



**Australian Government**  

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**Department of Health and Ageing**

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# Pharmaceutical Benefits Scheme Expanded and Accelerated Price Disclosure Arrangements

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## Procedural and Operational Guidelines

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# 1

## Introduction

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## Purpose

1. The purpose of these 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 will apply from 1 December 2010.

## 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 (generally pharmaceutical manufacturers);
  - Departmental staff and other government agencies;
  - The independent Service Provider; 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 and National Health (Pharmaceutical Benefits) Regulations 1960 (as amended).

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## Definitions

7. Terms used in the Procedural Guidelines have the following meanings:

### **Agreed Quantity**

The agreed quantity for a brand of a pharmaceutical item, is the quantity or number of units of the pharmaceutical item by reference to which the appropriate maximum price for sales of the brand of the pharmaceutical item to approved pharmacists has been:

- a) Agreed under section 85AD, or
- b) Determined under subsection 85B(2)

### **Applicable Approved ex-manufacturer price**

The applicable approved ex-manufacturer price, of a brand of a pharmaceutical item, is the approved ex-manufacturer price of the brand on the last day of the data collection period for the disclosure cycle for the brand.

### **Bioequivalent**

Bioequivalent as determined by the TGA.

### **Biosimilar**

Biosimilar as determined by the TGA.

### **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.

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## 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 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.

## Data Collection Period

In each disclosure cycle there is a data collection period for which data is collected 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, and
- b) all brands of pharmaceutical items that have the same drug and manner of administration have the same data collection period, and
- 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, 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 to compliance with EAPD requirements, and
- b) data is processed, and
- c) a reduction day occurs.

Under EAPD the following types of disclosure cycles exist:

- a) Main Disclosure Cycles,
- b) Supplementary Cycle A, and
- c) Supplementary Cycle B.

## Drug

A drug or medicinal preparation in relation to which a declaration under subsection 85 (2) of the *National Health Act 1953* is in force.

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## Expanded and Accelerated Price Disclosure (EAPD)

Under Expanded and Accelerated Price Disclosure all non exempt drugs on the F2 Formulary of the PBS will become subject to EAPD from 1 December 2010.

### F1 Formulary

F1 will contain drugs that:

- a) Have only one brand of each form and strength listed on the PBS; and
- b) Are not interchangeable at the patient level with a drug that has multiple brands listed on the PBS (i.e. not part of a Therapeutic Group that has multiple brands).

### F2 Formulary

F2 will contain all drugs that do not meet the criteria for F1.

### Form (Dosage form)

The pharmaceutical form in which a product is presented for therapeutic administration e.g. tablet or cream etc.

### 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

The route by which the drug enters the body, including but not limited to:

- 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

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- Urethral
  - Vaginal

For the purposes of price disclosure, medicines are grouped on the basis of 'manner of administration'. Therefore the same medicine with a different manner of administration 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 is bioequivalent to a form and strength of an existing brand (or in the case of biologicals, 'biosimilar' to an existing brand). A bioequivalent brand will usually have the same form and strength as an existing brand, but this will not always be the case.

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

A PBS item that may also be purchased over the counter without a prescription.

### **PBS**

The Pharmaceutical Benefits Scheme.

### **PBS item**

A particular form and strength of a drug covered by a unique PBS item code.

### **PBS branded item**

A brand of a PBS item.

### **PBAC**

The Pharmaceutical Benefits Advisory Committee.

### **Pricing Quantity**

The lowest PBS priced pack size of *any* brand of that pharmaceutical item. The approved ex-manufacturer price is a price for the **pricing quantity**.

### **Processing Period**

The six month period following the data collection period and leading up to the reduction day, which includes,

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

### **Reduction day**

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

- a) 1 April,
- b) 1 August, and
- c) 1 December.

### **Reporting Period**

Reporting period is the period for which a Responsible person must provide data submissions. There will be 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 *National Health Act 1953* to be the responsible person for the

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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.

### **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.

### **TGA**

Therapeutic Goods Administration.

### **The Department**

The Department of Health and Ageing.

### **Unadjusted price Reduction**

The unadjusted price reduction for a brand of a pharmaceutical item is calculated as a part of the WADP calculation. This typically corresponds to 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.

### **Unit of volume**

The unit of volume for disclosure purposes is the pack size. In disclosing information to the Department, responsible persons will report based on the pack size of the brand as supplied to wholesalers and pharmacists. Where there is more than one pack size, the responsible person will report separately for each pack size. In calculating the weighted average price, the Department will convert all volumes to the volumes that would have applied if the pack sizes were equivalent to the pricing quantity for dispensing in the *Schedule of Pharmaceutical Benefits*.

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## EAPD Arrangements

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# 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 into pharmacies, but only as part of listing a new brand of an existing PBS item.
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 will mean that as of 1 December 2010 all non exempt F2 Drugs will become subject to price disclosure provisions.

## Commencement of EAPD

5. EAPD arrangements will commence from 1 December 2010 and will apply to all non exempt F2 drugs.
6. The responsible person is the entity that is responsible for meeting the requirements of EAPD.

## 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 when a Responsible Person becomes subject to the EAPD requirements.

## Treatment of the combination items for purposes of the EAPD

8. Single brand combination items on the combination list will not be subject to EAPD requirements. They will, however, be subject to price reductions brought about by price disclosure in any of their component drugs.
9. Combination items will move to the F2 formulary upon listing of a new brand of the combination item. EAPD rules will then apply to the combination item as all other drugs in the formulary. EAPD price reductions in component drugs do not flow on to combination items not on the combination list

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## Exemptions to the EAPD arrangements

10. PBS listed items, as determined under section 84AH of the *National Health Act 1953*, are exempt from EAPD arrangements. The full list of these exempt PBS items is available on the website: [www.pbs.gov.au/info/industry/pricing/pbs-items/items-exempt-price-reductions](http://www.pbs.gov.au/info/industry/pricing/pbs-items/items-exempt-price-reductions).

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# 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 and volume of sales.
12. This is required:
  - For all brands of all items of that drug with the same manner of administration, supplied by that responsible person
  - To be submitted separately for each brand and each form and strength.
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 forms and strengths of Zeus with the same manner of administration.

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

Dionysius Pty Ltd collects and 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.

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

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- b) The volume sold, based on the number of packs sold (for all pack sizes, including non-PBS 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 should reflect the prices charged according to invoices or order forms. Any discounts, charge backs or other incentives provided must be provided in the data submission for the reporting period.
  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: 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/manner of administration moved to F2).
  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 6 weeks from the end of the reporting period.
  21. All amounts should be expressed in Australian dollars and be exclusive of GST.

#### **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 following incentives** relating to the sales of the brand which is the subject of the disclosure:
  - 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;

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- 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.
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 PBS item, non-PBS 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.

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## Sales to hospitals

30. Data relating to the sales of PBS items to **public** hospitals must be **excluded** from the data submitted.
31. In cases where an extraction of such 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 PBS items **must be included**. This includes sales of PBS items to **private** hospitals and **over the counter PBS items** (whether or not supplied under the PBS).

## EAPD Disclosure Cycles and Reporting Periods

33. From October 2012, the EAPD disclosure cycles are:

- Main Disclosure Cycles;
- Interim Supplementary Disclosure Cycle;
- Supplementary Cycles A; and
- Supplementary Cycles B.

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

### Main Disclosure Cycles

35. All brands of drugs/manners of administration that were subject to price disclosure on or before 1 December 2010 are now in the Main Disclosure Cycle.

36. If a brand of a drug/manner of administration that is not currently subject to price disclosure lists on **1 July, 1 August, 1 September or 1 October** of any year, all brands of the drug/manner of administration will join the subsequent Main Disclosure Cycle. Data collection for a brand will commence the date it is listed.

37. The *first* Main Disclosure Cycle commenced on 1 December 2010 and included all non-exempt brands on the F2 Formulary not previously subject to Price Disclosure requirements. All “subsequent” Main Disclosure Cycles commence on 1 October and will end at the end of 30 September in the following year.

38. Main Disclosure Cycles have the following reporting periods:

Main Disclosure Cycle no.	Reporting period	Start date	End date	Submission Deadlines	Scheduled reduction day
2	1	1 October 2011	31 March 2012	12 May 2012	1 April 2013
	2	1 April 2012	30 September 2012	11 November 2012	
3	1	1 October 2012	31 March 2013	12 May 2013	1 April 2014
	2	1 April 2013	30 September 2013	11 November 2013	
4	1	1 October 2013	31 March 2014	12 May 2014	1 April 2015
	2	1 April 2014	30 September 2014	11 November 2014	

## Interim Supplementary Disclosure Cycle

39. There is one Interim Supplementary Disclosure Cycle to allow new F2 drug listings **occurring after 1 December 2010 and before 1 July 2011**, to have a disclosure cycle of at least eighteen months.
40. The data collection period for the Interim Supplementary Disclosure Cycle ended on 31 May 2012. The Interim Supplementary Disclosure Cycle has the following reporting periods:

Reporting period	Start date	End date	Submission Deadlines	Scheduled reduction day
1	1 January 2011 – 1 March 2011*	31 March 2011	12 May 2011	1 December 2012
2	1 April 2011 – 1 June 2011*	30 September 2011	11 November 2011	
3	1 October 2011	31 March 2012	12 May 2012	
4	1 April 2012	31 May 2012	11 July 2012	

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

41. The reporting period for the Interim Supplementary Disclosure Cycle ended on 31 May 2012. The scheduled reduction day is 1 December 2012.
42. All brands in the Interim Supplementary Disclosure Cycle will move to Main Disclosure Cycle number Three. The data collection period for these brands began 1 June 2012 and will end 30 September 2012.

## Supplementary Cycle A

43. If a brand of a drug/manner of administration that is not currently subject to price disclosure lists on **1 November, 1 December, 1 January or 1 February** of any year (inclusive) it will join Supplementary Cycle A.
44. Supplementary Cycle A allows new F2 drugs listing between 2 October and 1 February, where the drug and manner of administration, or a new manner of administration first becomes subject to EAPD requirements, to have a disclosure cycle of at least eighteen months.
45. Data collection for these brands will commence the date it becomes subject to EAPD. 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	
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47. Following its completion of the Supplementary Cycle A, the brand will merge into the next available Main Disclosure Cycle. The first reporting period in the Main Disclosure Cycle will be 1 February – 31 March.

### Supplementary Cycle B

48. If a brand of a drug/manner of administration that is not currently subject to price disclosure lists on **1 March, 1 April, 1 May or 1 June** of any year (inclusive) it will join Supplementary Cycle B.

49. Supplementary Cycle B allows new F2 drugs listing between 2 February and 1 June, where the drug and manner of administration or a new manner of administration first becomes subject to EAPD requirements, to have a disclosure cycle of at least eighteen months.

50. Data collection for these brands will commence the date it becomes subject to EAPD. The data collection period for a Supplementary Cycle B ends on 31 May.

51. 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)

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

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# Submission

## Timeframe for submission of the information

53. Responsible persons are required to submit price disclosure data (including incentives data) within 6 weeks from the day after the end of the reporting period.

**NOTE:**

All EAPD data must be submitted within 6 weeks of the end of each reporting period no matter which cycle a brand of drug is allocated.

## Certification requirements

54. When a responsible person submits EAPD data to the PDDA, the Chief Executive Officer (or his or her authorised delegate) 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 *National Health (Pharmaceutical Benefits) Regulations 1960 (as amended 2010)*.

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# Calculation

## The entity responsible for calculations

55. 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 approved ex-manufacturer price.

## Responsible person's calculations

56. Responsible persons are responsible for performing calculations relating to collection and submission of six monthly data (including any calculations relating to collection and apportioning of cost of any brand and non brand specific incentives relating to the brand subject to disclosure).
57. Calculations may also be required to remove information relating to sales to public hospitals from the data sets.
58. 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.
59. 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 monthly data

60. Responsible persons are responsible for collection and submission of the data namely:
  - Brand specific information on sales revenue; and
  - The volume sold in units of PBS items.

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

61. Responsible persons are responsible for the collection of any specific incentives that apply to the brand.
62. 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 - Annual Incentive Data for Zeus<sup>®</sup> (as submitted by Dionysius Pty Ltd)**

Brand and Form	Brand specific Incentives	Incentives that apply to multiple brands and/or forms	Sales revenue
Zeus 25 mg	\$653,084	N/A	\$2,245,049
Zeus 50 mg	\$10,000	N/A	\$2,254,951
<b>Zeus (Overall)</b>	N/A	\$150,000	\$4,500,000

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

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

Where:

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

$I_T$  is the Total value of overall Zeus incentives

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

$S_T$  is the Total sales revenue of Zeus

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

Total incentive amount for Zeus 25:

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

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

$I_{Z25}$  = Incentives for Zeus 25

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

A similar calculation can be performed for Zeus 50:

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

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## Department's calculations

### The Weighted Average Disclosed Price (WADP) calculation

63. To perform a WADP calculation, the Weighted Average Percentage Difference must be calculated for each form and strength of the appropriate drug with the relevant manner of administration (Pharmaceutical Item) using the data provided by Responsible Persons.
64. The Weighted Average Percentage Difference for each Pharmaceutical Item of a drug with the same manner of administration is then weighted according to its PBS volume data to calculate the Unadjusted Price Reduction for that drug with that manner of administration.
65. If the Unadjusted Price Reduction for a drug with a manner of administration is 10% or more, all the approved ex-manufacturer prices for all brands of that drug and manner of administration will decrease by the Unadjusted Price Reduction, resulting in the Weighted Average Disclosed Prices (WADPs).
66. The WADP calculation is performed under Section 37G of the *National Health (Pharmaceutical Benefits) Regulations 1960* (as amended).
67. The WADP calculation is performed separately for each drug and manner of administration within a disclosure cycle.

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

68. The minimum data necessary to determine a weighted average disclosed price is 12 continuous months\* for at least one brand of the drug for a manner of administration.

\*Note: the *first* Main Disclosure Cycle will have a weighted average disclosed price calculated based on 10 months data.

69. 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.
70. 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

71. The PDDA will notify the Department of the outcome of the weighted average disclosed price calculation for all cycles.

### Department makes Determination

72. The Department will make a Determination via Legislative Instrument as to whether a price reduction will take place.

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# Changes to Price as a Result of Price Disclosure

## Department provides notification of the change in price

73. Whether a price reduction is to take place or not, all responsible persons of that drug with the same manner of administration will be able to access the determination for the calculation outcome via the legislative instrument.

## When will price changes take place

74. The price reduction will occur on the first scheduled reduction day after the Department has made the determination.
75. There are three scheduled reduction days each year:
- 1 April;
  - 1 August; and
  - 1 December.

## Drugs that will be affected by the change in price

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

## Price disclosure and Statutory Price Reductions

77. For PBS items on F2:
- Those items which have been subject to a price reduction due to price disclosure will not be subject to any remaining Statutory Price Reductions;
  - In the event of a Statutory Price Reduction occurring during the disclosure cycle, the approved ex-manufacturer price used in calculations shall be that which is current at the end of the data collection period for the disclosure cycle.

## Price Disclosure and other Price Reductions

78. In the event of price decreases occurring during the disclosure cycle, for any reason, the approved ex-manufacturer price used in calculations shall be that which is current at the end of the data collection period for the disclosure cycle.

## Circumstances when a price change will not occur

79. There will be no change to the approved ex-manufacturer price if the unadjusted price reduction calculated is less than 10%.
80. If the price changes as a result of price disclosure were to result in an increase to the approved ex-manufacturer price, then there will be no change to the current approved ex-manufacturer price.

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# 3

## Compliance Guidelines

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## A compliance culture

81. It is expected that responsible persons will operate within an organisational framework and culture which supports compliance.
82. They should practice good corporate governance and have appropriate systems in place.
83. Their financial records are expected to be maintained in accordance with applicable Australian Accounting Standards.
84. Compliant organisations tend to:
  - establish aligned values;
  - 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.
85. 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.
86. 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.
87. 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.
88. All documents, methodologies, detailed transactional records and any other documents relating to price disclosure arrangements must be kept for two years from the end of the annual collection cycle to which those records relate.

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## Non-compliance

89. 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.

90. 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.

91. 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.

92. If a responsible person knows prior to the due date that it will be unable to comply then the responsible person should notify the service provider of the likely non-compliance as soon as it becomes aware of it. 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.

93. 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 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

94. There are a range of actions that may be evoked for non compliance by the responsible persons. Non compliance is considered to be failure to disclose price information to the Department in accordance with the legislative requirements of price disclosure. 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

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- 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.

95. Not all penalties will all 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 have 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.

96. Not all penalties will all 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 have occurred;
- the duration of each non-compliance;
- the reason for the non-compliance;
- whether the reasons are, in the opinion of the Minister, reasonable; and
- any other matter that the Minister thinks is relevant.

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# 4

## Security Arrangements for Commercial in Confidence Material

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## Confidentiality of the responsible persons' disclosed price information

97. The Department considers all information submitted by responsible persons to be commercial-in-confidence, and recognises the responsible persons' expectation that commercial in confidence information will be protected from inadvertent, unintended or improper disclosure.
98. In accordance with its legal responsibilities the Department 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;
  - must be disclosed to the Department's solicitors, auditors, insurers, advisers or Commonwealth Ombudsman;
  - is reasonably necessary for the enforcement of the criminal law or for the protection of public revenue;
  - is generally available to the public.

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# 5

## Related Information

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## Where to go for further information

- Regulations and Determinations: [www.frli.gov.au](http://www.frli.gov.au)
- The *National Health Act 1953*: [www.comlaw.gov.au](http://www.comlaw.gov.au)
- Department of Health and Ageing website: [www.health.gov.au/pbsreform](http://www.health.gov.au/pbsreform)
- Pharmaceutical Benefits Scheme (PBS) website: <http://www.pbs.gov.au/info/industry/pricing/eapd>

### Contacting the PDDA

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

Telephone: 1300 336 062

### Contacting the Department

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

Telephone: (02) 6289 2303

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