



Australian Government

Department of Health

Pharmaceutical Benefits Scheme Expanded and Accelerated Price Disclosure Arrangements

Procedural and Operational Guidelines

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Introduction

Purpose

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

Name of Guidelines

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

Commencement of disclosure arrangements

3. EAPD arrangements apply from 1 December 2010. Price disclosure arrangements first commenced following the 2007 PBS Reforms.

Intended Audience

4. These Procedural Guidelines are intended for use by:
 - Responsible persons for products provided under the PBS and products listing on or intending to list a new brand of a drug on the PBS F2 Formulary (generally pharmaceutical manufacturers);
 - Departmental staff and other government agencies;
 - The independent Price Disclosure Data Administrator (PDDA); and
 - Other relevant stakeholders.

What is covered in this document

5. This document covers procedural guidelines, standard operating procedures, compliance guidelines and security arrangements for commercial in confidence material for:
 - EAPD;
 - Use of the EAPD information; and
 - Changes to price as a result of EAPD.

Relevant legislation, policies and documents

6. Legislation governing these Procedural Guidelines is the *National Health Act 1953* (the Act) and *National Health (Pharmaceutical Benefits) Regulations 1960* (the Regulations).
7. Other useful information is available on the EAPD webpage at <http://www.pbs.gov.au/info/industry/pricing/eapd>

Definitions

8. Terms used in the Procedural Guidelines have the following meanings.

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. 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.

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 on the last day of the data collection period* for its disclosure cycle (however, for the 2013 Main Cycle it was the price on 1 October 2012).

There are special provisions in the Regulations for the applicable approved ex-manufacturer price to be used in calculations for brands that were not listed on the last day of the data collection period (e.g. delisted brands). See regulation 37FA and regulation 37G(16).

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.

Bonus Stock

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

Brand

Brand of a pharmaceutical item 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 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 on the combination drug list or a drug on the F2 formulary.

Data Collection Period

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

In a disclosure cycle:

- a) there is only one data collection period for each brand of a pharmaceutical item;
- b) all brands of pharmaceutical items that have the same drug and manner of administration (drug/MoA) have the same data collection period;
- c) the data collection periods for brands of pharmaceutical items that have different drugs or that have the same drug with a different manner of administration (MoA), can commence on different days; and
- d) all data collection periods in the disclosure cycle end on the same day.

Disclosure Cycles

For the purpose of determining the weighted average disclosed price of a listed brand of pharmaceutical item there are several kinds of disclosure cycles during which:

- a) information is provided in compliance with EAPD requirements; and
- b) data is processed; and
- c) a reduction day or reduction days occur.

Under EAPD the following types of disclosure cycles exist:

- a) Main Cycles;
- b) Supplementary Cycles A; and
- c) Supplementary Cycles B.

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)

Under Expanded and Accelerated Price Disclosure all brands of non-exempt pharmaceutical items containing drugs on the F2 Formulary of the PBS are subject to the price disclosure requirements.

F1 Formulary

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

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

F2 Formulary

F2 will contain all drugs that do not meet the criteria for F1 and are not on the 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, and can be identified in the formulary allocation list on the *Pricing of PBS Items* webpage: www.pbs.gov.au/info/industry/pricing/pbs-items

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 some 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.

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'. Therefore the same medicine with a different manner of administration (MoA) may not be affected by a price reduction, or may incur a different level of reduction.

New Brand

A new brand of a drug already listed on the PBS, which may be a brand of a new or existing pharmaceutical item.

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

Means a pharmaceutical item as defined in the Act. For example particular drugs in different strengths or forms and MoA have different pharmaceutical items. 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 EAPD. Contact details for the PDDA can be found on the last page of this document.

Pricing Quantity

The lowest PBS priced pack size of any brand of each pharmaceutical item. The approved ex-manufacturer price is a price 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 generally a period of six months.

Reduction day

The date on which a price reduction as a result of EAPD may come into effect:

- a) 1 April;
- b) 1 August; or
- c) 1 December.

Reporting Period

Reporting period is the period for which a responsible person must collect data for submissions. There are two or more reporting periods in a data collection period.

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 EAPD purposes should be consistent with the responsible person's financial accounting policies and standards.

The Department

The Commonwealth Department of Health.

Unadjusted Price Reduction

This is the difference between:

- a) the applicable approved ex-manufacturer price of the brand of the pharmaceutical item; and
- b) the weighted average disclosed price of the brand of the pharmaceutical item

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

It is typically the reduction percentage outcome published for each price disclosure cycle at <http://www.pbs.gov.au/info/industry/pricing/eapd>

Weighted Average Disclosed Price (WADP)

Means weighted average disclosed price as determined under the Act and Regulations. WADP determinations are publicly available on the Comlaw website: www.comlaw.gov.au

Where a reduction is required, this price becomes the adjusted approved ex-manufacturer price (generally the new ex-manufacturer level price on reduction day).

Weighted Average Percentage Difference (WAPD)

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

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

It is worked out under steps eight and 10 of regulation 37G in the Regulations. The drug/MoA level WAPD is typically the reduction percentage outcome published for each price disclosure cycle at <http://www.pbs.gov.au/info/industry/pricing/eapd>

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EAPD Arrangements

Initiation

What is Expanded and Accelerated Price Disclosure (EAPD)?

1. EAPD is an extension of the 2007 PBS Reforms price disclosure program that commenced in August 2007.
2. Under the 2007 reforms pharmaceutical suppliers are required to advise the Department of the price at which PBS medicines are sold. Initially this obligation only applied as part of listing a new brand of an existing pharmaceutical item with a drug that was or would be on F2 when the brand listed.
3. Under price disclosure the price that Government pays for PBS listed drugs will move closer to the actual price at which those drugs are supplied in the market.
4. The extension of the price disclosure program in 2010 meant that as of 1 December 2010 all brands of non-exempt pharmaceutical items containing F2 drugs became subject to price disclosure provisions.

Commencement of EAPD

5. EAPD arrangements commenced from 1 December 2010 and apply to all brands of non-exempt pharmaceutical items containing F2 drugs.
6. The responsible person is the entity that is responsible for meeting the requirements of EAPD. This responsibility continues in relation to a delisted brand until the responsible person has fulfilled the reporting obligations for that delisted brand in its last reporting period.

Entity receiving the information to be disclosed

7. EAPD data submissions are 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 EAPD.

NOTE: The PDSU software will be provided by the PDDA immediately before the end of the first reporting period when a responsible person becomes subject to EAPD requirements. Responsible persons wishing to discuss what is required for the data submission process should contact the PDDA. Contact details can be found on the last page of this document.

Treatment of combination drug list brands

8. Brands containing drugs on the combination drug list will not be subject to EAPD data collection requirements. They will, however, be subject to price reductions brought about by price disclosure in any of their component drugs. There is a discretion not to apply the component drug reduction if relevant PBAC advice is in place under subsection 101 (4AC) of the Act.
9. Combination items will move to the F2 formulary upon listing of a new brand of the combination item. EAPD data collection and rules will then apply to the combination item in the same way as for all other drugs in the F2 formulary. EAPD price reductions in *component* drugs therefore do not flow on to combination items on F2.

Exemptions to the EAPD arrangements

10. Pharmaceutical items determined under section 84AH of the Act are exempt from EAPD 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

Collection

Information to be collected and submitted

11. For each brand which is subject to EAPD 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 37H.
12. This information is required:
 - for all brands of all pharmaceutical items of that drug/MoA, supplied by that responsible person. This includes both listed brands and any brands delisted during the reporting period. This obligation continues until the price disclosure requirements have been completed, even after the responsible person ceases to be a responsible person for the brand.
 - to be submitted separately for each brand and each pharmaceutical item.
13. This information will be used to calculate the weighted average disclosed price.

EXAMPLE - Data collection and submission for a brand that is subject to EAPD

Based on EAPD requirements, Dionysius Pty Ltd has to disclose price information for a drug with brand name Zeus that has two strengths:

1. **Zeus tablet 25 mg; and**
2. **Zeus tablet 40 mg.**

Dionysius Pty Ltd starts collecting sales revenue, volume and incentive data from the day Zeus 25 mg and Zeus 40 mg became subject to EAPD (e.g. 1 December 2010) for all pharmaceutical items containing Zeus that have the same MoA.

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

Dionysius Pty Ltd submits via the PDSU two sets of data to the PDDA for Zeus 25 mg and Zeus 40 mg for each reporting period, this data includes:

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

Data provided for a reporting period should be aggregated over the duration of the reporting period. However, the first month of data is supplied separately for new brands.

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

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

14. The responsible persons will need to **collect** and **submit for each reporting period** the following brand specific information:
 - a) The sales revenue, excluding sales to public hospitals;
 - b) The volume sold, based on the number of packs sold (for all pack sizes, including non-PBS priced pack sizes);
 - c) The kind of incentives (if any) given for the brand for the reporting period; and
 - d) The value of the incentives given for the brand for the reporting period.
15. 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. Any incentives related to sales of the brand must be provided in the data submission for the reporting period. Details about incentives are set out further below.
16. The methods used by the responsible person to define sales, recognise and measure revenue for EAPD purposes should be consistent with the responsible person's financial accounting policies.
17. Responsible persons must begin collecting data:
 - a) for new brands containing a drug listed on F2: the day that the brand listed on the PBS;
 - b) for listed brands: the day that the brand became subject to EAPD (usually on the day that the drug/MoA moved to F2).Data is not required to be collected for brands of exempt items.
18. Depending on when a brand becomes subject to EAPD the responsible person may be required to collect and submit data for part of the reporting period only.
19. Thereafter the responsible person is required to collect and submit data for all subsequent reporting periods.
20. All data is required to be submitted within six weeks from the end of the reporting period.
21. If a brand is delisted during a data collection period in a disclosure cycle, data is required to be collected and submitted for the period until delisting. If a brand delists during a reporting period, that is the last reporting period for which disclosure is required.

Incentives information that responsible persons need to collect

22. In addition the responsible persons will 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 which is the subject of the disclosure, including the following:

- bonus stock;
- bundling discounts;
- cash discounts;
- 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 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 from wholesalers and distributors) 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.

23. 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.

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24. 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.
 25. Any discounts and 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 and incentives).
 26. 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.
 27. 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.
 28. 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 reporting 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.
 29. 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

30. Data relating to the sales of pharmaceutical items to **public** hospitals must be **excluded** from the data submitted.
31. 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.
32. All other sales of the PBS listed brand of pharmaceutical item **must be included**. This includes sales of pharmaceutical items to **private** hospitals and **over the counter pharmaceutical items** (whether or not supplied under the PBS).

EAPD Disclosure Cycles and Reporting Periods

33. The current EAPD disclosure cycles are:

- Main Cycles;
- Supplementary Cycles A; and
- Supplementary Cycles B.

34. A list of drugs/MoA subject to price disclosure and the relevant EAPD disclosure cycle is available at: www.pbs.gov.au/info/industry/pricing/eapd/eapd-drugs

Main Cycles

35. All brands of drug/MoAs that were subject to price disclosure on or before 1 December 2010 are now in the EAPD Main Cycle (including those that were in transitional cycles and the interim supplementary cycle).

36. The *first* Main Cycle commenced on 1 December 2010. It included all brands of non-exempt pharmaceutical items with a drug on the F2 Formulary on 1 December 2010 that had not previously been subject to price disclosure requirements.

37. All “subsequent” Main Cycles for drugs in previous Main Cycles commence on 1 October each year and cease at the end of 30 September in the following year.

38. Any brand of a drug/MoA that becomes subject to price disclosure (i.e. moves to F2) on **1 July, 1 August, 1 September or 1 October** of any year also joins the Main Cycle. Data collection commences on the date its drug moves to F2. For a new brand containing an F2 drug, data collection commences the date the brand lists.

39. Main Cycles have the following reporting periods:

Main Cycle	Reporting period	Start date*	End date	Submission deadlines**	Scheduled reduction day
2013	1	1 October 2011	31 March 2012	12 May 2012	1 April 2013
	2	1 April 2012	30 September 2012	11 November 2012	
2014	1	1 October 2012	31 March 2013	12 May 2013	1 April 2014
	2	1 April 2013	30 September 2013	11 November 2013	
2015	1	1 October 2013	31 March 2014	12 May 2014	1 April 2015
	2	1 April 2014	30 September 2014	11 November 2014	

*The reporting periods table above does not include extra reporting periods for brands new to price disclosure or transferring to Main Cycle with data collection starting prior to the regular Main Cycle data collection start date (e.g. brands new to price disclosure 1 August, start data collection 1 August and collect 2 months of additional data. Drugs transitioning from Supplementary Cycle A to Main Cycle, start collecting data on 1 February and collect 2 months of additional data).

**Or the next day that is not a weekend or holiday.

Interim Supplementary Cycle

40. There was one Interim Supplementary Cycle to allow drugs new to F2 after 1 December 2010 and up to 1 June 2011 (inclusive) to have a disclosure cycle of at least eighteen months, and not wait until the next available Main cycle for their first potential reduction.
41. All brands in the Interim Supplementary Cycle moved to the 2014 Main Cycle. The data collection period for these brands folding into the 2014 Main Cycle began 1 June 2012 and ended 30 September 2013. They then became part of the regular Main Cycle.
42. There will be no further Interim Supplementary Cycles.

Supplementary Cycle A

43. If a brand of a drug/MoA becomes subject to price disclosure (i.e. moves to F2) on **1 November, 1 December, 1 January or 1 February** of any year (inclusive) it joins Supplementary Cycle A. Existing and new brands with that drug/MoA are in Supplementary Cycle A.
44. Supplementary Cycle A allows drugs new to F2 between 2 October and 1 February, where the drug/MoA, or a new MoA becomes subject to EAPD requirements, to have a disclosure cycle of at least eighteen months. This means the drug/MoA does not wait until the next available Main Cycle for its first potential reduction.
45. Data collection for these brands commences the date they become subject to EAPD (i.e. the listing day for brands new to F2, or the day the drug moves to F2 for existing brands). The data collection period for Supplementary Cycle A ends on 31 January.
46. Supplementary Cycle A has the following reporting periods:

Reporting period	Start date	End date	Submission deadlines**	Scheduled reduction day
1	1 November – 1 February*	31 March	12 May	1 August
2	1 April	30 September	11 November	
3	1 October	31 January	14 March	

*Start date is the date on which the brand becomes subject to price disclosure (which can vary).

**Or the next day that is not a weekend or holiday.

47. Following its completion of the Supplementary Cycle A, the brands will merge into the next available Main Cycle. The first reporting period in the Main Cycle will be 1 February – 31 March.

Supplementary Cycle B

48. If a brand of a drug/MoA becomes subject to price disclosure (i.e. moves to F2) on **1 March, 1 April, 1 May or 1 June** of any year (inclusive) it joins Supplementary Cycle B. Existing and new brands with that drug/MoA are in Supplementary Cycle B.
49. Supplementary Cycle B allows drugs new to F2 between 2 February and 1 June, where the drug/MoA or a new MoA becomes subject to EAPD requirements, to have a disclosure cycle of at least eighteen months. This means the drug/MoA does not wait until the next available Main Cycle for its first potential reduction.
50. Data collection for these brands commences the date they become subject to EAPD (i.e. the listing day for brands new to F2, or the day the drug moves to F2 for existing brands). The data collection period for a Supplementary Cycle B ends on 31 May.

Supplementary Cycle B has the following reporting periods:

Reporting period	Start date	End date	Submission deadlines**	Scheduled reduction day
1	1 March*	31 March	12 May	1 December
2	1 April – 1 June*	30 September	11 November	
3	1 October	31 March	12 May	
4	1 April	31 May	11 July	

*Start date is the date on which the brand becomes subject to price disclosure (which can vary).

**Or the next day that is not a weekend or holiday.

51. Following its completion of the Supplementary Cycle B, the brand will merge into the next available Main Cycle. The first reporting period in the Main Cycle will be 1 June – 30 September.

Submission

Timeframe & Responsibility for submission of the information

52. Responsible persons are required to submit price disclosure data (including incentives data) to the PDDA within six weeks from the day after the end of the reporting period, or the next day that is not a weekend or holiday.

NOTE: All EAPD data must be submitted within six weeks of the end of each reporting period no matter which disclosure cycle a brand of drug is allocated.

53. 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.

54. 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.

55. Notification about who will submit data in cases of early transfer of commercial responsibility for 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. A letter from the new commercially responsible person should then undertake to make the disclosure for the specified brands for the specified period. This could be achieved through one co-signed letter.

56. The letter or letters giving the relevant authorisation and undertaking should be addressed to the EAPD team in the Department and be sent to both the Department and to the PDDA. An emailed pdf version of the letter will be sufficient - email details can be found on the last page of this document.

57. If you require further information about the submission process please contact the PDDA. Contact details can be found on the last page of this document.

Certification requirements

58. When a responsible person submits EAPD data to the PDDA, the authorised representative for the responsible person is required to certify via the PDSU, 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 Regulations.

Calculation

The entity responsible for calculations

59. Both responsible persons and the Department are responsible for performing calculations that will contribute to determining the weighted average disclosed price and whether any change should be made to the AEMP.

Responsible person's calculations

60. Responsible persons are responsible for performing calculations relating to collection and submission of six monthly or other relevant period of data. This might include calculations relating to collection and apportioning of the cost of any brand and non-brand specific incentives relating to the brand subject to disclosure.
61. Calculations may also be required to remove information relating to sales to public hospitals from the data sets.
62. 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.
63. 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 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.

Calculations relating to collection and submission of data

64. Responsible persons are responsible for the calculations required to ensure accurate collection and submission of the data, namely:
 - Brand specific information on sales revenue; and
 - The volume of the brand sold, based on the number of packs sold.

Calculations relating to apportioning the cost of any incentives relating to a brand

65. Responsible persons are responsible for the calculations required to ensure accurate collection of any specific incentives that apply to the brand.
66. Responsible persons are also responsible for calculations relating to 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® (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:

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

Department's calculations

The Weighted Average Disclosed Price calculation

67. To perform a weighted average disclosed price calculation, the weighted average percentage difference must be calculated for each pharmaceutical item of the appropriate drug /MoA using the data provided by responsible persons.
68. The weighted average percentage difference for each pharmaceutical item of a drug /MoA is then weighted according to its total adjusted disclosed volume and approved ex-manufacturer price to calculate the weighted average percentage difference for the drug /MoA. This is typically the reduction percentage outcome published for each price disclosure cycle at:
<http://www.pbs.gov.au/info/industry/pricing/eapd>
69. All the approved ex-manufacturer prices for all non-exempt brands with each drug /MoA are reduced by the weighted average percentage difference, giving the weighted average disclosed prices.
70. A legal determination is made setting out the weighted average disclosed prices for each brand of each non-exempt pharmaceutical item for every drug/MoA in each cycle.
71. The weighted average disclosed price calculation is performed under regulation 37G, which sets out the calculation steps in detail.
72. The weighted average disclosed price calculation is performed separately for each drug/MoA within a disclosure cycle.

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

73. The minimum data necessary to determine a weighted average disclosed price is 12 continuous months* for at least one brand of the drug/MoA. The minimum data set can be made up of listed or delisted brands containing the same drug/MoA.

Note: the 2012 Main Cycle had a weighted average disclosed price calculated based on 10 months data.

74. Non-compliance by a responsible person will not prohibit the PDDA from proceeding with the calculation providing that the minimum data requirement stated above has been met.
75. 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 weighted average disclosed price from being distorted.

Department notified of calculation outcome

76. The PDDA will notify the Department of the outcome of the weighted average disclosed price calculations for all brands of pharmaceutical items listed during their data collection period in all disclosure cycles.

Department makes Determination

77. A delegate of the Minister in the Department will make a determination via legislative instrument for weighted average disclosed prices for brands that were listed brands during the data collection period. Brands of drug/MoAs that have an unadjusted price reduction of 10% or more will be in Schedule 1 to the instrument and those under 10% (i.e. no reduction) will be in Schedule 2. For the drug/MoAs in Schedule 1 (i.e. taking a reduction) the weighted average disclosed price is also determined to be the adjusted AEMP.

Changes to Price as a Result of Price Disclosure

Department provides notification of the change in price

78. All responsible persons will be able to access the determined weighted average disclosed price outcome via the legislative instrument. The determination includes brands with a percentage difference between the old AEMP and the determined weighted average disclosed price of less than 10%. The percentage outcome for drug/MoAs taking a reduction, and a link to the weighted average disclosed price legislative instrument, are placed on the Department's website shortly after the instrument is published on the Comlaw website: www.pbs.gov.au/info/industry/pricing/eapd. An email is also sent to all responsible persons advising that the outcome is available.

When will price changes take place

79. It is intended that the price disclosure reductions occur on the first potential reduction day after the determination has been made.
80. There are three potential reduction days each year:
- 1 April;
 - 1 August; and
 - 1 December.

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

81. Any changes in the approved ex-manufacturer price that result from price disclosure apply to all brands of all non-exempt pharmaceutical items containing the drug with the same MoA.
82. Any **new brands of existing pharmaceutical items** containing the relevant drug/MoA that list after the end of the data collection period for the disclosure cycle do not require a legal determination for their weighted average disclosed price and adjusted ex-manufacturer price. The Act provides that the same reduction applies to new brands as was determined for the existing brands. No specific notice of a reduction is provided to responsible persons for these new brands.
83. 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(s) of that new pharmaceutical item.
84. Flow on's are also applied where appropriate to brands of single brand combination drugs that contain a component drug affected by price disclosure. Any PBAC advice concerning single brand combination items is taken into account. Pricing Section will contact responsible persons affected by single brand combination drug list flow-on's.

Changes to Pricing Quantity after the end of Data Collection

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

The following example demonstrates how an adjustment will be made if a change to PBS pack size causes a change to the pricing quantity for a brand after the last day of the data collection period 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 last day of the data collection period.

The WADP for the pricing quantity is \$20.

A new pack size of 10 lists after the end of the data collection period.

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:

	Zeus tablet 25 mg (20) WADP	×	New pricing quantity	=	Zeus tablet 25 mg (10) price on reduction day
	<hr style="width: 100%;"/>				
	Old pricing quantity				
i.e.	$\frac{\$20}{20 \text{ tablets}}$		$\times 10 \text{ tablets}$	=	$\$10 =$ Approved ex-manufacturer price on reduction day

Claimed Price Reductions – Premium adjustments under Price Disclosure

86. 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.

A new 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 (**AEMP**)
2. Adjusted Approved (Commonwealth) Ex-Manufacturer Price on the reduction day - usually the Adjusted AEMP in the price disclosure determination (**Adjusted AEMP**)
3. Current 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:

AEMP	–	Adjusted AEMP	× 100	=	calculated percentage
<hr style="width: 100%;"/>					
AEMP					
<p>Current Claimed Price – calculated percentage = New Claimed Price</p>					

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

EXAMPLE – Calculating a new Premium for Price Disclosure

Step 1: Identify the prices required for the calculation

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

Step 2: Calculate the New Claimed Price

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

$$\$1.42 \text{ (current Claimed Price)} - 10.59\% = \$1.27$$

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

Step 3: Calculate the new Premium

Calculate the Claimed DPMQ

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

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

Calculate DPMQ

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

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

Calculate Premium

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

(Claimed DPMQ – DPMQ = Premium)

Price disclosure and Statutory Price Reductions

87. For pharmaceutical items containing a drug on F2:

- Those items which are or have been subject to a price reduction due to price disclosure will not be subject to a 'first new brand' Statutory Price Reduction.
- In the event of a Statutory Price Reduction occurring during the cycle, the approved ex-manufacturer price used in calculations is the approved ex-manufacturer price current at the end of the data collection period for the disclosure cycle.

Price Disclosure and other Price Reductions

88. In the event of price changes occurring for any reason during the disclosure cycle, the approved ex-manufacturer price used in calculations is the current approved ex-manufacturer price at the end of the data collection period for the disclosure cycle.

Circumstances when a price change will not occur

89. There will be no change to the approved ex-manufacturer price if the unadjusted price reduction calculated is less than 10%.
90. If the price changes as a result of price disclosure 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 change to the approved ex-manufacturer price.

3

Compliance Guidelines

A compliance culture

91. It is expected that responsible persons will operate within an organisational framework and culture which supports compliance.
92. They should practice good corporate governance and have appropriate systems in place.
93. Their financial records are expected to be maintained in accordance with applicable Australian Accounting Standards.
94. 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.
95. Serious penalties apply for non-compliance with EAPD 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 EAPD arrangements and how these affect their record keeping and reporting requirements.
96. 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.
97. 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 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.
98. 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

99. 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.
100. 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.
101. For example if the data which the responsible person submitted at the due date was incomplete the Department may notify the responsible person that the data was missing and ask the responsible person to submit the required data within 2-3 business days.
102. 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.
103. 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

104. 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:
 - failure to comply with price disclosure requirements
 - knowingly or recklessly providing false and misleading information;
 - 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.
105. 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

106. 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.
107. 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);
 - must be disclosed to the Department's solicitors, auditors, insurers, advisers or Commonwealth Ombudsman;
 - is reasonably necessary for the enforcement of the criminal law or for the protection of public revenue;
 - is generally available to the public.

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Related Information

Where to go for further information

- The *National Health (Pharmaceutical Benefits) Regulations 1960* and the Weighted Average Disclosed Price Determinations: www.comlaw.gov.au
- The *National Health Act 1953*: <http://www.comlaw.gov.au/Current/C2013C00083> or www.comlaw.gov.au
- Pharmaceutical Benefits Scheme (PBS) website: www.pbs.gov.au/info/industry/pricing/eapd

Contacting the PDDA

Email: admin@pricedisclosure.com.au

Telephone: 1300 336 062

Contacting the Department

Email: eapd@health.gov.au

Telephone: (02) 6289 2303