within the Department; or
- (b) a person from time to time holding or acting in such other position notified by the Commonwealth to the Guild in writing from time to time.

Determination means the determination in force from time to time under subsection 98B(1)(a) of the Act.

Extemporaneously-Prepared Pharmaceutical Benefit or **EPPB** means a pharmaceutical benefit that is not a Ready-Prepared Pharmaceutical Benefit.

Ex-Manufacturer Price means, as applicable, the:

- (a) approved ex-manufacturer price; or
- (b) proportional ex-manufacturer price for a pack quantity (other than the pricing quantity),

of a listed brand.

Financial Year means each successive period of twelve months commencing on 1 July and ending on the immediately following 30 June.

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

Guild Representative means:

- (a) the person from time to time holding or acting in the position of Executive Director of the Guild; or
- (b) a person from time to time holding or acting in such other position notified by the Guild to the Commonwealth in writing from time to time.

Indexation Date means each 1 July during the Term commencing on 1 July 2016.

Indexed means indexed in accordance with clause 7.8.

Information includes any material, data, statement, information, estimate, forecast, prediction, advice, plan, drawing or idea.

listed brand has the meaning given in Part VII of the Act.

Location Rules means the rules determined by the Minister under section 99L of the Act.

Maximum Co-Payment means, as applicable:

- (a) the general patient reduced charge;
- (b) the concessional beneficiary charge; or
- (c) the general patient charge,

as applying from time to time under Part VII of the Act.

Minister means the Minister who administers the Act.

Package means the package of savings measures, remuneration and funding described in clause 3.

pack quantity has the meaning given in Part VII of the Act.

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.

PGPA Act means the *Public Governance, Performance and Accountability Act 2013* (Cth).

pharmaceutical benefit has the meaning given in Part VII of the Act.

Premium Free Dispensing Incentive or **PFDI** means the incentive referred to in clause 5.3.

price to pharmacists has the meaning given in the Determination.

pricing quantity has the meaning given in Part VII of the Act.

proportional ex-manufacturer price has the meaning given in Part VII of the Act.

relevant quantity has the meaning given in Part 2 of the Determination.

Ready-Prepared Pharmaceutical Benefit or **RPPB** means a brand of a pharmaceutical item included in an operative determination in place under subsection 85(6) of the Act.

RPBS means the Repatriation Pharmaceutical Benefits Scheme established under the:

- (a) *Veterans' Entitlements Act 1986* (Cth);
- (b) *Military Rehabilitation and Compensation Act 2004* (Cth); and
- (c) *Australian Participants in British Nuclear Tests (Treatment) Act 2006* (Cth).

Safety Net means, as applicable:

- (a) the concessional beneficiary safety net; or
- (b) the general patient safety net,

as defined in Part VII of the Act.

Schedule equivalent has the meaning given in Part VII of the Act.

special patient contribution has the meaning given in Part VII 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.

Tribunal means the Pharmaceutical Benefits Remuneration Tribunal established under section 98A of the Act.

WCI9 means an index expressed as a percentage based on the change in wages and prices over the previous 12 month period, known as Wage Cost Index 9, as determined by the Department of the Treasury from time to time.

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

2. Term and commencement

2.1 Term of Agreement

Subject to clause 2.2, this Agreement commences on 1 July 2015 and expires on 30 June 2020.

2.2 Conditions precedent to commencement of Agreement

- 2.2.1 This clause 2.2 and clause 3.6 commence on the date of this Agreement.
- 2.2.2 This Agreement, other than this clause 2.2 and clause 3.6, will not commence until the following conditions precedent are satisfied, or waived by the Commonwealth in writing at its discretion:
- (a) the passage of the 2015 Bill through the Australian Parliament and the commencement of associated subordinate legislation in a form that will enable the achievement of the measures described in rows f, g, h, i and k in Table 1; and
 - (b) the achievement of amendments to the current deeds between the Commonwealth and CSO wholesalers to freeze the indexation of the CSO funding, as described in row c of Table 1.
- 2.2.3 The parties agree to use their respective best endeavours to ensure that the conditions in clause 2.2.2 are satisfied prior to 30 June 2015, with the exception of k in Table 1, which the Guild recognises is a matter for the Australian Government.
- 2.2.4 If the conditions in clause 2.2.2 are not satisfied or waived by 30 June 2015, any subsequent satisfaction or waiver of those conditions will not result in an extension of this Agreement beyond 30 June 2020.
- 2.2.5 If, by 25 June 2015, the parties consider that the 2015 Bill is unlikely to pass the Australian Parliament in the form required to satisfy the condition in clause 2.2.2(a) before 30 June 2015, the parties will consult with each other in relation to the arrangements after 30 June 2015.

3. PBS Access and Sustainability Package

- 3.1 The Package is intended to enable PBS and RPBS gross savings of \$6.6 billion (net savings of \$3.7 billion) over the Term through the implementation of the savings

measures described in Table 1. The Package provides for an estimated increase in remuneration and funding to the community pharmacy sector and wholesaler distributors of pharmaceuticals during the Term, which the Commonwealth estimates to be \$3.2 billion over and above 5CPA levels.

Table 1: Savings measures

Savings measures	
a.	From 1 July 2015, an increase in the number of times a year that PBS medicine prices can change from three times per year (as applying under the 5CPA), to six times per year.
b.	From 1 July 2015, a re-focusing of the PFDI to only apply where there is a brand premium.
c.	From 1 July 2015, freezing of the indexation on the CSO for a period of five years.
d.	The substitution of biosimilar medicines at the pharmacy level based on the clinical recommendations of the PBAC.
e.	From 1 January 2016, delisting of selected over-the-counter medicines from the PBS, based on the clinical recommendations of the PBAC.
f.	From 1 January 2016, an expansion of the PBS early supply provision, 'Safety Net 20 Day rule', so that it applies to all PBS medicines where it is considered appropriate for the patient population, based on the advice of the PBAC.
g.	From 1 April 2016, the component drug price disclosure arrangements under the Act are to be applied to F2 combination medicines.
h.	From 1 April 2016, a one-off statutory price reduction of 5 per cent to all brands of pharmaceutical items on the F1 formulary once the drug has been listed on the PBS for at least five years.
i.	From 1 October 2015, originator brands will be removed from the calculation of the weighted average disclosed price of medicines under price disclosure arrangements for those medicines that have been listed on the F2 formulary for three years or more.
j.	From 1 July 2016, a transfer of the distribution of National Diabetes Services Scheme products from Diabetes Australia to pharmaceutical wholesalers through the existing CSO arrangements.
k.	From 1 January 2016, approved pharmacists may (but are not obliged to) discount the PBS patient co-payment by a maximum of \$1 per PBS supply.

3.2 The savings measures in:

- 3.2.1 rows a and b in Table 1 are implemented under this Agreement;
- 3.2.2 rows f, g, h, i and k in Table 1 are contingent upon the passage of the 2015 Bill through the Australian Parliament and the commencement of associated subordinate legislation;
- 3.2.3 rows c and j in Table 1 require the agreement and cooperation of other participants in the pharmaceutical supply chain; and
- 3.2.4 rows d and e in Table 1 will be achieved under existing Part VII of the Act.

3.3 Following the passage of the 2015 Bill through the Australian Parliament, remuneration and funding of approved pharmacists and others in the pharmaceutical supply chain was restructured resulting in what the Commonwealth estimated would be \$18.9 billion in remuneration over the Term, comprising:

3.3.1 Commonwealth contributions of \$15.5 billion; and

3.3.2 patient contributions of \$3.4 billion.

3.4 The Commonwealth contributions in Table 2 include payments to pharmacists and wholesalers for medicines dispensed under the PBS and RPBS. A key element of the remuneration described in Table 2 is the new AHI Fee that forms part of the Commonwealth price. The AHI Fee replaces the former pharmacy mark-up and represents a significant change to the basis upon which community pharmacies are remunerated. Both parties recognise that the introduction of the AHI Fee (and de-linking pharmacy remuneration from medicine pricing) is intended to support the sustainability of the community pharmacy sector while removing a barrier to future PBS reform.

Table 2: Components of the remuneration and funding

Component	Contributor	\$million (estimated)
Pharmacy remuneration for dispensing, including dispensing fee, AHI Fee and dangerous drug fee	Commonwealth	11,112
	Patient	3,025
Premium Fee Dispensing Incentive funding	Commonwealth	655
	Patient	N/A
Community Pharmacy Programmes	Commonwealth	1,263
	Patient	As set under CPPs
Remuneration for wholesalers to hold and deliver medicines to approved pharmacists (excluding the CSO)	Commonwealth	1,414
	Patient	385
CSO funding pool	Commonwealth	976
	Patient	N/A
Fees for CSO distributors to distribute National Diabetes Services Scheme products	Commonwealth	28
	Patient	N/A
Fees for pharmacy to distribute National Diabetes Services Scheme products	Commonwealth	28
	Patient	No additional patient charge
Total	Commonwealth	15,476
	Patient	3,410
	Total	18,886¹
Chemotherapy compounding fees ²	Commonwealth	372

3.5 The Commonwealth also estimates that community pharmacy will receive up to a further \$4.8 billion from dispensing pharmaceutical items that are priced below the Maximum Co-Payment.

¹ This excludes remuneration when community pharmacies dispense medicines under Section 100 special arrangements.

² Compounding fees will be paid directly to chemotherapy compounders, who may not be approved suppliers.

- 3.6 As announced in the 2017 – 18 Budget, remuneration for community pharmacy and wholesalers will be increased as follows:
- 3.6.1 there will be a \$200,000,000 increase in the AHI Fee from 1 July 2017, to be implemented through the introduction of the Additional AHI Fee (as further described in clause 4.5);
 - 3.6.2 subject to the passage of the 2017 Bill through the Australian Parliament, there will be an additional \$10,000,000 in total funding made available for the Additional AHI Fee (as further described in clause 4.5.2); and
 - 3.6.3 there will be a \$15,000,000 increase in the value of the CSO on or about 1 July 2017 (as further described in clause 5.1.2A).
- 3.7 Recognising the significance of the Package and associated reforms, the Guild will provide all reasonable assistance to facilitate and support the measures in the Package, with the exception of row k of Table 1, which the Guild recognises is a matter for the Australian Government. The Australian Government will review the optional PBS co-payment discount in row k of Table 1 after the Pharmacy Remuneration and Regulation Review has delivered its final report. The Guild will communicate positively with its members and the public about the benefits of the Package as a whole.
- 3.8 The Guild acknowledges that there are a range of savings measures contained in the Package. No compensation will be considered by the Australian Government, or payable by the Commonwealth, in relation to these savings measures.

4. Commonwealth price

4.1 Purpose

This clause 4 is an agreement between the Minister and the Guild for the purposes of subsection 98BAA(1) of the Act.

4.2 Commonwealth price

- 4.2.1 The Commonwealth price has been set on the basis of a formula which comprises the Ex-Manufacturer Price plus allowances for the supply of PBS medicines over and above that price.
- 4.2.2 In agreeing to a Commonwealth price for a particular medicine, the Commonwealth includes allowances for:
 - (a) the cost to the approved pharmacist (price to pharmacists), which includes two components:
 - (i) production of the medicine (Ex-Manufacturer Price); and
 - (ii) wholesale distribution of the medicine;
 - (b) the administration, handling and storage costs entailed in dispensing medicines by the pharmacy, including associated infrastructure; and
 - (c) a pharmacist's specialised skills in dispensing the medicines.
- 4.2.3 The components of the Commonwealth price during the Term, as agreed by the Commonwealth and the Guild and updated as at 1 July 2017, are as set out in Table 3 below. Additional detail on how these components are defined, calculated and applied will be set out in the Determination.

Table 3: Components of the Commonwealth price

Payment type	Date of effect	Value of payment	
wholesale mark-up ^[1] (for RPPBs)	1 July 2017	Where the Ex- Manufacturer Price is up to and including \$930.06	7.52% of the Ex- Manufacturer Price per dispense
		Where the Ex- Manufacturer Price is over \$930.06	\$69.94 per dispense
administration, handling and infrastructure fee	1 July 2017	For a pack quantity of a listed brand with a price to pharmacists less than \$180	\$3.62, plus the Additional AHI Fee for the relevant Financial Year, per dispense
		For a pack quantity of a listed brand with a price to pharmacists from \$180 to \$2,089.71	\$3.62, plus the Additional AHI Fee for the relevant Financial Year and 3.5% of the amount by which the price to pharmacists exceeds \$180, per dispense
		For a pack quantity of a listed brand with a price to pharmacists more than \$2,089.71	\$72.43 per dispense
dispensing fee (for RPPBs)	1 July 2017	\$7.15 ^[2] per dispense	
dispensing fee (for EPPBs)	1 July 2017	Dispensing fee for RPPBs, plus \$2.04, per dispense	
dangerous drug fee (for RPPBs)	1 July 2017	\$3.01 per dangerous drug dispensed	

4.2.4 The:

- (a) AHI Fee (other than the component of the AHI Fee that is the Additional AHI Fee);
- (b) dispensing fee for RPPBs; and
- (c) dangerous drug fee for RPPBs,

as described in Table 3, will each be Indexed on the Indexation Date.

4.2.5 The wholesale mark-up set out in Table 3 will not be Indexed during the Term.

4.2.6 The only change to EPPB pricing under this Agreement is the introduction of the AHI Fee.

^[1] The wholesale mark-up for a pack quantity of a listed brand is calculated using the relevant quantity.

^[2] The dispensing fee for RPPBs has been subject to an agreed one-off reduction, after the application of clause 7.8 on 1 July 2017, to provide funding to remunerate eligible approved pharmacists for the supply of pharmaceutical benefits to individual patients of remote area Aboriginal Health Services. The dispensing fee for RPPBs following this reduction is \$7.15.

4.2.7 The Additional AHI Fee will not be Indexed and will be deemed not to form part of the AHI Fee for the purposes of Indexing the AHI Fee.

4.3 PBS price changes

PBS price changes will occur 6 times a year, on 1 February, 1 April, 1 June, 1 August, 1 October and 1 December. The price change dates applying under Division 3B of Part VII of the Act are not changed by this clause 4.3.

4.4 Wholesaler remuneration

The comprehensive review referred to in clause 8 will include a review of the remuneration paid to wholesale distributors of pharmaceuticals. The findings of the comprehensive review may result in changes to the remuneration of wholesale distributors of pharmaceuticals during the Term. The Commonwealth will consult with wholesale distributors of pharmaceuticals, and other stakeholders (including the Guild) as determined by the Minister, on any changes to wholesaler remuneration contemplated as a result of the comprehensive review. Should the recommendations of the review identify that the system is inadequately remunerating wholesaler distributors of pharmaceuticals, or such wholesalers will not be viable in the medium to long term, the remuneration arrangements for the pharmaceutical wholesale sector will be considered by the Commonwealth.

4.5 Additional AHI Fee

4.5.1 Subject to this clause 4.5, the Additional AHI Fees for each Financial Year during the Term commencing on and from 1 July 2017, as agreed by the Commonwealth and the Guild, are as set out in Table 4 below.

Table 4: Additional AHI Fee

Financial Year	Additional AHI Fee
Financial Year commencing 1 July 2017	\$0.32 per dispense
Financial Year commencing 1 July 2018	\$0.35 per dispense
Financial Year commencing 1 July 2019	\$0.35 per dispense

4.5.2 The total Additional AHI Fees paid by the Commonwealth during the Term are intended to equal the Additional AHI Fees Cap. The **Additional AHI Fees Cap** will be:

- (a) \$200,000,000; or
- (b) if the 2017 Bill passes the Australian Parliament and receives Royal Assent, \$210,000,000.

4.5.3 To seek to ensure that the Additional AHI Fees paid by the Commonwealth during the Term equal the Additional AHI Fees Cap, the Additional AHI Fee for the Financial Year commencing on 1 July 2019 will be adjusted in accordance with Appendix C.

5. CSO and other charges and incentives

5.1 Community Service Obligation Funding Pool

- 5.1.1 The Commonwealth has established the CSO to:
- (a) ensure that all approved pharmacists are able to obtain timely supply of section 85 PBS medicines, irrespective of:
 - (i) the size or location of the pharmacy;
 - (ii) the breadth of the PBS product range;
 - (iii) the cost of the PBS medicines; or
 - (iv) the cost of their distribution and supply to the pharmacy;
 - (b) ensure that all Australians have access to the PBS medicines they require, regardless of the cost of the medicine, or where they live; and
 - (c) remunerate eligible wholesale distributors of pharmaceuticals for the additional cost they incur in providing PBS medicines, as compared to those wholesalers who choose to distribute and supply a lesser range of PBS medicines.
- 5.1.2 The value of the CSO in each Financial Year during the Term will be up to \$195,220,000.
- 5.1.2A As announced in the 2017 – 18 Budget, the value of the CSO will be increased on or about 1 July 2017 by \$15,000,000.
- 5.1.2B The CSO will not be indexed during the Term.
- 5.1.3 The Commonwealth intends to undertake a formal process to appoint CSO distributors during the first Financial Year of the Term. Distributors will be required to satisfy CSO eligibility requirements, as determined by the Commonwealth, and as set out in the documentation released by the Commonwealth when calling for such applications.
- 5.1.4 The Commonwealth will:
- (a) consider the scope of future CSO service level arrangements; and
 - (b) consult with relevant stakeholders (including the Guild) as it considers appropriate regarding any revised CSO service level arrangements,
- prior to undertaking any formal process to appoint CSO distributors.
- 5.1.5 The cost of administering the CSO will be met from within the CSO. The Commonwealth intends to undertake a formal competitive process to appoint a CSO administrator during the first Financial Year of the Term. Actual CSO administration costs during the Term will be identified as part of that competitive process.
- 5.1.6 The Commonwealth intends to pursue administrative efficiencies as part of the CSO arrangements during the Term. This may include simplifying reporting requirements and other regulatory reforms that reduce the administrative burden on the wholesale distributors of pharmaceuticals, and reflect competitive business practices.

- 5.1.7 It is the common intention of the parties that CSO distributors:
- (a) will supply section 85 medicines under the CSO arrangements at or below the:
 - (i) price to pharmacists; or
 - (ii) the claimed price plus the wholesale mark-up (specified in Table 3);
 - (b) may not impose new or additional fees for the supply of section 85 medicines under the CSO arrangements that were not specifically allowed for under the CSO arrangements as at 1 July 2015; and
 - (c) may charge new or additional fees for section 85 medicines that are requested by the pharmacy to be supplied in a manner inconsistent with the CSO arrangements as they exist from time to time.
- 5.1.8 Without limiting clause 5.1.4, the Commonwealth will consult with the Guild prior to entering into any arrangements with CSO distributors that are inconsistent with the common intention of the parties set out in clause 5.1.7.

5.2 Charges for pharmaceutical benefits below Maximum Co-Payment

- 5.2.1 This clause 5.2 is an agreement between the Minister and the Guild for the purposes of subsection 84C(9) of the Act. Nothing in this clause 5.2 is intended to limit any other section of the Act, including any section which prescribes when amounts are, or are not to be, counted as accumulating towards a patient's Safety Net.
- 5.2.2 For Ready-Prepared Pharmaceutical Benefits that are priced below the Maximum Co-Payment (other than Admixed Ready-Prepared Pharmaceutical Benefits), approved pharmacists can charge the sum of:
- (a) the Commonwealth price;
 - (b) \$1.21; and
 - (c) a further additional patient charge amounting to 10% of the Maximum Co-Payment plus 50 cents,
- provided that such a sum does not exceed the Maximum Co-Payment.
- 5.2.3 For Extemporaneously-Prepared Pharmaceutical Benefits and Admixed Ready-Prepared Pharmaceutical Benefits that are priced below the Maximum Co-Payment, approved pharmacists can charge the sum of:
- (a) the Commonwealth price;
 - (b) \$1.57; and
 - (c) a further additional patient charge amounting to 10% of the Maximum Co-Payment plus 50 cents,
- provided that such a sum does not exceed the Maximum Co-Payment.
- 5.2.4 The additional patient charges referred to in clauses 5.2.2(c) and 5.2.3(c) will not accumulate, and must not be recorded by approved pharmacists as accumulating, towards consumers' Safety Nets.

- 5.2.5 Approved pharmacists must make consumers aware of any patient charges referred to in clauses 5.2.2(c) and 5.2.3(c) and of the fact that they are not Commonwealth initiated.
- 5.2.6 The fees specified in clauses 5.2.2(b) and 5.2.3(b) will be adjusted annually on 1 July during the Term based on changes in WCI9 and have been adjusted as at 1 July 2017.

5.3 Premium Free Dispensing Incentive

- 5.3.1 As at 1 July 2017, the PFDI is \$1.78. The PFDI will be Indexed annually on the Indexation Date.
- 5.3.2 The PFDI will be paid to an approved supplier (except an approved hospital authority for a public hospital) where the Commonwealth is satisfied that such approved suppliers have dispensed a pack quantity of a listed brand (**Dispensed Medicine**) in all the following circumstances:
- (a) the Dispensed Medicine is Schedule equivalent to one or more other listed brands;
 - (b) one or more pack quantities of the listed brands that are Schedule equivalent to the Dispensed Medicine have a special patient contribution;
 - (c) the pack quantity of the Dispensed Medicine does not have a special patient contribution; and
 - (d) before the addition of the PFDI, the Commonwealth price of the pack quantity of the Dispensed Medicine already exceeds the Maximum Co-Payment.
- 5.3.3 Where payable, the PFDI is separate from, and in addition to, the Commonwealth price.

5.4 Annual community pharmacy and wholesaler reconciliation

- 5.4.1A As part of the Compact, the Australian Government and the Guild have agreed that a fixed funding amount of \$200 million, no more, no less, will be provided to community pharmacy over remainder of the Term commencing on 1 July 2017 to address any variation in script volumes compared to estimates under the Agreement. This fixed funding amount will be paid in the form of the Additional AHI Fee. The parties agree that clauses 5.4.1 to 5.4.4 are inoperative.
- 5.4.1 As soon as practicable following the end of each Financial Year during the Term (**Relevant Financial Year**), except the last Financial Year, the Department will conduct, in consultation with the Guild, an annual reconciliation of actual versus estimated total community pharmacy and wholesaler remuneration, based on the actual PBS and RPBS prescription volumes in the Relevant Financial Year, as compared to the PBS and RPBS prescription volume estimates specified in Appendix A for that Financial Year.
- 5.4.2 Following the reconciliation described in clause 5.4.1, the Minister will report to the Australian Government any prescription volume variation for a Financial Year that is higher or lower than the percentage materiality threshold agreed by the parties under clause 5.4.3. If the Australian Government agrees, a risk sharing arrangement would be designed and implemented to address the identified variance.

- 5.4.3 The parties will seek to agree, on or before 31 May 2016, a materiality threshold (to be expressed as a percentage) to be applied in relation to any variance between actual and estimated PBS and RPBS prescription volumes. In the event that the parties are unable to agree the materiality threshold on or before 31 May 2016, either party may refer the issue for resolution in accordance with the process set out in clause 10.1.
- 5.4.4 The actual prescription volumes used for the purposes of the reconciliation described in clause 5.4.1 will be derived from the data sources specified in Appendix A.

6. Community Pharmacy Programmes

6.1 Allocation of Community Pharmacy Programme funding

- 6.1.1 The Commonwealth will make available up to \$1.26 billion in funding for evidence-based, patient-focused professional pharmacy programmes and services (**Community Pharmacy Programmes**) over the Term.
- 6.1.2 Funding for Community Pharmacy Programmes will be as approved by the Minister, following consultation by the Department with a range of stakeholders and bodies (including the Guild) as required, and is expected to:
- (a) be at a level of \$613 million over the Term as continued investment in a range of Community Pharmacy Programmes;
 - (b) be at a level of \$50 million over the Term as funding for a Pharmacy Trial Programme (**PTP**) relating to Community Pharmacy Programmes which are referred to in clause 6.1.4; and
 - (c) include access to additional funding of up to \$600 million over the Term to support new and expanded Community Pharmacy Programmes, and which are intended to be delivered through community pharmacies (excluding unapproved pharmacies), as set out in the Compact.
- 6.1.3 The Community Pharmacy Programmes set out in Appendix B will continue from 1 July 2015 until the Minister determines otherwise and will be subject to a cost-effectiveness assessment by an independent health technology assessment body (such as the Medical Services Advisory Committee or the PBAC) as determined by the Minister.
- 6.1.4 The PTP will be established by the Commonwealth to trial new and expanded Community Pharmacy Programmes which seek to improve clinical outcomes for consumers and/or extend the role of pharmacists in the delivery of primary healthcare services through community pharmacy. In determining priorities for the PTP and the trials to be undertaken, the Department will consult extensively with the Guild and a range of stakeholders and bodies as required. This process will inform recommendations to the Minister on PTP activities to be funded by the Commonwealth, and the quantum of funds to be allocated on an annual basis.
- 6.1.5 It is intended that a particular focus of the new, continuing and expanded Community Pharmacy Programmes will be those which benefit:
- (a) Aboriginal and Torres Strait Islander peoples; and
 - (b) consumers in rural and remote areas.

- 6.1.6 Any funding for a trialled Community Pharmacy Programme after the conclusion of the PTP for that Community Pharmacy Programme will be contingent on:
- (a) a recommendation to proceed with the programme or service by an independent health technology assessment body (such as the Medical Services Advisory Committee or the PBAC) determined by the Minister; and
 - (b) the programme or service satisfying funding priorities determined by the Minister.
- 6.1.7 Both parties acknowledge that input and support in the design and implementation of Community Pharmacy Programmes is expected to utilise involvement from a range of stakeholders and bodies from the public, pharmacy, pharmaceutical and medical sectors.
- 6.1.8 The cost of administering the PTP (including any approved communication activities) and any new or continuing Community Pharmacy Programmes will be drawn from the programme funding allocated by the Commonwealth and is expected to be up to 3.5 per cent of the total Community Pharmacy Programmes funding allocation under clause 6.1.2.
- 6.1.9 The Guild acknowledges that:
- (a) the Australian Government requires the achievement of real improvement in patient access to community pharmacies (including through increased opening hours) under Community Pharmacy Programmes; and
 - (b) funding for existing and any new or expanded Community Pharmacy Programmes under this Agreement will be contingent on the Guild and approved pharmacists actively working with the Department over the first Financial Year of the Term, and then on an ongoing basis, to achieve such improvement, including setting targets for improvement in the second Financial Year of the Term and beyond.
- 6.1.10 Subject to compliance with all applicable:
- (a) laws, including the PGPA Act;
 - (b) subordinate legislation; and
 - (c) programme objectives, deliverables, reporting requirements and key performance indicators,

and the approval of the Australian Government, the parties will use their best endeavours to ensure that all funds allocated by the Commonwealth to individual Community Pharmacy Programmes are fully and appropriately expended.

6.2 Programme governance

- 6.2.1 Subject to compliance with all requirements under the PGPA Act and its subordinate legislation, the current agreement between the Commonwealth and the Guild for the administration of existing Community Pharmacy Programmes will continue for the first Financial Year of the Term.
- 6.2.2 The Guild acknowledges that the Department intends to ascertain through a formal process whether there are any persons interested in, and capable of, providing administration support in respect of the Community Pharmacy Programmes after the end of the first Financial Year of the Term. Any such process and subsequent engagement of one or more persons will be conducted in accordance with all standards of accountability required of the Department and relevant officials under

the PGPA Act, including as set out in the Public Governance, Performance and Accountability Rule 2014, the Commonwealth Procurement Rules and the Commonwealth Grant Rules and Guidelines. The Guild may submit a response to any such formal process.

- 6.2.3 Any new or continuing arrangements entered into by the Commonwealth for the administration of Community Pharmacy Programmes will include clear programme objectives, deliverables, reporting requirements and key performance indicators so that the Commonwealth can assess the outcomes of such Community Pharmacy Programmes and their value to the Australian community.

7. Other arrangements

7.1 eHealth

- 7.1.1 Both parties will work together on an ongoing basis during the Term to encourage approved pharmacists to:
- (a) continue to drive greater uptake of My Health Records; and
 - (b) meet all relevant requirements of the eMedications Management Functional Framework (or equivalent requirements) as they are published by the ADHA from time to time.

- 7.1.2 In this clause 7.1:

ADHA means the Australian Digital Health Agency established under section 8 of the *Public Governance, Performance and Accountability (Establishing the Australian Digital Health Agency) Rule 2016*.

My Health Record has the meaning given in the *My Health Records Act 2012* (Cth).

7.2 Location Rules

- 7.2.1 The Location Rules are not altered by this Agreement.
- 7.2.2 The Location Rules will be continued beyond their current expiry date of 30 June 2015 until 30 June 2020.
- 7.2.3 The Australian Government intends to continue the community pharmacy location rules beyond the life of the 6CPA and will, at the earliest opportunity, introduce legislation to seek to remove the sunset dates of 30 June 2020 in sections 90(3C) and 99Y of the Act.

7.3 Availability of PBS medicines in pharmacy

The Guild agrees that approved pharmacists will keep adequate medicine stocks for the supply of pharmaceutical benefits to ensure reasonable and timely access to those medicines by consumers where the demand is, or should reasonably have been, anticipated by the relevant approved pharmacist.

7.4 New National Diabetes Services Scheme arrangements

- 7.4.1 The Commonwealth intends that from on or about 1 July 2016, product supply and delivery under the Commonwealth funded National Diabetes Services Scheme (**NDSS**) will be redirected through the established wholesale distribution network to approved pharmacists.

7.4.2 Under these new arrangements, approved pharmacists that supply NDSS products are intended to receive a payment of \$1 for each NDSS product supplied. The amount of this payment will remain fixed for the Term, with no indexation applied.

7.4.3 These arrangements will also include a \$1 per unit fee for CSO distributors for each NDSS product supplied through the CSO arrangements. The amount of this payment will also remain fixed for the Term, with no indexation applied.

7.5 Chemotherapy

7.5.1 The Commonwealth intends to reform the current arrangements for the payment of fees for chemotherapy infusions prepared under special arrangements made by the Minister under section 100 of the Act.

7.5.2 It is proposed that under the new arrangements:

- (a) fees would be paid directly to chemotherapy compounders under new arrangements determined by the Minister; and
- (b) the fees paid to compounders who are licensed by the TGA to undertake such compounding would be higher than those paid to compounders who are not licensed by the TGA, recognising that TGA licensed compounders incur additional costs in complying with the TGA's licensing requirements, as compared to chemotherapy compounders who are not TGA licensed.

7.5.3 Under this arrangement, the fees paid to compounders would be \$40 for non-TGA licenced providers and \$60 for TGA licenced providers (**Compound Fees**). Compound Fees will remain fixed for the Term, with no indexation applied.

7.5.4 The Commonwealth will implement changes to bring about the payment of Compound Fees in consultation with chemotherapy compounders and approved pharmacists who supply chemotherapy infusions.

7.6 Obligations of approved suppliers

The Guild will use its best endeavours to ensure that approved suppliers comply with their obligations as set out in this Agreement.

7.7 Data from approved suppliers

7.7.1 Approved suppliers must provide the Commonwealth with data on each PBS or RPBS prescription supplied by an approved supplier that is priced below the Maximum Co-Payment, including:

- (a) the patient's name;
- (b) the patient's Medicare number;
- (c) information about the prescription (including the date of prescribing and supply, the PBS or RPBS code number, the listed brand, the quantity dispensed and the number of repeats);
- (d) the PBS prescriber number;
- (e) the approved supplier number; and
- (f) the price charged by the approved supplier.

7.7.2 Each time an approved supplier allows a discount to the patient co-payment, as permitted under the Act, in relation to a PBS or RPBS prescription (**Co-Payment Discount**), the approved supplier must provide the Commonwealth with details of:

- (a) the amount of the Co-Payment Discount;
- (b) the patient's name;
- (c) the patient's Medicare number;
- (d) information about the prescription (including the date of prescribing and supply, the PBS or RPBS code number, the listed brand, the quantity dispensed and the number of repeats);
- (e) the PBS prescriber number;
- (f) the approved supplier number; and
- (g) the price charged by the approved supplier.

7.8 Indexation

7.8.1 Where this Agreement specifies that an amount is to be Indexed under this Agreement, the amount will be varied on the Indexation Date by applying the following formula:

$$\text{New Amount} = \text{Last Amount} \times \left(\frac{\text{MRIN}}{\text{LIN}} \right)$$

7.8.2 In this clause 7.8:

index number, in relation to a quarter, means the All Groups Consumer Price Index number that is the weighted average of the 8 capital cities and is published by the Australian Statistician in respect of that quarter.

Last Amount means the amount immediately before the relevant Indexation Date.

LIN means the quarterly index number, as published for the same quarter as the MRIN in the year immediately preceding the year of the MRIN.

MRIN means the most recently published quarterly index number as at the relevant Indexation Date.

New Amount means the amount, rounded to the nearest cent, on and from the relevant Indexation Date.

7.9 Payment times

7.9.1 The Guild and its members recognise that, by submitting a PBS or RPBS claim, approved suppliers are acknowledging that they have complied with all relevant Commonwealth, State and Territory legislative requirements for the dispensing of a PBS or RPBS medicine, including:

- (a) the codes, guidelines and policies established by the Pharmacy Board of Australia (or any other registering authority);
- (b) the codes, guidelines, professional practice standards and competency standards established by the Pharmaceutical Society of Australia;

- (c) the standards and requirements as established by other authorities, including the TGA and Society of Hospital Pharmacists (as applicable to specialised areas of practice);
- (d) any regulations or requirements as established by States and Territories with respect to one or more of the registration, practice or handling of medicines established within that State or Territory;
- (e) all applicable State, Territory and Commonwealth laws with respect to the conduct of their profession; and
- (f) any other requirements not stated above but that are covered by the *National Health (Pharmaceutical Benefits) (Conditions of approval for approved pharmacists) Determination 2007*.

7.9.2 Subject to circumstances beyond the Commonwealth's control, payments for payable prescriptions transmitted and assessed online will be processed within 9 to 16 days from receipt of electronic assessment.

7.10 Increasing uptake of biosimilar medicines

7.10.1 The Guild will support the introduction of measures that improve the uptake of biosimilar medicines as recommended by the PBAC on a case-by-case basis, including the introduction of preferred prescribing of a biosimilar brand for treatment naïve patients, streamlined authorities for biosimilars compared to the reference biologic, and enhancements to prescribing and dispensing software to establish default prescribing by active ingredient rather than by brand (unless overridden by the prescriber).

7.10.2 The Guild will also continue to support the appropriate dispensing of biosimilar medicines with a view to increase the uptake of biosimilar medicines by working with the Commonwealth in promoting the Biosimilars Awareness Initiative and any related initiatives to support community pharmacists to proactively engage with prescribers and consumers, along with enhancements to its ScriptMAP tool to enable pharmacies to benchmark their uptake of biosimilar medicines.

8. Comprehensive review of pharmacy remuneration and regulation

8.1 The Commonwealth will appoint a panel of three eminent independent reviewers to conduct a comprehensive review of matters including:

8.1.1 remuneration for supplying government subsidised medicines; and

8.1.2 rules about the location of pharmacies.

8.2 The comprehensive review will be based on specific terms of reference determined by the Minister. The Minister will determine the terms of reference for the comprehensive review after consultation with the Guild. It is anticipated that the review:

8.2.1 will consider:

(a) the Location Rules, and their role in supporting access to PBS medicines;

(b) remuneration of community pharmacy, both in terms of the level of funding and how it is provided to pharmacies for the dispensing of PBS medicines; and

- (c) PBS supply chain arrangements, such as the logistics and distribution of medicines, including their regulatory requirements and cost to the Commonwealth and the Australian community,

including how the matters set out in clauses 8.2.1(a), 8.2.1(b) and 8.2.1(c) contribute to patient health outcomes and improve the quality use of medicines; and

8.2.2 provide recommendations as to:

- (a) how to promote the most effective models for facilitating access to PBS medicines for consumers; and
- (b) any regulatory changes that may be required to promote high standards of delivery and accountability amongst community pharmacies and other persons receiving funding under the PBS and this Agreement, including wholesalers.

8.3 It is intended that the comprehensive review will commence on or about 1 September 2015 and will deliver its final report by 1 September 2017.

8.4 The basis of community pharmacy remuneration specified in Table 3 and the PFDI will not be changed during the Term based on the outcomes of the comprehensive review.

8.5 The Location Rules will not be changed during the Term based on the outcomes of the comprehensive review or otherwise, except with the express written agreement of the parties.

8.6 Changes to arrangements with the wholesale distributors of pharmaceuticals based on the outcomes of the comprehensive review may be agreed between the Commonwealth and the relevant wholesalers during the Term.

8.7 The Guild undertakes to provide its full support to the comprehensive review, including by:

8.7.1 providing such Information within its possession or control as is requested by the reviewers; and

8.7.2 taking all reasonable steps to ensure that its members provide such Information within their possession or control as is requested from them by the reviewers,

provided that the Guild or its members (as applicable depending on who is being asked to provide the Information) have no legitimate obligation of confidence to a third party in respect of such Information. Nothing in this clause 8.7 requires the Guild or its members to provide Information that they are not lawfully entitled to disclose under the Australian Privacy Principles set out in the *Privacy Act 1988* (Cth).

8.8 In the development of its response to the comprehensive review, the Australian Government undertakes to work with the Guild to ensure that the response maintains the community pharmacy model and secures a viable community pharmacy sector. The Australian Government intends to continue the pharmacy location rules beyond the life of the 6CPA, as outlined in clause 7.2.3.

9. Governance and consultation

9.1 Agreement consultation framework

- 9.1.1 The Department is responsible for the management, monitoring and evaluation of all aspects of the 6CPA. This will be undertaken consistent with the framework established by the PGPA Act and government best practice in order to effectively discharge advisory, accountability, governance, administration, performance reporting and contract management obligations.
- 9.1.2 The decisions of the Department may be informed through consultation with one or more stakeholders as appropriate (in particular the Guild), which may include time limited working groups or multilateral forums.
- 9.1.3 During the first 6 months of the Term:
- (a) the ACC will continue on the same basis as it did immediately prior to the end of the 5CPA; and
 - (b) the parties will consult in relation to establishing governance arrangements:
 - (i) that will enable the Department and the Guild to effectively oversee the 6CPA (including to enable the Department to discharge its responsibilities described in clause 9.1.1 and undertake the consultation described in clause 9.1.2); and
 - (ii) that will apply thereafter for the remainder of the Term.
- 9.1.4 The parties acknowledge that:
- (a) Community Pharmacy Programmes will be subject to a cost-effectiveness assessment by an independent health technology assessment body (such as the Medical Services Advisory Committee or the PBAC), as determined by the Minister;
 - (b) the remuneration for supplying government subsidised medicines and rules about the location of pharmacies will be evaluated as part of the comprehensive review described in clause 8; and
 - (c) there will be an annual reconciliation under clause 5.4 of total pharmacy and wholesaler remuneration based on prescription volumes,
- the results of which will be made publicly available.

9.2 Pharmaceutical Services Federal Committee of Inquiry

The Guild acknowledges that the Minister intends to establish a Pharmaceutical Services Federal Committee of Inquiry under section 113 of the Act to investigate allegations of non-compliance with PBS approval requirements.

10. General matters

10.1 Issue resolution

- 10.1.1 Any issue or dispute arising in connection with, or from the operation of, this Agreement (other than under clause 4) will be resolved as follows:
- (a) the party with the issue or dispute will send to the other party a notice setting out the nature of the issue or dispute (**Notice of Dispute**);
 - (b) the Department Representative and the Guild Representative will then try to resolve the issue or dispute by direct negotiation;
 - (c) if the issue or dispute is not so resolved by direct negotiation under clause 10.1.1(b) within 20 Business Days from the date the Notice of Dispute is given, either party may refer the matter for direct negotiation between the Minister and the National President of the Guild; and
 - (d) if the dispute is not resolved under clause 10.1.1(c), either party may immediately request the dispute be referred to mediation, to be conducted by a person agreed between the parties. If the parties cannot agree on a mediator within 20 Business Days after a request for mediation under this clause 10.1.1(d), either party may ask the chair of LEADR & IAMA ACN 008 651 232 or the chair's nominee to appoint a mediator.
- 10.1.2 Despite the reference of a dispute or issue to mediation under clause 10.1.1(d), the parties must continue to perform their obligations under this Agreement.
- 10.1.3 Any issue arising from the operation of clause 4 of this Agreement will be determined as follows:
- (a) the party claiming that there is an issue will send to the other party a notice setting out the nature of the issue;
 - (b) the Department Representative and the Guild Representative will then try to resolve the issue by direct negotiation;
 - (c) if the dispute is not so resolved either party may immediately request the dispute to be referred to the Tribunal for mediation, and if mediation fails, resolution; and
 - (d) if the parties resolve the dispute they shall, if required, present the agreement reached between them to the Tribunal for an appropriate determination.
- 10.1.4 Each party will bear its own costs arising from the process set out in this clause 10.1.

10.2 Consultation

Where, during the Term, the Australian Government has made a decision as part of a health-related budget initiative that has a significant and sustained impact on the viability of community pharmacy, the Commonwealth will consult with the Guild about that impact.

10.3 Variation

This Agreement may only be varied in writing, signed by the Guild and the Minister, or a delegate of the Minister.

10.4 Arrangements at the end of this Agreement

The parties will use their best endeavours to ensure that negotiations for any new community pharmacy agreement to apply after the expiry of this Agreement will commence 12 months prior to the expiry of this Agreement, and conclude by 31 March 2020.

10.5 Entire agreement

This Agreement constitutes the entire agreement of the parties about its subject matter and supersedes all previous agreements.

10.6 Words and headings

In this Agreement, unless expressed to the contrary:

- 10.6.1 words denoting the singular include the plural and vice versa;
- 10.6.2 the word 'includes' in any form is not a word of limitation;
- 10.6.3 where a word or phrase is defined, another part of speech or grammatical form of that word or phrase has a corresponding meaning;
- 10.6.4 headings and sub-headings are for ease of reference only and do not affect the interpretation of this Agreement; and
- 10.6.5 no rule of construction applies to the disadvantage of the party preparing this Agreement on the basis that it prepared or put forward this Agreement or any part of it.

10.7 Specific references

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

- 10.7.1 a section is a reference to a section of the Act;
- 10.7.2 any legislation (including subordinate legislation) is to that legislation as amended, re-enacted or replaced and includes any subordinate legislation issued under it;
- 10.7.3 any document (such as a deed, agreement or other document) is to that document (or, if required by the context, to a part of it) as amended, novated, substituted or supplemented at any time;
- 10.7.4 writing includes writing in digital form;
- 10.7.5 'this Agreement' is to this Agreement as amended from time to time;
- 10.7.6 'A\$', '\$', 'AUD', 'dollars' or 'cents' is a reference to Australian units of currency;
- 10.7.7 a clause, schedule, table or attachment is a reference to a clause, schedule, table or attachment in or to this Agreement;
- 10.7.8 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
- 10.7.9 any body (**Original Body**) which no longer exists or has been reconstituted, renamed, replaced or whose powers or functions have been removed or transferred to another body or agency, is a reference to the body which most closely serves the purposes or objects of the Original Body.

10.8 Notices

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

(a) if given by the Guild 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 the Guild - addressed to:

Executive Director
The Pharmacy Guild of Australia
Level 2, 15 National Circuit
Barton ACT 2600

PO Box 7036
Canberra Mail Centre ACT 2610,

or as otherwise notified by the Guild.

10.8.2 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.

10.8.3 Communications take effect from the time they are received or taken to be received under clause 10.8.4 (whichever happens first) unless a later time is specified.

10.8.4 Communications are taken to be received:

- (a) if sent by post, three days after posting (or seven days after posting if sent from one country to another); or
- (b) if sent by 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.

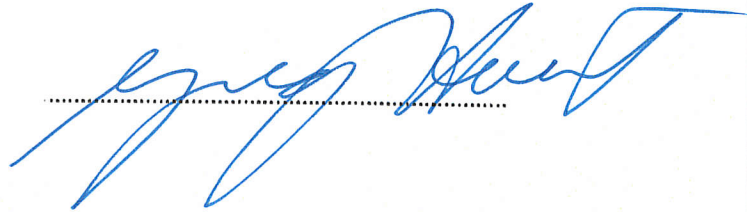
10.8.5 A notice received, or taken to be received under clause 10.8.4 after 5.00 pm, or on a day that is not a Business Day in the place of receipt, is deemed to be effected on the next Business Day.

Signing Page

Executed as an agreement

Amended and Restated as at 1 July 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

The Common Seal of The Pharmacy Guild of
Australia was affixed pursuant to a resolution
of its National Council in the presence of:


.....
National President

GEORGE TAMBASSIS
.....
Full name

)
)
)

.....
Executive Director

David James Quilty
.....
Full name

Appendix A

Annual community pharmacy and wholesaler reconciliation

[Clause 5.4]

1. The parties agree that the global sum for pharmacists' and wholesalers' remuneration in respect of their core dispensing and distribution function is modelled by reference to estimated prescription volumes.
2. The Commonwealth estimates that the PBS and RPBS prescription volumes of listed brands, dispensed by community pharmacies during the Term, will be as follows:

Table 5: Estimates of PBS and RPBS prescription volumes of listed brands

Prescription type	Financial Year 2015-16	Financial Year 2016-17	Financial Year 2017-18	Financial Year 2018-19	Financial Year 2019-20
PBS and RPBS prescription volumes (m)	227.067	232.472	238.049	243.730	248.754
Prescriptions under the Maximum Co-Payment (m)	74.567	80.994	87.706	94.484	101.089
Total volume (m)	301.634	313.466	325.755	338.214	349.843

3. The parties agree that, for the purposes of the calculation of prescriptions variances under clause 5.4, prescription volume means the combined total of PBS, RPBS and general prescriptions under the Maximum Co-Payment, for items listed under section 85 of the Act that are dispensed by community pharmacies. The parties further agree to use the actual PBS and RPBS Date of Supply data published by the Commonwealth for the purposes of calculations under clause 5.4.

Appendix B

Indicative Allocations for Community Pharmacy Programmes

[Clause 6.1]

Programme name	Description of Programme [¥]	Year 1 of 6CPA \$m	Years 2 – 5 of 6CPA* \$m	Total \$m
Medication Adherence Programmes:	To support medication adherence programmes that are designed to improve medication compliance through the provision of community pharmacy services	65.6	123.6	189.2
Dose Administration Aids (DAA)**	To assist consumers in the community to better manage their medicines, with the objective of avoiding medication misadventure and improving medication compliance.	58.4	*	*
Staged Supply**	To support the provision of PBS medicines in instalments when requested by the prescriber (excluding the section 100 opioid dependency treatment programme). These instalments may be daily, weekly, or as otherwise agreed with the prescriber. The service is particularly targeted to patients with a mental illness, drug dependency or who are otherwise unable to manage their medicines safely.	7.2	*	*
Medication Management Programmes:	To support quality use of medicines services that are designed to reduce adverse medicine events and associated hospital admissions or medical presentations	63.4	114.9	178.3
Clinical Interventions	To identify, resolve and document drug-related issues that are identified within community pharmacy. The Programme seeks to improve patient health outcomes and improve quality use of medicines.	19.8	*	*
Home Medicines Reviews	To enhance the quality use of medicines and reduce the number of adverse medicine events, by assisting consumers to better manage and understand their medicines through a medication review conducted by an accredited pharmacist in the patient's home.	14.5	*	*
Residential Medication Management Reviews	To enhance the quality use of medicines for consumers in approved Australian Government funded aged care facilities, by assisting consumers and their carers to better manage their medicines. The programme will also support activities that are designed to improve quality use of medicines across approved Australian Government funded aged care facilities.	14.2	*	*
MedsCheck	To provide an in-pharmacy medicine review between pharmacists and consumers to enhance quality use of medicines and reduce the number of adverse medicines events.	14.9	*	*
Aboriginal and Torres Strait Islander Specific Programmes:	To support targeted programmes and services which improve quality use of medicines and culturally-appropriate services for Aboriginal and Torres Strait Islander (ATSI) consumers	6.1	33.9	40.0
QUMAX	To enable pharmacies to work with rural and urban Aboriginal Health Services to improve the quality use of medicines by clients of those services who access PBS medicines.	2.5	*	*
S100 Support Allowance	To provide an allowance to approved pharmacies and approved hospital authorities to improve the quality use of medicines by clients of Remote Aboriginal Health Services that participate in the s100 supply arrangements.	3.3	*	*

Programme name	Description of Programme [¥]	Year 1 of 6CPA \$m	Years 2 – 5 of 6CPA* \$m	Total \$m
ATSI Workforce Programme	<i>To fund a range of initiatives designed to strengthen and support the ATSI pharmacy workforce, which in turn will provide improved, culturally-appropriate pharmacy services for ATSI consumers.</i>	0.3	*	*
Rural Support Programmes:	To support targeted programmes and services which improve access to PBS medicines and services for people living in rural and remote regions of Australia	21.2	99.1	120.3
Rural Pharmacy Workforce Programme	<i>To fund a range of initiatives designed to strengthen and support the rural pharmacy workforce, in turn to provide increased access to quality pharmacy services for consumers residing in rural and remote regions of Australia.</i>	6.9	*	*
Rural Pharmacy Maintenance Allowance	<i>To support improved access to PBS medicines and pharmacy services for people in rural and remote regions of Australia, through the provision of a support allowance which recognises the additional financial burden of maintaining a pharmacy in these areas.</i>	14.3	*	*
eHealth:	To support initiatives designed to improve outcomes through sharing of information as part of a personally-controlled electronic health record	12.7	48.3	61.0
Electronic Prescription Fee ('EPF')	<i>To support payment of an electronic prescription fee per transaction to approved suppliers for eligible electronic prescriptions.</i>	12.7	*	*
Other activity:	To support additional activities under this Agreement	8.3	15.9	24.2
Programme administration and audit	<i>To support payment administration and audit activity to be undertaken to support implementation, ongoing management and any audit activity associated with programmes that are approved to continue by the Minister.</i>	6.8	14.4	21.2
Comprehensive review of pharmacy remuneration and regulation	<i>To support a comprehensive, independent and public review of pharmacy regulation and remuneration (including wholesaler remuneration), within the first two years of the Term.</i>	3 million		
TOTAL		177.3	435.7	613.0

Table notes:

[¥] Compliance arrangements will be used to ensure ongoing accountability.

* Funding for Community Pharmacy Programmes under this Agreement will be subject to a cost-effectiveness assessment as outlined in clause 6.1.3.

** Based on evidence already collected and available, the likelihood of these programmes being found cost-effective and being recommended for further expansion is very high. Therefore, both parties acknowledge that up to an additional \$122 million (within the total funding limit specified in clause 6.1) may be made available for Financial Years 4 and 5, subject to cost-effectiveness assessment outcomes from the Medical Services Advisory Committee (or other health technology assessment body, as determined by the Minister) and decisions by the Minister.

Appendix C

Adjustment of the Additional AHI Fee in the Financial Year commencing 1 July 2019

[Clause 4.5]

1. To seek to ensure that the total Additional AHI Fees paid by the Commonwealth during the Term is equal to the Additional AHI Fees Cap, the Additional AHI Fee for the Financial Year commencing on 1 July 2019 will be adjusted in the circumstances and on the basis set out in this Appendix C.
2. The amount of the Additional AHI Fee payable by the Commonwealth (as set out in Table 4) is based on the following estimates:

Table 6: Additional AHI Fee

Financial Year	Total Additional AHI Fee paid by the Commonwealth
1 July 2017 to 30 June 2018	\$66,700,000
1 July 2018 to 31 December 2018	\$39,435,000
Total AAF Estimate	\$106,135,000

3. The total Additional AHI Fee paid by the Commonwealth between 1 July 2017 and 31 December 2018 (**Total AAF Paid**) will be determined by multiplying the Additional AHI Fee in the relevant Financial Year (or part thereof) by the number of PBS and RPBS prescriptions over the Maximum Co-Payment in that Financial Year (or part thereof). The number of PBS and RPBS prescriptions over the Maximum Co-Payment in the relevant Financial Year (or part thereof) will be determined based on PBS and RPBS 'Date of Supply' data published by the Commonwealth with respect to that period. It is expected that such data will be available for the period up to 31 December 2018 by on or about April 2019.
4. If the total amount determined under paragraph 3 varies from the total estimate set out in Table 6 by more than one percent then an adjustment will be made to the Additional AHI Fee specified in Table 4 for the Financial Year commencing on 1 July 2019 by applying the following formula:

$$\text{New AAF} = \text{AAF plus or minus AAF Adjustment}$$

where:

AAF means Additional AHI Fee in the Financial Year commencing 1 July 2019, as set out in Table 4.

AAF Adjustment means the TAAFV divided by the TEP.

New AAF means the Additional AHI Fee that will be payable by the Commonwealth in the Financial Year commencing 1 July 2019.

TAAFV means the Total AAF Estimate set out in Table 6 less the Total AAF Paid.

TEP means the estimated above Maximum Co-Payment prescription volume for the Financial Year commencing on 1 July 2019 which will equal the number of PBS and RPBS prescriptions over the Maximum Co-Payment during the 12 months ending 31 December 2018 as determined based on PBS and RPBS 'Date of Supply' data published by the Commonwealth with respect to that period.

5. The parties intend to promptly conduct a final reconciliation of the total Additional AHI Fee paid by the Commonwealth during the final 3 Financial Years of the Term to determine if it was equal to the Additional AHI Fee Cap. The final reconciliation will be conducted by multiplying the actual number of PBS and RPBS prescriptions over the Maximum Co-Payment in each of those 3 Financial Years by the Additional AHI Fee paid by the Commonwealth in the relevant Financial Year. The actual number of PBS and RPBS prescriptions will be determined based on PBS and RPBS 'Date of Supply' data published by the Commonwealth with respect to that period. This paragraph 5 will survive the expiry of the Term.

6. The parties will negotiate in good faith to include a mechanism in any new community pharmacy agreement to apply after the expiry of this Agreement to address any difference between the actual Additional AHI Fees paid by the Commonwealth under this Agreement and the Additional AHI Fee Cap.

Appendix D

Compact

See following document.

Strengthening PBS

Agreement with Pharmacy Guild to vary the Sixth Community Pharmacy Agreement

Purpose

The Australian Government and the Pharmacy Guild have entered into the Sixth Community Pharmacy Agreement (6CPA), which operates until 30 June 2020, to support the National Medicines Policy and the sustainability of the Pharmaceutical Benefits Scheme, contributing to the Government's investment of \$4.9 billion in new medicine listings, and providing greater certainty of Government revenue to community pharmacies, in an environment of ongoing medicine price reductions associated with price disclosure.

The parties have been negotiating the appropriate response to an identified shortfall in the volume of dispensed medicines against forecasts in the first year of operation of the 6CPA. This agreement will resolve this issue, and secure community pharmacy support for a range of further reforms, including those that are currently being negotiated with Medicines Australia.

The Agreement is underpinned by the shared principles of:

- **stewardship** of the health system and a shared responsibility for its ongoing sustainability, in particular a shared responsibility for the stewardship of the PBS;
- **partnership** in the delivery of Australia's National Medicines Policy;
- **stability and certainty** of the Government's investment in the medicine supply chain, and the timely availability of medicines to all Australians through a well-distributed community pharmacy network; and
- **integrity** of Australia's world class health system, including patient safety and high value clinical care.

Statement of Intent for the Government

The Government recognises the significant pressures on the health system, including a growing burden of chronic disease, an ageing population, and growing demand for high-cost, high-tech services and breakthrough medicines. It also recognises the pivotal role of the community pharmacy sector in delivering medicines to Australian patients.

The Government is committed to ensuring it implements its obligations under the 6CPA, and secures the support of community pharmacy in making further PBS reforms.

\$200m Support for Pharmacists in recognition of lower than expected script volumes

The Government will provide financial support to pharmacies in recognition of lower than expected PBS prescription volumes under the 6CPA. In 2015-16, total script volumes were 2.14 per cent lower than forecast in the 6CPA.

It is proposed that a fixed funding amount of \$200 million, no more, no less, be provided to community pharmacy over the remaining life of the 6CPA. This would be achieved through an increase to the AHI, which can be done immediately. This increase to AHI is expected to cease at the end of the 6CPA (30 June 2020).

Improved 6CPA Community Pharmacy Programs

The Government also recognises the key role that community pharmacy plays in the primary health care team, and the assistance that community pharmacy can provide in achieving the whole-of-health system goals of providing the right care in the right place at the right time.

The Government will work with the Guild to modernise community pharmacy programs to provide better primary health care for Australians in the key areas of:

- medication adherence (effective support for dose administration aids and staged supply for those patients that would benefit from these services);
- medication management (effective support for pharmacists to identify issues with patient medicines, and ensure appropriate clinical responses, including through making contact with the patient's doctors and providing advice to patients – this will support pharmacy services in locations that suit the needs of patients, including in the pharmacy, at the patient's home or aged care facility (and within Aboriginal Health Services); and
- improved medication support for Aboriginal and Torres Strait Islanders, including through greater capacity for remote dispensing, and culturally appropriate care.

The pharmacy programs will also be redesigned to support the collection of information to allow assessment of the effectiveness of these interventions, and will be funded through a combination of maintaining existing levels of pharmacy program funding, and through an additional investment from the \$600 million held in the Contingency Reserve for new and expanded community pharmacy programs. Specifically, from 1 July 2017, the \$600 million held in the Contingency Reserve will support new and expanded pharmacy programs including:

- Dose Administration Aids (\$340m of \$600m)
- Staged Supply (\$80m of \$600m)
- Expansion of MedsCheck and Diabetes MedsCheck program (\$90m of \$600m)
- Inclusion of follow up services for Home Medicines Reviews (\$60m of \$600m)
- Incorporating medication management programs within Health Care Homes (\$30m of \$600m)

The Government commits to deliver the full value of \$600 million within the period of the 6CPA. Individual program projections are indicative and may be varied in writing by mutual consent of the Guild and the Government.

The Government commits to this funding being made available (through an appropriately phased approach) from 1 July 2017 until the expiry of the 6CPA. The Government will make decisions regarding changes to Program Guidelines and related matters in sufficient time to enable the Guild as the administrator of the community pharmacy programs to make the requisite changes to its systems and processes from 1 July 2017.

Removal of the Sunset Provision for Location Rules

The Government has provided a commitment to the continuation of the community pharmacy location rules beyond the life of the 6CPA by amending the relevant sections of the *National Health Act 1953* at the earliest opportunity.

Pharmacy Remuneration and Regulation Review

The Government will work with the Pharmacy Guild to ensure that the response to the Pharmacy Remuneration and Regulation Review maintains the community pharmacy model and secures a viable community pharmacy sector.

Optional co-payment discount of up to \$1 per script

The Government has indicated it is willing to review the optional co-payment discount of up to \$1 per script following the report of the Pharmacy Remuneration and Regulation Review. However, its willingness to undertake this review does not indicate a current predisposition to discontinue the \$1 discount.

Compensation for community pharmacy and wholesalers

The Government will provide \$10 million in compensation for community pharmacy over the life of the 6CPA as a result of the reduced remuneration driven by the pricing measures included under the Strategic Agreement (SA) with Medicines Australia. This \$10 million will be paid in 2018-19 and 2019-20 through a further adjustment to the AHI commencing on 1 July in each of these years.

A further \$15 million will be provided to wholesalers over the 6CPA as compensation for both the lower than expected script volumes, and reduced remuneration as a result of the measures under the SA.

Statement of Intent for the Pharmacy Guild

The Pharmacy Guild recognises that stewardship is important to ensure the long term sustainability of the health system.

Support PBS price reforms

The Guild will support the further pricing reforms that have been negotiated with Medicines Australia to ensure the sustainability of the PBS. Notably, support:

- extended/additional F1 statutory price reductions; and
- increasing the 16% Statutory Price Reduction to 25% on the entry of the first generic or biosimilar brand competition.

Support PBS Stewardship measures

The Guild will support the introduction of measures that improve the uptake of biosimilar medicines as recommended by the Pharmaceutical Benefits Advisory Committee on a case-by-case basis, including the introduction of preferred prescribing of a biosimilar brand for treatment naïve patients, streamlined authorities for biosimilars compared to the reference biologic, and enhancements to prescribing and dispensing software to establish default prescribing by active ingredient rather than by brand (unless overridden by the prescriber).

The Guild will also continue to support the appropriate dispensing of biosimilar medicines with a view to increase the uptake of biosimilar medicines by working with the Government in promoting the Biosimilars Awareness Initiative and any related initiatives to support community pharmacists to proactively engage with prescribers and consumers, along with enhancements to its ScriptMAP tool to enable pharmacies to benchmark their uptake of biosimilar medicines.

6CPA Provisions regarding Reconciliation and Materiality Threshold

Recognising the additional \$200 million in support that the Government is providing community pharmacies for dispensing through to 30 June 2020, the Guild agrees that it will not seek any further amelioration for variations in PBS and RPBS prescription volumes under clause 5.4 of the 6CPA for the remainder of the term of the 6CPA.

Support Effective Implementation of Reformed Pharmacy Programs and increase the role of community pharmacy in primary care and Health Care Homes

As administrator of the community pharmacy programs, the Guild will assist in making timely changes to allow reformed programs to be delivered from 1 July 2017.

The Guild will seek to build on the collaborative primary health care arrangements in place within the Primary Health Networks (PHNs) that involve community pharmacies in the provision of support to patients, seeking to further improve their health outcomes. To this end, the Government will work collaboratively with the PHNs to update the PHN guidelines and relevant documents, in consultation with the Guild, at the earliest possible time to ensure that community pharmacies together with General Practices are identified and represented as key stakeholders.

Building on this, the Health Care Homes (HCH) trials will focus on patients with chronic and complex conditions, providing flexibility at the local level to establish and enhance existing arrangements, including the central role of community pharmacies in delivering medicines and related care. The Government will advise participating HCHs that the shared care plans for HCH patients should include a plan to manage their medication needs, where clinically relevant, working with the patient's pharmacy, enabling the provision of necessary medication support. The Guild will work with its member pharmacies in HCH trial areas to build awareness of the trials and facilitate their engagement and collaboration with HCHs participating in the trials.

In addition to this, the Guild will continue to work cooperatively with the Government on the development of new and innovative ideas to expand the role of community pharmacy in supporting primary health care for patients, including appropriate evaluation of such measures, as well as working in partnership with the Australian Digital Health Agency to maximise the uptake and clinical use of the MyHealth Record by community pharmacies.