



Australian Government
Department of Health

Request for Approved Ex-manufacturer Price

PB11a

(price agreed under section 85AD or determined under section 85B of the **National Health Act 1953**)

Instructions for completing a PB 11a form are available on the PBS website at <http://www.pbs.gov.au/info/industry/useful-resources/pbs-forms>

Responsible Person (s84AF of the Act)	Responsible Person's Full Postal Address	Responsible Person's Authorised Representative:	
		• Name	
		• Telephone (Direct)	
		• E-mail address	

Drug:						Requested Effective Date:			
PBS Code	Form (including strength)	Manner of Admin	Brand	Pricing Quantity	Price for Agreement or Determination (Ex-man price for pricing quantity) (AEMP)	Manufacturer's PBS Pack Sizes	Proportional Ex-manufacturer Price for other pack sizes (PEMP)	Price Claimed by Responsible Person (Ex-Man for pack size) (where applicable)	Comment

The Responsible Person requests:

- A) agreement to the price in the 'Price for Agreement or Determination' column in the table above where:
 - there is no Price Claimed for the pricing quantity, and the responsible person has a pack size equal to that quantity; or
 - the responsible person does not have a pack size equal to the pricing quantity, and there is at least one Manufacturer's PBS Pack Size that does not have a Price Claimed;
- B) a price premium/special patient contribution for pack sizes for which the Price Claimed is completed.

Signature (Responsible Person's Authorised Representative mentioned above): _____ Date: _____

For Department of Health and Ageing completion only:			
Pricing accords with amount negotiated and recommended for agreement	Signed:	Date:	
Comments (if any):			

INSTRUCTIONS FOR COMPLETING A PB 11a FORM

Overview of Pharmaceutical Benefits Scheme (PBS) Pricing

The key elements of PBS pricing are:

1. There must be one **approved ex-manufacturer price (AEMPs)** for each brand of a pharmaceutical item.
2. The AEMP is a price for the **pricing quantity**, which is the lowest PBS priced pack size of any brand of that pharmaceutical item.
3. PBS prices for other pack sizes are calculated proportionally from the AEMP for the **pricing quantity**. These prices are called **proportional ex-manufacturer prices (PEMPs)**.
4. The AEMP may be an **agreed price** (ie, a price agreed by the responsible person and the Minister's delegate) or it may be a **determined price**. A determined price is necessary when all manufacturer's PBS pack sizes of a brand of a pharmaceutical item have a **special patient contribution (SPC)** eg: a brand premium). In this case, the Minister's delegate will determine in a legislative instrument the price the Minister would have agreed if there was no SPC. This **determined price** will be the AEMP. The price the responsible person wants (the **claimed price**) will also be included in the legislative instrument. Both the **determined price** and the **claimed price** are prices at the ex-manufacturer level. The difference between these prices, with marked up to the retail level, becomes the premium which the patient pays. Where there is a **claimed price** for a **pack quantity** other than the **pricing quantity**, the SPC/premium is based on the difference between the ex-manufacturer price for the pack quantity (PEMP) and the **claimed price** for that quantity.
5. A separate AEMP must be agreed or determined for each brand of a pharmaceutical item. A brand of a pharmaceutical item is a PBS listed brand of a drug with a particular form and manner of administration. Where there are several brands of a pharmaceutical item, the AEMPs for all brands must be the same amount, which is approved for the pricing quantity.

Brand of pharmaceutical item

In the example below, *Brand 1* is a brand of *two different pharmaceutical items* that contain the same drug.

Pharmaceutical Item			
Drug	Form (incl strength)	Manner of Administration	Brand
Drug A	Tablet 20mg	Oral	Brand 1
Drug A	Solution for IV infusion 100mg in 10mL	Injection	Brand 1

PBS 'Item Codes' (eg. 1234W) are not the same as 'pharmaceutical items'. Where a brand of a pharmaceutical item has multiple Item Codes published in the Schedule of Pharmaceutical Benefits (eg, for different maximum quantities, restrictions, or methods of supply), these are not different 'pharmaceutical items'.

In the example below, **Brand 1** of both 1234W and 5678P Item Codes is one 'brand of a pharmaceutical item':

Item Code	Pharmaceutical Item				Maximum Quantity
	Drug	Form (incl strength)	Manner of Administration	Brand	
1234W	Drug A	Tablet 20mg	Oral	<i>Brand 1</i>	20
5678P	Drug A	Tablet 20mg	Oral	<i>Brand 1</i>	40

The legislative instrument setting out PBS listed pharmaceutical items and brands, and the other listing details, is available at <http://www.comlaw.gov.au/>. It is called the *National Health (Listing of Pharmaceutical Benefits) Instrument*. It is referred to in this document as the **main PBS listing instrument**.

Information to be entered on the form

Responsible person details

The **Responsible Person** is the person (usually a corporation) who has been determined by the Minister to be the responsible person for the brand of pharmaceutical item under s84AF of the Act, or if no determination has been made, the person who has notified the Minister under s84AF that they will be the supplier of the brand of pharmaceutical item.

The **Responsible Person's Authorised Representative** is required to be a person who has the authority to request, on behalf of the Responsible Person, an Agreed Price, or a Claimed Price resulting in an SPC/price premium.

Drug

A separate PB11a form must be completed for each drug.

The description of **Drug** is to match the existing or expected PBS listing details, as set out in the **main PBS listing instrument**.

Requested Effective Date

This is the date on which it is proposed the prices shown on the form come into effect.

PBS Code

The **PBS Code** is not part of the brand of the pharmaceutical item, but is fundamental to administration of the PBS. A particular brand of a pharmaceutical item may have several PBS codes because it has several maximum quantities, or restrictions, or methods of supply.

Form (including strength) and Manner of Administration

The description of *Form (including strength), and Manner of Administration*, are to match the existing or expected PBS listing details, as set out in the *main PBS listing instrument*.

Brand

The *Brand* must also match the existing or expected PBS listing details, as set out in the *main PBS listing instrument*.

Pricing Quantity

The *Pricing Quantity* is the lowest pack size/*pack quantity* of any brand of the particular pharmaceutical item, ie, any brand of the same drug with the same form and same manner of administration. It does not matter if the responsible person does not have a pack size equal to the *pricing quantity*; a PBS price must be agreed or determined for this quantity so that all brands of a pharmaceutical item have an AEMP for the same quantity.

The lowest pack size will be able to be found by looking at the entries for the pharmaceutical item (ie, the particular form of the drug with the same manner of administration) on the PBS on-line (www.pbs.gov.au). The Department will notify the responsible person if a new lower pack size is to be listed on or before the expected effective date for the prices on the form.

If the responsible person has a pack size equal to the *pricing quantity*, that pack size and the *pricing quantity* should be entered on the one line.

If the responsible person does not have a pack size equal to the *pricing quantity*, the *pricing quantity* and AEMP for that quantity must still be entered because this is the formal approved price. This is because the AEMP must be agreed or determined for the *pricing quantity*, which is the lowest pack quantity of any brand of the pharmaceutical item. All *pack quantities* not equal to the *pricing quantity* will have a *proportional ex-manufacturer price* (PEMP) automatically calculated from the AEMP.

In the example below, the pricing quantity for Zeus brand of Alpha, Tablet 20mg, Oral, is 5. That is because the lowest pack size for any PBS listed brand of the pharmaceutical item is a pack of 5. The responsible person for the Zeus brand inserts the pricing quantity of 5 even if there is no Zeus pack of 5.

Drug: Alpha						Requested Effective Date:			
PBS Code	Form (including strength)	Manner of Admin	Brand	Pricing Quantity	Price for Agreement or Determination (Ex-man price for pricing quantity) (AEMP)	Manufacturer's PBS Pack Sizes	Proportional Ex-manufacturer Price for other pack sizes (PEMP)	Price Claimed by Responsible Person (Ex-Man for pack size) (where applicable)	Comment
1234X	Tablet 20mg	Oral	Zeus	5					
5678Y	Tablet 20mg	Oral	Zeus						

Price for Agreement or Determination (ex-man price for pricing quantity)

The price the responsible person understands will be proposed as the *AEMP* should be entered in this column. This price is called the *proposed price* in the remainder of this explanation. It is an ex-manufacturer price for the *pricing quantity*. This *proposed price* may become an *agreed price* or a *determined price*.

It will become an ***Agreed Price*** in the following situations:

No premium / special patient contribution (SPC) requested

- Where the responsible person has a pack size equal to the *pricing quantity* and agrees to the *proposed price* - that is, they do not wish to have a premium/SPC for that pack size. [In this case, they will not enter a price for the *pricing quantity* in the *Price Claimed* column.]
- Where the responsible person does not have a pack size equal to the *pricing quantity* and is happy with the *proportional ex-manufacturer prices* that will be derived from the *proposed price* for at least one of their pack sizes, they are requesting the proposed price be an Agreed price. [The responsible person will not enter a Price Claimed for these pack sizes because they do not wish to claim a premium/SPC for them - they may still request a premium/SPC for other pack sizes.]

It will become a ***Determined Price*** in the following situations:

Premium / special patient contribution requested

- Where the responsible person has a pack size equal to the *pricing quantity* and enters a price in the Price Claimed column for this quantity, ie, they want to have a premium/special patient contribution for that pack size;
- Where the responsible person does not have a pack size equal to the *pricing quantity*, and enters a price in the Price Claimed column for all of their pack sizes. This shows that they want to have a premium/special patient contribution for all their pack sizes. They are indicating that they do not wish to agree to the proposed price as it would apply to any pack size.

As there may be only one AEMP for each brand of a pharmaceutical item, there must be only one price proposed to be the Agreed Price or the Determined Price for that brand of pharmaceutical item.

In the example below, the price in the **Price Agreed or Determined** column is the price for the pricing quantity of 5. The price for the quantity of 5 may be either agreed or determined (it will be determined if all of the Manufacturer's PBS Pack Sizes for the pharmaceutical item have a premium or special patient contribution).

Drug: Alpha						Requested Effective Date:			
PBS Code	Form (including strength)	Manner of Admin	Brand	Pricing Quantity	Price for Agreement or Determination (Ex-man price for pricing quantity) (AEMP)	Manufacturer's PBS Pack Sizes	Proportional Ex-manufacturer Price for other pack sizes (PEMP)	Price Claimed by Responsible Person (Ex-Man for pack size) (where applicable)	Comment
1234X	Tablet 20mg	Oral	Zeus	5	\$6.25				
5678Y	Tablet 20mg	Oral	Zeus						

Manufacturer's PBS Pack Sizes

All **Pack Sizes** for which the responsible person requires a PBS price should be listed. These will be determined to be *pack quantities* for the purposes of the Act. Enter each pack size on a separate line so that the pricing information in later columns can be lined up against the relevant pack size.

In the example below, the Manufacturer's PBS pack sizes for Zeus brand of Alpha, Tablet 20mg, Oral, are 10 and 25. The lowest pack size for any PBS listed brand of the pharmaceutical item is the pricing quantity for Zeus brand even though the Zeus brand has no 5 pack. A sample PB11a at the end of this instruction paper shows the brand with the pack of 5 for this pharmaceutical item.

Drug: Alpha						Requested Effective Date:			
PBS Code	Form (including strength)	Manner of Admin	Brand	Pricing Quantity	Price for Agreement or Determination (Ex-man price for pricing quantity) (AEMP)	Manufacturer's PBS Pack Sizes	Proportional Ex-manufacturer Price for other pack sizes (PEMP)	Price Claimed by Responsible Person (Ex-Man for pack size) (where applicable)	Comment
1234X	Tablet 20mg	Oral	Zeus	5	\$6.25	10			
5678Y	Tablet 20mg	Oral	Zeus			25			

Proportional Ex-manufacturer Price (PEMPs) for other pack sizes

The information in this column is used to calculate the Dispensed Price for Maximum Quantity (DPMQ) for pack sizes other than the pricing quantity. Where the only Manufacturer's PBS Pack Size is the same as the pricing quantity this column will be blank.

A manufacturer can also decide, after working out the PEMP, if they want a premium / SPC for the PEMP pack size.

The PEMP is not part of the price agreement or determination, but should be calculated proportionally for each pack size from the **Requested Agreed Price or Price for Determination**.

In the example below the Zeus brand of Alpha, Tablet 20mg, Oral, has PEMPs for both Manufacturer's PBS pack sizes 10 and 25, because Zeus has no pack equal to the pricing quantity of 5. A sample PB11a at the end of these instructions shows the brand with the pack of 5 for this pharmaceutical item.

Drug: Alpha						Requested Effective Date:			
PBS Code	Form (including strength)	Manner of Admin	Brand	Pricing Quantity	Price for Agreement or Determination (Ex-man price for pricing quantity) (AEMP)	Manufacturer's PBS Pack Sizes	Proportional Ex-manufacturer Price for other pack sizes (PEMP)	Price Claimed by Responsible Person (Ex-Man for pack size) (where applicable)	Comment
1234X	Tablet 20mg	Oral	Zeus	5	\$6.25	10	\$12.50		
5678Y	Tablet 20mg	Oral	Zeus			25	\$31.25		

Price Claimed by Responsible Person

A **Price Claimed** should be entered when a price premium/special patient contribution is wanted. A premium/special patient contribution may be requested for any, or all, pack sizes. Enter a Price Claimed against each pack size for which you wish to have a premium/special patient contribution.

Where a Claimed Price is entered for the *pricing quantity*, or if Claimed Prices are entered for all Manufacturer's PBS Pack Sizes of the particular pharmaceutical item, the price entered by the responsible person in the column headed "Requested Agreed Price or Price for Determination" will become a determined price. This price (the *Determined Price*) will be included in a legislative instrument, together with the *Claimed Price or Prices*. All of these prices are prices at the ex-manufacturer level.

As there may only be one *claimed price* for a *pack quantity*, the **Price Claimed by Responsible Person** must be the same for each of the PBS Code lines for that *pack quantity* for that brand of pharmaceutical item.

In the example below the responsible person for the Zeus brand of Alpha, Tablet 20mg, Oral, wants a price premium for both its Manufacturer's PBS Pack Sizes of 10 and 25 – the Price Claimed column is therefore completed with an ex-manufacturer level claimed price. This claimed price will be used as the basis for calculating the premium. The sample PB11a at the end of these instructions shows that no premium / special patient contribution is sought for the brand with the pack of 5.

Drug: Alpha						Requested Effective Date:			
PBS Code	Form (including strength)	Manner of Admin	Brand	Pricing Quantity	Price for Agreement or Determination (Ex-man price for pricing quantity) (AEMP)	Manufacturer's PBS Pack Sizes	Proportional Ex-manufacturer Price for other pack sizes (PEMP)	Price Claimed by Responsible Person (Ex-Man for pack size) (where applicable)	Comment
1234X	Tablet 20mg	Oral	Zeus	5	\$6.25	10	\$12.50	\$13.00	
5678Y	Tablet 20mg	Oral	Zeus			25	\$31.25	\$32.00	

Comment

The responsible person may enter any comments about the prices in this column. For example:

- an effective price where there is a special pricing arrangement in place (where available – you will have discussed this with the Department), or
- a special patient contribution/premium resulting from the claimed price.

In the example below the Zeus brand of Alpha, Tablet 20mg, Oral, would have a published price based on an AEMP of \$6.25 for the pricing quantity (\$12.50 for pack of 10 & \$31.25 for pack of 25). An effective price is offered - \$10 for the pack of 10 and \$25 for the pack of 25.

Drug: Alpha						Requested Effective Date:			
PBS Code	Form (including strength)	Manner of Admin	Brand	Pricing Quantity	Price for Agreement or Determination (Ex-man price for pricing quantity) (AEMP)	Manufacturer's PBS Pack Sizes	Proportional Ex-manufacturer Price for other pack sizes (PEMP)	Price Claimed by Responsible Person (Ex-Man for pack size) (where applicable)	Comment
1234X	Tablet 20mg	Oral	Zeus	5	\$6.25	10	\$12.50	\$13.00	Effective PEMP \$10.00
5678Y	Tablet 20mg	Oral	Zeus			25	\$31.25	\$32.00	Effective PEMP \$25.00



Australian Government
Department of Health

Request for Approved Ex-manufacturer Price

SAMPLE PB11a

ONE PHARMACEUTICAL ITEM, TWO PACK SIZES/CODES WITH PREMIUMS , NO PRICING QUANTITY PACK
(price agreed under section 85AD or determined under section 85B of the **National Health Act 1953**)

Instructions for completing a PB 11a form are available on the PBS website at <http://www.pbs.gov.au/info/industry/useful-resources/pbs-forms>

Responsible Person (s84AF of the Act)	Manufacturer A	Responsible Person's Authorised Representative:	
Responsible Person's Full Postal Address	PO Box 4321 Sydney NSW 1111	• Name	Sally Smith
		• Telephone (Direct)	(02) 8570 1111
		• E-mail address	Sally.Smith@ManufacturerA.com

Drug: Alpha						Requested Effective Date:			
PBS Code	Form (including strength)	Manner of Admin	Brand	Pricing Quantity	Price for Agreement or Determination (Ex-man price for pricing quantity) (AEMP)	Manufacturer's PBS Pack Sizes	Proportional Ex-manufacturer Price for other pack sizes (PEMP)	Price Claimed by Responsible Person (Ex-Man for pack size) (where applicable)	Comment
1234X	Tablet 20mg	Oral	Zeus	5	\$6.25	10	\$12.50	\$13.00	BP = \$0.62
5678Y	Tablet 20mg	Oral	Zeus			25	\$31.25	\$32.00	BP = \$0.81

The Responsible Person requests:

A) agreement to the price in the 'Price for Agreement or Determination' column in the table above where:

- there is no Price Claimed for the pricing quantity, and the responsible person has a pack size equal to that quantity; or
- the responsible person does not have a pack size equal to the pricing quantity, and there is at least one Manufacturer's PBS Pack Size that does not have a Price Claimed;

B) a price premium/special patient contribution for pack sizes for which the Price Claimed is completed.

Signature (Responsible Person's Authorised Representative mentioned above): _____ Date: _____

For Department of Health and Ageing completion only:

Pricing accords with amount negotiated and recommended for agreement	Signed: _____	Date: _____
Comments (if any): _____		



Australian Government
Department of Health

Request for Approved Ex-manufacturer Price

SAMPLE PB11a

TWO PHARMACEUTICAL ITEMS, WITH MULTIPLE PACKS, WITH PREMIUMS

(price agreed under section 85AD or determined under section 85B of the **National Health Act 1953**)

Instructions for completing a PB 11a form are available on the PBS website at <http://www.pbs.gov.au/info/industry/useful-resources/pbs-forms>

Responsible Person (s84AF of the Act)	Manufacturer A	Responsible Person's Authorised Representative:	
		• Name	Sally Smith
Responsible Person's Full Postal Address	PO Box 4321 Sydney NSW 1111	• Telephone (Direct)	(02) 8570 1111
		• E-mail address	Sally.Smith@ManufacturerA.com

Drug: Alpha						Requested Effective Date:			
PBS Code	Form (including strength)	Manner of Admin	Brand	Pricing Quantity	Price for Agreement or Determination (Ex-man price for pricing quantity) (AEMP)	Manufacturer's PBS Pack Sizes	Proportional Ex-manufacturer Price for other pack sizes (PEMP)	Price Claimed by Responsible Person (Ex-Man for pack size) (where applicable)	Comment
1234X	Tablet 20mg	Oral	Zeus	5	\$6.25	10	\$12.50	\$13.00	BP = \$0.62
5678Y	Tablet 20mg	Oral	Zeus			25	\$31.25	\$32.00	BP = \$0.81
2345Z	Tablet 120mg	Oral	Zeus	5	\$37.50	10	\$75.00	\$79.00	BP = \$4.73
6789R	Tablet 120mg	Oral	Zeus			25	\$187.50	\$192.00	BP = \$4.84

The Responsible Person requests:

- A) agreement to the price in the 'Price for Agreement or Determination' column in the table above where:
- there is no Price Claimed for the pricing quantity, and the responsible person has a pack size equal to that quantity; or
 - the responsible person does not have a pack size equal to the pricing quantity, and there is at least one Manufacturer's PBS Pack Size that does not have a Price Claimed;
- B) a price premium/special patient contribution for pack sizes for which the Price Claimed is completed.

Signature (Responsible Person's Authorised Representative mentioned above): _____ Date: _____

For Department of Health and Ageing completion only:			
Pricing accords with amount negotiated and recommended for agreement	Signed:	Date:	
Comments (if any):			



Australian Government
Department of Health

Request for Approved Ex-manufacturer Price

SAMPLE PB11a

TWO PHARMACEUTICAL ITEMS, FOUR PBS ITEM CODES, ONE PACK SIZE THAT IS THE PRICING QUANTITY, NO PREMIUM

(price agreed under section 85AD or determined under section 85B of the **National Health Act 1953**)

Instructions for completing a PB 11a form are available on the PBS website at <http://www.pbs.gov.au/info/industry/useful-resources/pbs-forms>

Responsible Person (s84AF of the Act)	Manufacturer B	Responsible Person's Authorised Representative:	
		• Name	Joe Winder
Responsible Person's Full Postal Address	PO Box 3322 Sydney NSW 1111	• Telephone (Direct)	(02) 8444 3333
		• E-mail address	joe.winder@ManufacturerB.com

Drug: Alpha						Requested Effective Date:			
PBS Code	Form (including strength)	Manner of Admin	Brand	Pricing Quantity	Price for Agreement or Determination (Ex-man price for pricing quantity) (AEMP)	Manufacturer's PBS Pack Sizes	Proportional Ex-manufacturer Price for other pack sizes (PEMP)	Price Claimed by Responsible Person (Ex-Man for pack size) (where applicable)	Comment
1234X	Tablet 20mg	Oral	Hera	5	\$6.25	5			
5678Y	Tablet 20mg	Oral	Hera	5	\$6.25	5			
2345Z	Tablet 120mg	Oral	Hera	5	\$37.50	5			
6789R	Tablet 120mg	Oral	Hera	5	\$37.50	5			

The Responsible Person requests:

- A) agreement to the price in the 'Price for Agreement or Determination' column in the table above where:
- there is no Price Claimed for the pricing quantity, and the responsible person has a pack size equal to that quantity; or
 - the responsible person does not have a pack size equal to the pricing quantity, and there is at least one Manufacturer's PBS Pack Size that does not have a Price Claimed;
- B) a price premium/special patient contribution for pack sizes for which the Price Claimed is completed.

Signature (Responsible Person's Authorised Representative mentioned above): _____ Date: _____

For Department of Health and Ageing completion only:			
Pricing accords with amount negotiated and recommended for agreement	Signed:	Date:	
Comments (if any):			