



Australian Government



MEMORANDUM OF UNDERSTANDING SEPTEMBER 2010

1. This Memorandum of Understanding (MOU) records the understanding reached between Medicines Australia and the Commonwealth of Australia, represented by the Honourable Nicola Roxon MP, Minister for Health and Ageing, in relation to the Pharmaceutical Benefits Scheme (PBS).
2. Both parties agree that the MOU will be effective from the date of its execution until 30 June 2014.
3. Both parties intend that the MOU will promote the efficiency and sustainability of the PBS and support, by the provision of a stable pricing policy environment, a viable and responsible medicines industry in Australia, consistent with the objectives of the National Medicines Policy.
4. The Commonwealth undertakes not to implement new policy to generate price-related savings from the PBS during the period of agreement, that is, measures that would change the ex-manufacturer price of particular medicines, other than that reflected by this MOU.
5. The Commonwealth confirms its commitment to the principles and architecture of PBS Reform and, in particular, to maintain in accordance with the *National Health Act 1953*:
 - the separation of drugs between the F1 and F2 formularies and combination drug list; and
 - the different price setting and maintenance mechanisms which underpin the formularies.
6. Medicines Australia undertakes to support legislative changes required to effect policy changes arising from, or which reflect, this MOU.
7. Both parties undertake to jointly monitor trends in, and the drivers of, PBS expenditure through the Access to Medicines Working Group (AMWG), which will also develop a framework for this purpose. This will commence not later than 1 January 2011. The Commonwealth agrees to share with Medicines Australia, without cost, the information and analyses required to achieve this.
8. Both parties undertake to develop a mechanism to monitor and report progress on implementation of the MOU through the AMWG. This mechanism will be agreed between the parties and operational by 1 October 2010. The AMWG will report annually to the Minister for Health and Ageing on the progress and implementation of the MOU.

9. Medicines Australia undertakes to establish a mechanism for “horizon scanning”. In the context of this MOU, the purpose is to gauge the likely impact on the work of the Pharmaceutical Benefits Advisory Committee (PBAC), and on expenditure through the PBS, of the drugs in respect of which PBS listing is likely to be sought in the future and to provide information to the Commonwealth. The AMWG provides a forum for this purpose. This will commence not later than 1 January 2011. Medicines Australia and the Commonwealth recognise that any such mechanism must have due regard to the commercially sensitive nature of much of this information.

Price reductions

10. From 1 February 2011, price reductions applied to single-brand PBS drugs on listing of a competitor brand will increase from 12.5 percent to 16 percent.
11. On 1 February 2011, a two percent price reduction will be applied to all drugs listed on F2A as at 11 October 2010. This is in addition to the two percent price reduction occurring on 1 August 2010.
12. On 1 February 2011, a five percent price reduction will be applied to all drugs listed on F2T as at 11 October 2010. Single-brand on-patent drugs listed on F2T that are subject to staged 25 percent price reductions will have this five percent price reduction applied as if the full 25 percent price reduction had already been applied.

Price disclosure

13. From 1 December 2010, strengthened price disclosure arrangements will apply as follows:
 - (a) All brands of all drugs in the F2 formulary will be subject to price disclosure.
 - (b) All items containing drugs in the F2 formulary, including section 100-only listings and items on the combination drug list with an F2 component, will be subject to price reductions resulting from price disclosure.
 - (c) Price reduction points for the purposes of price disclosure will be 1 April, 1 August and 1 December.
 - (d) Apart from the first main cycle, the total period for a price disclosure cycle will be at least 18 months. This will comprise a data collection period, and a combined data submission, analysis and notification period, of not less than 12 months and six months, respectively. The first main cycle commencing 1 December 2010, will be 16 months, incorporating a 10 month data collection period.
 - (e) Price reductions will apply in the same way as under current price disclosure arrangements (except as described below for drugs subject to price disclosure in the cycle commencing 1 December 2010 under (g)).
 - (f) The provisions requiring the first month of data for any new brand subject to price disclosure to be collected, but not used, for calculating the weighted average price disclosed will continue to apply.
 - (g) For all F2 drugs not already subject to price disclosure, the first data collection period will be from 1 December 2010 to 30 September 2011. The price reductions from this cycle will apply from 1 April 2012.
 - (h) The Commonwealth will not seek to amend the *National Health Act 1953* to alter the provision under subsection 99ADA(3) that an item be exempt from price disclosure.

Price disclosure cycle of 1 December 2010 to 1 April 2012

14. (a) The weighted average price disclosure related price reduction for those F2 drugs included in the cycle, scheduled to commence on 1 December 2010 and to conclude on 1 April 2012, will be a minimum of 23 percent. As per paragraph 13(b), price reductions incurred by drugs in this cycle will flow-on to section 100 listings of the relevant drugs, and relevant F2 components of drugs listed on the combination drug list.
- (b) A minimum price reduction of 23 percent from price disclosure will apply only to the 1 December 2010 to 1 April 2012 cycle. Drugs in this cycle will subsequently be subject to the rules applying to other price disclosure cycles.
- (c) As a first step, the weighted average disclosed price (WADP) for each drug will be calculated.
- (d) No price reduction will be applied to any drug where the difference between the initial WADP and the approved ex-manufacturer price is less than 10 percent and these drugs will remain excluded from price reduction adjustments in this cycle.
- (e) If the minimum price reduction for the 1 December 2010 to 1 April 2012 cycle is reached, the calculated price disclosure related reductions will be applied.
- (f) If the minimum price reduction for the 1 December 2010 to 1 April 2012 cycle, calculated in accordance with the WADP method, is not reached, the average price reduction of 23 percent will comprise:

- the price reductions calculated in accordance with WADP, plus
- additional administrative price reductions calculated according to the following guarantee adjustment proportion algorithm.

- (i) A guarantee adjustment proportion (GAP) is calculated as:

$$\text{GAP} = 0.23/\text{average price reduction}$$

- (ii) The GAP is applied proportionally to WADP-based price reductions calculated for each remaining drug to derive new price reductions. For example, if, say, the average price reduction is 20.9 percent, then the GAP is 1.1. This would lead to the following GAP-adjusted price reductions:

Drug	price reduction	GAP-adjusted reduction
A.	0.0%	n/a
B.	9.7%	n/a
C.	10.2%	11.2%
D.	30%	33%

- (iii) No price would be reduced below the lowest disclosed price of a brand of that drug.
- (iv) The average price reduction is then recalculated: and
- the algorithm is applied iteratively until the minimum 23 percent weighted average price reduction is met; or
 - all items in the price disclosure cycle have reached the lowest disclosed price for a brand of that item.

15. (a) The methodology and systems used to calculate price disclosure outcomes will be:
 - (i) made available to Medicines Australia and representatives of other suppliers of medicines to the PBS; and
 - (ii) independently verified by a third party.
- (b) The calculations undertaken for price disclosure will be independently checked by a third party.
- (c) Companies providing data under price disclosure arrangements will have the data verified in a manner to be agreed.
- (d) The Commonwealth will work with Medicines Australia and representatives of other suppliers of medicines to the PBS to determine how quality assurance and dispute resolution processes will be implemented to ensure the accuracy of the data received under price disclosure.

Therapeutic Groups

16. The Commonwealth undertakes not to form any new Therapeutic Groups during the period of this MOU unless:
 - (a) the Commonwealth believes that a sponsor is seeking to list a minor variation of one of its already-listed drugs, and where the PBAC, using the evidence available to it, forms a view that the new drug offers no meaningful clinical advantage over the existing drug and is interchangeable on an individual patient basis. Some examples of minor variations for this purpose include, but are not limited to:
 - (i) salts;
 - (ii) enantiomers;
 - (iii) metabolites;
 - (iv) isomers;
 - (v) prodrugs; or
 - (vi) formulation, dosage or delivery changes; *and*
 - (b) the sponsor or marketer of the new drug is:
 - (i) the same or a related entity that listed or marketed the listed drug; or
 - (ii) has entered into a direct or indirect commercial arrangement with the sponsor or marketer of the listed drug.
17. The Commonwealth will provide sponsors with reasonable notice of its intention to form any new Group, and seek sponsor comment prior to determination of any new Group.
18. The three Therapeutic Groups which the Commonwealth had announced an intention to form in the 2009 Mid-Year Economic and Fiscal Outlook, do not represent new Therapeutic Groups for the purposes of paragraphs 16 and 17 and, thus, are not covered by this MOU. These comprise drugs for the treatment of depression, osteoporosis, and Paget disease.

19. A drug which is a new or extended listing may be added to an extant Therapeutic Group, if the PBAC advises that it is interchangeable on an individual patient basis with members of the extant Therapeutic Group. Consistent with paragraph 17, the Commonwealth will provide sponsors with reasonable notice of its intention in this respect and seek sponsor comment prior to inclusion in the Therapeutic Group.

Consistent treatment of brands of drugs sold at the same price

20. During the period of this MOU, the Commonwealth undertakes not to introduce any measure (noting paragraph 21), which favours the prescribing or dispensing of generic brands of a drug over originator brands of the same drug, for which the approved price to pharmacists (or where agreed as the approved ex-manufacturer price, the ex-manufacturer price) is the same, without the agreement of Medicines Australia.
21. Both parties agree that the Commonwealth can continue with its \$1.53 (or as indexed from time to time) incentive in relation to the dispensing of premium-free brands of drugs. The Commonwealth does not intend to make any variation in the amount of the incentive, without the agreement of Medicines Australia.
22. For the avoidance of doubt, nothing in this MOU is taken to exclude the Commonwealth:
 - (a) undertaking awareness campaigns about any medicines (including generic medicines) where such campaigns are factual in nature, during the period of this MOU; or
 - (b) acting on any recommendation of the PBAC which may impact on the price of drugs (noting the Commonwealth's undertakings under, and where this is consistent with, paragraphs 4, 5 and 16 of this MOU).

Comparators

23. The Commonwealth and Medicines Australia will work together to formally document the impact on pricing of lower comparator prices where comparators are listed in the F2 formulary and provide an annual report to the Minister for Health and Ageing. The AMWG provides a forum to develop a framework for collecting data, documenting any impact and determining reporting for this purpose.

Parallel TGA and PBAC processes

24. From 1 January 2011, the Commonwealth will no longer require the respective registration and reimbursement evaluation and assessment processes for major submissions to be undertaken sequentially, noting the following:
 - (a) A PBS listing cannot occur prior to the product being listed on the Australian Register of Therapeutic Goods;
 - (b) A PBAC recommendation will not be made public before a decision by the Therapeutic Goods Administration (TGA) that a product is registrable for the relevant indications;
 - (c) Publication of PBAC outcomes will not occur until TGA outcomes are known; and
 - (d) Current arrangements for publication that an application has been made to the PBAC will continue.

25. Any additional costs in processing PBAC applications resulting from any consequent misalignment of applications through the two processes will be borne by applicants under cost recovery arrangements.

Managed Entry Scheme

26. From 1 January 2011, the Commonwealth undertakes to introduce a mechanism whereby the PBAC may recommend PBS coverage at a price justified by the existing evidence, pending submission of more conclusive evidence of cost-effectiveness to support listing of the drug at a higher price. The PBAC will provide advice in relation to sources of uncertainty and specific evidence required to support a subsequent application.
27. It is agreed that the application of this mechanism will initially be restricted to submissions where the PBAC agrees that there is a clinical need for the intervention, and when:
 - the PBAC would not otherwise recommend the listing of the drug at the proposed price because the extent or value of the clinical effect is uncertain; and
 - there is a randomised clinical trial (or comparable “fit-for-purpose” evidence), due to report within a reasonable timeframe, which the PBAC is satisfied will resolve the identified area of uncertainty.

The parties note that this does not preclude use of other tools for managing uncertainty (e.g. risk-sharing agreements) where appropriate.

Timing and Maximum Time Frames

28. The Commonwealth will work with industry to examine possible methods to reduce the time taken to finalise PBS pricing negotiations after a PBAC recommendation, including for those PBS submissions that require Cabinet approval prior to listing and this will be monitored by the AMWG through a mechanism to be agreed.
29. For those submissions required to be approved by Cabinet, the Commonwealth will use its best endeavours to implement a maximum time frame of six months for consideration and decision by Cabinet. The six months will commence from the date of notification by the Department of Health and Ageing to the sponsor that pricing is agreed.

Resolution of issues in good faith

30. This Memorandum of Understanding has been signed to indicate the agreement of Medicines Australia and the Commonwealth of Australia to the matters contained herein to promote the efficiency and sustainability of the PBS and the viability of the medicines industry.
31. In the event that a dispute occurs between the Commonwealth and Medicines Australia in relation to the operation of this MOU, and that cannot be settled in discussion with the relevant Deputy Secretary, the Chief Executive of Medicines Australia and the Secretary of the Department of Health and Ageing will meet in the first instance to resolve the issue. In the event that the dispute is still not resolved, the matter will be referred to a meeting between the Minister for Health and Ageing and representatives of the Medicines Australia Board.

32. In the event that circumstances eventuate that affect the parameters of this agreement, the MOU may be varied by either party subject to the agreement of the other. Where such an event occurs, the parties to this MOU undertake to negotiate in good faith.

SIGNED by for and on behalf of the **COMMONWEALTH OF AUSTRALIA** as represented by the **HONOURABLE NICOLA ROXON MP, MINISTER FOR HEALTH AND AGEING**:

28/9/10

Date

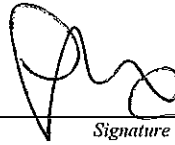


Signature

in the presence of:

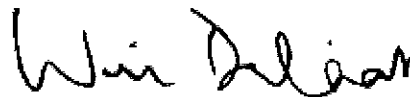
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Printed name of Witness



Signature of Witness

SIGNED by **WILL DELAAT, CHAIRMAN**, for and on behalf of **MEDICINES AUSTRALIA**



28 September 2010

Date

Signature

in the presence of:

Dr Brendan Shaw

Printed name of Witness



Signature of Witness