PBS Price Disclosure
Quick Reference Guide - August 2007

Australian Government
Department of Health and Ageing

Purpose

The purpose of this document is to provide an overview of requirements under the Pharmaceutical Benefits Scheme (PBS) price disclosure arrangements.

You cannot rely on this document alone to fulfill your requirements under the arrangements. You must also refer to the following PBS Price Disclosure Arrangements booklets:

- Procedural and Operational Guidelines
- Business Rules.

What is price disclosure?

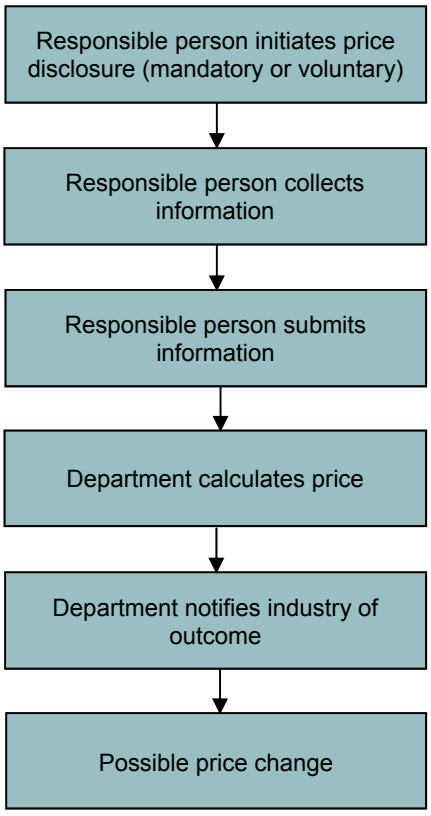
Under Division 3B of Part VII of the *National Health Act (1953),* responsible persons are required to provide information to the Department of Health and Ageing in relation to the sale of brands of pharmaceutical items that are subject to disclosure requirements.

Based on the information provided by responsible persons, the price of certain brands of pharmaceutical items may be reduced.

The responsible person is the entity responsible for meeting the price disclosure requirements.

Price disclosure lifecycle

The price disclosure lifecycle is as follows:



Initiation

Mandatory price disclosure

Mandatory price disclosure is required by responsible persons that list a new brand of drug on the F2A formulary of the PBS that is bioequivalent or biosimilar to an existing brand.

From 1 January 2011, price disclosure will also apply to new bioequivalent and biosimilar brands listing on the F2 formulary.

You will be notified by the department if you have a mandatory price disclosure requirement.

The following listings do not trigger a price disclosure requirement:

- new brands that are not bioequivalent or biosimilar to another listed brand
- new brands of drugs listed on the F2T formulary before 1 January 2011.

Voluntary price disclosure

Once a new brand has triggered price disclosure, the Department will formally notify the responsible persons of other brands (of the same drug and manner of administration), and advise that they may elect to volunteer to be subject to the price disclosure requirements.

To elect to volunteer, you must complete the *Election for voluntary compliance with the price disclosure requirements* form, and return it to the Department within seven days of your election to volunteer to disclose.

Once you elect to disclose voluntarily you are bound by the price disclosure arrangements for these brands, and cannot later 'opt-out' of the arrangements.

If you elect to volunteer to comply with the price disclosure requirements, you must do so for all brands and all forms and strengths of that drug with the same manner of administration for which they are the responsible person.

The manner of administration is how the drug enters the body. A list of manners of administration is available at www.health.gov.au/pbsreform

Collection

What must be collected

Responsible persons that are required to collect information for price disclosure purposes, must collect information for each brand, form and strength of a drug with the same manner of administration as the brand that triggered price disclosure (the trigger brand).

Over-the-counter PBS items (whether supplied under PBS or not) should be included.

Exempt items should be excluded.

Public hospital data should be excluded.

A list of exempt items is available at:
www.health.gov.au/pbsreform

Monthly collection

For each brand subject to price disclosure, you must collect the following information monthly:

- sales revenue (ex-GST in Australian dollars),
- the volume sold in units of brand, and
- the pack size that applies to each form and strength of the drug as supplied to pharmacists and wholesalers.

Monthly data collection commences as follows:

Brand type	Begin collecting monthly data...
Trigger	From the date the brand is listed on the PBS. **Note: Not all data is used in the Department's calculations.**
Subsequent mandatory	From the date of listing on the PBS.
Voluntary	From the first day of the month following election to voluntarily disclose.

Annual collection

Responsible persons must also collect annual data about the value of discounts and incentives relating to the sales of the brand subject to price disclosure. If the discounts/incentives also relate to other products and brands, then the value should be apportioned across all those products and brands.

The value of any discounts already incorporated in the monthly data should not be disclosed as part of the annual incentive data.

For information on incentives and apportioning, refer to the Procedural and Operational Guidelines, pages 25-26.

Annual collection [cont]

Annual data collection times must commence as follows:

Brand type	Begin collecting annual data...
Trigger	From the start of the next collection cycle.
Subsequent mandatory	From the start of the month after listing. **Note: If listing before the first data collection cycle, from the start of the first data collection cycle.**
Voluntary	From the start of the month after the election to disclose. **Note: If volunteered before the start of the first data collection cycle, from the start of the first data collection cycle.**

Data collection cycles

All disclosed data must fit into one of three annual collection cycles, with start dates of:

- 1 January
- 1 May
- 1 September.

The data collection cycle that applies will be the first after the trigger brand lists.

Each data collection cycle has four quarterly collection periods. The first data collection period always commences on the 1st day of the data collection cycle. All collection periods are of three months duration, but responsible persons may be required to provide data from before the start of the first collection period.

For the first data collection cycle for all listing dates of trigger brands up to 1 August 2008, refer to the Key collection and submission dates table on of page 4 of this document and the Procedural and Operational Guidelines, pages 29-30.

Collection methodologies

Responsible persons should:

- use their own methodologies for extracting the required data
- complete submissions carefully
- keep adequate records to support the submissions.

Submission

When to submit information

The timeframes for submitting data are:

Data	Submissions due
Monthly information	Two calendar months after the end of the collection period. **Note: There are four quarterly collection periods in a collection cycle.**
Annual incentives information	Two calendar months after the end of the annual data collection cycle. **Note: For brands that did not initially trigger disclosure, the first submission of information may cover a period of less than 12 months.**

How to submit information

The responsible person must submit pricing information to the Department either electronically or in hard copy.

All pricing information submitted to the Department must be certified by the responsible person's Chief Executive Officer (or their authorised delegate). You should factor this in to your timeframes for collecting and submitting price disclosure information.

The following table details the appropriate steps to follow for both of these formats:

Electronic submission	Paper-based submission
Follow steps 1-6 below.	Follow steps 1-3 and 6 below.

1. Go to www.health.gov.au/pbsreform
2. Download the *Submission Package* (electronic or paper-based).

The available electronic data formats are:

Data format	Description
.XLS	A format for you to manually complete for submission.
.XML	A technical format to submit your data. Your technical area can use the data format as base instructions.
.CSV	A second technical format to submit your data. Your technical area can use the data format as base instructions.

How to submit information [cont]

3. Complete the downloaded template or paper form for all brands for which you are disclosing.
4. Save the data in the selected format, and burn to a CD/DVD.
5. Label the CD/DVD so the Department can easily match it to your Declaration form.
6. Send the data and Declaration form to:
   Price Disclosure Team
   Pricing Section
   Pharmaceutical Evaluation Branch
   MDP 83
   Department of Health and Ageing
   GPO Box 9848, Canberra ACT 2601

The Department recommends that you use registered post.

Manage incorrect data or errors

The Department processes all submissions and sends a *Price Disclosure Submission Confirmation* letter advising receipt of the information to the responsible person's contact person. You should check the confirmation thoroughly to ensure that the information is accurate and complete.

To make corrections to data that was submitted on disk:

1. Generate a complete new submission to replace the incomplete or inaccurate submission.

You cannot advise the Department of individual errors or omissions. A complete new submission must be completed and re-submitted.

2. Ensure the new submission is complete, accurate and complies with price disclosure requirements.
3. Save the new submission to a CD/DVD.
4. Label the CD/DVD so the Department can easily match it to your declaration form.
5. Complete the *Price Disclosure Submission Declaration* form and for the question **Resubmission of previous data?**, answer **Yes**.
6. Send the CD/DVD by registered post to:
   Price Disclosure Team
   Pricing Section
   Pharmaceutical Evaluation Branch
   MDP 83
   Department of Health and Ageing
   GPO Box 9848, Canberra ACT 2601

If you need to correct information that was submitted on a paper form, please contact the Pricing Section.

Once submitted, the Department repeats the confirmation process.

Calculation

The Department's calculations

The Department will use the price disclosure information to calculate a weighted average disclosed price for all forms and strengths of that drug that have the same manner of administration. The Department will:

1. Define the group for disclosure calculations (this includes all mandatory and voluntary price disclosure items).
2. Calculate the net revenue for each brand within the group, by using the submitted monthly and annual data.

Net revenue is 12 month sales revenue less the value of 12 months of incentives attributable to that brand.

3. Calculate the weighted average price (WAP) for each form and strength, based on the net revenue and sales volumes provided.
4. Calculate the percentage difference between the WAP and the approved ex-manufacturer price for each form and strength.
5. Calculate the weighted average percentage price difference for the group, using the information calculated in Step 4, and weighted by PBS price and volume data.

For further details about each step, refer to the Procedural and Operational Guidelines, page 37.

Weighted average percentage effect

If the weighted average percentage price difference is:

- ≥ 10%, the approved ex-manufacturer price of each PBS item will be reduced by the weighted average percentage difference to give a Weighted Average Disclosed Price.

Note: This is the new approved ex-manufacturer price.

- < 10%, there is no price change and the approved ex-manufacturer price remains the same.

Changes to price

If there is a price change due to price disclosure, the Department will formally advise industry at least six months before it takes effect. Price reductions due to price disclosure can only take place on 1 April or 1 August.

The change will occur at the first price change point after the expiration of the six month notice period.

Any changes in the approved ex-manufacturer price that result from price disclosure will flow on to all forms and strengths of all brands of that drug with the same manner of administration as the brand that triggered disclosure.

Compliance

There are penalties for responsible persons that fail to comply with the price disclosure requirements.

For the penalty details, refer to the Procedural and Operational Guidelines, page 51.

Further reference material

Resources

Refer to the PBS Price Disclosure Arrangements:

- Procedural and Operational Guidelines
- Business Rules.

Websites

Refer to the following websites:

- www.frli.gov.au (regulations and determinations)
- www.comlaw.gov.au (*National Health Act 1953*)
- www.health.gov.au
- www.health.gov.au/pbsreform
- www.pbs.gov.au

Key collection and submission dates (for trigger brands)

Date of listing for trigger brand	Date collection starts	Date collection finishes	Quarters Collection Periods				Submission date for the 4th quarter	Data used in calculations
			1	2	3	4		
01 August 2007	01 Aug 2007	31 Aug 2008	01/08/07-30/11/07	01/12/07-29/02/08	01/03/08-31/05/08	01/06/08-31/08/08	01 Nov 2008	1 Sep '07-31 Aug '08
01 September 2007	01 Sep 2007	31 Dec 2008	01/09/07-31/03/08	01/04/08-30/06/08	01/07/08-30/09/08	01/10/08-31/12/08	01 Mar 2009	1 Jan '08-31Dec '08
01 October 2007	01 Oct 2007	31 Dec 2008	01/10/07-31/03/08	01/04/08-30/06/08	01/07/08-30/09/08	01/10/08-31/12/08	01 Mar 2009	1 Jan '08-31Dec '08
01 November 2007	01 Nov 2007	31 Dec 2008	01/11/07-31/03/08	01/04/08-30/06/08	01/07/08-30/09/08	01/10/08-31/12/08	01 Mar 2009	1 Jan '08-31Dec '08
01 December 2007	01 Dec 2007	31 Dec 2008	01/12/07-31/03/08	01/04/08-30/06/08	01/07/08-30/09/08	01/10/08-31/12/08	01 Mar 2009	1 Jan '08-31Dec '08
01 January 2008	01 Jan 2008	30 Apr 2009	01/01/08-31/7/08	01/08/08-31/10/08	01/11/08-31/01/09	01/02/09-30/04/09	01 Jul 2009	1 May '08 – 30 Apr '09
01 February 2008	01 Feb 2008	30 Apr 2009	01/02/08-31/7/08	01/08/08-31/10/08	01/11/08-31/01/09	01/02/09-30/04/09	01 Jul 2009	1 May '08 – 30 Apr '09
01 March 2008	01 Mar 2008	30 Apr 2009	01/03/08-31/7/08	01/08/08-31/10/08	01/11/08-31/01/09	01/02/09-30/04/09	01 Jul 2009	1 May '08 – 30 Apr '09
01 April 2008	01 Apr 2008	30 Apr 2009	01/04/08-31/7/08	01/08/08-31/10/08	01/11/08-31/01/09	01/02/09-30/04/09	01 Jul 2009	1 May '08 – 30 Apr '09
01 May 2008	01 May 2008	31 Aug 2009	01/05/08-30/11/08	01/12/08-28/02/09	01/03/09-31/05/09	01/06/09-31/08/09	01 Nov 2009	1 Sep '08- 31 Aug '09
01 June 2008	01 Jun 2008	31 Aug 2009	01/06/08-30/11/08	01/12/08-28/02/09	01/03/09-31/05/09	01/06/09-31/08/09	01 Nov 2009	1 Sep '08- 31 Aug '09
01 July 2008	01 Jul 2008	31 Aug 2009	01/07/08-30/11/08	01/12/08-28/02/09	01/03/09-31/05/09	01/06/09-31/08/09	01 Nov 2009	1 Sep '08- 31 Aug '09
01 August 2008	01 Aug 2008	31 Aug 2009	01/08/08-30/11/08	01/12/08-28/02/09	01/03/09-31/05/09	01/06/09-31/08/09	01 Nov 2009	1 Sep '08- 31 Aug '09