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Please refer to the 'Price Disclosure Guidelines' page on the PBS website:
www.pbs.gov.au/info/industry/pricing/price-disclosure-spd/price-disclosure-guidelines



Australian Government

Department of Health

Pharmaceutical Benefits Scheme Price Disclosure Arrangements

Procedural and Operational Guidelines

Please note: Price Disclosure Procedural and Operation Guidelines are currently being updated. A [PBS News Item will be circulated to subscribers](#) when updated Guidelines are published.

Guidelines have not been updated to reflect amendments to the price disclosure requirements under Division 3B of the *National Health Act 1953* by the [National Health Amendment \(Pharmaceutical Benefits—Budget and Other Measures\) Act 2018](#).

Information on changes can be found in the following documents under 'Explanatory Materials':

- [Fact Sheet – 30% Unadjusted Price Reduction](#)
- [Price Disclosure – 42 Month Clock Examples](#)

Also refer to the Explanatory Memorandum for the [National Health Amendment \(Pharmaceutical Benefits—Budget and Other Measures\) Bill 2017](#).

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Introduction

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, modified by Simplified Price Disclosure (SPD) amendments in 2014 and further modified by changes from the PBS Access and Sustainability package in 2015. Amendments to support the 2015 changes were made to the *National Health Act 1953* (the Act) and *National Health (Pharmaceutical Benefits) Regulations 1960* (the Regulations) and commenced on 26 June 2015 and 18 September 2015 respectively. For more information about the 2015 changes to the price disclosure arrangements, see: www.pbs.gov.au/info/industry/pricing/price-disclosure-spd/pbs-pricing-fact-sheet-2015-price-disclosure-changes
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

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:
 - a) price disclosure;
 - b) use of the price disclosure information; and
 - c) 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

Definitions

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

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Price Disclosure Arrangements

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. Following 2015 changes, in some cases the price the Government pays will move closer to the prices at which generic brands of the medicine are supplied, not necessarily the prices of all brands. More details about these changes are provided later.
12. Initially the price disclosure obligation only applied for each drug after a new brand of an existing pharmaceutical item with the same drug was listed following commencement of the 2007 PBS reforms. 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
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
14. Further amendments to the price disclosure arrangements were made under the Simplified Price Disclosure (SPD) initiative in 2014. The first price disclosure reductions based on the SPD modifications occurred on 1 October 2014, based on information submitted for data collection periods ending 31 March 2014.
15. Since the SPD amendments, price disclosure operates with:
 - a) six monthly data collection periods*;
 - b) a single ongoing rolling cycle of 12 months**;
 - c) two regular reduction days each year (1 April and 1 October)***; and
 - d) 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.

* 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

17. In 2015, the PBS Access and Sustainability package included amendments to the price disclosure arrangements that:

- a) provide for price disclosure reductions to component ingredient drugs to be applied to F2 combination items where this results in a lower price than direct application of price disclosure to the F2 combination item. Flow-on reductions from component ingredient drugs are already applied to combination items that have a drug on the single brand Combination Drug List (CDL);
- b) accelerate price disclosure arrangements through removal of originator brands as part of the calculation of the weighted average disclosed price (WADP) for medicines listed on the F2 formulary for 3 years or more where this results in a lower adjusted price; and
- c) provide for certain pharmaceutical items not to take a price disclosure reduction despite other pharmaceutical items with the same drug and manner of administration taking the reduction.

18. These changes were applied through amendments to the Act and Regulations. The first price disclosure reductions incorporating item a) and c) occurred on 1 April 2016 and for item b) will occur on 1 October 2016.

What medicines are subject to price disclosure?

19. 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

20. The Responsible Person is the entity responsible for meeting the requirements of price disclosure. This responsibility continues in relation to a brand delisted from the PBS 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

21. 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 is 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.

Exemptions to the Price Disclosure arrangements

22. 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

Treatment of single branded combination drug list brands

23. Brands containing drugs on the Combination Drug List (CDL) will not be subject to price disclosure data collection requirements. However, brands containing a drug on the CDL are subject to price reductions based on the reductions to a component drug (under section 99ACC of the Act).
24. A drug is on the CDL if:
 - a) its pharmaceutical items have component drugs, at least one of which is PBS listed; and
 - b) it is single branded (i.e., does not have bioequivalent / biosimilar brands and is not in a therapeutic group with a drug that has bioequivalent / biosimilar brands).
25. There is a discretion for the Minister or pricing delegate not to apply, or to partially apply, the component drug reduction to a combination list drug if relevant Pharmaceutical Benefits Advisory Committee (PBAC) advice is in place under subsection 101(4AC) of the Act.
26. When the price of a component drug is reduced due to price disclosure, any price agreement for a brand of a CDL drug will cease to apply on the reduction day. New agreements are required before the reduction day for brands of drugs on the CDL that have a component drug with a reduction. A new agreement is required even if the Minister or delegate decides not to apply the component price reduction to the CDL brand.
27. A drug on the CDL 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).

28. Brands containing the combination drug will then become subject to price disclosure – i.e., data collection and potential direct price disclosure reductions will then apply to the combination item.

Flow-on Reductions for F2 Combination Items

29. For the 2016 April cycle onward, after announcement of outcomes for each price disclosure cycle, potential flow-on reductions will be calculated from component drugs to any related F2 combination items. The flow-on reduction will be applied where it would result in a lower adjusted price for the combination item than applying the direct price disclosure outcome for the F2 combination item. The calculation method for potential direct price disclosure reductions is described under the **Calculation** heading below.
30. The process for applying these F2 flow-on combination item price disclosure reductions is similar to that already in operation for flowing on price disclosure reductions to single brand combination items on the CDL.
31. That is, the Act provides for prices of combination items that have component drugs taking a reduction to cease operation at the end of the day before reduction day. So, for a 1 October reduction day, prices cease at the last moment of 30 September. That is, there is no automatic price on which a subsidy could be calculated for payment for a combination item that has a component taking a price disclosure reduction. However, new prices are approved (agreed with companies or determined) in advance of 1 October reduction day, to come into operation on 1 October, reflecting either the flow-on reductions or the direct F2 price disclosure reduction for the combination item. The same applies for each other reduction day, for example 1 April each year.
32. Combination items that are exempt items do not take the reduction.
33. Combination items with s101(4AC) PBAC advice (significant improvement advice for combination items) will be considered under the discretion which allows the Minister or delegate to flow-on only part or none of the component drug reduction.
34. The flow-on of F2 component drug price disclosure reductions to F2 combination items commenced for the 1 April 2016 reduction day and continues for each price disclosure cycle.
35. There will be a back-capture reduction day for F2 combination item medicines on 1 October 2016 to ensure that all F2 combination items have been considered for application of component pricing. Any F2 combination item which does not have a component drug price reduction on 1 April 2016, or scheduled for 1 October 2016, will have a back-capture calculation done for the 1 October 2016 reduction day. The back-capture calculation will work out whether flowing on the F2 component drug price from the most recent price disclosure reduction (if any reduction has occurred) would result in a lower price than the current price for the combination item. If so, the flow-on reduction will be considered for application on 1 October 2016.

Disclosure Cycle - Summary

36. 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).
37. 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

Data Collection Period

38. 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.
39. 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 than 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.

Processing Period

40. 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

41. 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).

42. 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: <http://www.pbs.gov.au/industry/pricing/price-disclosure/spd/spd-presentation-slides-6-12-2013.pdf>

Length of First Cycles

43. Drug/MoAs may become subject to price disclosure on any month, however, there will be a data collection period of at least six months for a drug/MoA. As a result, a first price disclosure cycle can be up to 17 months long (i.e., 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

44. 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. Its first potential reduction day is 1 October of the year during which the data collection period finishes.
45. 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

46. 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. Its first potential reduction day is 1 April of the next year.
47. Information about collection and submissions of data for the first cycle is provided under the **Collection** and **Submission** headings below.

Ongoing Cycle

48. 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.

49. 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: <http://www.pbs.gov.au/industry/pricing/price-disclosure-spd/spd-presentation-slides-6-12-2013.pdf>
50. The example under the heading **Cycles Table – Relevant Dates** below also demonstrates the rolling cycle with six monthly reduction days.

Cycles Table - Relevant Dates

51. 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 (February, April, June, August, October and December each year).
52. 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 2015 Cronus has been on the F1 formulary on the PBS.

On 1 August 2015 Athenia Pty Ltd lists the Poseidon brand of the drug Cronus (25 mg tablet only). The drug Cronus moves to F2 on 1 August 2015 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 2016 October Cycle, named for its expected reduction day. The first data collection period starts on 1 August 2015 and ends 31 March 2016.

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 2015 to 30 September 2015 - by 11 November 2015, and
- for the period 1 October 2015 to 31 March 2016 - by 12 May 2016.

The processing period for the first cycle (the 2016 October Cycle) commences 1 April 2016 and concludes with its reduction day on 1 October 2016.

The second cycle for Cronus Oral and Cronus Injection brands is the 2017 April Cycle. It commences 1 April 2016 and has a six month data collection period running from 1 April 2016 to 30 September 2016 (coinciding with the six month processing period for the first cycle). The processing period for the second cycle commences 1 October 2016 and concludes with its reduction day on 1 April 2017.

The third cycle for Cronus Oral and Cronus Injection brands is the 2017 October Cycle. It commences 1 October 2016 and has a six month data collection period running from 1 October 2016 to 31 March 2017 (coinciding with the six month processing period for the second cycle). The processing period for the third cycle commences 1 April 2017 and concludes with its reduction day on 1 October 2017.

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

First Cycles Table				
Start of Price Disclosure for Drug/MoA	First Cycle	First Data Collection Period	Data Due Date(s) for First Data Collection Period*	First Potential Reduction Day
Nov-2015	2017 April Cycle	1 November 2015 to 30 September 2016	12 May 2016 and 11 November 2016	1 April 2017
Dec-2015	2017 April Cycle	1 December 2015 to 30 September 2016	12 May 2016 and 11 November 2016	1 April 2017
Jan-2016	2017 April Cycle	1 January 2016 to 30 September 2016	12 May 2016 and 11 November 2016	1 April 2017
Feb-2016	2017 April Cycle	1 February 2016 to 30 September 2016	12 May 2016 and 11 November 2016	1 April 2017
Mar-2016	2017 April Cycle	1 March 2016 to 30 September 2016	12 May 2016 and 11 November 2016	1 April 2017
Apr-2016	2017 April Cycle	1 April 2016 to 30 September 2016	11 November 2016	1 April 2017
May-2016	2017 October Cycle	1 May 2016 to 31 March 2017	11 November 2016 and 12 May 2017	1 October 2017
Jun-2016	2017 October Cycle	1 June 2016 to 31 March 2017	11 November 2016 and 12 May 2017	1 October 2017
Jul-2016	2017 October Cycle	1 July 2016 to 31 March 2017	11 November 2016 and 12 May 2017	1 October 2017
Aug-2016	2017 October Cycle	1 August 2016 to 31 March 2017	11 November 2016 and 12 May 2017	1 October 2017
Sep-2016	2017 October Cycle	1 September 2016 to 31 March 2017	11 November 2016 and 12 May 2017	1 October 2017
Oct-2016	2017 October Cycle	1 October 2016 to 31 March 2017	12 May 2017	1 October 2017
Nov-2016	2018 April Cycle	1 November 2016 to 30 September 2017	12 May 2017 and 11 November 2017	1 April 2018
Dec-2016	2018 April Cycle	1 December 2016 to 30 September 2017	12 May 2017 and 11 November 2017	1 April 2018
Jan-2017	2018 April Cycle	1 January 2017 to 30 September 2017	12 May 2017 and 11 November 2017	1 April 2018
Feb-2017	2018 April Cycle	1 February 2017 to 30 September 2017	12 May 2017 and 11 November 2017	1 April 2018
Mar-2017	2018 April Cycle	1 March 2017 to 30 September 2017	12 May 2017 and 11 November 2017	1 April 2018
Apr-2017	2018 April Cycle	1 April 2017 to 30 September 2017	11 November 2017	1 April 2018

Start of Price Disclosure for Drug/MoA	First Cycle	First Data Collection Period	Data Due Date(s) for First Data Collection Period*	First Potential Reduction Day
May-2017	2018 October Cycle	1 May 2017 to 31 March 2018	11 November 2017 and 12 May 2018	1 October 2018
Jun-2017	2018 October Cycle	1 June 2017 to 31 March 2018	11 November 2017 and 12 May 2018	1 October 2018
Jul-2017	2018 October Cycle	1 July 2017 to 31 March 2018	11 November 2017 and 12 May 2018	1 October 2018
Aug-2017	2018 October Cycle	1 August 2017 to 31 March 2018	11 November 2017 and 12 May 2018	1 October 2018
Sep-2017	2018 October Cycle	1 September 2017 to 31 March 2018	11 November 2017 and 12 May 2018	1 October 2018
Oct-2017	2018 October Cycle	1 October 2017 to 31 March 2018	12 May 2018	1 October 2018
Nov-2017	2019 April Cycle	1 November 2017 to 30 September 2018	12 May 2018 and 11 November 2018	1 April 2019
Dec-2017	2019 April Cycle	1 December 2017 to 30 September 2018	12 May 2018 and 11 November 2018	1 April 2019
Jan-2018	2019 April Cycle	1 January 2018 to 30 September 2018	12 May 2018 and 11 November 2018	1 April 2019
Feb-2018	2019 April Cycle	1 February 2018 to 30 September 2018	12 May 2018 and 11 November 2018	1 April 2019
Mar-2018	2019 April Cycle	1 March 2018 to 30 September 2018	12 May 2018 and 11 November 2018	1 April 2019
Apr-2018	2019 April Cycle	1 April 2018 to 30 September 2018	11 November 2018	1 April 2019
May-2018	2019 October Cycle	1 May 2018 to 31 March 2019	11 November 2018 and 12 May 2019	1 October 2019
Jun-2018	2019 October Cycle	1 June 2018 to 31 March 2019	11 November 2018 and 12 May 2019	1 October 2019
Jul-2018	2019 October Cycle	1 July 2018 to 31 March 2019	11 November 2018 and 12 May 2019	1 October 2019
Aug-2018	2019 October Cycle	1 August 2018 to 31 March 2019	11 November 2018 and 12 May 2019	1 October 2019
Sep-2018	2019 October Cycle	1 September 2018 to 31 March 2019	11 November 2018 and 12 May 2019	1 October 2019
Oct-2018	2019 October Cycle	1 October 2018 to 31 March 2019	12 May 2019	1 October 2019

* 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

Collection

Information to be collected and submitted

53. 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.
54. This information is required:
- a) 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.
 - b) to be submitted separately for each brand and each pharmaceutical item.
55. 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

56. 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):
- a) the sales revenue;
 - b) 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);
 - c) the kind of incentives (if any) given for the brand for the relevant period; and
 - d) the value of the incentives given for the brand for the relevant period.
57. 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 2015) 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

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

- a) for new brands containing an F2 drug: the day that the brand listed on the PBS;
- b) 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).

59. 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.

60. 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.

61. 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

62. 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).
63. 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.
64. 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.
65. 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.

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 2016, and the data collection period for a related brand ends on 30 September 2016:

- (a) the first data collection period starts on 1 July 2016; and
- (b) the first data collection period ends on 30 September 2016; and
- (c) subsequent data collection periods will be the six month periods that start on 1 October 2016, 1 April 2017, 1 October 2017 and so on.

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

New brand start day of 1 August 2016:

- (a) the first data collection period starts on 1 August 2016; and
- (b) the first data collection period ends on 31 March 2017; and
[there will be two data submissions for the first data collection period (i.e., after 30 Sept 2016 and after 31 March 2017)]
- (c) subsequent data collection periods will be the six month periods that start on 1 April 2017, 1 October 2017, 1 April 2018 and so on.

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

New brand start day of 1 December 2016:

- (a) the first data collection period starts on 1 December 2016; and
- (b) the first data collection period ends on 30 September 2017; and
[there will be two data submissions for the first data collection period (i.e., after 31 March 2017 and after 30 September 2017)]
- (c) subsequent data collection periods will be the six month periods that start on 1 October 2017, 1 April 2018, 1 October 2018 and so on.

Incentives information that responsible persons need to collect

66. 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.
67. 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.
68. 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.
69. 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.
70. 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).

71. 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.
72. 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.
73. 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.
74. 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

75. 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*. To obtain the status of a particular hospital, email [Hospital Declarations](#).
76. 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.
77. 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.

Data Preparation

78. 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 (i.e., all brands with an F2 drug).
79. The responsible person must ensure correct disclosure of:
 - a) brand specific information on sales revenue; and
 - b) 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
 - c) apportioning of the cost of any brand and non-brand specific incentives relating to a brand subject to disclosure (more information provided below).

80. 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.
81. 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

82. Responsible persons are responsible to ensure accurate collection of any specific incentives that apply to the brand.
83. 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.

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

84. 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.
85. 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.
86. 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.
87. The following example (on the next page) illustrates the importance of:
 - a) carefully considering the method used when preparing data for price disclosure purposes.
 - b) 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.

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 October 2015 to 31 March 2016, a responsible person sells 100 units of a product to a wholesaler for \$10 (after discounts).
- For the reporting period ending 31 March 2016, the responsible person reports volume of 100 and revenue of \$1,000.
- A PBS price reduction takes effect on 1 April 2016, resulting in a new lower PBS ex-manufacturer price of \$4.
- On 1 April 2016, 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 30 September 2016, which is not the period when the relevant sales were made.

The timing mismatch results in:

- **Revenue in the period 1 October 2015 - 31 March 2016** 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 April 2016 – 30 September 2016** being reduced because the stock on hand rebate of \$6 (negative revenue) is recorded in this period despite applying to sales prior to 1 October 2015.

An alternative approach which may better reflect the circumstances, may involve:

- The responsible person deducting the stock on hand rebates from sales reported or the period 1 October 2015 to 31 March 2016. Under this approach, there is a need to rapidly quantify any stock on hand rebates associated with a particular reduction - in order to disclose these within the six week submission period immediately following the reduction day.

Submission

Timeframe & responsibility for submission of the information

88. 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 2015;
- First data collection period is 1 August 2015 to 31 March 2016 (eight months);
- Data is to be submitted after both:
 - 30 September 2015 (two months of data submitted by 11 November 2015); and
 - 31 March 2016 (six months of data submitted by 12 May 2016).

Submitting data

89. 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.

90. 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

91. 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.

92. 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

93. 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.
94. If:
- a) a responsible person passes commercial responsibility for a brand to another company before the legal change to responsible person; and
 - b) 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.
95. 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.
96. 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.
97. 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

98. 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.*”

Calculation

The entity responsible for calculations

99. 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.
100. Calculations for reduction days from 1 April 2016 onward are affected by amendments to the Act and Regulations flowing from the 2015 PBS Access and Sustainability package. Details of changes to the calculation method are set out below. Links to the relevant amendments are on the price disclosure (SPD) web page: www.pbs.gov.au/info/industry/pricing/price-disclosure-spd
101. The Department finalises calculations to assist the Minister (or delegate) in making the WADP determinations that are the basis for price disclosure reductions. The Department carries out subsequent calculations and publishing processes required for reductions applicable on a reduction day.

2016 April Cycle Onward - Low Volume / Low Discount No Reduction Items

102. Prior to 1 April 2016, all brands of pharmaceutical items with the same drug and manner of administration took the reduction based on discounting across the drug and manner of administration.
103. The relationship between products with the same drug/MoA will generally be maintained by continuing the price disclosure grouping by drug/MoA.
104. From the April 2016 reduction day onward the Act provides for certain pharmaceutical items with low volume and low discounting to be allowed no reduction, even where other items with the same drug/MoA take a reduction. Originator brand data is not removed for assessing whether pharmaceutical items meet this 'no reduction' criteria. All criteria must be met.
105. The criteria for brands of a pharmaceutical item not to take a reduction, despite others with the same drug/MoA taking a reduction, are:
 - a) there is some volume of sales for the pharmaceutical item. That is, not '0' total volume across all brands of the pharmaceutical item;
 - b) the 'total adjusted volume' for the particular pharmaceutical item is not more than 10% of the aggregated total adjusted volumes for all pharmaceutical items for the drug/MoA. The total adjusted volume for a pharmaceutical item includes the volume for all brands of the pharmaceutical item (including originator). Volume of a pharmaceutical item is adjusted to the pricing quantity. For example, if there are brands of the same pharmaceutical item with pack size 25 and pack size 50, the volume for the pharmaceutical item is adjusted to the pack quantity of 25;
 - c) the percentage discount calculated across all brands of the pharmaceutical item is no more than 3%. That is, the pharmaceutical item level discount is considered, not the brand level or drug/MoA level percentage discount;

- d) there are no brands of the pharmaceutical item that are bioequivalent or biosimilar to brands of another pharmaceutical item that does not meet a), b) and c) above.
 - e) There is no advice from the PBAC that the pharmaceutical item 'does not provide a significant improvement in efficacy or a reduction in toxicity over alternative therapies'. 'Alternative therapies' is not confined to other products with the same drug, or to therapies on the PBS. The PBAC advice will be sought, where considered necessary, under s101(3) of the Act.
106. The PBAC advice may not be received until after the first time a pharmaceutical item avoids a reduction due to meeting the other criteria. If 'no significant improvement' advice is provided by the PBAC, brands of the pharmaceutical item may take a reduction thereafter even if they meet criteria a) to d) above. This simply applies the same outcome as occurred before the April 2016 reduction day.
107. For brands of a pharmaceutical item that meet the 'no reduction' criteria, their weighted average disclosed price is taken to be their applicable PBS price (usually the current price since the last reduction day), rather than the reduced price that would normally be determined along with other brands of a drug/MoA taking a reduction. This means the 'no reduction' brands do not meet the 10% test, so no reduction is applied under the Act.

2016 October Cycle Onward - Removal of Originator Brand Data

Not removed before 1 October 2016 reduction day

108. Removal of originator brand data during calculation of weighted average disclosed prices will first apply to the price disclosure cycle that commenced on 1 October 2015, with a 1 October 2016 reduction day. It will then apply in each subsequent cycle.

Not removed if calculation does not result in a lower price

109. The 'originator brand removed' calculation will be considered for determination as the 'weighted average disclosed price' (potential reduced price) if it results in a lower new price than including the originator brand data. This means the originator brand data is collected and used for all calculations, and the lower outcome is applied through the legal determination of the 'weighted average disclosed price'.

Not removed if is an 'originator only pharmaceutical item'

110. Originator brand(s) data is not removed where the originator is the only brand(s) of a pharmaceutical item. This is the case even if the drug/Moa meets the F2/multi-branded criteria mentioned below for removal of originator brand data. Originator brand data will not be removed unless there is a non-originator brand also listed for each of the months the originator brand is listed for the cycle. This approach is demonstrated in the [Treatment as Single Originator Brand Pharmaceutical Item Examples](#) document.

Not removed unless F2/multi-branded at least three years at time of calculation

111. In general, originator removal calculation will apply to price disclosure data submitted for the data collection period commencing when a drug has been on F2 at least 2.5 years, with:
- the first calculations for originator removal therefore being at least three years after the drug has been on F2; and
 - the first reduction day for originator removed calculations being at least 3.5 years after movement to F2.
112. However, there are some cases where the period of 2.5 years (prior to first affected data collection period) does not start when the drug moves to F2. In addition to being on F2 for at least 2.5 years, there must have been, on a day at least 2.5 years before the affected data collection period:
- i. A pharmaceutical item that contains the drug/MoA has two or more brands (brands with the same drug/MoA are called related brand in the Act and Regulations); or
 - ii. Two or more bioequivalent or biosimilar brands that contain the same drug/MoA.
- The criteria above are referred to as the 'F2/multi-branded criteria'.
113. The F2/multi-branded criteria means that any single branded drug moving to F2 due to being in a therapeutic group with a multi-branded drug will not start the clock for the period of time before originator brand removal on its entry to F2. The same applies for single branded manners of administration that enter F2 as a result of another manner of administration that has the same drug becoming multi-branded. The clock starts when the drug/MoA first meets all the F2/multi-branded criteria.
114. The running of the 30 month clock to identify the first cycle for originator removal is not stopped if a drug/MoA becomes single branded again at a point after the clock had started.
115. The F2/multi-branded criteria are demonstrated in the [Price Disclosure Originator Removal 30 Month Clock](#) document.

Determination of Originator Brands

116. Section 99ADB of the Act provides that the Minister (or delegate) may determine by legislative instrument that a brand of a pharmaceutical item that has a drug on F2 is an 'originator brand'. Determination of an originator brand does not necessarily mean that the data for that brand will always be removed. Details of the criteria for removal are discussed above.
117. When determining originator brands for drugs that move to F2 after 31 March 2016, the Minister must take into account whether the brand was PBS listed when the drug was on the F1 formulary or the CDL. This provides assurance that the general approach will be to consider the brand(s) that move from F1 to F2, as an 'originator brand'. However, an originator brand is not always required to be determined on movement of a drug to F2 (for example if it is considered that there is no PBS listed originator), and an originator brand may be determined after the drug moves to F2 (for example if a first new brand of a new manner of administration lists; or an originator brand variant lists as mentioned below).

118. Amendments to the originator brand determination will be considered upon movement of a drug from F1 to F2.
119. The policy for removal of originator brands from price disclosure calculations also includes all variants of the originator brand name. Therefore, any variants to the originator brand name will also be considered for addition to the 'originator brand' determination when they are listed while a drug is on F2.
120. For example, the brands:
- *Zovirax 200 mg*
 - *Zovirax 800 mg*
- are both originator brands that contain the drug aciclovir.
- And the brands:
- *Amoxil*
 - *Amoxil Forte*
- are both originator brands that contain the drug amoxicillin.
121. To improve the readability of the legal instrument determining originator brands, in most instances the brands will be determined by reference only to the name of the drug they contain. This means that a listing of the determined brand in any form and for any manner of administration is to be treated as an originator brand. Where the determination of the brand as an originator may need to be confined to a particular form or manner of administration, then the determination can also be made by reference to a particular form or manner of administration.

The Weighted Average Disclosed Price Calculations

122. Price disclosure reductions are based on a WADP determined for a 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.
123. The method for calculating WADPs is set out in regulations 37G to 37SC. 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). This calculation is performed with and without the originator brand where the drug/MoA meets the F2/multi-branded criteria (30 month clock) and where the pharmaceutical item is not 'originator only'.

- The resultant 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 result that produces the higher weighted average percentage difference (WAPD) for the brand and all related brands is chosen.
- 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. A 10% test is then applied to work out whether a reduction based on the WADP 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))

initial month – for a brand of a pharmaceutical item that was not a listed brand immediately before the brand’s start day, means the first month of the brand’s first data collection period

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

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

Originator brands – Reg 37SC

For cases where the drug/MoA met the F2/multi-branded criteria (30 month clock) re-do the calculations for a drug/MoA removing originator brand data, except for 'originator only' pharmaceutical items (paragraph 37SC(1)(a)). Use the calculation that results in the higher weighted average percentage difference (WAPD) for the brand and all related brands of a drug/MoA to calculate the WADP (37SC (3) – see step 11 below).

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) (using originator removed WAPD where required and where it gives a higher WAPD).

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

When weighted average disclosed price is the same as the applicable ex-manufacturer price - Reg 37SA

For brands of a pharmaceutical item that meet the 'no reduction' criteria, their WADP is taken to be their applicable PBS price, rather than the reduced price that would normally be determined along with other brands of a drug/MoA taking a reduction.

This means the 'no reduction' brands do not meet the 10% test, so no reduction is applied under the Act. More information about the 'no reduction criteria can be found in the *No Reduction Items – Low Volume/Low Discounts* section under the heading **initiation and Overview** above.

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 Minister (or delegate) determines a WADP where 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. If the percentage difference between a determined WADP and the AEMP on the relevant day is less than 10%, there is no price disclosure reduction.

A sample calculation can be found at:

www.pbs.gov.au/industry/pricing/price-disclosure-spd/removal-originator-brand-sample-pd-calculation.pdf

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

124. 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*.
125. Non-compliance by a responsible person will not prohibit the PDDA from proceeding with the calculation.
126. 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

127. 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

128. The Minister may determine WADPs for listed brands in the cycle but this is generally done by a delegate of the Minister in the Department – 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.
129. 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).
130. 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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131. The relevant day is the day after the end of the data collection period (e.g. for the data collection period ending 31 March 2016 [for 1 October 2016 reduction day] the relevant day was 1 April 2016 which was the previous cycle reduction day for at least some brands).
 132. 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.
 133. 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.
 134. 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 provides for the brands of a pharmaceutical item for a drug/MoA to be treated equally for the cycle.
 135. The legal determination of WADPs can also be amended to deal with disputes or errors or other matters relevant to the reduction. Affected companies would be notified individually of any such amendments.

Notification of Outcomes

136. 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.
137. A Price Disclosure Outcomes Summary is published on the [Price Disclosure \(SPD\)](#) web page of the www.pbs.gov.au website. The Summary mentions the pharmaceutical items of drug/MoAs taking price disclosure reductions on the relevant reduction day, including the proposed reduced ex-manufacturer price. All brands of those pharmaceutical items are taking reductions (i.e., they meet the 10% test for reduction). It does not mention the flow-on reductions to combination items from component drugs that are taking a reduction. The negotiations for flow-on reduction prices occur directly with affected companies.
138. 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.
139. An email is sent to all responsible persons advising when the outcome is available.

140. It is intended that the details of combination items for which flow-on reductions are expected for a reduction day will be published at least two months before the relevant reduction day on the [Price Disclosure \(SPD\)](#) web page of the www.pbs.gov.au website. The relevant component drugs from which the reductions are being flowed on will be identified.

141. The Department also endeavours to provide as much notice as possible of the proposed new price to pharmacy, dispensed prices and any premiums (eg, brand premiums). This includes publishing on the [Price Disclosure \(SPD\)](#) web page of the www.pbs.gov.au website:

- indicative prices for direct price disclosure reductions about two to two and a half months before reduction day, and
- confirmation of reduced prices about three to four weeks before reduction day.

Advance notice of flow-on reduced prices for combination items is not published on the public website because of the timing and nature of the process for negotiation of those prices. The reduced prices from flow-on to combination items are known to each individual affected responsible person (pharmaceutical company) well in advance of reduction day because negotiations commence shortly after announcement of the direct price disclosure reduction outcomes.

Administrative Disputes Process

142. 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

143. It is intended that price disclosure reductions occur on the first potential reduction day after the determination has been made.

144. There are generally two potential reduction days each year:

- 1 April; and
- 1 October.

145. 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

146. Any **new brands of existing pharmaceutical items that have a WADP determined** 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 of the pharmaceutical item. No specific notice of a reduction is provided to responsible persons for these new brands.
147. 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.
148. Flow-on reductions are also applied where appropriate to brands of combination drugs that contain a component drug affected by price disclosure. Any PBAC advice concerning combination items is taken into account. Pricing Section will contact responsible persons affected by combination drug flow-ons shortly after publication of direct price disclosure outcomes. 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

149. 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:
 - a. 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
 - b. the approved ex-manufacturer price applying on the reduction day will be adjusted to reflect the new pricing quantity.

The example on the following page 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:

$$\frac{\text{Zeus tablet 25 mg (20) WADP}}{\text{Old pricing quantity}} \times \text{New pricing quantity} = \text{Zeus tablet 25 mg (10) price on reduction day}$$

$$\text{i.e., } \frac{\$20}{20 \text{ tablets}} \times 10 \text{ tablets} = \$10 = \text{Approved ex-manufacturer price on reduction day}$$

Claimed Price Reductions – Premium adjustments under Price Disclosure

150. 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

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

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

Calculate DPMQ

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

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

Calculate Premium

$$\$8.21 - \$7.57 = \$0.64\text{¢}$$

(Claimed DPMQ – DPMQ = Premium)

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

www.medicareaustralia.gov.au/provider/pbs/pharmacists/pricing.jsp

Price disclosure, Statutory Price Reductions & other price changes

151. 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.
152. Where brands of a drug in a therapeutic group take a price disclosure reduction, that drug will be removed from its therapeutic group.

153. 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

154. 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.
155. For brands of a pharmaceutical item that meet the 'no reduction' criteria, their weighted average disclosed price is taken to be their applicable PBS price (usually the current price since the last reduction day), rather than the reduced price that would normally be determined along with other brands of a drug/MoA taking a reduction. This means the 'no reduction' brands do not meet the 10% test, so no reduction is applied under the Act. See the *Low Volume / Low Discount No Reduction Items* section under the heading **Calculation** above.
156. 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.

3

Compliance Guidelines

A compliance culture

157. It is expected that responsible persons will operate within an organisational framework and culture which supports compliance.
158. They should practice good corporate governance and have appropriate systems in place.
159. Their financial records are expected to be maintained in accordance with applicable Australian Accounting Standards.
160. 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.
161. 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.
162. 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.
163. 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.
164. 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.

Non-compliance

165. 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.
166. 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.
167. 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.
168. 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.
169. 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.

Consequences of non-compliance with disclosure requirements

170. 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.
171. 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.

4

Security Arrangements for Commercial in Confidence Material

Confidentiality of the responsible persons' disclosed price information

172. 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.
173. 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.

5

Definitions

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: <http://www.pbs.gov.au/industry/pricing/price-disclosure-spd/removal-originator-brand-sample-pd-calculation.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

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.

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 administrative cycle of at least 12 months, 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 has been 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 (there can be multiple brands of a pharmaceutical item if they are not considered to be bioequivalent or biosimilar);
- 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.

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 brands with the same drug but a different manner of administration (MoA) may incur a different level of reduction, or one MoA may have a reduction while the other does not.

New Brand

A brand newly listing on the PBS.

Originator Brand

Section 99ADB of the Act provides that the Minister (or delegate) may determine by legislative instrument that a brand of a pharmaceutical item that has a drug on F2 is an 'originator brand'. A brand of an exempt item is not an originator brand due to section 99ADA of the Act.

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

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.

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

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.

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 (EAPD was the first). SPD operates with:

- 6 monthly data collection periods*;
- A single ongoing 12 monthly administrative 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.

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.

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 which may be 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 Legislation website: www.legislation.gov.au

Where a reduction is required (i.e., 10% test is met), this price is also 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. 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 WAPD for each brand.

Where a drug/MoA meets the 30 month clock/multi-branded criteria for originator brand removal, the WAPD will also be calculated using data for all brands except the originator brand. However, originator brand data will still be used for a drug/MoA originator removal calculation where it is an 'originator only' pharmaceutical item. See further information under the heading **2016 October Cycle Onward - Removal of Originator Brand Data** in the **Calculation Section** above.

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Related Information

Where to go for further information

- The *National Health (Pharmaceutical Benefits) Regulations 1960* and the Weighted Average Disclosed Price Determinations: www.legislation.gov.au
- The National Health Act 1953: www.legislation.gov.au/Details/C2016C00527 or www.legislation.gov.au
- Pharmaceutical Benefits Scheme (PBS) website price disclosure page: www.pbs.gov.au/info/industry/pricing/price-disclosure-spd

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