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[www.pbs.gov.au/info/industry/pricing/price-disclosure-spd/price-disclosure-guidelines](http://www.pbs.gov.au/info/industry/pricing/price-disclosure-spd/price-disclosure-guidelines)



**Australian Government**

**Department of Health**

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# Pharmaceutical Benefits Scheme Price Disclosure Arrangements

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## Procedural and Operational Guidelines

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# 1

## Introduction

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## Purpose

1. The purpose of these Guidelines is to provide operational and procedural guidelines on the implementation of the Pharmaceutical Benefits Scheme (PBS) Price Disclosure arrangements.

## Name of Guidelines

2. These guidelines are the Pharmaceutical Benefits Scheme Price Disclosure Arrangements Procedural and Operational Guidelines (“Guidelines”).

## Commencement of price disclosure arrangements

3. Price disclosure arrangements first commenced as part of the 2007 PBS Reforms. The arrangements were expanded and accelerated from 1 December 2010, and further modified by Simplified Price Disclosure (SPD) amendments in 2014. SPD amendments to the *National Health Act 1953* commenced 13 March 2014 and to the *National Health (Pharmaceutical Benefits) Regulations 1960* on 3 June 2014. For more information about initiation and changes to the price disclosure arrangements, see: [www.pbs.gov.au/info/industry/pricing/price-disclosure-spd](http://www.pbs.gov.au/info/industry/pricing/price-disclosure-spd)
4. The method for working out potential price disclosure reductions is set out in detail later in these Guidelines. A step by step guide and a sample calculation, is also available on the price disclosure web page, see: [www.pbs.gov.au/info/industry/pricing/price-disclosure-spd](http://www.pbs.gov.au/info/industry/pricing/price-disclosure-spd)

## Intended Audience

5. These Guidelines are intended for use by:
  - responsible persons for products listed on the PBS, and particularly those with a brand, or soon to be listed brand, of a drug on the PBS F2 Formulary (pharmaceutical companies);
  - Departmental staff and other government agencies;
  - the independent Price Disclosure Data Administrator (PDDA); and
  - other relevant stakeholders.

## What is covered in this document

6. This document covers procedural guidelines, standard operating procedures, compliance guidelines and security arrangements for commercial in confidence material for:
  - price disclosure;
  - use of the price disclosure information; and
  - changes to price as a result of price disclosure.

## Relevant legislation, policies and documents

7. Legislation governing these Guidelines is the *National Health Act 1953* (the Act) and *National Health (Pharmaceutical Benefits) Regulations 1960* (the Regulations).
8. Other useful information is available on the Price Disclosure web page: [www.pbs.gov.au/info/industry/pricing/price-disclosure-spd](http://www.pbs.gov.au/info/industry/pricing/price-disclosure-spd)

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## Definitions

9. Definitions for the Guidelines are in Chapter 5 at the back of this document.

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# 2

## Price Disclosure Arrangements

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## Initiation and Overview

### What is Price Disclosure?

10. Price Disclosure for PBS listed medicines was introduced as part of PBS Reforms in 2007.
11. Suppliers of certain PBS listed brands of medicines are required to advise the Department of information, via the Price Disclosure Data Administrator (PDDA), in relation to supply of their brands for data collection periods. The disclosed information is used to work out the price at which their brands are sold. Under arrangements in the Act and Regulations the price Government pays for the PBS listed medicines will move closer to the price at which they are supplied in the market, based on the information disclosed by suppliers.
12. Initially the price disclosure obligation only applied as part of listing a new brand of an existing pharmaceutical item with a drug that was on F2 when the new brand listed. Disclosure was voluntary for some brands. More details about the original price disclosure arrangements are available at:  
[www.pbs.gov.au/info/industry/pricing/disclosure](http://www.pbs.gov.au/info/industry/pricing/disclosure)
13. Under the first extension of the price disclosure arrangements, known as Expanded and Accelerated Price Disclosure (EAPD), from 1 December 2010 all brands of non-exempt pharmaceutical items containing F2 drugs became subject to price disclosure provisions. Under EAPD the data collection period for regular ongoing cycles was 12 months, with a 6 month processing period. There was a main cycle which covered most medicines subject to the arrangements, with a potential reduction day on 1 April each year. There were also two supplementary cycles each year for some drug/MoAs new to price disclosure, with potential reduction days on 1 August and 1 December each year. After their first supplementary cycle, drugs merged into the main cycle. The last reduction under EAPD occurred on 1 August 2014. More details about the price disclosure arrangement under EAPD are available at:  
[www.pbs.gov.au/info/industry/pricing/eapd](http://www.pbs.gov.au/info/industry/pricing/eapd)
14. Further amendments to the price disclosure arrangements were made under the Simplified Price Disclosure (SPD) initiative in 2014. Amendments to the Act for SPD commenced on 13 March 2014, with associated amendments to the Regulations commencing on 3 June 2014. The first price disclosure reductions based on the SPD modifications will occur on 1 October 2014, based on information submitted for data collection periods ending 31 March 2014. The weighted average disclosed prices for the 1 October 2014 reduction day were determined on 17 June 2014 under the amended Regulations. Reduction days are intended to occur every six months.
15. Following SPD amendments, price disclosure operates with:
  - six monthly data collection periods\*;
  - a single ongoing rolling cycle of 12 months\*\*;
  - two regular reduction days each year (1 April and 1 October)\*\*\*; and
  - the price disclosed by companies for a data collection period being compared to an average PBS ex-manufacturer price for brands of a pharmaceutical item during the period.

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\* The first data collection period may be longer than 6 months (more information is available under the heading **Collection** below).

\*\* The first cycle may be longer than 12 months (more information available under the section describing the **Disclosure Cycle – Summary** below).

\*\*\* There is also provision in the Regulations for reduction days on 1 August and 1 December each year if required.

16. More details about the SPD amendments to price disclosure are available at: [www.pbs.gov.au/info/industry/pricing/price-disclosure-spd](http://www.pbs.gov.au/info/industry/pricing/price-disclosure-spd)

## What medicines are subject to price disclosure?

17. All brands of pharmaceutical items containing a drug on the F2 formulary are subject to price disclosure (except brands of exempt items). This means information must be disclosed for those brands and they are subject to potential price disclosure price reductions. The method for calculating price disclosure outcomes is applied to groupings of related brands (i.e., brands of pharmaceutical items that contain the same F2 drug with the same manner of administration - drug/MoA).

## Entity responsible for meeting Price Disclosure Obligations

18. The Responsible Person is the entity responsible for meeting the requirements of price disclosure. This responsibility continues in relation to a delisted brand until the responsible person has fulfilled the reporting obligations for the data collection period in which the brand delisted.

## Entity receiving the information to be disclosed

19. Price disclosure data is submitted electronically to the Price Disclosure Data Administrator (PDDA), through the Price Disclosure Submission Utility (PDSU). The PDDA is an independent service provider contracted by the Department to provide data services for price disclosure. More information about data that is required to be disclosed is set out under the **Collection** heading below.

**NOTE:** The PDSU software will be provided by the PDDA immediately before the end of the first period for which a responsible person will be required to submit data after it has a brand of pharmaceutical item that becomes subject to price disclosure requirements. Responsible persons wishing to discuss what is required for the data submission process should contact the PDDA. Contact details can be found on the last page of this document.

## Treatment of combination drug list brands

20. Brands containing drugs on the combination drug list will not be subject to price disclosure data collection requirements. However, brands containing a drug on the combination drug list are subject to price reductions based on the reductions to a component drug (under section 99ACC of the Act).
21. There is a discretion for the Minister or pricing delegate not to apply the component drug reduction to a combination list drug if relevant PBAC advice is in place under subsection 101(4AC) of the Act.
22. When the price of a component drug is reduced due to price disclosure, any price agreement for a combination drug list brand will cease to apply on the reduction day. New agreements are required before the reduction day for brands of medicines on the combination drug list that have a component drug with a reduction.

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A new agreement is required even if the Minister or delegate decides not to apply the component price reduction to the combination drug list brand.

23. A drug on the combination drug list will move to the F2 formulary when it no longer meets the criteria under subsection 85AB (5) of the Act (i.e., it has more than one bioequivalent / biosimilar brand or is in a therapeutic group with a drug that has more than one bioequivalent / biosimilar brand).
24. Brands containing the combination drug will then become subject to price disclosure – i.e., data collection and rules for working out potential reductions will then apply to the combination item in the same way as for all other drugs in the F2 formulary. Price disclosure reductions in component drugs therefore do not flow on to combination items that contain a drug on F2.

### Exemptions to the Price Disclosure arrangements

25. Pharmaceutical items determined under section 84AH of the Act are exempt from price disclosure arrangements. The full list of these exempt pharmaceutical items is available on the website: [www.pbs.gov.au/info/industry/pricing/pbs-items/items-exempt-price-reductions](http://www.pbs.gov.au/info/industry/pricing/pbs-items/items-exempt-price-reductions)

## Disclosure Cycle - Summary

26. The **ongoing regular** disclosure cycle consists of:
  - a data collection period of six months;
  - a processing period (intended to be six months); and
  - a reduction day(s).
27. A list of drug/MoAs subject to price disclosure, and their relevant cycles, is available under the Primary Sources heading at: [www.pbs.gov.au/info/industry/pricing/price-disclosure-spd](http://www.pbs.gov.au/info/industry/pricing/price-disclosure-spd)

### Data Collection Period

28. Sales revenue, incentives and volume data is to be collected for ongoing six monthly data collection periods for each cycle. Details of the information to be collected are set out under the **Collection** heading below.
29. First data collection periods can be longer or shorter than six months. In summary, when a *drug/MoA first becomes subject to price disclosure* (i.e., brands of a drug/MoA first enter F2 or there is a new MoA for an F2 drug), the first data collection period for the first new brands can be longer six months. New brands of a *drug/MoA already subject to price disclosure* can have a shorter first data collection period as they join the data collection period that is in progress for related brands (i.e., brands with the same drug/MoA). Information about the first data collection period is set out under the **Collection** heading below.

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## Processing Period

30. The processing period is intended to be six months – including:

- six weeks for submission of data (see the Cycles Table below, and details under the heading **Submission** for exact dates);
- calculations and preparation of the relevant legal instruments (see below under the heading **Calculations** for details of the calculation method);
- notification of outcomes for a cycle, which is intended to occur at least three months in advance of reduction day (see below under the heading **Notification of Outcomes** for details);
- a period for administrative dispute resolution (see below under the heading **Administrative Dispute Resolution** for details);
- publication processes.

## Reduction Day

31. It is expected that each cycle have only one reduction day (1 April and 1 October each year). However, there is potential for reductions to occur on different reduction days for a cycle if necessary (the Regulations prescribe 1 August and 1 December as additional reduction days in case it becomes necessary to use either of these instead of the usual reduction day - e.g. delay associated with legal proceedings).

32. Once a brand finishes its first disclosure cycle it continues in rolling cycles, being subject to potential reductions every six months thereafter. A diagram explaining the ongoing nature of cycles is in the presentation slides for the SPD stakeholder information sessions at: [www.pbs.gov.au/info/industry/pricing/price-disclosure-spd](http://www.pbs.gov.au/info/industry/pricing/price-disclosure-spd)

## Transition from EAPD to SPD arrangements

33. All brands of drug/MoAs that were subject to price disclosure (i.e., drug in F2) on or before 1 October 2013, and where the drug/MoA had collected six months of data by 31 March 2014, became part of the cycle with a potential reduction day on 1 October 2014 (first cycle under SPD amendments).

This includes brands that were previously in the following EAPD Cycles:

- 2015 Main Cycle (i.e., next potential EAPD reduction day was 1 April 2015):
  - i. previously 2014 Main Disclosure Cycle (started collecting for 2015 Main Cycle on 1 October 2013 – moved to 2014 October Cycle);
  - ii. brands that entered directly into the 2015 Main Cycle and had collected six months of data prior to 31 March 2014;
  - iii. previously 2013 Supplementary Disclosure Cycle A (started collecting for 2015 Main Cycle on 1 February 2013 – moved to 2014 October Cycle); and
  - iv. previously 2013 Supplementary Disclosure Cycle B (started collecting for 2015 Main Cycle on 1 June 2013 – moved to 2014 October Cycle);
- 2014 Supplementary Disclosure Cycle A.

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34. Details of the drugs in these categories are set out in the Factsheet 1 at:  
[www.pbs.gov.au/info/industry/pricing/price-disclosure-spd](http://www.pbs.gov.au/info/industry/pricing/price-disclosure-spd)

### Length of First Cycles

35. Drug/MoAs may become subject to price disclosure on any month. However, there will be a six month data collection period, across brands of a drug/MoA. As a result, a first price disclosure cycle can be up to 17 months long (ie: up to 11 months of data collection plus six months processing). Information about the first data collection period is provided under the **Collection** heading below.

### Allocation to First Cycle - Brands becoming subject to price disclosure between 2 April and 1 October each year

36. Any brand of a drug/MoA that becomes subject to price disclosure (i.e., moves to F2) **between 2 April and 1 October** each year will be in a cycle with its *first* data collection period ending on the next 31 March. It's first potential reduction day is 1 October of the year during which the data collection period finishes.
37. Information about collection and submissions of data for the first cycle is provided under the **Collection** and **Submission** headings below.

### Allocation to First Cycle - Brands becoming subject to price disclosure between 2 October and 1 April each year

38. Any brand of drug/MoA that becomes subject to price disclosure (i.e., moves to F2) **between 2 October and 1 April** each year will be in a cycle with its *first* data collection period ending on the next 30 September. It's first potential reduction day is 1 April of the next year.
39. Information about collection and submissions of data for the first cycle is provided under the **Collection** and **Submission** headings below.

### Ongoing Cycle

40. Immediately at the end of each data collection period the brand commences collecting data in its next cycle. The previous cycle continues with a processing period and ends with its reduction day, which is intended to occur immediately after the six month processing period.
41. Six monthly data collection, plus six months processing periods continue in 12 month cycles. As the rolling data collection and processing periods overlap, there is a reduction day every 6 months. A diagram explaining the ongoing nature of cycles is in the presentation slides for the SPD stakeholder information session at:  
[www.pbs.gov.au/info/industry/pricing/price-disclosure-spd](http://www.pbs.gov.au/info/industry/pricing/price-disclosure-spd)
42. The example under the heading **Cycles Table – Relevant Dates** below also demonstrates the rolling cycle with six monthly reduction days.

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## Cycles Table - Relevant Dates

43. The First Cycles Table below sets out the first price disclosure cycle and relevant dates for brands with a drug/MoA joining price disclosure in the month in the first column of the table (usually the day a drug moves to F2). The months when most drug/MoAs will join price disclosure are highlighted (April, August, and December each year).
44. To assist in understanding the First Cycles Table, a sample first cycle and ongoing cycles are described below.

### **EXAMPLE – First and ongoing cycle**

Dionysius Pty Ltd is the responsible person for the originator Zeus brand of the drug Cronus (two strengths of tablet - 25mg and 40mg, and a 25mg/100mL injection). Prior to 1 August 2014 Cronus has been on the F1 formulary on the PBS.

On 1 August 2014 Athenia Pty Ltd lists the Poseidon brand of the drug Cronus (25 mg tablet only). The drug Cronus moves to F2 on 1 August 2014 and all brands containing Cronus are subject to price disclosure from that date. The Cronus oral brands (Zeus and Poseidon 25mg tablets and Zeus 40mg tablet) will be in one price disclosure calculation grouping (drug/MoA related brands) and the Cronus injection brand (Zeus 25mg/100mL injection) will be in a second price disclosure calculation grouping.

The first cycle is the 2015 October Cycle, named for its expected reduction day. The first data collection period starts on 1 August 2014 and ends 31 March 2015.

Dionysius Pty Ltd and Athenia Pty Ltd are required to disclose data for their first data collection period for their Zeus (tablet and injection) and Poseidon (tablet) brands respectively:

- for the period 1 August 2014 to 30 September 2014 - by 11 November 2014, and
- for the period 1 October 2014 to 31 March 2015 - by 12 May 2015.

The processing period for the first cycle (the 2015 October Cycle) commences 1 April 2015 and concludes with its reduction day on 1 October 2015.

The second cycle for Cronus Oral and Cronus Injection brands is the 2016 April Cycle. It commences 1 April 2015 and has a six data collection period running from 1 April 2015 to 30 September 2015 (coinciding with the six month processing period for the first cycle). The processing period for the second cycle commences 1 October 2015 and concludes with its reduction day on 1 April 2016.

The third cycle for Cronus Oral and Cronus Injection brands is the 2016 October Cycle. It commences 1 October 2015 and has a six month data collection period running from 1 October 2015 to 31 March 2016 (coinciding with the six month processing period for the second cycle). The processing period for the third cycle commences 1 April 2016 and concludes with its reduction day on 1 October 2016.

Twelve month rolling cycles continue thereafter with six monthly data collection and reduction days.

<b>First Cycles Table</b>				
<b>Start of Price Disclosure for Drug/MoA</b>	<b>First Cycle</b>	<b>First Data Collection Period</b>	<b>Data Due Date(s) for First Data Collection Period*</b>	<b>First Potential Reduction Day</b>
	2014 October Cycle	ended 31 March 2014	12 May 2014	1 October 2014
<b>Nov-2013</b>	2015 April Cycle	1 November 2013 to 30 September 2014	12 May 2014 & 11 November 2014	1 April 2015
<b>Dec-2013</b>	2015 April Cycle	1 December 2013 to 30 September 2014	12 May 2014 & 11 November 2014	1 April 2015
<b>Jan-2014</b>	2015 April Cycle	1 January 2014 to 30 September 2014	12 May 2014 & 11 November 2014	1 April 2015
<b>Feb-2014</b>	2015 April Cycle	1 February 2014 to 30 September 2014	12 May 2014 & 11 November 2014	1 April 2015
<b>Mar-2014</b>	2015 April Cycle	1 March 2014 to 30 September 2014	12 May 2014 & 11 November 2014	1 April 2015
<b>Apr-2014</b>	2015 April Cycle	1 April 2014 to 30 September 2014	11 November 2014	1 April 2015
<b>May-2014</b>	2015 October Cycle	1 May 2014 to 31 March 2015	11 November 2014 and 12 May 2015	1 October 2015
<b>Jun-2014</b>	2015 October Cycle	1 June 2014 to 31 March 2015	11 November 2014 and 12 May 2015	1 October 2015
<b>Jul-2014</b>	2015 October Cycle	1 July 2014 to 31 March 2015	11 November 2014 and 12 May 2015	1 October 2015
<b>Aug-2014</b>	2015 October Cycle	1 August 2014 to 31 March 2015	11 November 2014 and 12 May 2015	1 October 2015
<b>Sep-2014</b>	2015 October Cycle	1 September 2014 to 31 March 2015	11 November 2014 and 12 May 2015	1 October 2015
<b>Oct-2014</b>	2015 October Cycle	1 October 2014 to 31 March 2015	12 May 2015	1 October 2015
<b>Nov-2014</b>	2016 April Cycle	1 November 2014 to 30 September 2015	12 May 2015 and 11 November 2015	1 April 2016
<b>Dec-2014</b>	2016 April Cycle	1 December 2014 to 30 September 2015	12 May 2015 and 11 November 2015	1 April 2016
<b>Jan-2015</b>	2016 April Cycle	1 January 2015 to 30 September 2015	12 May 2015 and 11 November 2015	1 April 2016
<b>Feb-2015</b>	2016 April Cycle	1 February 2015 to 30 September 2015	12 May 2015 and 11 November 2015	1 April 2016
<b>Mar-2015</b>	2016 April Cycle	1 March 2015 to 30 September 2015	12 May 2015 and 11 November 2015	1 April 2016

<b>Apr-2015</b>	2016 April Cycle	1 April 2015 to 30 September 2015	11 November 2015	1 April 2016
<b>May-2015</b>	2016 October Cycle	1 May 2015 to 31 March 2016	11 November 2015 and 12 May 2016	1 October 2016
<b>Jun-2015</b>	2016 October Cycle	1 June 2015 to 31 March 2016	11 November 2015 and 12 May 2016	1 October 2016
<b>Jul-2015</b>	2016 October Cycle	1 July 2015 to 31 March 2016	11 November 2015 and 12 May 2016	1 October 2016
<b>Aug-2015</b>	2016 October Cycle	1 August 2015 to 31 March 2016	11 November 2015 and 12 May 2016	1 October 2016
<b>Sep-2015</b>	2016 October Cycle	1 September 2015 to 31 March 2016	11 November 2015 and 12 May 2016	1 October 2016
<b>Oct-2015</b>	2016 October Cycle	1 October 2015 to 31 March 2016	12 May 2016	1 October 2016
<b>Nov-2015</b>	2017 April Cycle	1 November 2015 to 30 September 2016	12 May 2016 and 11 November 2016	1 April 2017
<b>Dec-2015</b>	2017 April Cycle	1 December 2015 to 30 September 2016	12 May 2016 and 11 November 2016	1 April 2017
<b>Jan-2016</b>	2017 April Cycle	1 January 2016 to 30 September 2016	12 May 2016 and 11 November 2016	1 April 2017
<b>Feb-2016</b>	2017 April Cycle	1 February 2016 to 30 September 2016	12 May 2016 and 11 November 2016	1 April 2017
<b>Mar-2016</b>	2017 April Cycle	1 March 2016 to 30 September 2016	12 May 2016 and 11 November 2016	1 April 2017
<b>Apr-2016</b>	2017 April Cycle	1 April 2016 to 30 September 2016	11 November 2016	1 April 2017
<b>May-2016</b>	2017 October Cycle	1 May 2016 to 31 March 2017	11 November 2016 and 12 May 2017	1 October 2017
<b>Jun-2016</b>	2017 October Cycle	1 June 2016 to 31 March 2017	11 November 2016 and 12 May 2017	1 October 2017
<b>Jul-2016</b>	2017 October Cycle	1 July 2016 to 31 March 2017	11 November 2016 and 12 May 2017	1 October 2017
<b>Aug-2016</b>	2017 October Cycle	1 August 2016 to 31 March 2017	11 November 2016 and 12 May 2017	1 October 2017
<b>Sep-2016</b>	2017 October Cycle	1 September 2016 to 31 March 2017	11 November 2016 and 12 May 2017	1 October 2017
<b>Oct-2016</b>	2017 October Cycle	1 October 2016 to 31 March 2017	12 May 2017	1 October 2017
<b>Nov-2016</b>	2018 April Cycle	1 November 2016 to 30 September 2017	12 May 2017 and 11 November 2017	1 April 2018
<b>Dec-2016</b>	2018 April Cycle	1 December 2016 to 30 September 2017	12 May 2017 and 11 November 2017	1 April 2018

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<b>Jan-2017</b>	2018 April Cycle	1 January 2017 to 30 September 2017	12 May 2017 and 11 November 2017	1 April 2018
<b>Feb-2017</b>	2018 April Cycle	1 February 2017 to 30 September 2017	12 May 2017 and 11 November 2017	1 April 2018
<b>Mar-2017</b>	2018 April Cycle	1 March 2017 to 30 September 2017	12 May 2017 and 11 November 2017	1 April 2018
<b>Apr-2017</b>	2018 April Cycle	1 April 2017 to 30 September 2017	11 November 2017	1 April 2018

\* Data due date of 12 May is for a period ending 31 March and data due date of 11 November is for a period ending 30 September

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## Collection

### Information to be collected and submitted

45. For each brand that is subject to price disclosure (all brands of non-exempt pharmaceutical items containing a drug on the F2 formulary) the responsible person is required to disclose information about sales revenue, incentives and volume of sales (for each pack size). The content of information required is set out at regulation 37T and more detail is provided below.
46. This information is required:
  - for all brands of all pharmaceutical items subject to price disclosure that are supplied by the responsible person. This includes both listed brands and any brands that delisted during the data collection period. This obligation continues until the price disclosure requirements have been completed for the data collection period in which the brand was delisted, even after the responsible person ceases to be a responsible person for the brand.
  - to be submitted separately for each brand and each pharmaceutical item.
47. This information will be used to calculate the weighted average disclosed price, which is the basis for any price disclosure reduction.

### Brand specific information that responsible persons are required to collect for each period

48. Responsible persons will need to **collect** and **submit** the following brand specific information in relation to the supply of a brand of a pharmaceutical item (other than supply to a public hospital):
  - the sales revenue;
  - the volume sold, based on the number of packs sold (for all pack sizes of a brand of pharmaceutical item, including packs of the brand of pharmaceutical item that are not pack quantities in the PBS listing instrument);
  - the kind of incentives (if any) given for the brand for the relevant period; and
  - the value of the incentives given for the brand for the relevant period.
49. All monetary amounts should be expressed in Australian dollars and be exclusive of GST. The sales revenue disclosed in the data will generally reflect the prices charged according to invoices or order forms, but may also reflect a rebated price. Any incentives related to sales of the brand must be provided in the data submission for the relevant period. Details about periods for which data is required to be submitted and about incentives are set out below.

### **EXAMPLE - Data collection and submission for a brand that is subject to price disclosure**

Based on price disclosure requirements, Dionysius Pty Ltd has to disclose price information for a drug with brand name Zeus that has two strengths of tablet and one of injection:

1. **Zeus tablet 25 mg (28 pack); and**
2. **Zeus tablet 40 mg (14 pack)**
3. **Zeus injection 25mg/100mL (4 vial pack).**

Dionysius Pty Ltd starts collecting sales revenue, volume and incentive data from the day its Zeus brands became subject to price disclosure (e.g. 1 August 2014) for all pharmaceutical items containing Zeus, i.e.: both the oral and the injection MoA.

Dionysius Pty Ltd will use its own internal methodology for extracting the required data.

Dionysius Pty Ltd submits separate sets of data to the PDDA via the PDSU for sales of the Zeus 25 mg and 40 mg tablet packs and the Zeus 25mg/100mL injection packs for each period when data is required to be submitted. This data includes:

- a. Total sales revenue and volume of sales; and
- b. Total incentive data and type of incentive.

Data provided should be aggregated over the duration of each period for which data is being submitted. However, the first month of data is supplied separately for brands *new to the PBS*.

For detailed instructions on how to make a data submission to the PDDA, please refer to the user guide in the PDSU.

### **Commencement and timing for data collection**

50. Responsible persons must begin collecting data on the start day for a brand, which is:

- for new brands containing an F2 drug: the day that the brand listed on the PBS;
- for brands already listed on the PBS when they become subject to price disclosure: the day that the brand became subject to price disclosure (usually on the day its drug/MoA moved to F2).

51. Data is not required to be collected for brands of exempt items. If an exempt item becomes no longer exempt during a data collection period, then brands of that pharmaceutical item will be required to collect data from the date the pharmaceutical item became no longer exempt.

52. All data is required to be submitted after each 31 March (by 12 May) and 30 September (by 11 November). More information about submission of data is provided under the heading **Submission** below.

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53. If a brand is delisted during a period for which data is required to be submitted, then data is required to be collected and submitted for the period until delisting. The deadline for submitting data is the same as for all other continuing brands. If a brand delists during a data collection period, that is the last data collection period for which disclosure is required.

#### **First data collection period**

54. Ongoing data collection periods will generally involve only one submission of data (every six months). However, for the first data collection period there may be two submissions of data if no brands of a drug/MoA were subject to price disclosure for six months before the next 31 March or 30 September (see Data collection timelines example below).
55. The maximum *first* data collection for a brand is 11 months. An 11 month collection period will only occur for a brand of a drug/MoA first becoming subject to price disclosure (i.e., moving to F2) on 1 November or 1 May. Brands of a drug/MoA that become subject to price disclosure on 1 December or 1 June will have a first data collection period of 10 months. Brands of a drug/MoA that become subject to price disclosure on 1 April or 1 October will have a first data collection period of six months. See examples 2 and 3 in the Data Collection Timelines example below.
56. A new brand, where there are already related brands subject to price disclosure, does not need to collect six months of data for its first collection period – the first data collection period ends at the same time as the data collection period for related brands. See example 1 in the Data Collection Timelines example below.
57. Thereafter the responsible person is required to collect and submit data for all subsequent data collection periods (i.e., every six months).

Examples of first data collection period timelines are on the next page.

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## **EXAMPLE - Data collection timelines**

### **Example 1: New brand where there are already related brands subject to price disclosure**

New brand start day of 1 July 2014, and the data collection period for a related brand ends on 30 September 2014:

- (a) the first data collection period starts on 1 July 2014; and
- (b) the first data collection period ends on 30 September 2014; and
- (c) subsequent data collection periods will be the six month periods that start on 1 October 2014, 1 April 2015, 1 October 2015 and so on.

### **Example 2: New brand where there is no related brands subject to price disclosure**

New brand start day of 1 August 2014:

- (a) the first data collection period starts on 1 August 2014; and
- (b) the first data collection period ends on 31 March 2015; and  
*[there will be two data submissions for the first data collection period (i.e., after 30 Sept 2014 and after 31 March 2015)]*
- (c) subsequent data collection periods will be the six month periods that start on 1 April 2015, 1 October 2015, 1 April 2016 and so on.

### **Example 3: New brand where there is no related brands subject to price disclosure**

New brand start day of 1 December 2014:

- (a) the first data collection period starts on 1 December 2014; and
- (b) the first data collection period ends on 30 September 2015; and  
*[there will be two data submissions for the first data collection period (i.e., after 31 March 2015 and after 30 September 2015)]*
- (c) subsequent data collection periods will be the six month periods that start on 1 October 2015, 1 April 2016, 1 October 2016 and so on.

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## Incentives information that responsible persons need to collect

58. Responsible persons need to **collect and submit incentive data, which comprises** the cost to the responsible person of **the incentives** relating to the sales of the brand that is subject to price disclosure.
59. An incentive would include any of the following:
- bonus stock;
  - bundling discounts;
  - cash discounts or rebates;
  - charge backs;
  - co-operative advertising;
  - competitions;
  - computer hardware and software;
  - conference attendance;
  - coupons;
  - free or reduced price-services;
  - patient support programs and other patient level incentives;
  - goods in kind;
  - grants;
  - hospitality;
  - in-store merchandising;
  - loyalty or other rebates;
  - prompt payment discounts;
  - samples;
  - share offers;
  - up-front payments;
  - volume discounts;
  - the cost of any **brand specific** rebates and/or discounts (including any charge backs) which **have not** already been deducted from the disclosed monthly sales revenue data;
  - any other monetary incentives; and
  - the monetary value of any other in kind incentives.
60. This is not intended to be an exhaustive list and the Department may update it at any time. Responsible persons are required to disclose the types and cost of all incentives which they provide that relate to brands subject to the price disclosure arrangements. This includes incentives to customers and others in the PBS supply chain.
61. Any incentive made prior to being subject to price disclosure where an obligation to purchase (or otherwise) has been entered into which remains in effect during part or all of the disclosure cycle should be included and fairly apportioned.
62. Any discounts, rebates or incentives already incorporated in the data collected for sales revenue should not be disclosed as part of the incentive data (to prevent double counting of discounts, rebates and incentives because incentives are deducted from gross revenue to arrive at net revenue as part of the method under the Regulations).

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63. Responsible persons are not required to disclose data for all the incentives that they provide, only those which relate fully or in part to the brand which they are disclosing price information for.
  64. Incentives may cover more than one pharmaceutical item, non-PBS listed items, over the counter items, non-drug products (e.g. make-up, baby care products) and may fall across reporting cycles.
  65. The cost of any monetary incentives, and the monetary value of in-kind benefits, offered on multiple PBS drugs and other items should be fairly apportioned to each brand for the period in question. This apportionment should use an explicit and clear methodology which will be maintained as part of data records and which should be available upon request by the Department. Details of how incentives might be apportioned or valued are under the heading **Data Preparation** below.
  66. For those incentives that fall under the categories of “any other monetary incentives” or “any other non-monetary incentives” the responsible person must provide a description of them.

### Sales to hospitals

67. Data relating to the sales of pharmaceutical items to **public hospitals must be excluded** from the data submitted. Public Hospital is defined in the Act, by reference to the *Private Health Insurance Act 2007*. The instruments for declaration of public hospitals are managed by the Data Management Section, Finance and Analysis Branch, Acute Care Division in the Department. If you are unsure about the status of a particular hospital you can contact the Data Management Section via the following email address: [hospital.declarations.info@health.gov.au](mailto:hospital.declarations.info@health.gov.au)
68. In cases where an extraction of such public hospital data from the rest of the data is complex or where an estimate has to be made, the responsible person will need to develop an explicit and clear methodology which will be maintained as part of the data records and which should be available upon request by the Department.
69. All other sales of the PBS listed brand of pharmaceutical item **must be included**. This includes sales of pharmaceutical items to **private hospitals** and other sales that are not public hospital sales, regardless of the eventual dispensing circumstances.

### Data Preparation

70. Responsible persons must work out the brands of pharmaceutical items for which information must be collected and submitted. Although the PDDA will pre-populate the PDSU with brands of pharmaceutical items at the beginning of each submission period, the responsible person must ensure all relevant brands of pharmaceutical items are included (ie: all brands with an F2 drug).
71. The responsible person must ensure correct disclosure of:
  - brand specific information on sales revenue; and
  - the volume of the brand sold, based on the number of packs sold (for all pack sizes of a brand of pharmaceutical item, including packs of the brand of pharmaceutical item that are not pack quantities in the PBS listing instrument, but excluding public hospital sales); and

- apportioning of the cost of any brand and non-brand specific incentives relating to a brand subject to disclosure (more information provided below).
72. Responsible persons should use their own methodologies for extracting the required data. Responsible persons should ensure that appropriate methodologies for extracting and/or estimating data have been developed, documented and applied in a consistent manner.
73. The Department may request that a responsible person agrees to participate in an audit of their price disclosure data and methodologies. This may involve the Department or its appointed auditor seeking answers to questions, and/or checking business records against the submitted disclosure statements. Responsible persons should therefore complete their submissions carefully and keep adequate records to support their submissions.

### Apportioning the cost of any incentives relating to a brand

74. Responsible persons are responsible to ensure accurate collection of any specific incentives that apply to the brand.
75. Responsible persons are also responsible for apportioning incentives that apply across more than one brand and/or form, using their own methodologies. These methodologies should be reasonable and well documented.

*The following example demonstrates how a responsible person may wish to apportion incentives, which apply to more than one form, across those forms.*

<b>EXAMPLE - Incentive Data for Zeus® oral brands (as submitted by Dionysius Pty Ltd)</b>			
<b>Brand and Form</b>	<b>Brand specific Incentives</b>	<b>Incentives that apply to multiple brands and/or forms</b>	<b>Sales revenue</b>
Zeus tablet 25 mg	\$653,084	N/A	\$2,245,049
Zeus tablet 50 mg	\$10,000	N/A	\$2,254,951
<b>Zeus (Overall)</b>	N/A	\$150,000	\$4,500,000

Apportioning the incentives that apply to Zeus overall to Zeus tablet 25 mg:

$$I_{T(Z25)} = I_T \times \frac{S_{Z25}}{S_T} = \$150,000 \times \frac{\$2,245,049}{\$4,500,000} = \$74,835$$

Where:

$I_{T(Z25)}$  is the Overall Zeus incentives, apportioned for Zeus tablet 25 mg

$I_T$  is the Total value of overall Zeus incentives

$S_{Z25}$  is the Sales Revenue for Zeus tablet 25 mg

$S_T$  is the Total sales revenue of Zeus

### EXAMPLE – Calculating a Total Incentive Amount for Zeus 25 and Zeus 50

Total incentive amount for Zeus tablet 25 mg:

$$I_{Z25} = I_{BF(Z25)} + I_{T(Z25)}$$

$$I_{Z25} = \$653,084 + \$74,835 = \$727,919$$

$I_{Z25}$  = Incentives for Zeus tablet 25 mg

$I_{BF(Z25)}$  = Incentives specific to Zeus tablet 25 mg

A similar calculation can be performed for Zeus tablet 50 mg:

$$I_{Z50} = \$10,000 + \$75,165 = \$85,165$$

$I_{Z50}$  = Incentives for Zeus tablet 50 mg

### Data alignment in disclosure preparation

76. The method used when preparing data for price disclosure purposes has the potential to affect pricing calculations for brands and, potentially, the overall price disclosure outcome for a drug/MoA.
77. Responsible persons should consider their method in terms of the alignment of sales revenues, discounts/incentives, and volumes for each period for which data is submitted.
78. The methods used to define sales and to recognise and measure revenue for price disclosure purposes should be consistent with the responsible person's financial accounting policies.
79. The following example (on the next page) illustrates the importance of:
  - carefully considering the method used when preparing data for price disclosure purposes.
  - working out the medicines for which submissions will be required early in a submission period. Although some data may not be available until later in the submission period, early checks will assist to identify what is required so that disclosed revenue and incentive information is accurate.

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### EXAMPLE – ‘Stock on hand’ rebate

- A ‘stock on hand’ rebate might be paid by a responsible person to a wholesaler following a reduction in the PBS ex-manufacturer price.
- Over the period 1 April 2014 to 30 September 2014, a responsible person sells 100 units of a product to a wholesaler for \$10 (after discounts).
- For the reporting period ending 30 September 2014, the responsible person reports volume of 100 and revenue of \$1,000.
- A PBS price reduction takes effect on 1 October 2014, resulting in a new lower PBS ex-manufacturer price of \$4.
- On 1 October 2014, a wholesaler has 20 units of the product in stock purchased at the higher price (\$10).
- To account for the reduction in stock on hand value, the responsible person issues a stock on hand rebate valued at \$120 (20 unit’s × \$6 reduction).
- The value of the stock on hand rebate (\$120) is reported in the subsequent reporting period, ending 31 March 2015, which is not the period when the relevant sales were made.

The timing mismatch results in:

- **Revenue in the period 1 April 2014 - 30 September 2014** being inflated because some units, recorded as sold at \$10, were effectively sold at \$4 when the \$6 stock on hand rebate is taken into account; and
- **Revenue in the period 1 October 2014 – 31 March 2015** being reduced because the stock on hand rebate of \$6 (negative revenue) is recorded in this period despite applying to sales prior to 1 April 2014.

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## Submission

### Timeframe & responsibility for submission of the information

80. Responsible persons are required to submit price disclosure data (including incentives data) to the PDDA for periods ending on:

- 31 March – submission due by 12 May\* in that year; and
- 30 September – submission due by 11 November\* in that year.

\*If 12 May or 11 November is a weekend or public holiday, the data is due on the next business day.

**NOTE:** Price disclosure data is required to be submitted by 12 May and 11 November, regardless of the length of the period for which data is available.

For example,

- Price disclosure start day for a brand is 1 August 2014;
- First data collection period is 1 August 2014 to 31 March 2015 (eight months);
- Data is to be submitted after both:
  - 30 September 2014 (two months of data submitted by 11 November 2014); and
  - 31 March 2015 (six months of data submitted by 12 May 2015).

### Submitting data

81. Price disclosure data is submitted electronically to the PDDA, through the Price Disclosure Submission Utility (PDSU). The PDDA is an independent service provider contracted by the Department to provide data services for price disclosure.

**NOTE:** The PDSU software will be provided by the PDDA immediately before the end of the first period for which a responsible person will be required to submit data after it has a brand of pharmaceutical item that becomes subject to price disclosure requirements. Responsible persons wishing to discuss what is required for the data submission process should contact the PDDA. Contact details can be found on the last page of this document.

82. In the unlikely event that the current PDDA is unable to receive data, the Department can give notice to responsible persons to submit data to the Department directly.

### Timely submission of data

83. Responsible persons are encouraged to collate data as early as possible in the data submission period. The Department recommends an early check of brands in the PDSU to ensure the list covers all the products for which there is a legal obligation to provide data. Although some data may not be available until later in the submission period, early checks will assist to identify what is required.

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84. Some responsible persons have requested an extension to the submission deadline when unexpected absences or other issues arise. Extensions cannot be provided as the submission period is set by the Regulations. Making an early start on data collection reduces the risk of difficulty meeting disclosure deadlines. Late disclosure will constitute non-compliance.

### Change of responsible person during a data collection period

85. It is the responsibility of the company that is the legal responsible person during the data collection period to submit data. If the responsible person changes during the data collection period, then each responsible person must report for the period it was responsible for the brand. The PDSU will be opened for each of the responsible persons to submit data for their relevant periods.

86. If:

- a responsible person passes commercial responsibility for a brand to another company before the legal change to responsible person; and
- the relevant companies prefer the new commercially responsible company to make the disclosure for the period it was selling the product,

the companies must notify the Department and the PDDA about who is intended to submit the data.

87. Notification about who will submit data in cases of early transfer of commercial responsibility for a brand can be done by letter. A letter from the legally responsible person should authorise the new commercially responsible person to disclose for the specified brands of pharmaceutical items for specified periods or from a specified date. A letter from the new commercially responsible person should then undertake to make the disclosure for the specified brands for the specified period or from a specified date. This could be achieved through one co-signed letter.

88. The letter or letters giving the relevant authorisation and undertaking should be addressed to the Price Disclosure Team in the Department and copies sent to both the Department and to the PDDA. An emailed PDF version of the letter is acceptable. Email details can be found on the last page of this document.

89. If further information about the submission process is required please contact the PDDA. Contact details can be found on the last page of this document.

### Certification requirements

90. When a responsible person submits price disclosure data to the PDDA, the authorised representative for the responsible person is required to certify via the PDSU, that  
**“in accordance with the certification procedures that I have caused reasonable reviews of the information to be done. To the best of my knowledge and belief, the information is true, complete and accurate, as of the date it is submitted and in accordance with the *National Health (Pharmaceutical Benefits) Regulations 1960.*”**

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## Calculation

### The entity responsible for calculations

91. The PDDA completes preliminary calculations in accordance with the method set out in the Act and the Regulations to assist in the making of determinations of weighted average disclosed prices (WADPs), which are used as the basis for any reductions.
92. Calculations for reduction days from 1 October 2014 onward are completed in accordance with the Act and Regulations as amended for Simplified Price Disclosure (SPD). The Act amendments for SPD commenced on 13 March 2014 and the associated regulation amendments commenced on 3 June 2014. Links to the relevant amendments are on the price disclosure (SPD) web page: [www.pbs.gov.au/info/industry/pricing/price-disclosure-spd](http://www.pbs.gov.au/info/industry/pricing/price-disclosure-spd)
93. The Department finalises calculations to assist the Minister (or delegate) in making the WADP determinations required as the basis for price disclosure reductions. The Department carries out subsequent calculations and publishing processes required for reductions applicable on a reduction day.

### The Weighted Average Disclosed Price Calculations

94. Price disclosure reductions are based on a WADP determined for each brand of pharmaceutical item in a cycle. The calculation is performed by grouping related brands (i.e., brands with the same drug/MoA). The calculation and outcome does not apply to exempt items.
95. The method for calculating WADPs is set out in regulations 37G to 37S. A detailed description of the steps is provided below, with a link to a sample calculation. In summary:
  - the weighted average percentage difference is calculated between disclosed prices and the average PBS approved ex-manufacturer prices for brands of each pharmaceutical item containing related brands (i.e., brands with the same drug /MoA).
  - The weighted average percentage difference for each pharmaceutical item of a drug /MoA is then weighted according to its total disclosed volume and its average PBS approved ex-manufacturer price to give the weighted average percentage difference across all brands containing the same drug /MoA.
  - The average PBS approved ex-manufacturer prices for each brand of each drug /MoA are then reduced by the weighted average percentage difference for the drug/MoA, giving a WADP for each brand of pharmaceutical item.
  - A legal determination is made setting out the WADPs for each brand of each pharmaceutical item for every drug/MoA in the cycle. This will be the basis for price disclosure reductions for applicable brands. A 10% test is then applied to work out whether a reduction will apply.

## Method - Weighted average disclosed price of a listed brand of pharmaceutical item

### Definitions and abbreviations:

**av. AEMP** - average approved ex-manufacturer price for brand (see regulation 37J)

**data collection period** - (see regulation 37C)

**final day** - last day of the data collection period (see subregulation 5(1))

**MoA** - manner of administration (see section 84AB and subsection 85(5) of the Act)

**price sampling day** – first day of a calendar month in the data collection period of a brand of a pharmaceutical item (see regulation 37D)

**PQ** - pricing quantity (see subsection 84AK (1) of the Act)

**relevant day** - day after last day of data collection period, i.e. first day of next period (see subsection 99ADB (1) of the Act). Will generally be a reduction day from a previous cycle.

**rounding [\*]** - amounts if not whole cents are rounded to the nearest cent, 0.5 cents upwards (see section 84AI of the Act)

**WADP** - weighted average disclosed price (see subsections 99ADB (1) and (4) of the Act and regulation 37S)

**10% test** for price reductions - See paragraph 99ADH (1) (c), subsections 99ADB (1) and (3A) of the Act)

### Step 1 - Net revenue for brand – Reg 37G

Work out the net revenue (revenue minus incentives) for the listed brand of the pharmaceutical item for the data collection period (other than initial month). Pack size information is required for all supplies.

### Step 2 - Adjusted volume for brand – Reg 37H

Work out the adjusted volume of the brand expressed as the number of packs, adjusted as if the pack size for all supplies equals the pricing quantity (PQ) on the final day.

### Step 3 - Average approved ex-manufacturer price (av.AEMP) for brand of the pharmaceutical item – Reg 37J

Sum the approved ex-manufacturer price (AEMP) on each price sampling day for the data collection period, adjusted if necessary, to reflect the PQ on the final day. Divide by the number of months in the period. [\* round]

### Step 4 - Disclosed price for brand - Reg 37K

Divide the net revenue (step 1) by the adjusted volume (step 2). [\*] If more than av.AEMP, adjust to av.AEMP.

### Step 5 - Price percentage difference of brand - Reg 37L

Subtract the disclosed price (step 4) from the av.AEMP (step 3). Divide that amount by av.AEMP (step 3). Express result as a percentage to 2 decimal places.

**Step 6 - Repeat steps 1 to 5 for each brand of the same pharmaceutical item – Reg 37M**

Calculate steps 1 to 5 for each other brand which has been a listed brand during the data collection period.

If brand has delisted, use the PQ of a listed brand on final day (used in step 2), or the PQ of last listed brand.

**Step 7 - Total adjusted volumes of brands of the same pharmaceutical item - Reg 37N**

Add the adjusted volumes for each brand of the same pharmaceutical item.

**Step 8 - Weighted average percentage difference for the pharmaceutical item - Reg 37P**

Sum the adjusted volume (step 2) multiplied by the price percentage difference (step 5) for each brand. Divide that amount by the total adjusted volume of the brands (step 7). Express result as percentage to 2 decimal places.

**Step 9 - Repeat steps 1 to 8 for each pharmaceutical item with related brands (e.g., different forms) - Reg 37Q**

**Step 10 - Weighted average percentage difference for all related brands with drug/manner of administration - Reg 37R**

Multiply the total adjusted volume (step 7) by the av.AEMP (step 3) for each pharmaceutical item. Sum the results.

- a) Multiply the total adjusted volume (step 7) by the av.AEMP (step 3) for each pharmaceutical item and by the weighted average percentage difference (step 8) for each pharmaceutical item. Sum the results.
- b) Divide (b) by (a). Express result as a percentage to 2 decimal places.

**Step 11 - Weighted average disclosed price for each related listed brand of drug/manner of administration - Reg 37S**

Reduce the av.AEMP (step 3) for the brand by the weighted average percentage difference for all related brands (step 10).

Adjust the WADP (step 11), if necessary, to the PQ on the relevant day (first day of next data collection period).

**10% Test - Compare WADP for brand (adjusted to the same PQ as AEMP on relevant day) with AEMP on relevant day - 99ADH (1) (c)**

Subtract the WADP (step 11) from the AEMP on the relevant day and express as a percentage of the AEMP. If the difference is 10% or more, a price reduction will occur on the next price reduction day unless the price on the reduction day is already the same or lower. This may occur if a lower price comes into force between the relevant day and the reduction day. If the difference is less than 10%, there is no price disclosure reduction.

A sample calculation can be found at:

<http://www.pbs.gov.au/industry/pricing/price-disclosure-spd/sample-price-disclosure-calculation-1-oct-reduction-day-onward.pdf>.

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## Minimum data available for the calculation of a weighted average disclosed price

96. Calculations are carried out for the data collection period for related brands of pharmaceutical items (i.e., all brands for the same drug/MoA). If responsible persons comply with the disclosure requirements, there will be at least six months of data available across brands of a drug/MoA before a calculation is completed. The data set can be made up of listed or delisted brands with the same drug/MoA and not all brands will necessarily have six months of data (e.g. brand listed after the start of price disclosure for the drug/MoA). The first month of data is not used in the calculation for *new listing brands*.
97. Non-compliance by a responsible person will not prohibit the PDDA from proceeding with the calculation.
98. Where a responsible person submits some but not all of the data they are required to submit, the Department may discard the data provided by the responsible person to prevent the calculation of the WADP from being distorted.

## Department provided with calculation outcome

99. The PDDA will advise the Department of the outcome of the preliminary calculation of WADPs for all brands of pharmaceutical items listed during a data collection period in a disclosure cycle.

## Making the WADP Determination

100. A delegate of the Minister in the Department will determine by legislative instrument the WADPs for listed brands in the cycle – see subsection 99ADB of the Act. The determination will also include a brand of any *new pharmaceutical item* that listed between the end of the data collection period and the making of the legal instrument.
101. A WADP is not determined for *new brands of existing items* (or subsequent new brands of a pharmaceutical item listing after the end of the data collection period). The price for those new brands will be reduced on reduction day, where applicable, along with the other brands that do have a WADP (see section 99ADHA of the Act).
102. WADPs are determined in two Schedules to the legal instrument:
  - **Schedule 1** - where the WADP is at least 10% lower than the PBS approved ex-manufacturer price on the relevant day – these are **brands expected to have a price disclosure reduction** on the reduction day mentioned in the instrument; and
  - **Schedule 2** - where the WADP is not at least 10% lower than the PBS approved ex-manufacturer price on the relevant day – these are **brands not taking a price disclosure reduction** on the reduction day mentioned in the instrument.

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103. The relevant day is the day after the end of the data collection period (e.g. for the data collection period ending 31 March 2014, the relevant day was 1 April 2014 – which was a price disclosure reduction day for a previous cycle for at least some brands).
  104. The division of the WADPs into two schedules reflects the 10% test set out in subsection 99ADH (1) (c) of the Act. Under the 10% test a price disclosure reduction will only be applied if the unadjusted price reduction is at least 10%. The unadjusted price reduction is the difference between the AEMP on the relevant day and the WADP determined in the legal instrument, expressed as a percentage of the AEMP on the relevant day.
  105. The WADP is also determined as the adjusted approved ex-manufacturer price for brands that meet the 10% test (i.e., those in Schedule 1 to the legal instrument). The adjusted approved ex-manufacturer price will be the new AEMP on reduction day unless there are other intervening pricing changes (e.g. lower price or change in pricing quantity). More information about the new prices is provided under the heading **Changes to Price as a Result of Price Disclosure** below.
  106. If a new brand of a *new pharmaceutical item* with a drug/MoA that is to take a reduction is listed after making of the determination and before reduction day, then the determination will be amended to add a WADP for a first new brand of the new pharmaceutical item. This ensures that all brands of pharmaceutical items for a drug/MoA are treated equally for the cycle.
  107. The legal determination of WADPs can also be amended to deal with disputes or errors. Affected companies would be notified individually of any such amendments.

## Notification of Outcomes

108. The Department intends that the WADP determination and outcomes notification for each price disclosure cycle be made available at least three months before the relevant reduction day. The WADP determination is not legally required to be made within this timeframe.
109. A Price Disclosure Outcomes Summary is published on the [Price Disclosure \(SPD\)](#) web page of the [www.pbs.gov.au](http://www.pbs.gov.au) website. The Summary mentions the pharmaceutical items of drug/MoAs taking price disclosure reductions on the relevant reduction day. All brands of those pharmaceutical items are taking reductions (i.e., they meet the 10% test for reduction). It does not mention the single brand combination items that will have flow-on reductions from component drugs taking a reduction. These are dealt with directly with affected companies.
110. The WADP outcome for brands of drug/MoAs not taking reductions on the relevant reduction day can be found in the WADP legal determination (Schedule 2). A link to the WADP legal determination, published on [the Federal Register of Legislative Instruments](#), is included with the Price Disclosure Outcomes Summary.
111. An email is sent to all responsible persons advising when the outcome is available.

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## Administrative Disputes Process

112. An agreed process for responsible persons to raise any questions or concerns arising from a price disclosure cycle outcome is set out in the Price Disclosure Dispute Resolution Administrative Process, which is available on the [Price Disclosure \(SPD\)](#) web page. The date for notice of any dispute by a responsible person to the Department (via the Departmental email set out on the last page of this Guideline), is close of business, five Working Days after the outcomes are notified.

## Changes to Price as a Result of Price Disclosure

### When will price changes take place

113. It is intended that price disclosure reductions occur on the first potential reduction day after the determination has been made.
114. There are generally two potential reduction days each year:
- 1 April; and
  - 1 October.
115. Regulation 37A provides that 1 August and 1 December are also prescribed days. These days are prescribed in case it becomes necessary to use either of these instead of the usual reduction day (e.g. delay associated with legal proceedings).

### Brands and drugs that will be affected by the change in price

116. Any changes in the approved ex-manufacturer price that result from price disclosure apply to all brands of all non-exempt pharmaceutical items containing the drug with the same MoA.
117. Any **new brands of existing pharmaceutical items** containing the relevant drug/MoA that list after the end of the data collection period for the disclosure cycle do not require a legal determination for their weighted average disclosed price and adjusted ex-manufacturer price. The Act provides that the same reduction applies to new brands as was determined for the existing brands. No specific notice of a reduction is provided to responsible persons for these new brands.
118. Any **new brands of new pharmaceutical items** (e.g. where the first brand of a new strength or formulation lists after the end of the data collection period) require a legal determination for the weighted average disclosed price and any adjusted ex-manufacturer price. Where the first brand of the new pharmaceutical item lists after the weighted average disclosed price determination is made for a disclosure cycle, an amending legal instrument will be made specifically for the first new brand of that new pharmaceutical item.
119. Flow-on reductions are also applied where appropriate to brands of single brand combination drugs that contain a component drug affected by price disclosure. Any PBAC advice concerning single brand combination items is taken into account. Pricing Section will contact responsible persons affected by single brand combination drug list flow-on's. See the *Treatment of combination drug list brands* section under the heading **Initiation and Overview** above.

## Changes to Pricing Quantity after the end of Data Collection

120. If changes to pack size for a **PBS pack quantity** of a brand of pharmaceutical item occur after the relevant day (i.e., day after the end of the data collection period), causing a change to the pricing quantity for the brand, then:
- the weighted average disclosed price (and adjusted ex-manufacturer price for any brand that will have a reduction) will be determined based on the pricing quantity that applied on the relevant day; and
  - the approved ex-manufacturer price applying on the reduction day will be adjusted to reflect the new pricing quantity.

*The following example demonstrates how an adjustment will be made if a change to PBS pack size causes a change to the pricing quantity for a brand after the relevant day and on / before the reduction day.*

### EXAMPLE – Apportioning if pricing quantity changes

#### **Example – Working out the approved ex-manufacturer price on the reduction day**

Zeus tablet 25 mg has a pricing quantity of 20 tablets on the relevant day (i.e.: day after the last day of the data collection period).

The WADP for the pricing quantity is \$20.

A new pack size of 10 lists after the relevant day.

Zeus tablet 25 mg has a new pricing quantity of 10 tablets applicable on the reduction day.

The following formula is applied to calculate the new price on the reduction day for the new pricing quantity:

$$\begin{array}{l}
 \frac{\text{Zeus tablet 25 mg (20) WADP}}{\text{Old pricing quantity}} \times \text{New pricing quantity} = \text{Zeus tablet 25 mg (10) price on reduction day} \\
 \\
 \text{i.e., } \frac{\$20}{20 \text{ tablets}} \times 10 \text{ tablets} = \$10 = \text{Approved ex-manufacturer price on reduction day}
 \end{array}$$

## Claimed Price Reductions – Premium adjustments under Price Disclosure

121. Any brand with a premium (brand premium, therapeutic group premium or other special patient contribution) that is subject to a price disclosure reduction in a disclosure cycle requires a reduction to the claimed price for the pack quantity of the brand of pharmaceutical item. The new reduced premium for a brand of a pharmaceutical item that has a price determination in force under subsection 85B (3) of the Act can be calculated by following the steps below:

### **Step 1: Identify the prices to be used in the calculation**

1. Price that would have been the Approved (Commonwealth) Ex-Manufacturer Price on reduction day if there was no price disclosure reduction (**Current AEMP**)
2. Adjusted Approved (Commonwealth) Ex-Manufacturer Price on the reduction day - usually the price in the price disclosure determination (**Adjusted AEMP**)
3. Claimed (Manufacturer's) ex-manufacturer price on the day before the reduction day (**Current Claimed Price**)

### **Step 2: Calculate the New Claimed Price (i.e., New Manufacturer's Ex-manufacturer Price)**

To work out a new claimed price calculate the reduction percentage that needs to apply to the current claimed price, as prescribed in subsection 99ADH (4) of the Act. This method is tabled below:

$\frac{\text{Current AEMP} - \text{Adjusted AEMP}}{\text{Current AEMP}} \times 100 = \text{calculated percentage}$
$\text{Current Claimed Price} - \text{calculated percentage} = \text{New Claimed Price}$

### **Step 3: Calculate the Premium**

#### **Calculate the Claimed DPMQ (i.e., Manufacturer's Dispensed Price for Maximum Quantity, including Premium)**

New Claimed Price + applicable wholesale mark-up + applicable pharmacy mark-up + applicable dispensing fee = Claimed DPMQ

#### **Calculate the DPMQ (i.e., Commonwealth Dispensed Price for Maximum Quantity with no Premium)**

Adjusted AEMP + applicable wholesale mark-up + applicable pharmacy mark-up + applicable dispensing fee = DPMQ

#### **Calculate the Premium**

Claimed DPMQ – DPMQ = new Premium

An example calculation is provided below.

## EXAMPLE – Calculating a new Premium for Price Disclosure

### Step 1: Identify the prices required for the calculation

- a. Current AEMP = \$0.85¢
- b. Adjusted AEMP = \$0.76¢
- c. Current Claimed Price = \$1.42

### Step 2: Calculate the New Claimed Price

$$\text{i.e., } \frac{\$0.85\text{¢} - \$0.76\text{¢}}{\$0.85\text{¢}} \times 100 = 10.59\% \text{ (reduction percentage)}$$

\$1.42 (current Claimed Price) – 10.59% = \$1.27

The new Claimed Price for this brand of pharmaceutical item is \$1.27

### Step 3: Calculate the new Premium

#### Calculate the Claimed DPMQ

$$\$1.27 + (\$1.27 \times 7.52\%) + (\$1.37 \times 15\%) + \$6.63 = \mathbf{\$8.21}$$

(New Claimed Price + applicable wholesale mark-up + applicable pharmacy mark-up + applicable dispensing fee = Claimed DPMQ)

#### Calculate DPMQ

$$\$0.76\text{¢} + (\$0.76\text{¢} \times 7.52\%) + (\$0.82\text{¢} \times 15\%) + \$6.63 = \mathbf{\$7.57}$$

(Adjusted AEMP + applicable wholesale mark-up + applicable pharmacy mark-up + applicable dispensing fee = DPMQ)

#### Calculate Premium

$$\$8.21 - \$7.57 = \mathbf{\$0.64\text{¢}}$$

(Claimed DPMQ – DPMQ = Premium)

Details about calculation of fees and mark-ups are available in the Medicare Australia Explanation of PBS Pricing - see:

<https://www.medicareaustralia.gov.au/provider/pbs/pharmacists/pricing.jsp>

## Price disclosure, Statutory Price Reductions & other price changes

122. Brands of pharmaceutical items which are taking or have taken a price disclosure reduction will not be subject to a 'first new brand' Statutory Price Reduction.
123. Where brands of a drug in a therapeutic group take a price disclosure reduction, that drug will be removed from its therapeutic group.

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124. In the event of a price change during a data collection period (e.g. price disclosure or other statutory price reduction, an administrative reduction or a price increase), the PBS price used to calculate the weighted average disclosed price is the average of the approved ex-manufacturer prices that were applicable during the data collection period. See Regulation 37J and the definition of 'price sampling day' in the Regulations.

**Circumstances when a price change will not occur**

125. There will be no change to the approved ex-manufacturer price if there is not a 10% difference between the weighted average disclosed price determined for a brand of pharmaceutical item and the approved ex-manufacturer price for the brand on the relevant day. The relevant day is the day after the end of the data collection period, which will usually be a price disclosure reduction day.
126. If application of the price disclosure outcome would result in an increase to the approved ex-manufacturer price on the reduction day (e.g. because there has been a lower price offered since the end of data collection) then there will be no price disclosure related change to the approved ex-manufacturer price.

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# 3

## Compliance Guidelines

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## A compliance culture

127. It is expected that responsible persons will operate within an organisational framework and culture which supports compliance.
128. They should practice good corporate governance and have appropriate systems in place.
129. Their financial records are expected to be maintained in accordance with applicable Australian Accounting Standards.
130. Compliant organisations tend to:
  - establish values aligned with compliance;
  - build systems which are consistent with, and support, the delivery of these values;
  - promote, recognise and reward behaviours which are consistent with the delivery of these values;
  - ensure adequately skilled resources exist to manage and respond to rules or obligations applied to the business;
  - develop, design and implement policies and processes to support the intent to be compliant;
  - deliver effective compliance testing and monitoring; and
  - obtain independent assurance that the overall system of internal control and compliance operates as intended.
131. Serious penalties apply for non-compliance with price disclosure requirements. Responsible persons should develop a working knowledge of how the price disclosure process works. Responsible persons will need to make themselves aware of their obligations under the price disclosure arrangements and how these affect their record keeping and reporting requirements.
132. Responsible persons should ensure that appropriate methodologies for extracting and/or estimating data have been developed, documented and applied in a consistent manner. A detailed audit trail should be documented and maintained so that data submitted can be traced to the underlying transactional data.
133. The Department may request that a responsible person agrees to participate in an audit of their price disclosure data and methodologies. This may involve the Department, the PDDA, or an alternative appointed auditor checking business records against the disclosure statements submitted to the Department. Responsible persons should therefore complete their submissions carefully and keep adequate records to support their submissions.
134. All documents, methodologies, detailed transactional records and any other documents relating to price disclosure arrangements must be kept for two years from the end of the annual collection cycle to which those records relate.

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## Non-compliance

135. There are a number of different ways in which a responsible person can be considered to be non-compliant with the price disclosure requirements. These include the following:
- the responsible person did not submit any data when required to do so;
  - the responsible person submitted partial and/or incomplete data;
  - the responsible person submitted inaccurate data; and
  - the responsible person submitted all required data, however, it was late.
136. On identifying a case of non-compliance the Department will formally notify the responsible person that:
- non-compliance has occurred;
  - the nature of the non-compliance;
  - the details of the non-compliance;
  - the action which the Department is now asking the responsible person to take and the timeframes for that action; and
  - any action which the Department now intends to take and the timeframes for that action.
137. For example if the data which the responsible person submitted at the due date was incomplete or appears inaccurate the Department may notify the responsible person and ask for submission of the required data as soon as possible, and no longer than 1 business day.
138. If a responsible person knows prior to the due date that it will be unable to comply then the responsible person should notify the PDDA of the likely non-compliance as soon as it becomes aware of it. The PDDA or the Department will then advise the responsible person what course of action the responsible person and Department will need to take to minimise the impact of the non-compliance. Responsible persons should take all reasonable actions to ensure submission by the due date – it should not leave preparation for submissions until late in the submission period.
139. If, after the submission due date, the responsible person becomes aware that it has acted in a non-compliant manner then it should advise the PDDA or the Department immediately. The Department will then advise the responsible person what course of action the responsible person and Department will need to take to minimise the impact of the non-compliance.

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## Consequences of non-compliance with disclosure requirements

140. There are a range of potential actions for non-compliance by responsible persons. Non-compliance is considered to be failure to disclose price disclosure information to the Department in accordance with the legislative requirements. Penalties for non-compliance include:
- criminal penalties for:
    - i. failure to comply with price disclosure requirements
    - ii. knowingly or recklessly providing false and misleading information;
  - financial penalties of up to 60 penalty units for each offence; and
  - non-compliance may result in delisting from the PBS for brands not providing data and any other listed brands of the responsible person and/or refusal to list new brands of the same responsible person depending on the reason for non-supply of data and the period of non-compliance.
141. Not all penalties will apply in all circumstances. In deciding whether to take one of the actions above, the Minister may take into account:
- the number of times that the responsible person did not comply with the price disclosure requirements;
  - the period of time over which the various failures to comply with the EAPD requirements occurred;
  - the duration of each non-compliance;
  - the reason for the non-compliance;
  - whether the reasons are, in the opinion of the Minister, reasonable; and
  - any other matter that the Minister thinks is relevant.

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# 4

## Security Arrangements for Commercial in Confidence Material

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## Confidentiality of the responsible persons' disclosed price information

142. The Department and the PDDA consider sales and incentive information submitted by responsible persons to be commercial-in-confidence, and recognise the responsible persons' expectation that commercial-in-confidence information will be protected from inadvertent, unintended or improper disclosure.
143. In accordance with its legal responsibilities the Department and the service provider will treat all information received from the responsible person as confidential and will not disclose that information to any person without the prior consent of the responsible person (which consent will not be unreasonably withheld), except where the confidential information:
- is required, or authorised, to be disclosed by law, (including disclosure within the Department and its contractors for administration of the PBS, or for court proceedings);
  - must be disclosed to the Department's solicitors, auditors, insurers, advisers or Commonwealth Ombudsman;
  - is reasonably necessary for the enforcement of the criminal law or for the protection of public revenue;
  - is generally available to the public.

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# 5

## Definitions

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### **Adjusted Approved Ex-Manufacturer Price (Adjusted AEMP)**

Where a price disclosure reduction is to apply, this will usually be the new ex-manufacturer price on reduction day. It is the same price as the weighted average disclosed price in the price disclosure legal determination. However, adjustments might be required to this new price if there are other pricing or listing changes between the end of the data collection period and the reduction day. See subsection 99ADB (1) of the Act.

### **Applicable Approved Ex-Manufacturer Price**

The applicable approved ex-manufacturer price of a brand of a pharmaceutical item is the *PBS Approved Ex-Manufacturer Price of the brand the day after the end of the corresponding data collection period*. See subsection 99ADB (3A) of the Act.

### **Approved Ex-Manufacturer Price (AEMP)**

The base price for PBS pricing subsidy. It is the price agreed or determined under the Act for the Pricing Quantity of a brand. See sections 85AD and 85B of the Act.

### **Authorised Representative**

An authorised representative is an individual who has company authority to enter into price agreements, submit price disclosure data and otherwise deal with the Minister, the Department of Health and its delegates in relation to the responsible person's brands of pharmaceutical items.

### **Average Approved Ex-Manufacturer Price (Average AEMP)**

The average AEMP is worked out in accordance with regulation 37J of the Regulations.

In summary, the average approved ex-manufacturer price of a brand of pharmaceutical item is the weighted average AEMP across the data collection period for the brand (weighted by time). It is the price used to compare to disclosed prices and from which the 'weighted average percentage difference' (WAPD) will be deducted to calculate the determined weighted average disclosed price (WADP).

Broadly speaking, the average AEMP is based on the price for brands of a pharmaceutical item in each month of the data collection period, divided by the number of months in that collection period. The method for working out the average AEMP is set out in the Regulations and is explained in the Explanatory Memorandum for the *National Health (Pharmaceutical Benefits) Amendment (Price Disclosure) Regulation 2014*. An example of how it works is in the sample calculation on the price disclosure web page, see: [www.pbs.gov.au/industry/pricing/price-disclosure-spd/sample-price-disclosure-calculation-1-oct-reduction-day-onward.pdf](http://www.pbs.gov.au/industry/pricing/price-disclosure-spd/sample-price-disclosure-calculation-1-oct-reduction-day-onward.pdf)

### **Bonus Stock**

Stock supplied free of charge as an incentive to purchase the disclosing brand.

### **Brand**

Brand of a pharmaceutical item is defined in subsection 84(1) of the Act. It means:

- a) the trade name under which the person who is or will be the responsible person supplies the pharmaceutical item; or

- 
- b) if there is no trade name – the name of the person who is or will be the responsible person.

### **Bundling Discounts**

Discount offered when multiple brands are bundled and sold together by the responsible person.

### **Charge Backs**

A charge back occurs when the wholesaler sells a PBS item to its customer at a contract price and then “charges back” an additional amount to the responsible person. It may also occur when a pharmacist purchases a product from a wholesaler and then claims back a rebate from the responsible person.

### **Combination Drug List**

The combination drug list is the list of single brand combination drugs that meet the criteria under subsection 85AB (5) of the Act. They can be identified in the formulary allocation list on the *Pricing of PBS Items* webpage: [www.pbs.gov.au/info/industry/pricing/pbs-items](http://www.pbs.gov.au/info/industry/pricing/pbs-items)

### **Combination Item**

Combination item is defined in subsection 84(1) of the Act. In summary, combination item means a pharmaceutical item that has a drug that contains at least two other drugs or medicinal preparations, at least one of which is a PBS listed drug. It may be an item containing a drug(s) on the combination drug list or a drug on the F2 formulary.

### **Data Collection Period**

Data collection period is defined in regulation 37C of the Regulations.

In summary, for each cycle there is a data collection period for brands for which data is collected by responsible persons about brands of pharmaceutical items.

Responsible persons are required to submit data about their brands of pharmaceutical items for periods ending on 31 March and 30 September each year (data is required to be submitted by 12 May and 11 November respectively).

Data will be collected for a period of at least six months across brands of each drug and manner of administration - a responsible person may therefore be required to submit data twice for their first data collection period. More detail about collection of data and the relevant submission periods is set out under the headings **Collection** and **Submission**.

Subsequent data collection periods start immediately after the end of the previous data collection period.

In a disclosure cycle:

- a) there is only one data collection period for each brand of a pharmaceutical item (there may be two data submissions for the first data collection period);
- b) the data collection periods for different brands of pharmaceutical items can commence on different days (depending on when they list or become subject to price disclosure); and
- c) all data collection periods for related brands end on the same day.

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## Data Submission Period

The period ending approximately six weeks after each 31 March and 30 September:

- For the period ending 31 March, data is to be submitted by 12 May\*
- For the period ending 30 September, data is to be submitted by 11 November\*.

\*If 12 May or 11 November falls on a weekend or a public holiday, data submission is required on the next business day.

## Disclosure Cycle

There is one ongoing 12 month administrative cycle, consisting of:

- a six month data collection period\* (ending 31 March and 30 September each year);
- six months for data submission and processing, publication of prices, and any administrative dispute resolution; and
- corresponding regular reduction days on 1 October and 1 April, respectively\*\*.

\*For the first administrative cycle for a drug and manner of administration the data collection period may be longer than six months.

\*\* There is also provision in the Regulations for reduction days on 1 August and 1 December each year if required.

## Drug

A drug or medicinal preparation in relation to which a declaration under subsection 85 (2) of the Act is in force (PBS listed drug).

## Expanded and Accelerated Price Disclosure (EAPD)

EAPD commenced on 1 December 2010 and was the first extension of price disclosure arrangements. Under EAPD all brands of non-exempt pharmaceutical items containing drugs on the F2 Formulary of the PBS became subject to price disclosure requirements. The last reduction under EAPD occurred on 1 August 2014. For reduction days thereafter the Simplified Price Disclosure method will be used for calculations.

## F1 Formulary

F1 contains drugs that are determined to be on F1 in the relevant legal instrument made under the Act. Generally this will be drugs that:

- a) have only one brand of each pharmaceutical item listed on the PBS;
- b) are not considered to have bioequivalent or biosimilar brands of different pharmaceutical items; and
- c) are not in a therapeutic group with a drug on the F2 formulary (i.e., a therapeutic group made under section 84AG of the Act).

## F2 Formulary

F2 contains all drugs that do not meet the criteria for F1 and are not on the combination drug list. Generally this is multi-branded drugs or those that have been multi-branded.

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## Form

The form for a PBS listed drug as determined under subsection 85 (3) of the Act. This refers to the strength, type of unit (e.g. tablet or capsule), size of unit (e.g. quantity) or other distinguishing criteria.

## Incentive

An incentive is defined in sub regulation 5(1) of the Regulations. Broadly, it is any benefit which is offered to encourage a purchase to be made of the disclosing brand or a product range which includes the disclosing brand. These include both monetary and non-monetary benefits. The Regulations define 'incentive' as follows:

***incentive***, for a brand of a pharmaceutical item, includes anything given as an incentive to take supply of the brand (including a delisted brand before it was delisted) whether the incentive is given:

- (a) before the supply of the brand, but on condition of taking supply; or
- (b) at, or after, the time of the supply of the brand; or
- (c) over a period of time; or
- (d) directly for the brand; or
- (e) indirectly for the brand (for a group of brands of pharmaceutical items or other products, for example).

## Manner of Administration (MoA)

The route by which the drug enters the body or is applied as determined under subsection 85 (5) of the Act. For example:

- Application
- Application to the ear
- Application to the eye
- Application to the eye/ear
- Buccal
- Buccal/sublingual
- For external use
- Inhalation by mouth
- Inhalation
- Implantation
- Implantation/oral
- Injection
- Injection/oral
- Injection/intravesical
- Intrauterine
- Intravesical
- Nasal

- 
- Oral
  - Oral application
  - Rectal
  - Sublingual
  - Transdermal
  - Urethral
  - Vaginal

For the purposes of price disclosure, medicines are grouped on the basis of 'drug/MoA' – i.e., related brands. Therefore the same medicine with a different manner of administration (MoA) may not be affected by a price reduction, or may incur a different level of reduction.

### **New Brand**

A brand newly listing on the PBS.

### **Over the Counter PBS Item**

A brand of pharmaceutical item that is the same as a medicine that may also be purchased over the counter without a prescription.

### **PBS**

The Pharmaceutical Benefits Scheme administered under Part VII of the Act.

### **Pharmaceutical item**

A pharmaceutical item as defined in section 84AB of the Act. It is a particular drug, in a specified form with a particular manner of administration.

For example a particular drug with different forms and MoA will have different pharmaceutical items. The 'form' of a pharmaceutical item may include reference to its strength, type of unit, size of unit or other defining characteristic.

A pharmaceutical item may be supplied under more than one unique PBS item code (e.g. for different indications or under different PBS programs).

For further information about the difference between 'pharmaceutical item' and 'PBS item codes' see the following document explaining changes to PBS pricing that is located on the *2012 Changes to PBS Pricing Arrangements* webpage:

[www.pbs.gov.au/industry/pricing/pricing-arrangements/proposed-ex-manufacturer-pricing-for-the-pbs.pdf](http://www.pbs.gov.au/industry/pricing/pricing-arrangements/proposed-ex-manufacturer-pricing-for-the-pbs.pdf)

### **PBAC**

The Pharmaceutical Benefits Advisory Committee.

### **Price Disclosure Submission Utility (PDSU)**

The electronic facility operated by the Price Disclosure Data Administrator for submission of price disclosure data.

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## Price Disclosure Data Administrator (PDDA)

The PDDA is an independent service provider contracted by the Department to provide data services for price disclosure. Contact details for the PDDA can be found on the last page of this document.

## Pricing Quantity

The lowest pack quantity specified in the PBS listing instrument for any brand of each pharmaceutical item. The base PBS price (AEMP) is approved for the **pricing quantity** for each brand of a pharmaceutical item. For further information about 'pricing quantity' and 'pack size' and prices for pack sizes different to the pricing quantity see the following document explaining changes to PBS pricing that is located on the *2012 Changes to PBS Pricing Arrangements* webpage: [www.pbs.gov.au/industry/pricing/pricing-arrangements/proposed-ex-manufacturer-pricing-for-the-pbs.pdf](http://www.pbs.gov.au/industry/pricing/pricing-arrangements/proposed-ex-manufacturer-pricing-for-the-pbs.pdf)

In disclosing information to the Department, responsible persons will report based on the pack size(s) of their brands as supplied to wholesalers, pharmacists and others. Where there is more than one pack size, the responsible person will report separately for each pack size. In calculating the weighted average disclosed price, the Department will convert all volumes to the volumes that would have applied if the pack sizes were equivalent to the pricing quantity.

## Processing Period

The period following the data collection period and leading up to the reduction day. This includes:

- a) data submission;
- b) calculation;
- c) determination;
- d) dispute resolution; and
- e) data transfer/publication.

This is a period of six months.

## Reduction day

The date on which a price reduction as a result of price disclosure may come into effect - generally:

- a) 1 April;
- b) 1 October

It may also be another day prescribed in the Regulation. Regulation 37A provides that 1 August and 1 December are prescribed days. These days are prescribed in case it becomes necessary to use either of these instead of the usual reduction day (e.g. delay associated with legal proceedings).

## Related Brands

Brands with the same drug and manner of administration.

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## Responsible person

Responsible person for a brand of a pharmaceutical item means the person determined by the Minister under section 84AF of the Act to be the responsible person for the brand of the pharmaceutical item. This is a legal term and in many cases it will be referring to an entity, such as a company, rather than an individual.

Each responsible person appoints at least one authorised representative. An authorised representative is an individual who has company authority to enter into price agreements, submit price disclosure data and otherwise deal with the Minister, the Department of Health and its delegates in relation to the responsible person's brands of pharmaceutical items.

## Sales revenue

Sales revenue is the revenue which is generated from the sale of the disclosing brand. The methods used by the responsible person to define sales, recognise and measure revenue for price disclosure purposes should be consistent with the responsible person's financial accounting policies and standards.

## Simplified Price Disclosure (SPD)

SPD is the second extension of price disclosure arrangements. SPD will operate much the same way as EAPD, but with:

- A reduced data collection period – now 6 monthly periods\*;
- A single ongoing administrative cycle – now a 12 monthly cycle\*\*;
- Two regular reduction days (1 April and 1 October)\*\*\*; and
- Comparison of the disclosed price against an average PBS approved ex-manufacturer subsidised price.

\* The first data collection period may be longer than 6 months.

\*\* The first administrative cycle may be longer than 12 months.

\*\*\* There is also provision in the Regulations for reduction days on 1 August and 1 December each year if required.

Amendments to the Act for SPD commenced on 13 March 2014, with the associated Regulation amendments commencing on 3 June 2014. The first price disclosure reductions under the amended SPD method will occur on 1 October 2014.

## Start day

The start day for a brand of pharmaceutical item means the day on which the brand was first required to comply with the price disclosure requirements - the day the brand moved to F2, or was first listed on the PBS in F2.

## The Department

The Commonwealth Department of Health.

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## **Unadjusted Price Reduction – 10% test**

This is the difference between:

- a) the applicable approved ex-manufacturer price of the brand of the pharmaceutical item (price on the relevant day – i.e., day after the end of the data collection period); and
- b) the weighted average disclosed price determined for the brand of the pharmaceutical item,

expressed as a percentage of the applicable approved ex-manufacturer price.

A price disclosure reduction occurs if the unadjusted price reduction is at least 10% (see subsection 99ADH (1) (c) of the Act).

## **Weighted Average Disclosed Price (WADP)**

Means the weighted average disclosed price as determined under the Act and Regulations. See subsection 99ADB (4) of the Act and Subdivision 2 of Part 6A of the Regulations. WADP determinations are publicly available on the Comlaw website: [www.comlaw.gov.au](http://www.comlaw.gov.au)

Where a reduction is required (i.e., 10% test is met), this price is determined as the adjusted approved ex-manufacturer price, which generally becomes the new approved ex-manufacturer level price on reduction day\*.

\*Adjustments may be required to this new price if there are other pricing or listing changes between the end of the data collection period and the reduction day.

## **Weighted Average Percentage Difference (WAPD)**

The weighted average percentage difference is the percentage difference between the disclosed price and the average AEMP for either:

- a) all brands of a pharmaceutical item, or
- b) all brands of all pharmaceutical items containing a drug/MoA (i.e., related brands).

The drug/MoA level WAPD is published for each price disclosure cycle at [www.pbs.gov.au/info/industry/pricing/price-disclosure-spd](http://www.pbs.gov.au/info/industry/pricing/price-disclosure-spd). See regulation 37R of the Regulations. This is the percentage by which the Average AEMP for brands of each pharmaceutical item is reduced to arrive at the WADP for each brand.

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# 6

## Related Information

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## Where to go for further information

- The *National Health (Pharmaceutical Benefits) Regulations 1960* and the Weighted Average Disclosed Price Determinations: [www.comlaw.gov.au](http://www.comlaw.gov.au)
- The National Health Act 1953: [www.comlaw.gov.au/Details/C2014C00131](http://www.comlaw.gov.au/Details/C2014C00131) or [www.comlaw.gov.au](http://www.comlaw.gov.au)
- Pharmaceutical Benefits Scheme (PBS) website price disclosure page: <http://www.pbs.gov.au/info/industry/pricing/price-disclosure-spd>

## Contact Details

### Contacting the PDDA

Email: [admin@pricedisclosure.com.au](mailto:admin@pricedisclosure.com.au)

Telephone: 1300 336 062

### Contacting the Department

Email: [pricedisclosure@health.gov.au](mailto:pricedisclosure@health.gov.au)

Telephone: (02) 6289 2303