Your ref: C2007/1896 Our ref: PFH:20120224

27 April 2017



General Manager
Adjudication Branch
Australian Competition and Consumer Commission
23 Marcus Clarke Street
CANBERRA ACT 2601

BY EMAIL: adjudication@accc.gov.au

Dear Mr Jones

Authorisation A91348 lodged by eRx Script Exchange Pty Ltd

We refer to earlier correspondence and confirm we act on behalf of eRx in respect of an Application for Authorisation.

To that end we attach:

- 1. Form B Application for Authorisation signed on behalf of eRx.
- 2. Annexure A (Commercial Interchange Agreement dated 17 December 2012).
- 3. Annexure B (Sixth Community Pharmacy Agreement dated 24 March 2015).
- 4. Annexure C (Definition of Relevant Market and Participants).
- 5. Letter Department of Health to ACCC dated 20.04.17
- Westpac Payment Detail Report dated 26 April 2017 in respect of the payment of the ACCC lodging fee of \$7,500 on behalf of eRx Script Exchange Pty Ltd.

As the existing Authorisation ends on 30 June 2017, eRx requests an Interim Authorisation and in respect of that request:

1. The present Authorisation came into force on 29 March 2013 (and the related Interim Authorisation on 6 December 2012). It is submitted that the relevant market will continue to operate as it has since December 2012, and will not change if an Interim Authorisation is granted.



PRINCIPALS

Anthony Riordan

BCom, LLB, MTax Accredited Tax Law Specialist

Paul Hesse

LLB, Accredited Commercial Litigation Specialist

Simon Jay

BA, LLB

SENIOR ASSOCIATES

Craig Healy

LLB

Carmel Woodward

BA, LLB (Hons) Accredited Commercial Tenancy Law Specialist, Accredited Wills & Estates Specialist

- 2. The present Authorisation ends on 30 June 2017 and the Applicant seeks the Interim Authorisation so that the status quo can continue until this Authorisation Application is dealt with.
- 3. If the Interim Authorisation is denied and the present Authorisation Application is not granted before 30 June 2017, the Applicant will have to cease dealing with MediSecure under the Commercial Interchange Agreement, and the number of prescriptions processed under the PES (because of the ceasing of the Commercial Interchange Agreement) will decrease, which will have an adverse impact on Quality Use of Medicines (QUM) and will also adversely impact on the income of both eRx and MediSecure as the number of eligible prescriptions (and fees shared on those prescriptions) for each PES will decrease.
- 4. As noted in paragraph 2 (d) of the Application, eRx is not aware of any other potential entrants, so that the granting of an Interim Authorisation will not adversely affect any potential entrants.
- 5. The Applicant is of the view that there will be no detriment caused to the public in granting an Interim Authorisation, and given that the existing Authorisation ceases to be of force after 30 June 2017, there is a benefit to the public by granting the Interim Authorisation in that it will allow the Commercial Interchange Agreement to continue until the granting of an Authorisation (in the event that the Authorisation is not granted before 30 June 2017).

We note that Clause 48 of the Commercial Interchange Agreement provides that if the present Authorisation is subsequently withdrawn or otherwise ends for any reason, then the Commercial Interchange Agreement shall automatically end regardless of any other expressed or implied rights of termination. For this reason, our client's preference is for the present Authorisation to be extended (rather than a new Authorisation be granted) to avoid the need to make changes to the Commercial Interchange Agreement. The Applicant requests for the Commission to take this into account when deciding whether to extend or renew the existing Authorisation.

As previously noted, Norman O'Bryan SC prepared the Application in respect of the existing Authorisation, and has settled the attached Application. For that reason, if you have any queries, or wish to organise a meeting, we are happy to organise that with Norman O'Bryan SC if you wish.

Yours faithfully, **Riordans Lawyers**

Paul Hesse

Principal 03 9907 2552 (DIR)

Attach.

Copy to: Mr Theo Kelly

Form B

Commonwealth of Australia

Competition and Consumer Act 2010 — subsections 88 (1A) and (1)

AGREEMENTS AFFECTING COMPETITION OR INCORPORATING RELATED CARTEL PROVISIONS: APPLICATION FOR AUTHORISATION

To the Australian Competition and Consumer Commission:

Application is hereby made under subsection(s) 88(1)/(1A) of the Competition and Consumer Act 2010 for an authorisation:

- to make a contract or arrangement, or arrive at an understanding, a provision of which would be, or might be, a cartel provision within the meaning of Division 1 of Part IV of that Act (other than a provision which would also be, or might also be, an exclusionary provision within the meaning of section 45 of that Act).
- to give effect to a provision of a contract, arrangement or understanding that is, or may be, a cartel provision within the meaning of Division 1 of Part IV of that Act (other than a provision which is also, or may also be, an exclusionary provision within the meaning of section 45 of that Act).
- to make a contract or arrangement, or arrive at an understanding, a provision of which would have the purpose, or would or might have the effect, of substantially lessening competition within the meaning of section 45 of that Act.
- to give effect to a provision of a contract, arrangement or understanding which provision has the purpose, or has or may have the effect, of substantially lessening competition within the meaning of section 45 of that Act.

(Strike out whichever is not applicable)

PLEASE FOLLOW DIRECTIONS ON THE BACK OF THIS FORM

1. Applicant

(a) Name of Applicant: (Refer to direction 2)

A91579

eRx Script Exchange Pty Ltd (ACN 132 844 658) ("eRx")

(b) Short description of businesses carried on by applicant: (Refer to direction 3)

The applicant operates an electronic pharmaceutical prescription exchange system. The eligible transactions through the PES were previously funded by the Commonwealth of Australia under the Fifth Community Pharmacy Agreement

until 30 June 2015, and are currently funded through the Sixth Community Pharmacy Agreement until 30 June 2020.

- (c) Address in Australia for service of documents on the applicant:20 Trenerry Crescent, Abbotsford, Victoria, 3067.
- (d) Electronic address for service of documents on the applicant (this is optional and does not replace the need to provide an address in Australia at paragraph(c)):

 david.freemantle@fred.com.au

2. Contract, arrangement or understanding

(a) Description of the contract, arrangement or understanding, whether proposed or actual, for which authorisation is sought:

(Refer to direction 4)

Authorisation is sought to continue a contract (Commercial Interchange Agreement) which has the purpose of allowing eRx to continue operating its prescription exchange system (PES) interoperably with IP MDS Pty Ltd's (formerly MediSecure Pty Ltd) (MDS) PES and vice-versa and sharing the Qualifying Prescription fee that is paid to the dispensing pharmacist by the Commonwealth of Australia under the Sixth Community Pharmacy Agreement and in turn charged by the Dispensing PES to that dispensing pharmacist. Clause 14 of the contract, which is the subject of this application, is on page 2 of the attached copy of the Commercial Interchange Agreement dated 17 December 2012 which is attached and marked as annexure A.

(b) Description of those provisions of the contract, arrangement or understanding described at 2 (a) that are, or would or might be, cartel provisions, or that do, or would or might, have the effect of substantially lessening competition:

(Refer to direction 4)

Clause 14 provides that eRx and MDS will share equally in the fee which is charged to a pharmacy user and the Commonwealth by the PES to which the pharmacy is connected in respect of each prescription that has originated on the PES of the other party.

(c) Description of the goods or services to which the contract, arrangement or understanding (whether proposed or actual) relate:

The provision by eRx and MDS of the services of their respective PESs for use by pharmaceutical prescribers (usually doctors) and dispensers (usually pharmacists), which are capable of carrying electronic messages between doctors and pharmacists to facilitate the dispensing of pharmaceutical prescriptions safely, accurately, quickly and securely, and associated computerised record keeping and other information systems and processes.

(d) The term for which authorisation of the contract, arrangement or understanding (whether proposed or actual) is being sought and grounds supporting this period of authorisation:

Authorisation is requested until such time as the contract made between the applicant and MDS referred to in paragraph 2(a) above has terminated, expired or otherwise been brought to an end, or until funding under the Sixth Community Pharmacy Agreement ends on 30 June 2020. As the existing authorisation ends on 30 June 2017, an interim authorisation is sought to allow the applicant and MDS to continue to operate their respective PESs interoperably pursuant to the Commercial Interchange Agreement dated 17 December 2012 until a decision is made on this application for authorisation.

3. Parties to the proposed arrangement

(a) Names, addresses and descriptions of business carried on by other parties or proposed parties to the contract or proposed contract, arrangement or understanding:

Name: IP MDS Pty Ltd (ACN 132 172 957) (formerly MediSecure Pty Ltd) (MDS)

Address: 127 Erskine Street, Middle Park, Victoria, 3206

Business: MDS operates an electronic pharmaceutical prescription exchange system.

(b) Names, addresses and descriptions of business carried on by parties and other persons on whose behalf this application is made: (Refer to direction 5)

Not applicable.

4. Public benefit claims

(a) Arguments in support of authorisation: (Refer to direction 6)

Supporting the uptake and use of electronic prescriptions is a significant policy component of the Sixth Community Pharmacy Agreement. It aims to improve the quality use of medicines through supporting the use of electronic transfer of prescriptions. The benefit of interoperability is that the prescriber provides an electronic prescription that is accessible by pharmacies so that they do not have to rekey the information, leading to a reduction in transcription errors. The policy has had and is forecast to continue to create potential improvements to healthcare, in particular medication management which will help to reduce unnecessary burden on the health

system, as well as providing for general efficiency benefits for both prescribers and dispensers (pharmacies).

A key component of this policy is the payment of an "Electronic Prescription Fee" (EPF) which is being used to fund the costs to pharmacy associated with accessing or downloading an electronic prescription. The value of the EPF is set through consultation with the Pharmacy Guild of Australia (which is a signatory to the Sixth Community Pharmacy Agreement with the Australian Government). The Sixth Community Pharmacy Agreement states that the EPF Programme is part of the eHealth Programme, and the eHealth Programme is described as a programme "to support initiatives designed to improve outcomes through sharing of information as part of a personally controlled electronic health record".

The success of the policy is measured by the uptake and use of electronic prescriptions, with all eligible electronic prescriptions¹ attracting a payment of the EPF to the pharmacy. A PES vendor charges pharmacies based on the number of electronic prescriptions and repeats transferred through its service. Currently this charge is 15 cents, the same as the EPF. This charge is currently paid by the pharmacy to the relevant PES with the PESs having their own commercial agreements with partner vendors of pharmacy and general practitioner desktop software involved in each electronic prescription transaction.

The number of eligible electronic prescriptions for 2011-12 was less than expected. Early analysis revealed that there were a large numbers of electronic prescriptions being lodged to the PES by prescribers, but the number being downloaded by dispensers was quite low. One of the causes identified was that the patient presents to a pharmacy which is not connected to the PES containing the electronic prescription.

Under an interoperable environment PESs are able to share prescriptions and repeats. The EPF is currently paid to the pharmacy which then pays the PES which downloaded the prescription for dispensing by a pharmacist. The Applicant had to negotiate with MDS an acceptable "Inter-PES Transaction Fee" to ensure that the PEPF is

(c) the electronic prescription is processed through a Prescription Exchange Service; and

¹ An 'eligible electronic prescription' means:

⁽a) it is a PBS or RPBS prescription (including prescriptions for items priced below the maximum general patient contribution as defined in the *National Health Act 1953*) dispensed by an approved supplier that is generated electronically in accordance with the process described in the definition of 'electronic prescription' contained in this Schedule and with the National eHealth Transition Authority specification for the Electronic Transfer of Prescriptions, or

⁽b) a repeat authorisation and/or a deferred supply authorisation:

⁽i) downloaded from a PES; and

⁽ii) related to an original electronic prescription satisfying (a)

and

⁽d) if the electronic prescription relates to an item priced below the maximum General patient contribution as defined in the *National Health Act 1953*, the following information in the electronic prescription has been validated and, if necessary, corrected by the approved supplier:

⁽i) the patient's name;

⁽ii) the patient's Medicare number;

⁽iii) information about the prescription (including the date of prescribing and supply, the PBS code number, the drug name and form, the quantity dispensed and the number of repeats);

⁽iv) the prescriber approval number; and

⁽v) the approved supplier number.

appropriately apportioned in circumstances where different PESs hold the original electronic prescription and connect to the pharmacy that dispenses the prescription.

Under clause 14 of the contract the parties share equally in the Commercial Fee so as to eliminate any incentive which might otherwise exist for either of them to seek to ensure that prescriptions which have originated on their system (i.e. at the point of original prescribing) remain on their system at the point of dispensing (i.e. in the pharmacy). Interoperability is best promoted if neither party has any economic or commercial incentive to seek to capture or retain prescriptions down to the point of dispensing (at which point payments are made and received for the pharmaceuticals, including the costs associated with their supply).

Additional submissions in support of the public benefits of the Interoperability Project, and the need to ensure that the applicant's interests in respect of the success of the project remain aligned through the equal sharing of the Commonwealth's fees, are contained in annexure C.

(b) Facts and evidence relied upon in support of these claims:

The Sixth Community Pharmacy Agreement which is dated 24 May 2015 and expires on 30 June 2020, a true copy of which is attached to this application and marked as annexure B.

5. Market definition

Provide a description of the market(s) in which the goods or services described at 2 (c) are supplied or acquired and other affected markets including: significant suppliers and acquirers; substitutes available for the relevant goods or services; any restriction on the supply or acquisition of the relevant goods or services (for example geographic or legal restrictions):

(Refer to direction 7)

See annexure C

6. Public detriments

(a) Detriments to the public resulting or likely to result from the authorisation, in particular the likely effect of the contract, arrangement or understanding, on the prices of the goods or services described at 2 (c) and the prices of goods or services in other affected markets:

(Refer to direction 8)

There are submitted to be no public detriments arising out of the contract, for the reasons identified in annexure C

(b) Facts and evidence relevant to these detriments:

N/A

7. Contract, arrangements or understandings in similar terms

This application for authorisation may also be expressed to be made in relation to other contracts, arrangements or understandings or proposed contracts, arrangements or understandings, that are or will be in similar terms to the abovementioned contract, arrangement or understanding.

(a) Is this application to be so expressed?

No.

- (b) If so, the following information is to be furnished:
 - (i) description of any variations between the contract, arrangement or understanding for which authorisation is sought and those contracts, arrangements or understandings that are stated to be in similar terms:

 (Refer to direction 9)

N/A

(ii) Where the parties to the similar term contract(s) are known—names, addresses and descriptions of business carried on by those other parties:

N/A

(iii) Where the parties to the similar term contract(s) are not known—description of the class of business carried on by those possible parties:

N/A

8. Joint Ventures

(a) Does this application deal with a matter relating to a joint venture (See section 4J of the Competition and Consumer Act 2010)?

No.

(b) If so, are any other applications being made simultaneously with this application in relation to that joint venture?

N/A

(c) If so, by whom or on whose behalf are those other applications being made?

N/A

9. Further information

(a) Name and address of person authorised by the applicant to provide additional information in relation to this application:

Mr David Freemantle, General Manager Government and Enterprise, FRED IT Group Pty Ltd ACN 109 546 901, 20 Trenerry Crescent, Abbotsford, Victoria, 3067 (eRx Script Exchange Pty Ltd is a wholly owned subsidiary of FRED IT Group Pty Ltd)

Dated	26	(April	2017
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Signed by/on behalf of the applicant

For effy Script Exchange Pty Ltd:	
(Signature) DAVA FREBUTUTE	
(Full Name)	
GENERAL MANAGER, GOVERNMENT AND	ENTERPRISE
(Position in Organisation)	

DIRECTIONS

1. Use Form A if the contract, arrangement or understanding includes a provision which is, or might be, a cartel provision and which is also, or might also be, an exclusionary provision. Use Form B if the contract, arrangement or understanding includes a provision which is, or might be, a cartel provision or a provision which would have the purpose, or would or might have the effect, of substantially lessening competition. It may be necessary to use both forms for the same contract, arrangement or understanding.

In lodging this form, applicants must include all information, including supporting evidence, that they wish the Commission to take into account in assessing the application for authorisation.

Where there is insufficient space on this form to furnish the required information, the information is to be shown on separate sheets, numbered consecutively and signed by or on behalf of the applicant.

- 2. Where the application is made by or on behalf of a corporation, the name of the corporation is to be inserted in item 1 (a), not the name of the person signing the application and the application is to be signed by a person authorised by the corporation to do so.
- 3. Describe that part of the applicant's business relating to the subject matter of the contract, arrangement or understanding in respect of which the application is made.
- 4. Provide details of the contract, arrangement or understanding (whether proposed or actual) in respect of which the authorisation is sought. Provide details of those provisions of the contract, arrangement or understanding that are, or would or might be, cartel provisions. Provide details of those provisions of the contract, arrangement or understanding that do, or would or might, substantially lessen competition.

In providing these details:

- (a) to the extent that any of the details have been reduced to writing, provide a true copy of the writing; and
- (b) to the extent that any of the details have not been reduced to writing, provide a full and correct description of the particulars that have not been reduced to writing.
- 5. Where authorisation is sought on behalf of other parties provide details of each of those parties including names, addresses, descriptions of the business activities engaged in relating to the subject matter of the authorisation, and evidence of the party's consent to authorisation being sought on their behalf.
- 6. Provide details of those public benefits claimed to result or to be likely to result from the proposed contract, arrangement or understanding including quantification of those benefits where possible.
- 7. Provide details of the market(s) likely to be effected by the contract, arrangement or understanding, in particular having regard to goods or services that may be substitutes for the good or service that is the subject matter of the authorisation.
- 8. Provide details of the detriments to the public which may result from the proposed contract, arrangement or understanding including quantification of those detriments where possible.

- 9. Where the application is made also in respect of other contracts, arrangements or understandings, which are or will be in similar terms to the contract, arrangement or understanding referred to in item 2, furnish with the application details of the manner in which those contracts, arrangements or understandings vary in their terms from the contract, arrangements or understanding referred to in item 2.
- 10. If an address is to be provided in this form, an electronic address may be provided in addition to the address required.

Annexure A

(to eRx Script Exchange Pty Ltd Form B Authorisation Application lodged on 28 April 2017)

Clause 14

- 14. eRx and MDS agree that before a technical solution for interoperability can be found, a commercial interchange agreement must be struck between the parties. eRx and MDS agree that where a QP is collected by one PES and dispensed by any other PES, the interchange fee will be:
 - a. the Originating PES will receive 50% of the Commercial Fee; and
 - b. the Dispensing PES will receive 50% of the Commercial Fee.



Sixth Community Pharmacy Agreement

The Honourable Sussan Ley MP, Minister for Health and Minister for Sport on behalf of the Commonwealth of Australia and

The Pharmacy Guild of Australia

Contents

1.	Definitions			
2.	Term and commencement			
	2.1	Term of Agreement		
	2.2	Conditions precedent to commencement of Agreement	7	
3.	PBS A	access and Sustainability Package	7	
4.	Comm	onwealth price	10	
	4.1	Purpose	10	
	4.2	Commonwealth price		
	4.3	PBS price changes		
	4.4	Wholesaler remuneration		
5.	CSO a	nd other charges and incentives	12	
	5.1	Community Service Obligation Funding Pool		
	5.2	Charges for pharmaceutical benefits below Maximum Co-Payment		
	5.3	Premium Free Dispensing Incentive		
	5.4	Annual community pharmacy and wholesaler reconciliation		
6.	Comm	unity Pharmacy Programmes	15	
	6.1	Allocation of Community Pharmacy Programme funding		
	6.2	Programme governance		
7.	Other	arrangements		
	7.1	eHealth		
	7.2	Location Rules		
	7.3	Availability of PBS medicines in pharmacy		
	7.4	New National Diabetes Services Scheme arrangements		
	7.5	Chemotherapy	18	
	7.6	Obligations of approved suppliers		
	7.7	Data from approved suppliers		
	7.8	Indexation		
	7.9	Payment times		
8.	Comp	rehensive review of pharmacy remuneration and regulation	20	
9.	Gover	nance and consultation	21	
	9.1	Agreement consultation framework	21	
	9.2	Pharmaceutical Services Federal Committee of Inquiry	22	
10.	General matters			
	10.1	Issue resolution	22	
	10.2	Consultation		
	10.3	Variation	_	
	10.4	Arrangements at the end of this Agreement		
	10.5	Entire agreement		
	10.6	Words and headings		
	10.7 10.8	Specific references		
A				
Appei	ndix B		28	

Sixth Community Pharmacy Agreement

Dated May 2015

Parties

Name
The Honourable Sussan Ley MP Minister for Health and Minister for Sport on behalf of the Commonwealth of Australia

Commonwealth

The Pharmacy Guild of Australia (ABN 84 519 669 143)

Level 2, 15 National Circuit, Barton in the Australian Capital Territory

Background

Short name

- 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:

Guild

- 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.

1. Definitions

1.1 In this Agreement, unless the contrary intention appears:

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).

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.

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

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.

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 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 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
ما	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 will be implemented under this Agreement;
- 3.2.2 rows f, g, h, i and k in Table 1 are contingent upon the passage of the 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.
- Once the Bill passes through the Australian Parliament, remuneration and funding of approved pharmacists and others in the pharmaceutical supply chain will be restructured resulting in what the Commonwealth estimates to 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,

as set out in Table 2.

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
dispensing fee, All I fee and dangerous drug fee	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	Commonwealth	1,414
the CSO)	Patient	385
CSO funding pool	Commonwealth	976
	Patient	N/A
Fees for CSO distributors to distribute National	Commonwealth	28
Diabetes Services Scheme products	Patient	N/A
Fees for pharmacy to distribute National	Commonwealth	28
Diabetes Services Scheme products	Patient	No additional patient charge
Total	Commonwealth	15,476
	Patient	3,410
	Total	18,886 ¹
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.
- 3.6 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 Guild will communicate positively with its members and the public about the benefits of the Package as a whole.

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.

3.7 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, 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 2015	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

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

Payment type	Date of effect	Value of payment	
administration, handling and infrastructure fee	1 July 2015	For a pack quantity of a listed brand with a price to pharmacists less than \$180	\$3.49 per dispense
		For a pack quantity of a listed brand with a price to pharmacists from \$180 to \$2,089.71	\$3.49, plus 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	\$70.00 per dispense
dispensing fee (for RPPBs)	1 July 2015	\$6.93 per dispense	
dispensing fee (for EPPBs)	1 July 2015	Dispensing fee for RPPBs, plus \$2.04, per dispense	
dangerous drug fee (for RPPBs)	1 July 2015	\$2.91 per dangerous drug dispensed	

4.2.4 The:

- (a) 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.

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.

5. CSO and other charges and incentives

5.1 Community Service Obligation Funding Pool

- 5.1.1 The Commonwealth has established the CSO to:
 - 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. 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.
- 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) \$1.17; 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.

- 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) \$1.53; 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.

5.3 Premium Free Dispensing Incentive

- 5.3.1 As at 1 July 2015, the PFDI is \$1.72. 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

- 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, subject to clauses 6.1.4 and 6.1.6, 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).
- 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.
- 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.

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 the personally controlled electronic health records; and
 - (b) meet all relevant requirements of the eMedications Management Functional Framework (or equivalent requirements) as they are published by NEHTA from time to time.

7.1.2 In this clause 7.1:

personally controlled electronic health record has the meaning given in the *Personally Controlled Electronic Health Records Act 2012* (Cth) or means an equivalent record.

NEHTA means National E-Health Transition Authority Ltd ACN 114 638 336 or its successor.

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 parties acknowledge that the Bill contains amendments to the Act to extend the sunset dates of 30 June 2015 in sections 90(3C) and 99Y of the Act to 30 June 2020.

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;
 - 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;
 - 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:

New Amount = Last Amount x
$$\left(\begin{array}{c} MRIN \\ IIN \end{array}\right)$$

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);
- 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.

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 March 2017.
- 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).

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 noncompliance 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

Dated 24 May 2015

Signed by The Honourable Sussan Ley MP, Minister for Health and Minister for Sport on behalf of the Commonwealth of Australia

in the presence of:

Witness

Ferry Mines

Name of witness 4

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

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 4: 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			*	*
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	*	*

Programme name	Description of Programme¥	Year 1 of 6CPA \$m	Years 2 – 5 of 6CPA* \$m	Total \$m
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	*	*
ATSI Workforce Programme	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.	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	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.	6.9	*	*
Rural Pharmacy Maintenance Allowance	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.	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')	To support payment of an electronic prescription fee per transaction to approved suppliers for eligible electronic prescriptions.	12.7	*	*
Other activity:	To support additional activities under this Agreement	8.3	15.9	24.2
Programme administration and audit	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.	6.8	14.4	21.2
Comprehensive review of pharmacy remuneration and regulation	To support a comprehensive, independent and public review of pharmacy regulation and remuneration (including wholesaler remuneration), within the first two years of the Term.		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.

Annexure C

eRx Script Exchange Pty Ltd Authorisation Application

A. DESCRIPTION OF RELEVANT MARKET AND PARTICIPANTS

eRx Script Exchange Pty Ltd (the applicant for authorization) and IP MDS Pty Ltd (formerly MediSecure Pty Ltd) operate the two Prescription Exchange Services (**PESs**) which exist today in Australia. The market in which they operate is best described as the market for the provision of electronic (i.e. computerized) services for the communication of prescription information between prescribers (usually doctors), their patients and the pharmacies where the overwhelming majority of pharmaceutical prescriptions are dispensed. These services consist of sophisticated computer systems, programs and equipment which are designed to ensure seamless, reliable and private communication of prescription information, which is naturally of great importance to the patients concerned (effectively all Australians, since everyone has prescriptions).

B. PUBLIC BENEFITS OF THE PROPOSED ARRANGEMENTS

The Commonwealth Department of Health considers that it is an important priority to continue to improve the uptake and use of electronic prescriptions in Australia¹. If a prescriber (usually a doctor) lodges an electronic prescription for a patient with a PES, the patient may be able to have their prescription downloaded by a pharmacy through the pharmacy accessing the PES. However, this occurs only where the pharmacy software connects to the particular PES where the prescription was lodged by the prescriber. Prior to the existing Authorisation there was no interconnection between the computer systems operated by the two PESs to enable a pharmacy connected to one PES to access electronic prescriptions which were held by the other (if the pharmacy was not also connected to the other PES, which was usually the case). As a result of the Commonwealth's PES

The Fifth Community Pharmacy Agreement definition of an electronic prescription states: "An 'electronic prescription' means an electronic prescription which is generated in accordance with a process by which a prescription is electronically generated by a prescriber, authenticated (electronically signed), securely transmitted (either directly or indirectly) for dispensing and supply, seamlessly integrated into the pharmacy dispensing software and, in the case of Pharmaceutical Benefits Scheme (PBS) prescriptions, is available to be electronically sent to Medicare Australia for claiming purposes. This definition does not preclude the use of paper based processes to support ePrescribing activity."

Interoperability Project electronic prescriptions can now be accessed by all pharmacies, no matter which PES the electronic prescription was originally lodged with.

Supporting the uptake and use of electronic prescriptions was a significant policy priority of the Commonwealth's Fifth Community Pharmacy Agreement² and continues to be under the Commonwealth's Sixth Community Pharmacy Agreement, supported by ongoing funding. The Sixth Community Pharmacy Agreement provides funding of \$12.7M per year to fund payments to pharmacists of 15 cents per eligible electronic prescription where the prescription is downloaded by a pharmacy through the pharmacy accessing the PES. The Commonwealth aims to improve the quality use of medicines³ through supporting the use of electronic transfer of prescriptions via the PESs. The expected outcome is that there will continue to be increases in prescribers providing an electronic prescription that is accessible by all pharmacies so that they do not have to re-key the information, leading to a reduction in transcription errors. Presently approx. 75% of doctors and over 90% of pharmacies use a PES, and it is hoped to continue to increase that number. The Commonwealth Government's quality use of medicines policy is expected to result in broad improvements to healthcare in Australia, in particular medication management, which will reduce unnecessary burdens on the Australian health system caused by errors in prescription dispensing, as well as eliminating pharmaceutical wastage and providing for a general workload reduction, particularly for dispensers (pharmacies).

A key component of the implementation of the Commonwealth's policy is the payment of an "Electronic Prescription Fee" (EPF), which is used to fund the costs to pharmacies associated with accessing or downloading electronic prescriptions. The amount of the EPF is set by the Commonwealth following consultation with the Pharmacy Guild of Australia (which is a signatory to the Sixth Community Pharmacy Agreement with the Australian Government).

The success of the policy is measured in part by the uptake and use of electronic prescriptions, with all eligible electronic prescriptions⁴ attracting a payment of the EPF to the pharmacy. A

http://www.health.gov.au/internet/main/publishing.nsf/Content/CFF66BFC540B84BBCA2578AA007DDC84/\$File/5CPA%20Agreement%2005%20August%202010.pdf

²See

³ See section D below

An 'eligible electronic prescription' means:

PES charges pharmacies based on the number of eligible electronic prescriptions and repeats which are transferred through its service. Currently this charge is 15 cents, the same as the EPF. This charge is currently paid to the relevant PES by the dispensing pharmacist (and the dispensing pharmacist is paid the 15 cents by the Commonwealth under the Sixth Community Pharmacy Agreement) and a proportion is subsequently paid by the PES onto partner vendors of pharmacy and general practitioner desktop software, based on agreements between the PES and the other vendors involved in the electronic prescription supply chain.

The number of eligible electronic prescriptions for 2011-12 was less than expected. Early analysis revealed that there were large numbers of electronic prescriptions being lodged to the PES by prescribers (doctors), but the number being downloaded by dispensers (pharmacies) was quite low. The main cause identified was that the patient presented to a pharmacy which is not connected to the particular PES containing the relevant electronic prescription.

Below is a graph which shows the number of users (both doctors and pharmacists) of the Applicant's PES. The graph shows that, since the granting of interim authorization on 6 December 2012, the number of users has increased markedly, and that since 2012 the number has more than doubled. It is expected that these numbers will continue to increase with continued interoperability of the two existing PESs. The Applicant does not have figures for the Medisecure PES, but expects that the percentage growth would have been similar over the same period.

⁽a) it is in PBS or RPBS prescription (including prescriptions for items priced below the maximum general patient contribution as defined in the *National Health Act 1953*) dispensed by an approved supplier that is generated electronically in accordance with the process described in the definition of 'electronic prescription' contained in this Schedule and with the National eHealth Transition Authority specification for the Electronic Transfer of Prescriptions, or

⁽b) in repeat authorisation and/or a deferred supply authorisation:

⁽i) downloaded from a PES; and

⁽ii) related to an original electronic prescription satisfying (a)

and

⁽c) the electronic prescription is processed through a Prescription Exchange Service; and

⁽d) if the electronic prescription relates to an item priced below the maximum General patient contribution as defined in the *National Health Act 1953*, the following information in the electronic prescription has been validated and, if necessary, corrected by the approved supplier:

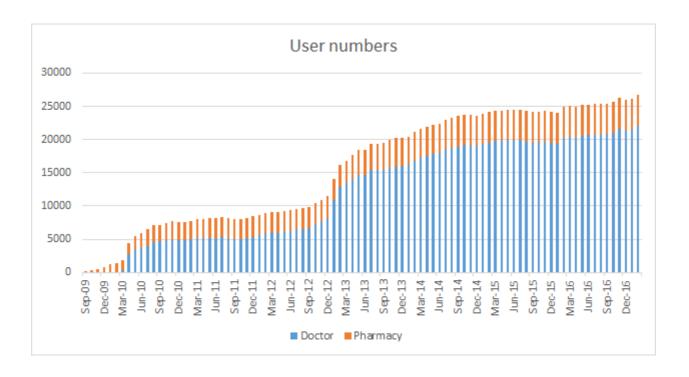
⁽i) the patient's name;

⁽ii) the patient's Medicare number;

⁽iii) information about the prescription (including the date of prescribing and supply, the PBS code number, the drug name and form, the quantity dispensed and the number of repeats);

⁽iv) the prescriber approval number; and

⁽v) the approved supplier number.



C. The Commonwealth's PES interoperability Project

The purpose of the Commonwealth's PES Interoperability Project, which was funded by the Department of Health (the Funding Agreement was Annexure B to the first Application for Authorisation), was to allow electronic prescriptions to be accessed by all pharmacies, no matter which PES the electronic prescription was originally lodged with. This has been achieved.

Under an interoperable environment, PESs are currently able to share all prescriptions and repeats. The EPF is currently paid to the pharmacy by the Commonwealth, and the pharmacy then pays the PES which held the downloaded prescription. The PESs have previously negotiated between themselves an acceptable "Inter-PES Transaction Fee" to ensure that the PEPF is appropriately apportioned in circumstances where different PESs hold the original electronic prescription and connect to the pharmacy that dispenses the prescription. In order to eliminate any incentive for one PES to profit at the expense of the other (which would subvert the intended outcome of maximum interoperability), the PESs agreed (subject to authorization) to divide the PEPF equally between them when a prescription that originates with one of them is dispensed at a pharmacy connected to the other of them. Following the granting of the interim authorization on 6 December 2012, the PESs entered into a

Commercial Exchange Agreement dated 17 December 2012, which in clause 14 (a copy of clause 14 was Annexure A to the first authorisation application) provided that eRx and MediSecure agreed that the Originating PES and the Dispensing PES would each receive 50% of the interchange fee (which was and continues to be 15 cents per eligible prescription).

The public benefits derived from interoperability of the PESs, as described above, are submitted to clearly outweigh any anti-competitive effect which might arguably arise from the agreement between the PESs to share equally the PEPFs that are payable where interoperability is utilised (i.e. a prescription originating on one PES is completed by the other). Equal sharing is fair, equitable and eliminates any economic incentive for either PES to 'hoard' prescriptions or in any other way hinder interoperability.

The ongoing interoperability of PESs will allow the continued growth of utilization of electronic prescriptions. The graph contained on page 4 of this document demonstrates the growth in the number of electronic prescription transactions processed by the eRx PES since the authorisation.

The Applicant is not aware of any prospective new providers who are developing or considering developing a PES, and the Applicant believes it would take any new provider longer than the authorisation period sought (i.e. beyond 30 June 2020) to develop the necessary systems and arrangements to be able to enter the market as a PES. The Commercial Interchange Agreement (Annexure A) in Clause 49 provides that the Applicant and MDS are free to enter into similar interchange agreements with any person or persons who develop a PES and who are permitted to commercialise the use of their PES by the Commonwealth. If an entity seeks to enter the market and establish a PES, the Applicant is willing to negotiate to extend the Commercial Interchange Agreement to that prospective entrant.

D. QUALITY USE OF MEDICINES ("QUM")

Australia's National Medicines Policy seeks to provide better health outcomes for Australians by focusing especially on people's access to, and wise use of, medicines, and seeks to achieve this by governments (Commonwealth, States and Territories) healthcare providers and others working together. The National Medicines Policy aims to meet medication and related service needs, so that both optimal health outcomes and economic objectives are achieved for Australians.

Quality Use of Medicines (QUM) is one of the central objectives of Australia's National Medicines Policy.

A national strategy for QUM has been developed and one of the objectives of the strategy is to improve QUM by health practitioners and health care providers.

The National Strategy for QUM recognises that health practitioner practices and health facilities require ways to advance and coordinate activities both within their practice or organisation and with other health professionals and organisations, and also require access to information that supports best practice.

The benefits of ongoing interoperability of PESs that allows the continued growth of utilisation of electronic prescriptions will allow for the recording and sharing of the medicines dispensed by pharmacists using a PES, which will yield benefits in healthcare services and better use of medicine.



20 April 2017

Mr David Jones General Manager of Adjudication Branch Australian Competition and Consumer Commission GPO Box 3131 Canberra ACT 2601

Dear Mr Jones

Application for Authorisation – Continuation of Interoperability Arrangement between IP MDS Pty Ltd (formerly MediSecure Pty Ltd) & eRx Script Exchange Pty Ltd

I refer to the application being made to the ACCC for authorisation to extend a contract between the two parties named above. I have read and offer my support for the proposed Form B application, a copy of which is attached to this letter (Attachment A).

In 2012 eRx and MediSecure agreed with the Commonwealth through the Department of Health (the Department) to make their respective Prescription Exchange Services interoperable. A Commercial Interchange Agreement (the Agreement) certifying this was established through ACCC Determination on 7 March 2013, authorisation number A91348.

The application seeks to extend the Agreement to 30 June 2020 to ensure interoperability between the two Prescription Exchange Services continues until the end of the current pharmacy agreement, the Sixth Community Pharmacy Agreement (6CPA). An interim authorisation is also being sought by eRx Script Exchange Pty Ltd from the original Agreement end date of 30 June 2017 until the ACCC makes a final Determination.

Interoperability between the two systems continues to be in the public interest as it enables patient choice of pharmacy and facilitates efficiencies through the widespread use of electronic prescriptions in pharmacies. Continuation of interoperability between the two Prescription Exchange Services also allows continued improvement of Australian medication management systems, better enables the Quality Use of Medicines (QUM) initiative under the National Medicines Policy and contributes to the broader digital health agenda.

The effecting of interoperability between these systems is a direct consequence of the policy outcomes sought by the Department of Health. In giving effect to the Government's policy in eHealth, which is for the general benefit of the Australian community and for ongoing maintenance of the health system, the Department of Health is of the view that electronic prescriptions are an essential component in any eHealth system.

The Department of Health supports continued authorisation of the proposed agreement on the basis that it is essential to the ongoing progression and development of electronic prescribing.

Should you require further information in support of the application, please contact Rowena Sierant, Director, Electronic Medication Management Section, Department of Health on (02) 6289 2343 or by email at rowena.sierant@health.gov.au.

Yours sincerely

Andrew Stuart

Deputy Secretary, Health Benefits

Department of Health