

First Pharmaceutical Wholesaler Agreement (1PWA)

The Signatories to this Agreement are
The Honourable Mark Butler MP, Minister for Health and Aged Care on behalf of the
Commonwealth of Australia
and
National Pharmaceutical Services Association Limited

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Background

- A. This Agreement is the Pharmaceutical Wholesaler Agreement between the Minister for Health and Aged Care (acting on behalf of the Commonwealth of Australia) and the National Pharmaceutical Services Association Limited (**Association**). It reflects the position reached by the Commonwealth of Australia (**Commonwealth**) with respect to the WMU Payments and CSO Payments that will be made available for payment to Pharmaceutical Wholesalers, following submissions made by the Association to the Commonwealth.
- B. The Association represents the majority (by number and volume) of Pharmaceutical Wholesalers.
- C. This Agreement recognises the central pillars of the National Medicines Policy 2022, which are:
- C.1 equitable, timely, safe and reliable access to medicines and medicines-related services, at a cost that individuals and the community can afford;
 - C.2 medicines meet the required standards of quality, safety and efficacy;
 - C.3 quality use of medicines and medicines safety; and
 - C.4 collaborative, innovative and sustainable medicines industry and research sectors with the capability, capacity and expertise to respond to current and future health needs.
- D. By establishing the basis of the WMU Payments and CSO Payments that will be made available for payment to Pharmaceutical Wholesalers for holding and supplying Pharmaceutical Benefits in connection with the Pharmaceutical Benefits Scheme, this Agreement sets the foundation upon which the Commonwealth and the Association will pursue medicines-related outcomes aligned with the National Medicines Policy 2022 during the Term.
- E. This Agreement is intended to operate separately to, but in parallel with, the Eighth Community Pharmacy Agreement between the Minister for Health and Aged Care on behalf of the Commonwealth of Australia and the Pharmacy Guild of Australia.

Agreement provisions

1. Overview of Pharmaceutical Wholesaler funding

- 1.1 Based on Commonwealth calculations, the amount of \$4.21B will be available for the purposes set out in this Agreement. Table 1 sets out details of the expected combined remuneration of Pharmaceutical Wholesalers to be made by the Commonwealth and patients during the Term.

Table 1: Components of Pharmaceutical Wholesaler funding

Component	\$Billion (estimated)
1. Wholesale Mark-up	\$2.1928B
2. Eligible Pharmaceutical Wholesaler CSO Funding	\$2.0145B
Total	\$4.2073B

2. Wholesale Mark-Up

2.1 Wholesale Mark-Up

- 2.1.1 The WMU Payments provide payments to Pharmaceutical Wholesalers to assist them to hold and deliver Pharmaceutical Benefits to Approved Pharmacists (excluding the CSO Payments).
- 2.1.2 The Wholesale Mark-Up will be applied in accordance with:
- (a) Table 2 from the Commencement Date until 30 June 2026 (inclusive) (in accordance with Table 3 of the 8CPA) in relation to Pharmaceutical Benefits listed under section 85 of the Act and dispensed by Approved Pharmacists; and
 - (b) Table 3 from 1 July 2026 until this Agreement expires or is terminated in relation to Pharmaceutical Benefits listed under section 85 and section 100 of the Act and dispensed by Approved Pharmacists, excluding medicines provided through the Efficient Funding of Chemotherapy Program.

Table 2: Wholesale Mark-Up Payment amounts — Commencement Date to 30 June 2026

Payment type	Value of WMU Payment	
Wholesale Mark-up for Pharmaceutical Benefits delivered to Approved Pharmacists*	When the Ex-Manufacturer Price is up to and including \$5.50	\$0.41 per dispense
	When the Ex-Manufacturer Price is over \$5.50 and up to and including \$720	7.52 percent of the Ex-Manufacturer Price per dispense
	When the Ex-Manufacturer Price is over \$720	\$54.14 per dispense

*The WMU per dispense of a Pack Quantity of a Listed Brand is calculated using the Relevant Quantity.

Table 3: Wholesale Mark-Up Payment amounts — 1 July 2026 onwards

Payment type	Value of WMU Payment	
Wholesale Mark-up for Pharmaceutical Benefits delivered to Approved Pharmacists *	When the Ex-Manufacturer Price is up to and including \$5.50	\$0.24 per dispense
	When the Ex-Manufacturer Price is over \$5.50 and up to and including \$1,000	4.3% of the Ex-Manufacturer Price per dispense
	When the Ex-Manufacturer Price is over \$1,000 and up to and including \$10,000	\$43 + 2% of the amount of the Ex-Manufacturer Price over \$1,000 per dispense
	When the Ex-Manufacturer Price is over \$10,000	\$223 per dispense

*The WMU Payment per dispense is no longer calculated using the Relevant Quantity. Instead, the WMU Payment is calculated using the Ex-Manufacturer Price for the Pack Quantity of a Listed Brand dispensed by the Approved Pharmacist.

- 2.1.3 The WMU Payment amounts set out in Tables 2 and 3 will not be subject to indexation during the Term.
- 2.1.4 The WMU Payments will be made as part of the payment of the Commonwealth Price to Approved Pharmacists in accordance with the Act. If there is an inconsistency between this Agreement and the Act (including the Determination) in relation to the payment of WMU Payments, whilst the Commonwealth may not act inconsistently with the Act, it will consult with the Association with a view to resolving the inconsistency (including by amending this Agreement, if necessary).
- 2.1.5 For clarity, the same WMU calculation will be applied to products that are dispensed under both s100 and s85.

3. Community Service Obligation (CSO) funding

3.1 CSO Wholesale Funding Pool

- 3.1.1 At the Commencement Date, the maximum baseline value of the CSO Wholesale Funding Pool available to for payment to Eligible Pharmaceutical Wholesalers is \$215M excluding GST (\$236.5M including GST) per annum, less the amount referred to in clause 4, with a further \$10M committed for Increased Maximum Dispensing Quantities.
- 3.1.2 The amount of the CSO Wholesale Funding Pool will be adjusted, with effect from each Adjustment Date, in accordance with Tables 4 and 5. The CSO Wholesale Funding Pool may also be increased in accordance with clause 11.

Table 4: CSO Wholesale Funding Base Amount and Top-Up Values

Code	Description of Amount or Top-Up Amount	Value (ex GST)
H1	Amount for First Half (H1) of FY2024-25 (including half of the previously committed \$10M IMDQ Top Up)	\$107.5M + \$5M = \$112.5M
BA BA/2	<u>Base Amount</u> (includes previously committed \$10M IMDQ Top Up) Half Base Amount	\$225M \$112.5M
MSM1 MSM2	<u>Medicine Shortages Management (MSM) Initial Top-Up</u> The MSM1 amount of \$9M is added to the Pool in FY24-25. The MSM2 amount of \$21M is added to the Pool in FY24-25 and will remain funded at that amount (subject to indexation) in each subsequent year of the Agreement, including in the last 6 month period.	\$9M FY24-25 \$21M (annual)
IMDQ	<u>Increased Maximum Dispensing Quantities (IMDQ) Top-Up</u> The IMDQ amount of \$10M is added to the Pool only in FY2025-26.	\$10M (one-off)
S100	<u>Section 100 Top-Up</u> The S100 amount will be added to the CSO Wholesale Funding Pool in FY2026-27, and will remain funded at that amount (subject to indexation) in each subsequent year of the Agreement.	\$78,624,234 (annual)
EGS	<u>Estimated Government Saving from WMU reforms</u> The EGS amount, once determined, will be added to the CSO Wholesale Funding Pool in FY2026-27 and will remain funded at that amount (subject to indexation) in each subsequent year of the Agreement.	Per clause 3.1.3 (est: \$115.5M)

Table 5: CSO Wholesale Funding Pool Adjustment Dates, Pool Amounts and Adjustment Process

The Adjustment Date is immediately prior to:	The Pool Period is:	Calculations and Pool Amounts	Formulae
1 January 2025	1 January 2025 to 30 June 2025	The 2024-25 CSO Wholesale Funding Pool of \$225M is halved to obtain the figure of \$112,500,000 and MSM2 is added (Amount A), and then MSM1 is added giving Amount B .	$A = BA/2 + MSM2$ $ (= \$112.5M + \$21M = \$133.5M)$ $B = A + MSM1$ $ (= \$133.5M + \$9M = \$142.5M)$
1 July 2025	1 July 2025 to 30 June 2026	Amount A is added to H1, and the total is indexed by CPI (per clause 3.1.5), giving Amount C , to which the IMDQ is added, giving Amount D .	$C = (H1 + A)*CPI$ $D = C + IMDQ$
1 July 2026	1 July 2026 to 30 June 2027	Amount C is indexed by CPI (per clause 3.1.5), to which the S100 and EGS are added, giving Amount E .	$E = C*CPI + S100 + EGS$
1 July 2027	1 July 2027 to 30 June 2028	At 1 July 2027, Amount E is indexed by CPI (per clause 3.1.5) giving Amount F .	$F = E*CPI$
1 July 2028	1 July 2028 to 30 June 2029	At 1 July 2028, Amount F is indexed by CPI (per clause 3.1.5), giving Amount G .	$G = F*CPI$
1 July 2029	1 July 2029 to 31 December 2029	At 1 July 2029, Amount G is indexed by CPI, (per clause 3.1.5) and then halved, giving Amount H . Half of MSM2 (indexed from FY24-25 to end FY28/29) is added, giving Amount I .	$H = G*CPI/2$ $I = H + MSM2*compound\ CPI$

3.1.3 The parties acknowledge and agree that:

- (a) as a result of transitioning from the Wholesale Mark-Up as described in Table 2, to the Wholesale Mark-Up as described in Table 3, the Commonwealth anticipates achieving a Government Saving;
- (b) the quantum of any Government Saving (including as applied pursuant to clause 3.1.2) will be as calculated by the Commonwealth on or before 1 July 2026 (and may rely on estimates, extrapolations, or both, made by the Commonwealth). For clarity, the Government Saving calculation will occur on a like for like basis (i.e. Section 85 volumes and values only) only using the Pack Quantity(not the Relevant Quantity) for FY26; and
- (c) for the purposes of this Agreement, the Commonwealth's calculation of the Government Saving will be conclusive, and is not a matter that is open to dispute by the Association.

3.1.4 All figures stated in this clause 3.1 are on a GST exclusive basis unless otherwise stated.

- 3.1.5 To index the relevant components of the CSO Wholesale Funding Pool by CPI, as required by clause 3.1.2, the following formula will be applied as at the relevant Adjustment Date:

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

- 3.1.6 For the purposes of clause 3.1.5:

- (a) **index number** means the All Groups Consumer Price Index number that is the weighted average of the eight capital cities published by the Australian Bureau of Statistics in respect of the quarter that ends on the last day of March in a calendar year.
- (b) **Last Amount** means the amount of the relevant component of the CSO Wholesale Funding Pool immediately after the last adjustment step was applied in accordance with clause 3.1.2.
- (c) **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.
- (d) **MRIN** means the most recently published index number as at the Adjustment Date.
- (e) **New Amount** means the amount, rounded to the nearest cent, of the relevant component of the CSO Wholesale Funding Pool, that will apply following the application of the formula in clause 3.1.5.

- 3.1.7 The Estimated CSO Wholesale Funding Pool Value over the Agreement Term is further illustrated in Appendix B.

3.2 CSO Payments

- 3.2.1 The following provisions summarise the basis on which CSO Payments are currently made, and are intended in the future to be made, to Eligible National Pharmaceutical Wholesalers and Eligible State Pharmaceutical Wholesalers under Wholesaler Deeds. To the extent of any inconsistency, the Wholesaler Deeds will take precedence over this Agreement.

- 3.2.2 CSO Payments will be made to Eligible National Pharmaceutical Wholesalers out of the portion of the CSO Wholesale Funding Pool allocated to Eligible National Pharmaceutical Wholesalers for that Financial Year in accordance with the following process:

- (a) Subject to clause 3.2.2(b), in each month, the amount payable to an Eligible National Pharmaceutical Wholesaler will be equal to the volume of Pharmaceutical Benefits supplied by that Eligible National Pharmaceutical Wholesaler to Approved Pharmacists, as a percentage of the total volume of Pharmaceutical Benefits supplied by all Eligible National Pharmaceutical Wholesalers to Approved Pharmacists in that same month.

Example: If:

- the CSO Wholesale Funding Pool allocated to Eligible National Pharmaceutical Wholesalers was \$180 million for the relevant financial year; and
- in September, Eligible National Pharmaceutical Wholesale ABC supplied 10% (by volume) of all Pharmaceutical Benefits supplied by all Eligible National Pharmaceutical Wholesalers in that month,

then ABC would be entitled to a payment of $\$180\text{M} \div 12 \times 10\% = \1.5M (subject to clause 3.2.2(b)).

- (b) The amount payable to Eligible National Pharmaceutical Wholesalers under clause 3.2.2(a) may, from time to time, as notified by the Department to the relevant Eligible National Pharmaceutical Wholesalers:
 - (i) reduce as a result of the application of one or more financial sanctions imposed on Eligible National Pharmaceutical Wholesalers in accordance with the Operational Guidelines; and
 - (ii) increase, if the amount of the CSO Wholesale Funding Pool allocated to Eligible State Pharmaceutical Wholesalers is not exhausted, and remaining funds from that amount are reallocated to the portion of the CSO Wholesale Funding Pool allocated to Eligible National Pharmaceutical Wholesalers.

3.2.3 Subject to clause 3.2.4, CSO payments will be made to Eligible State Pharmaceutical Wholesalers out of the portion of the CSO Wholesale Funding Pool allocated to Eligible State Pharmaceutical Wholesalers as follows:

- (a) A percentage of the total CSO Wholesale Funding Pool available to Eligible State Pharmaceutical Wholesalers will be allocated to each State or Territory. This percentage will be equal to the volume of Pharmaceutical Benefits supplied by Eligible State Pharmaceutical Wholesalers to Approved Pharmacists in that State or Territory, as a percentage of the volume of Pharmaceutical Benefits supplied by all Eligible State Pharmaceutical Wholesalers to Approved Pharmacists nationally.
- (b) Subject to clause 3.2.3(c), each Eligible State Pharmaceutical Wholesaler in a State or Territory will then receive a percentage of the funding allocated to that State or Territory under clause 3.2.3(a), equal to the volume of Pharmaceutical Benefits supplied by that Eligible State Pharmaceutical Wholesaler to Approved Pharmacists, as a percentage of the total volume of Pharmaceutical Benefits supplied by all Eligible State Pharmaceutical Wholesalers to Approved Pharmacists in that same State or Territory.

Example: If:

- the CSO Wholesale Funding Pool allocated to Eligible State Pharmaceutical Wholesalers was \$18 million for the relevant financial year;
- Eligible State Pharmaceutical Wholesaler XYZ is located in NSW;
- supply of Pharmaceutical Benefits by Eligible State Pharmaceutical Wholesalers to Approved Pharmacists in NSW accounts for 40% (by volume) of the supply of Pharmaceutical Benefits by Eligible State Pharmaceutical Wholesalers to Approved Pharmacists nationally;
- XYZ supplied 30% (by volume) of the Pharmaceutical Benefits supplied by Eligible State Pharmaceutical Wholesalers to Approved Pharmacists in NSW,

then XYZ would be entitled to a monthly payment of $\$18\text{M} \div 12 \times 40\% \times 30\% = \$180,000$ (subject to paragraph 3.2.3(c)).

- (c) The amount payable to one or more Eligible State Pharmaceutical Wholesaler(s) under clause 3.2.3(b) may, from time to time, as notified by the Department to the relevant Eligible State Pharmaceutical Wholesaler(s), reduce as a result of the application of one or more financial sanctions

imposed on that or those Eligible State Pharmaceutical Wholesaler(s) in accordance with the Operational Guidelines.

3.2.4 CSO payments to Eligible State Pharmaceutical Wholesalers will be subject to a National Cap, to ensure that the amount of the per-Unit payment to each Eligible State Pharmaceutical Wholesaler does not exceed the amount of the per-Unit payment made to each Eligible National Pharmaceutical Wholesaler.

3.2.5 The National Cap will be calculated:

- (a) monthly, prior to the application of any financial sanctions, or the distribution of any previous financial sanctions; and
- (b) by dividing the portion of the CSO Wholesale Funding Pool allocated to Eligible National Pharmaceutical Wholesalers in a month by the aggregate number of Units supplied by all Eligible National Pharmaceutical Wholesalers in that same month.

Example: If:

- the value for a particular month of the portion of the CSO Wholesale Funding Pool allocated to Eligible National Pharmaceutical Wholesalers was \$15 million; and
- collectively, all Eligible National Pharmaceutical Wholesalers sold 25.1 million Units in that month,

then the National Cap for that month $\$15 \text{ million} \div 25.1 \text{ million} = \0.60 .

If in a month, Eligible State National Pharmaceutical Wholesalers would otherwise be entitled to a CSO payment of an amount greater than \$0.60 per Unit, then, with the application of the National Cap, the CSO payment to these Eligible State National Pharmaceutical Wholesalers would be limited to \$0.60 per Unit.

3.2.6 The parties acknowledge that:

- (a) the CSO Payments provide payments to Eligible Pharmaceutical Wholesalers to assist them to meet operational and maintenance costs associated with meeting the CSO Operational Guidelines, including the CSO Service Standards and Compliance Requirements;
- (b) from the Commencement Date:
 - (i) CSO Payments will continue to be made to Eligible Pharmaceutical Wholesalers in accordance with existing Wholesaler Deeds ; and
 - (ii) the Commonwealth will take steps as necessary to address any inconsistencies between existing Wholesaler Deeds and this Agreement;
- (c) the Commonwealth intends, as soon as reasonably practicable following the Commencement Date, to conduct an ATM Process to establish new Wholesaler Deeds that will eventually replace the existing Wholesaler Deeds, as described in clause 5. The Commonwealth intends to prepare the new Wholesaler Deeds in a way that is consistent with the relevant provisions of this Agreement, including the term of this Agreement; and
- (d) following the establishment of new Wholesaler Deeds as contemplated by clause 3.2.6(c), CSO Payments will be made to Eligible Pharmaceutical Wholesalers in accordance with the terms of those new Wholesaler Deeds.

3.3 NDSS Payments

- 3.3.1 Under this Agreement, the Commonwealth will continue providing payments to support the distribution of products made available under the National Diabetes Services Scheme (**NDSS**) until 1 July 2026.
- 3.3.2 Eligible Pharmaceutical Wholesalers will be entitled to a payment of \$1 per Unit for each NDSS product that they supply through the CSO arrangements. Such payments will be made to Eligible Pharmaceutical Wholesalers in accordance with the terms of the applicable Wholesaler Deeds.
- 3.3.3 For clarity:
 - (a) the payments referred to in clause 3.3.1 are separate to, and not accounted for, in the quantum of the CSO Wholesale Funding Pool described in clauses 1.1 and 3.1; and
 - (b) the amount of the payments described in clause 3.3.2 will remain fixed until 1 July 2026, and will not be subject to indexation.

4. Administration of the CSO Wholesale Funding Pool arrangements

- 4.1 The cost of administering arrangements relating to the CSO Wholesale Funding Pool and CSO Payments will be met from the CSO Wholesale Funding Pool.

5. Approach to Market Process

- 5.1 Further to clause 3.2.6, the parties acknowledge and agree that, after the Commencement Date:
 - 5.1.1 the Commonwealth intends to conduct an ATM Process to establish new Wholesaler Deeds and the Commonwealth will use its best endeavours to conduct and complete that ATM Process as soon as reasonably practicable after the Commencement Date;
 - 5.1.2 the Commonwealth intends that:
 - (a) the new Wholesaler Deeds will be substantially based on the current Wholesaler Deeds and consistent with the principles set out in this Agreement (subject to clause 5.1.4);
 - (b) the assessment of responses to the ATM Process will consider, amongst other matters, the experience and performance of the signatories of current Wholesaler Deeds; and
 - (c) the new Wholesaler Deeds will not operate beyond the expiry of this Agreement in a manner that would inhibit the operation of any agreement intended to replace this Agreement.;
 - 5.1.3 it is possible that the outcomes of the ATM Process will have implications for matters contemplated by this Agreement, including the CSO Wholesale Funding Pool;
 - 5.1.4 as a result, it might be appropriate or desirable for the parties to amend this Agreement (in accordance with clause 14.3) to support, or otherwise reflect, outcomes of the ATM Process; and

- 5.1.5 they do not intend that the ATM Process will result in a reduction in the overall funding envelope available to Pharmaceutical Wholesalers or a change in the term of this Agreement.
- 5.2 Subject to clauses 5.3 and 5.4, as soon as practicable after becoming aware that the ATM Process may have implications for matters contemplated by this Agreement, the Commonwealth will notify the Association of those possible implications. The parties will then cooperate in good faith to determine what, if any, changes to this Agreement should be made, and to promptly implement those changes.
- 5.3 Nothing in clause 5.2 requires the Commonwealth to disclose any information to the Association that:
- 5.3.1 is confidential to the Commonwealth or a third party;
- 5.3.2 if disclosed, could jeopardise any ATM Process; or
- 5.3.3 the Commonwealth otherwise determines is not appropriate to be disclosed to the Association (for example, because it might be contrary to a Commonwealth policy, or provide an unfair market advantage or disadvantage to some Pharmaceutical Wholesalers over others).
- 5.4 The Commonwealth may make its disclosure of information pursuant to clause 5.2 subject to such conditions as it determines are appropriate, including in relation to the:
- 5.4.1 provision of confidentiality or other undertakings by the Association, or personnel representing the Association; and
- 5.4.2 storage, handling, destruction, and return, of the information.

6. Availability of PBS medicines

- 6.1 The Association agrees to take reasonable steps, to the extent lawful, to:
- 6.1.1 ensure that Association Wholesalers; and
- 6.1.2 encourage Industry Wholesalers,
- to:
- 6.1.3 purchase and maintain adequate medicine stocks of Pharmaceutical Benefits; and
- 6.1.4 maintain and continuously improve efficient, effective and reliable systems and processes for the supply of Pharmaceutical Benefits,
- so as to facilitate reasonable and timely access to Pharmaceutical Benefits by patients to the extent that the demand for those Pharmaceutical Benefits is, or should reasonably have been, anticipated by Pharmaceutical Wholesalers.
- 6.2 The parties acknowledge that the Operational Guidelines contain provisions setting out the consequences of default by Eligible Pharmaceutical Wholesalers in meeting service standards.

7. Managing medicine shortages

7.1 The parties acknowledge that:

- 7.1.1 Shortages have a significant impact on the health and wellbeing of Australians and, when they occur, it places pressure on other parts of the health care system as patients seek alternate support from primary and acute care settings;
- 7.1.2 the parties hold a shared desire to minimise the impact of Shortages on Australians;
- 7.1.3 Pharmaceutical Wholesalers provide several vital services that support the Commonwealth's management of Shortages and their impact on Australians; and
- 7.1.4 through the MSM Top-Ups, the Commonwealth is providing additional assistance to Eligible Pharmaceutical Wholesalers to contend with the growing cost of managing Shortages amidst the growth of the PBS, and uncertain global supply chains.

7.2 Without limiting clause 6, the Association must use its best endeavours, to the extent lawful, to:

- 7.2.1 provide to the Department advance warning of any Shortages of which the Association becomes aware, or that it believes are likely to occur;
- 7.2.2 support the Commonwealth in managing Shortages (including resultant risks, and any increases in severity or longevity);
- 7.2.3 proactively manage the supply of Pharmaceutical Benefits into regional, rural and remote areas of Australia, to ensure that access to Pharmaceutical Benefits is maintained in all of these areas;
- 7.2.4 triage inventory orders to support the guiding principles of the National Medicines Policy;
- 7.2.5 support the Commonwealth, and State and Territory Government Agencies, in times of natural disaster or emergency, to ensure the uninterrupted and continuing supply of Pharmaceutical Benefits and other health related products to Australians living in areas affected by those natural disasters or emergencies;
- 7.2.6 stock and supply non-PBS vaccines to Approved Pharmacists in a safe, secure and timely manner; and
- 7.2.7 work collaboratively with the Commonwealth towards the Commonwealth's implementation of new policy measures that will reduce the impact of Shortages on Australians.

7.3 The Association, to the extent lawful:

- 7.3.1 recognises;
- 7.3.2 must ensure that Association Wholesalers understand; and
- 7.3.3 must take reasonable steps to assist Industry Wholesalers to understand, that, by accepting payments in accordance with this Agreement, Pharmaceutical Wholesalers will be taken to be acknowledging that they have complied with all relevant

Commonwealth, State and Territory legislative requirements for the supply and distribution of PBS or RPBS medicines, including:

- 7.3.4 the *National Health Act 1953* (Cth);
- 7.3.5 the Australian Code of Good Wholesaling Practice for Medicines in Schedules 2, 3, 4 and 8;
- 7.3.6 the standards and requirements as established by other authorities, including the Therapeutic Goods Administration;
- 7.3.7 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; and
- 7.3.8 all applicable State, Territory and Commonwealth laws with respect to the conduct of their function.

8. Wholesaler Deeds

- 8.1 Without limiting any other provision of this Agreement, the parties acknowledge and agree that:
 - 8.1.1 this Agreement establishes broad principles intended to apply in relation to the payment of WMU Payments and CSO Payments to all Pharmaceutical Wholesalers,but:
 - 8.1.2 the Association and the Commonwealth are the only entities that are parties to this Agreement;
 - 8.1.3 Pharmaceutical Wholesalers are separate legal entities to the Association;
 - 8.1.4 the Association only represents a portion of Pharmaceutical Wholesalers (being Association Wholesalers); and
 - 8.1.5 it will be necessary for the Commonwealth to enter into Wholesaler Deeds with Pharmaceutical Wholesalers to give effect to the principles established by this Agreement, and to facilitate the payment of WMU Payments and CSO Payments to Eligible Pharmaceutical Wholesalers.
- 8.2 The Association agrees, to the extent lawful, to provide reasonable assistance to the Commonwealth to negotiate and enter into Wholesaler Deeds with Pharmaceutical Wholesalers, including by:
 - 8.2.1 providing information to the Commonwealth in relation to the pharmaceutical wholesale industry, Association Wholesalers, and Industry Wholesalers (to the extent the Association holds such information);
 - 8.2.2 assisting with the distribution of information to Pharmaceutical Wholesalers in relation to this Agreement, WMU Payments, CSO Payments, and the need for Pharmaceutical Wholesalers to enter into Wholesaler Deeds to receive WMU Payments and CSO Payments;
 - 8.2.3 encouraging Pharmaceutical Wholesalers to act reasonably and promptly in considering, and taking steps to enter, Wholesaler Deeds; and
 - 8.2.4 providing such other assistance as reasonably requested by the Commonwealth.

9. Agreement Oversight Committee

- 9.1 The Department will establish, at the Commencement Date, an Agreement Oversight Committee to facilitate regular discussions between the parties.
- 9.2 The Terms of Reference for the Committee are as set out in Appendix C.
- 9.3 The Committee will be chaired by an official from the Department, and comprise:
 - 9.3.1 officials from the Department;
 - 9.3.2 representatives from the Association; and
 - 9.3.3 if required, others approved by the Chair from time to time.

10. Consultation

- 10.1 Nothing in this Agreement, or any other document connected with this Agreement, limits the ability of the Commonwealth, or any other part of the Australian Government, to:
 - 10.1.1 announce or implement policy reforms that may have an impact on any industry, profession or sector, including Pharmaceutical Wholesalers, the community pharmacy sector or the pharmacy profession; or
 - 10.1.2 consult with any person in relation to any matter at any time.

11. Improving access to the Repatriation Pharmaceutical Benefits Scheme (RPBS)

- 11.1 The parties acknowledge and agree that:
 - 11.1.1 while many veterans benefit from access to Pharmaceutical Benefits via the CSO, RPBS-only listed products are not covered by this Agreement; and
 - 11.1.2 the parties share an intent to work towards including RPBS-only listed products within the scope of the CSO arrangements during the term of this Agreement, with an anticipated corresponding increase to the CSO Funding Pool. Any such changes would be made in accordance with clause 14.3.

12. Issue resolution

- 12.1 Any Issue arising in connection with, or from the operation of, this Agreement will be resolved as follows:
 - 12.1.1 the Signatory with the Issue will send the other Signatory a notice setting out the nature of the Issue (**Issue Notice**);
 - 12.1.2 the Signatories' Representatives will attempt to resolve the Issue by direct negotiation; and
 - 12.1.3 if the Issue is not so resolved by direct negotiation under clause 12.1.2 within three (3) months after an Issue Notice is given by a Signatory, or such longer period agreed between the Signatories, either Signatory may immediately request the Issue be referred to confidential mediation, to be conducted by a person agreed between the relevant Signatories. If the relevant Signatories cannot agree on a mediator within 20 Business Days after a request for mediation under this clause 12.1.3, a Signatory may ask the Chair of the Resolution Institute ACN 008

651 232 or their delegate to appoint a mediator. The mediation will be conducted in accordance with the rules specified by the mediator.

- 12.2 If an Issue is not resolved during a mediation conducted under clause 12.1.3, or within ten Business Days after the conclusion of that mediation, then either Signatory may refer the matter for direct negotiation between the Minister and the Chief Executive Officer of the Association.
- 12.3 Despite the reference of an Issue to negotiation or mediation under this clause 11, the Signatories must continue to perform their obligations under this Agreement.
- 12.4 Each Signatory will bear its own costs arising from the process set out in this clause 11.

13. Assistance with inquiries

- 13.1 The Association will, in good faith, provide reasonable assistance to the Commonwealth, as requested by the Commonwealth, to address specific inquiries of Association Wholesalers that are identified by the Commonwealth.

14. Other general matters

14.1 Term and commencement

This Agreement commences on the Commencement Date, and expires on 31 December 2029.

14.2 Transitional arrangements

- 14.2.1 The parties acknowledge that steps may need to be taken to facilitate the effective transition of arrangements from those that apply under the Eighth CPA to those provided for in this Agreement.
- 14.2.2 The parties agree to cooperate, and provide reasonable assistance to each other, to enable such steps to be taken, including as described in this clause 14.2.
- 14.2.3 In accordance with clause 3.2.6 of the Eighth CPA, the Department will consult with the Pharmacy Guild of Australia to assess whether any terms of this Agreement are likely to lead to a reduction in the total pharmacy remuneration provided for in the Eighth CPA. The Association will provide information and support as reasonably requested by the Department to conduct that consultation.
- 14.2.4 The Association will take reasonable steps to notify Pharmaceutical Wholesalers of the creation of this Agreement, and any implications that this Agreement's terms might have for those Pharmaceutical Wholesalers (for example, changes to the Wholesale Markup in accordance with clause 2).

14.3 Variation

This Agreement may only be varied by a document signed by the Minister and the Association.

15. Notices

- 15.1 A notice under this Agreement is only effective if it is in writing, and addressed to the relevant Signatory as specified in Appendix A, or as otherwise notified by that Signatory to the other Signatory in writing from time to time.

- 15.2 A notice is to be:
- 15.2.1 signed by the person giving the notice and delivered by hand;
 - 15.2.2 signed by the person giving the notice and sent by pre-paid post; or
 - 15.2.3 transmitted electronically by the person giving the notice by email.
- 15.3 Communications take effect from the time they are received or taken to be received under clause 15.4 (whichever happens first) unless a later time is specified.
- 15.4 Communications are taken to be received:
- 15.4.1 if sent by post, six (6) days after posting (or ten (10) days after posting if sent from one country to another); or
 - 15.4.2 if sent by email:
 - (a) when the sender receives an automated message confirming delivery; or
 - (b) four (4) 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.
- 15.5 A notice received, or taken to be received, under clause 15.4 after 5.00 pm, or on a day that is not a Business Day, is deemed to be effected on the next Business Day.

16. Interpretation

16.1 Words and headings

In this Agreement, unless expressed to the contrary:

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

16.2 Specific references

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

- 16.2.1 a decision or a determination of the Minister includes a decision or determination of the Minister's delegate;
- 16.2.2 consulting on a matter, means seeking the views of the relevant other Signatory or third party and is not an obligation to seek or obtain the agreement of any other Signatory or third party;
- 16.2.3 a section is a reference to a section of the Act;
- 16.2.4 any legislation (including subordinate legislation) is to that legislation as amended, re-enacted or replaced and includes any subordinate legislation issued under it;
- 16.2.5 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;
- 16.2.6 writing includes writing in digital form;
- 16.2.7 'this Agreement' is to this Agreement as amended from time to time;
- 16.2.8 'A\$', '\$', 'AUD', 'dollars' or 'cents' is a reference to Australian units of currency;
- 16.2.9 a clause, appendix, part, table or attachment is a reference to a clause, appendix, part, table or attachment in or to this Agreement;
- 16.2.10 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
- 16.2.11 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.

17. Definitions

17.1 In this Agreement, unless the contrary intention appears:

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

Adjustment Date means each period of time set out in table 5 in clause 3.1.2.

Agreement means this Pharmaceutical Wholesaler Agreement.

Appendix means an appendix to this Agreement.

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.

Association means the National Pharmaceutical Services Association.

Association Representative means:

- (a) the person from time to time holding or acting in the position of Chairperson of the Association; or
- (b) a person from time to time holding a senior executive position of the Association, as is notified by the Association to the Department Representative in writing from time to time.

Association Wholesalers means the pharmaceutical wholesalers represented by the Association.

ATM Process means any one or more approaches to market conducted by the Department (at times, and in the manner, determined by the Commonwealth but consistent with clause 5), with a view to establishing arrangements to support, or that might otherwise relate to, the supply of:

- (c) Pharmaceutical Benefits; or
- (d) other pharmaceutical-related or pharmaceutical-adjacent products or services.

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

Commencement Date means the date that this Agreement is executed by the last party to do so.

Commonwealth means the Minister, or the Department, on behalf of the Commonwealth of Australia.

Commonwealth Price means the price for a Pharmaceutical Benefit of a particular quantity or number of units, as set out in the Determination.

Community Service Obligation or **CSO** means the Commonwealth prescribed timeframes and services standards that Eligible Pharmaceutical Wholesalers must satisfy when providing the full range of PBS medicines to pharmacies in order to be eligible for Commonwealth funding.

CSO Compliance Requirements means the requirements of that name that are contained in the Operational Guidelines, as published by the Department from time to time.

CSO Payments means the payments by the Commonwealth to Eligible Pharmaceutical Wholesalers referred to in clause 3.

CSO Service Standards means the standards by that name as published by the Department from time to time.

CSO Wholesale Funding Pool means the Commonwealth funding available to remunerate Eligible Pharmaceutical Wholesalers through CSO Payments.

Department means:

- (a) the Department of Health and Aged Care; 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, Technology Assessment and Access Division within the Department; or
- (b) a person from time to time holding or acting in such other position notified by the Department to the Association Representative in writing from time to time.

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

Eligible, in relation to any kind of Pharmaceutical Wholesaler, means a Pharmaceutical Wholesaler that is eligible to receive payments in accordance with this Agreement because it has signed a Wholesaler Deed with the Commonwealth.

Eighth CPA means the Eighth Community Pharmacy Agreement between the Commonwealth and the Pharmacy Guild of Australia for the purposes of section 98BAA(1) of the Act and for related purposes.

Ex-Manufacturer Price means, the applicable:

- (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 (12) months during the Term 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.

Government Saving means a quantum of funds (as calculated by the Commonwealth) that, as a result of transitioning from the Wholesale Mark-Up as described in Table 2, to the Wholesale Mark-Up as described in Table 3, the Commonwealth has not spent, that it otherwise would have spent, had the transition not occurred, as conclusively determined by the Commonwealth in accordance with clause 3.1.3.

Industry Wholesaler means a pharmaceutical wholesaler that is not an Association Wholesaler.

Listed Brand has the meaning given in Part VII of the Act.

Minister means the Minister who administers the Act.

National Cap means the cap on CSO payments to Eligible State Pharmaceutical Wholesalers that is calculated and applied in accordance with clauses 3.2.4 and 3.2.5.

National Pharmaceutical Wholesaler means a Pharmaceutical Wholesaler that delivers Pharmaceutical Benefits to all States and Territories in Australia.

National Medicines Policy means the National Medicines Policy 2022 published by the Department, as amended or replaced from time to time.

Operational Guidelines means the *Community Service Obligation Operational Guidelines* published by the Department, as amended or replaced from time to time.

Pack Quantity has the meaning given in Part VII of the Act.

PBS or Pharmaceutical Benefits Scheme 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.

Pharmaceutical Wholesalers means Association Wholesaler and Industry Wholesalers.

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.

Representative means, as the context requires, one or more of:

- (a) the Department Representative; and
- (a) the Association Representative.

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 and British Commonwealth Occupation Force (Treatment) Act 2006* (Cth).

Signatory means, as the context requires in respect of this Agreement, either the Commonwealth, or the Association.

Shortage means a circumstance in which there is or may be an insufficient amount of Pharmaceutical Benefits to meet the demand for those Pharmaceutical Benefits in all or part of Australia.

State Pharmaceutical Wholesaler means a Pharmaceutical Wholesaler that delivers Pharmaceutical Benefits to one or more States or Territories (or both) in Australia, but not to all States and Territories in Australia.

Term means the term of this Agreement as set out in clause 14.1.

Unit means a Pack Quantity of a Pharmaceutical Benefit.

Wholesaler Deed means a deed between the Commonwealth and a Pharmaceutical Wholesaler for the payment of the WMU Payments, CSO Payments, or other matters.

WMU Payments means the Wholesale Mark-Up payments by the Commonwealth to Pharmaceutical Wholesalers referred to in clause 2.

- 17.2 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.

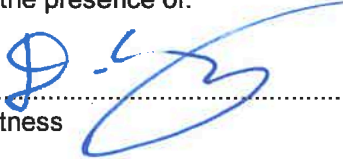
Signing page

Signed by **The Hon Mark Butler MP,**
Minister for Health and Aged Care on behalf
of the **Commonwealth of Australia**



in the presence of:


Witness



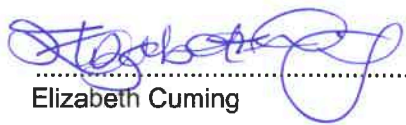
Duncan McIntyre
Name of witness

19/12/24
Date

Signed by the **National Pharmaceutical Services**
Association Limited ACN 087 033 216 by:


Richard Vincent

19 DEC 2024
Date


Elizabeth Cuming

19 Dec 2024
Date

Appendix A – Signatories

Name	The Honourable Mark Butler MP, Minister for Health and Aged Care on behalf of the Commonwealth of Australia
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Address for notices	First Assistant Secretary Technology Assessment and Access Division Department of Health and Aged Care Email: duncan.mcintyre@health.gov.au
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MDP 900
GPO Box 9848
CANBERRA ACT 2601

Name	The National Pharmaceutical Services Association Limited
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Address for notices	Elizabeth Cuming elizabeth@npsa.org.au
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73 Liddiard Street Hawthorn Vic 3122

Appendix B – Estimated CSO Pool Value over the Agreement Term

Year Code	ITEM	2024-25 H2	2025-26	2026-27	2027-28	2028-29	1/729-31/12/29
CSO	Baseline CSO	\$107,500,000	\$215,000,000*	\$215,000,000*	\$215,000,000*	\$215,000,000*	\$107,500,000*
EGS	Est. Gov. Saving from WMU reforms top-up	N/A	N/A	\$115,535,892	\$115,535,892*	\$115,535,892*	\$57,767,946*
IMDQ	IMDQ top-up	\$5,000,000	\$10,000,000	N/A	N/A	N/A	N/A
MSM2 MSM1	Medicine shortage support top-up	\$21,000,000 \$9,000,000	\$21,000,000*	\$21,000,000*	\$21,000,000*	\$21,000,000*	\$21,000,000*
S100	s100 top-up	N/A	N/A	\$78,624,234	\$78,624,234*	\$78,624,234*	\$39,312,117*
IND	Forecasted Indexation contribution	N/A	\$7,316,000‡	\$15,345,428‡	\$25,146,550‡	\$36,529,217‡	\$25,605,568‡
TOT	TOTAL CSO Pool by year	\$142,500,000	\$253,316,000‡	\$445,505,553‡	\$455,306,675‡	\$466,689,342‡	\$251,185,631‡
	Overall Total 1/1/25 – 31/12/29						\$2,014,503,201‡

Notes:

* = to be indexed from the previous year's amount, as estimated in the IND row.

‡ = forecast amount, to be replaced by actual when indexation figures available.

Appendix C – Terms of Reference for the Pharmaceutical Wholesaler Agreement Oversight Committee

1. Title of Committee

The Pharmaceutical Wholesaler Agreement Oversight Committee.

2. Establishment

The First Pharmaceutical Wholesaler Agreement (**1PWA**) is a five-year agreement between the Minister for Health and Aged Care, on behalf of the Commonwealth of Australia, and the National Pharmaceutical Services Association (**NPSA**), that governs, amongst other things, the payment arrangements for Community Service Obligation Wholesalers for the supply of medicines listed on the Pharmaceutical Benefits Scheme.

The Department of Health & Aged Care (**Department**) has responsibility for the implementation and management of the 1PWA on behalf of the Commonwealth of Australia.

Clause 9 of the 1PWA establishes consultation arrangements for the term of the Agreement, including the Pharmaceutical Wholesaler Agreement Oversight Committee (**PWAOC**).

The PWOAC is the primary consultation mechanism to support the achievement of the Commonwealth and the NPSA's objectives under the 1PWA. The PWAOC is not a decision-making body, but the PWAOC may provide advice or options to the signatories to the 1PWA for the purposes of the 1PWA.

3. Functions and Responsibilities

As the 1PWA sets the foundation upon which the Australian Government and the National Pharmaceutical Services Association will pursue medicines-related outcomes aligned with the National Medicines Policy 2022 during the term of the 1PWA, the Department and the NPSA will undertake such consultations and discussions to assist them to fulfil their responsibilities under the 1PWA and to progress the achievement of the objectives of the 1PWA.

The PWAOC provides a mechanism for open dialogue, in good faith, to allow for consultation on matters between the signatories to the 1PWA. This may include, if necessary, recommending an amendment of the terms of the 1PWA by mutual agreement to clarify and confirm the intentions of the parties.

4. Composition

The design of the PWAOC seeks to increase transparency over the management of the 1PWA.

Each party will have discretion to determine their own representatives at the PWAOC, provided that representatives have suitable expertise and authority to participate effectively. There will be a limit of three representatives from each side at any single meeting (not including the Chair) unless otherwise agreed in advance by the Chair.

The Department and/or NPSA may also propose additional attendees for PWAOC meetings, if they consider such attendees could add to consultations between the signatories on one or more matters. The Department and the NPSA will not unreasonably deny any such proposal from the other.

5. Chair of the PWAOC

The Chair will be a representative of the Department at a minimum level of Executive Level 2.

The Chair's role will be to lead and facilitate discussion on any items nominated for discussion and perform any other functions provided for under these Terms of Reference or designated by the Minister for Health & Aged Care.

It will be the responsibility of the Chair to ensure any discussion and agreed outcomes are clearly communicated and agreed for inclusion in meeting minutes.

6. Secretariat

The Department will provide secretariat support for the PWAOC. The Secretariat will:

- a. schedule meetings;
- b. invite observers and other visitors to attend PWAOC meetings when required;
- c. prepare agendas for meetings;
- d. distribute meeting papers before meetings;
- e. receive documents and information from third parties, and make these available to members of the PWAOC; and
- f. record minutes of each PWAOC meeting, and maintain such other records in relation to the PWAOC's activities and operations as are required.

At the conclusion of each meeting, the Secretariat will circulate a copy of the draft minutes to each attendee of the meeting for review and settling. As soon as practicable after the minutes are settled, the Secretariat will cause the minutes to be published on the Department's website.

7. Meetings

The PWAOC will meet:

- a. at least three times between 1 January 2025 and 30 June 2026;
- b. at least twice per Financial Year after 30 June 2026; and
- c. at such other times as required by the Chair.

Meetings will be in person or via electronic means, as agreed by the Chair.

8. Limitations of the PWAOC

The PWAOC participants must not:

- purport to make changes to the 1PWA. Additionally, the PWAOC cannot cease to conduct, or change the nature or scope of, the 1PWA arrangements; or
- disclose confidential information shared or discussed at a meeting of the PWAOC to any third party, except that such confidential information may be disclosed:
 - by PWAOC participants to other persons within their organisation, and to their professional advisers who have a need to know such information and who are subject to an obligation of confidence;
 - by the Department in response to a request by a Commonwealth Minister, by a House or Committee of Parliament or by a Secretary of another Commonwealth department;
 - by PWAOC participants when authorised or required by law; and

- by PWAOC participants who have the prior written consent of the organisation that contributed the information to the meeting.

In this section 8, 'confidential information' means information that is by its nature confidential and:

- identified by a PWAOC participant as being confidential; or
- otherwise of a kind that the recipient knew, or ought to have known, was confidential, based on the circumstances or the type of information,

but does not include information that is in the public domain without any breach of an obligation of confidence.

9. Establishment of working parties or subcommittees

The PWAOC may from time-to-time appoint working parties or subcommittees as it considers necessary. In this regard:

- Subject to the 1PWA, the Chair of the PWAOC may agree to a person being the chair of a working party or subcommittee.
- Each working party or subcommittee (via its chair if one is appointed) must report its proceedings to the PWAOC and must conduct its business in accordance with any rules or directions of the PWAOC.
- The existence of, or delegation to, a working party or subcommittee does not derogate from the powers to act in any manner consistent with these Terms of Reference.

10. Conflict of interest

A conflict of interest is where a financial or other interest of a representative to the PWAOC (or a working group or subcommittee) may reasonably be seen to be in conflict with duties undertaken as a representative to the PWAOC. Each representative to the PWAOC (or a working group or subcommittee) participant should be alert to any potential, actual or perceived conflicts of interest, financial or otherwise, and disclose these to the PWAOC Chair. This includes conflicts of interest that may arise between representatives to the PWOAC (or a working group or subcommittee).

A representative to the PWAOC must disclose any potential, actual or perceived conflict of interest at the earliest possible time.

The Chair may take any steps to resolve or otherwise deal with any disclosed conflicts in their absolute discretion.

11. Amendment of these Terms of Reference

No variation of these Terms of Reference is permitted unless agreed by the Department and the NPSA, and endorsed by the Minister for Health & Aged Care.