



Australian Government

Department of Health and Ageing

Pharmaceutical Benefits Scheme Price Disclosure Arrangements

Procedural and Operational Guidelines

July 2007

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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) price disclosure arrangements as announced as part of the PBS reform package by the Minister for Health and Ageing in November 2006.

Name of guidelines

2. These guidelines are the Pharmaceutical Benefits Scheme Price Disclosure Procedural Guidelines ("Procedural Guidelines").

Commencement of disclosure arrangements

3. The PBS price disclosure arrangements will apply from 1 August 2007.

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; 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:
 - Mandatory price disclosure;
 - Voluntary price disclosure;
 - Use of the price disclosure information; and
 - Changes to price as a result of disclosure.

Relevant legislation, policies and documents

6. Legislation governing these Procedural Guidelines is the *National Health Act 1953* and *National Health (Pharmaceutical Benefits) Regulations* (as amended).

Transition arrangements

7. The submission of price disclosure information will be an online process. However, during the early stages of implementation, some information may need to be submitted on paper-based forms and/or on electronic disks.

Definitions

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

Approved ex-manufacturer price

The ex-manufacturer price that corresponds to the approved price to pharmacists for the PBS items with the wholesale mark-up (as set out in the Fourth Community Pharmacy Agreement or its successors) removed.

Approved price to pharmacists

Approved price to pharmacists means:

- a) if a price agreement is in force in relation to the brand of the PBS item – the amount in force under the agreement as the amount that is taken to be the appropriate maximum price for sales of the brand of the PBS item to approved pharmacists; or
- b) if a price determination is in force in relation to the brand of the PBS item – the amount in force under the determination as the amount that is taken to be the appropriate maximum price for sales of the brand of the PBS item to approved pharmacists.

Bioequivalent

Bioequivalent as determined by the Therapeutic Goods Administration (TGA).

Biosimilar

Biosimilar as determined by the Therapeutic Goods Administration (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.

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.

Collection cycle

There are three annual data collection cycles that all disclosed data must fit into. The data collection cycle that applies is the first data collection cycle after the listing of the brand that triggered disclosure.

Collection period

Each data collection cycle consists of four quarterly collection periods of three calendar months for the collection of monthly data. The first quarterly collection period always commences on the first day of the data collection cycle.

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.

Co-operative advertising

When a responsible person contributes to the cost of advertising or a promotion by a wholesaler or retailer as an incentive for the wholesaler or retailer to purchase the disclosing brand.

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.

F1 formulary

F1 will contain drugs that:

- Have only one brand of each form and strength listed on the PBS; and
- 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.

F2A formulary

The F2A formulary consists of all drugs listed on Part A of the F2 formulary in the *National Health (Pharmaceutical Benefits) Regulations*, or that the Minister has determined are in Part A of the F2 formulary under section 85AC of the *National Health Act 1953*. The F2A formulary ceases to exist on 1 January 2011.

F2T formulary

The F2T formulary consists of all drugs listed on Part T of the F2 formulary in the *National Health (Pharmaceutical Benefits) Regulations*, or that the Minister has determined are in Part T of the F2 formulary under section 85AC of the *National Health Act 1953*. The F2T formulary ceases to exist on 1 January 2011.

Form (dosage form)

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

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.

Mandatory brand

Any new brand that must participate in price disclosure arrangements. This includes the trigger brand and any subsequent mandatory brands.

Manner of administration

The route by which the drug enters the body. The following are examples of different manners of administration:

- Oral
- Rectal
- Nasal
- Injection
- Intracranial
- Intrauterine
- Buccal
- Application to the eye
- Application to the ear
- Application to the skin (for local effects)
- Inhalation
- Subcutaneous implantation
- Intravesical
- Transdermal

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.

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 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 and recognise and measure revenue for price disclosure purposes should be consistent with the responsible person's financial accounting policies and standards.

Subsequent mandatory brand

Any new brand of a drug that must comply with price disclosure arrangements but is not the trigger brand.

TGA

Therapeutic Goods Administration.

The Department

Department of Health and Ageing.

Therapeutic Group

Therapeutic Group means a group of drugs which have been determined to be interchangeable at the patient level. Medicines in the following groups have been recommended by the Pharmaceutical Benefits Advisory Committee (PBAC) and determined by the Minister to be interchangeable at the patient level: ACE inhibitors, angiotensin II receptor antagonists, calcium channel blockers, H2 receptor antagonists, proton pump inhibitors and the HMG Coenzyme A reductase inhibitors (pravastatin & simvastatin only).

Trigger brand

The first new brand for a manner of administration for a drug that must comply with price disclosure arrangements.

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 maximum quantity for dispensing in the *Schedule of Pharmaceutical Benefits*.

Voluntary brand

A voluntary brand is one that has volunteered to participate in the price disclosure arrangements

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The Price Disclosure Life Cycle

Initiation

What is price disclosure?

9. Under price disclosure, the price that the Government pays for PBS listed drugs will move closer to the actual price at which those drugs are supplied in the market.
10. In order for this to happen, the Government requires the responsible person to provide information relating to the sales of those PBS listed drugs that are subject to disclosure requirements.
11. This information may be used to determine the price which the Government pays for PBS listed drugs.

Commencement of the price disclosure arrangements

12. The PBS price disclosure arrangements will commence from:
 - 1 August 2007 for drugs on F2A; and
 - 1 January 2011 for drugs on F2 (including all drugs previously on F2A and F2T).

Entity responsible for meeting the price disclosure requirements

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

Entity receiving the information to be disclosed

14. The price disclosure information is to be disclosed to the Department of Health and Ageing.

Mandatory price disclosure requirements

15. Any new brand of drug that lists on the PBS on or after 1 August 2007 will be subject to mandatory price disclosure requirements if it is bioequivalent or biosimilar to an existing brand (unless the drug was listed on the F2T formulary before 1 January 2011).
16. For drugs listed on the F2T formulary before 1 January 2011, any new brand that lists on the PBS on or after 1 January 2011 will be subject to price disclosure requirements if it is bioequivalent or biosimilar to an existing brand.
17. New forms and strengths do not trigger disclosure requirements unless they are considered bioequivalent or biosimilar to an already listed brand.
18. If the responsible person of the new brand (that is subject to the disclosure requirements) also has one or more already listed forms and strengths within the same manner of administration then they must also disclose in relation to each of those already listed forms and strengths. If the responsible person later lists one or more new forms and strengths with the same manner of administration, they must also disclose in relation to each of those forms and strengths.
19. The responsible person does not disclose for forms and strengths that have a different manner of administration to the brand which triggered disclosure.
20. When the first new brand that is bioequivalent or biosimilar to an existing brand of a drug on the combination list or F1 formulary lists on the PBS, the drug will move to the F2 formulary (or F2A prior to 1 January 2011) and the new brand will be subject to mandatory price disclosure requirements.

EXAMPLE - Responsible person triggers mandatory price disclosure

Drug Name: Delphy
Brand name: Zeus®
Responsible person: Dionysius Pty Ltd

The responsible person Dionysius Pty Ltd intends to list the drug Delphy under the brand name “Zeus®” and it follows standard procedures for listing on the PBS. Dionysius Pty Ltd already has the Tablet 40 mg and a cream listed on the PBS.

The existing listings for the drug Delphy are as follows:

Name of Drug	Form and Strength	Manner of Administration	Brand Name	Responsible Person
Delphy	Tablet 25mg	Oral	Iris [®]	Hera Pty Ltd
			Ares [®]	Olympia Pty Ltd
Delphy	Tablet 40mg	Oral	Zeus [®]	Dionysius Pty Ltd
			Iris [®]	Hera Pty Ltd
			Ares [®]	Olympia Pty Ltd
Delphy	Cream 1mg/gm, 30gm	Topical	Zeus [®]	Dionysius Pty Ltd

Dionysius Pty Ltd is now seeking to list Zeus[®] as a Tablet 25 mg.

Before listing the TGA determined that Zeus[®] is bioequivalent to an existing brand listed on the PBS.

Dionysius Pty Ltd lists Zeus[®] Tablet 25 mg on the PBS on 01 August 2007. Listing of Zeus[®] triggers mandatory price disclosure, as Zeus[®] is bioequivalent to the other listed brands of the Tablet 25 mg.

The listing of Zeus[®] Tablet 25 mg also triggers disclosure for all oral forms and strengths of Zeus[®] with the same manner of administration.

The Department informs Dionysius Pty Ltd of all forms and strengths of Zeus[®] with the same manner of administration for which disclosure is mandatory:

Zeus[®] Tablet 25 mg; and

Zeus[®] Tablet 40 mg.

The cream with a different manner of administration will not be subject to disclosure.

Treatment of the combination items for purposes of the price disclosure

21. Single brand combination items on the combination list will not be subject to price disclosure requirements. They will, however, be subject to price reductions brought about by price disclosure in any of their component drugs.
22. Combination items will move to the F2 formulary (or F2A before 1 January 2011) upon listing of a new brand of the combination item. The same price disclosure rules will then apply to the combination item as all other drugs in the formulary. Price disclosure price reductions in component drugs do not flow on to combination items not on the combination list.

Exemptions to the price disclosure arrangement

23. Some PBS listed items are exempt from the price disclosure arrangements and flow on effects. The full list of these exempt PBS items is set out in Legislative Instruments and is available on the website <http://www.health.gov.au/pbs>.

Voluntary price disclosure

Entity that can voluntarily choose to be subject to the price disclosure requirements

24. Once a new brand has triggered disclosure, any responsible person of any form or strength of that drug that has the same manner of administration as the new brand may voluntarily choose to be subject to the price disclosure requirements.
25. When a new brand has triggered price disclosure, the Department will formally notify the responsible persons of other brands (of the same manner of administration) inviting them to voluntarily submit to the price disclosure requirements.
26. This invitation will be issued at the time of the public release of the version of the *Schedule of Pharmaceutical Benefits* that contains the listing which triggers disclosure.

EXAMPLE – Other responsible persons who may voluntarily submit to price disclosure arrangements

Before listing, the Department identifies (through its databases) all other brands of Delphy with the same manner of administration as Zeus[®].

Based on that information, the Department then invites all other responsible persons (**Hera Pty Ltd** and **Olympia Pty Ltd**) to voluntarily submit to disclosure for Delphy with an oral administration.

Voluntary price disclosure requirements

27. The invitation to volunteer to disclose price information remains open and responsible persons may choose to accept it at any time. Responsible persons must officially accept the invitation by completing a “*Notification of Voluntary Participation in the Pharmaceutical Benefits Scheme Price Disclosure Arrangements Form*” (which will contain information similar to that required in the example form at Annex C) and by submitting it to the Department.

-
28. Responsible persons must notify the Department within seven days of their election to volunteer to disclose. If this notification is not received within seven days, the election to volunteer will be taken to have never been made.
 29. If a responsible person volunteers to submit price disclosure information for a drug then they must do so for all forms and strengths of that drug which have the same manner of administration for which they are the responsible person.
 30. Voluntary disclosure is an 'opt-in' process, however, once responsible persons have decided to disclose voluntarily they become bound by the price disclosure arrangements and cannot later 'opt-out' of the arrangements.

EXAMPLE – Hera Pty Ltd chooses to voluntarily submit to the price disclosure arrangements

Page 1 of the Notification of Voluntary Participation in the Pharmaceutical Benefits Scheme Price Disclosure Arrangements Form

THE PRICE DISCLOSURE LIFE CYCLE

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Australian Government
Department of Health and Ageing

Notification of Voluntary Participation in the Pharmaceutical Benefits Scheme Price Disclosure Arrangements

Voluntary price disclosure is an 'opt-in' process; however once you have decided to disclose voluntarily you will be bound by the price disclosure arrangements and cannot later 'opt-out' of the arrangements.

Please note that disclosure becomes mandatory once you have volunteered to join the price disclosure arrangements.

1. Responsible Person's Details

1.1 Responsible Person:

2. PBS Item

2.1. Drug Name:

2.2. Manner of Administration:

Please note that the Price Disclosure Arrangements will apply to all forms and strengths of the drug with the same manner of administration.

Brand name	Form of Manufacture	Strength	Pack size	Manufacturer's Code
Iris®	Tablet	25mg	25 tablets	ZI
Iris®	Tablet	40mg	20 tablets	ZI

COMMERCIAL IN CONFIDENCE

3. Responsible Person's Declaration

3.1. I,
(1) (Name of person signing) Mr. Boss
(2) (Title of person signing) CEO

declare:

- (i) that I am authorised by the Responsible Person named in this disclosure to make this declaration on its behalf;
- (ii) that the Responsible Person hereby consents to voluntarily disclose the prices of the PBS Drug referred to in this notification in accordance with the provisions of the Pharmaceutical Benefits Scheme (PBS) Price Disclosure Arrangements;
- (iii) that the Responsible Person has read the PBS Price Disclosure Arrangements and agrees to be bound by them;
- (iv) that the Responsible Person understands that its disclosure obligations in relation to the PBS Drug referred to in this notification are continuous and ongoing and that it cannot at any time opt –out of the Price Disclosure Arrangements.

I confirm that the Responsible Person will start collecting price data from the beginning of the next month and will submit this data in accordance with the PBS Price Disclosure Business Rules and the applicable legislation.

Signed by: _____

Date: _____

Collection

Information to be collected and submitted

31. For each brand which is subject to price disclosure the responsible person is required to disclose information about sales revenue and volume of sales.
32. This is required:
 - For all brands of all items of that drug supplied by that responsible person which have the same manner of administration as the brand that triggered disclosure.
 - To be submitted separately for each brand and each form and strength.
33. This information will be used to calculate the weighted average disclosed price.

EXAMPLE - *Data that Dionysius Ltd Pty will be disclosing to the Department*

Based on the information received from the Department, Dionysius Pty Ltd has to disclose price information for 2 drugs:

1. **Zeus[®] Tablet 25 mg; and**
2. **Zeus[®] Tablet 40 mg.**

Dionysius Pty Ltd starts collecting monthly information from the day of listing (i.e. 01 August 2007) 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 two sets of data to the Department for each Zeus[®] 25 mg and Zeus[®] 40 mg:

- a. 3 monthly PBS item specific data; and
- b. Annual incentives data.

Brand specific information that responsible persons need to collect on a monthly basis


34. The responsible persons will need to **collect monthly** and **submit 3 monthly (except for the initial period which may include more or less than three months data)** the following brand specific information:
 - a. The sales revenue;
 - b. The volume sold in units of brand; and
 - c. The pack size that applies to each form and strength of the drug as supplied to pharmacists and wholesalers (where a responsible person has more than one pack size for a form and strength of a brand of a drug, they must report on each pack size separately).
35. All monetary amounts should be expressed in Australian dollars and be exclusive of GST. The sales revenue disclosed in the monthly data should reflect the prices charged according to invoices or order forms. Any further discounts, charge backs and incentives provided separately can be reported in the annual submission.
36. The methods used by the responsible person to define sales and recognise and measure revenue for price disclosure purposes should be consistent with the responsible person's financial accounting policies.
37. Responsible persons must begin collecting monthly data:
 - a. For trigger brands, from the date that the brand is listed on the PBS;
 - b. For subsequent mandatory brands, from the date of listing on the PBS (the first month of data will not be used in any calculations); and
 - c. For voluntary disclosure brands, from the first day of the month following agreement to voluntarily disclose.
38. In the first collection period the responsible person may be required to collect and submit more or less than three months of data (a maximum of three months of data will be used in the calculation).
39. Thereafter the responsible person is required to collect and submit three months of data each collection period.
40. All data is required to be submitted within 2 calendar months from the day after the end of the collection period.

EXAMPLE – Responsible person (Dionysius Pty Ltd) collects monthly data

Dionysius Pty Ltd will fill out and later on submit the “**Monthly Data Form**” as follows:

Page 1 of the Dionysius Pty Ltd’s Monthly Data form

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Australian Government
Department of Health and Ageing

Monthly Data Form

1. Responsible Person’s Details

1.1 Responsible Person:

2. PBS Item

2.1. Manufacturer’s Code:

2.2. Drug Name:

2.3. Brand Name:

2.4. Strength:

2.5. Form of Manufacture:

2.6. Manner of Administration:

3. Monthly Data

3.1 Collection Period: 3.2 Period: of

3.3 Date to be submitted by:

3.4 Please provide monthly data in the below table:

	August 2007	Sept 2007	Oct 2007	Nov 2007
Sales revenue earned	\$ 185,610	\$ 185,764	\$ 185,353	\$ 182,527
Volume in units	7,225	7,231	7,215	7,206

Data should be:

- Expressed in Australian dollars;
- Rounded to the nearest whole dollar; and
- Exclusive of GST.

Page 1 of 2

Page 2 of the Dionysius Pty Ltd's Monthly data Form

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4. Responsible Person's Declaration

4.1. I, _____
(1) (Name of person signing) _____
(2) (Title of person signing) _____

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.

Signed by: CEO Dionysius Pty Ltd

Date: 31 January 2008

5. Contact Details

5.1 Person who completed this form:
5.2 Position:
5.3 Contact Telephone Number:
5.4. Contact E-mail address:

ELECTRONIC DATA

Brand specific and non-brand specific incentives information that responsible persons need to collect

41. In addition the responsible persons will need to **collect and submit annual 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
 - goods in kind
 - grants
 - hospitality
 - in-store merchandising
 - loyalty rebates
 - prompt payment discounts
 - share offers
 - stock replacement programs
 - 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.
42. 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.
43. Responsible persons must begin collecting annual data:
- a. For trigger brands, from the start of the next collection cycle;
 - b. For subsequent mandatory brands, from the start of the month after listing (or if listing before the first data collection cycle for that drug and manner of administration, from the start of the first data collection cycle); and
 - c. For voluntary disclosure brands, from the start of the month after the agreement to disclose (or if the agreement to disclose was made before the start of the first data collection cycle for that drug and manner of administration: from the start of the first data collection cycle).

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44. 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.
 45. Any discounts and incentives already incorporated in the monthly data for sales revenue should not be disclosed as part of the annual incentive data (to prevent double counting of discounts and incentives).
 46. 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.
 47. 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.
 48. 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 data collection cycle 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.
 49. All amounts should be expressed in Australian dollars and be exclusive of GST.
 50. 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


51. Data relating to the sales of PBS items to **public** hospitals must be excluded from the data submitted.
52. 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.
53. 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).

EXAMPLE - Responsible person (Dionysius Pty Ltd) collects annual incentive data

Dionysius Pty Ltd will fill out and later on submit the “**Annual Incentives Data Form**” as follows:

Page 1 of the Dionysius Pty Ltd’s Annual Incentive Data form

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Australian Government
Department of Health and Ageing

Annual Incentives Data Form

1. Responsible Person’s Details

1.1 Responsible Person:

2. PBS Item

2.1. Drug Name:

2.2. Brand Name:

2.2. Manufacturer’s Code:

2.3. Manner of Administration:

2.4. Form of Manufacture:

2.5. Strength:

3. Incentive Data

3.1 Collection Period:

3.2. Date to be submitted by:

Brand specific rebates and discounts already disclosed on the monthly data forms are not required to be disclosed again here.

Sale Incentives Provided	Indicate (✓) which incentives are used
bonus stock	
bundling discounts	
cash discounts	✓
charge backs	✓
co-operative advertising	
competitions	
computer hardware and software	
conference attendance	
coupons	
free or reduced price-services	
goods in kind	
grants	
hospitality	
in-store merchandising	
loyalty rebates	✓
prompt payment discounts	
share offers	

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Sale Incentives Provided	Indicate (✓) which incentives are used
stock replacement programs	
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	

Please provide total proportion of costs (in dollars) of brand and non-brand specific incentives relating to the drug specified in this form:

\$1,065,777

Please provide details of the nature of any incentives disclosed above under the categories of

"Any other monetary incentives" N/A
"Any other non- monetary incentives" N/A

Data should be:

- Expressed in Australian dollars;
- Rounded to the nearest whole dollar; and
- Exclusive of GST.

4. Responsible Person's Declaration

4.1. I, _____
 (1) (Name of person signing) _____
 (2) (Title of person signing) _____

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.

Signed by: CEO Dionysius Pty Ltd

Date: 31 October 2008

5. Contact Details

5.1 Person who completed this form:

5.2 Position:

5.3 Contact Telephone Number:

5.4. Contact Email address:

Three data collection cycles

54. There are three collection cycles that all disclosed data must fit into. These cycles have start dates of :
- 1st January;
 - 1st May; and
 - 1st September.
55. Responsible persons that initially trigger a mandatory price disclosure requirement will need to collect monthly data from the date of listing. However, the calculation of the weighted average disclosed price will only use 12 months of data, starting from the commencement date of the first collection cycle occurring after the listing date. That is either the 1st of January, 1st of May or 1st of September.
56. The data collection cycle that applies to a new brand that initially triggered disclosure will be the first cycle commencing after the listing date. All brands listing or voluntarily disclosing after price disclosure has already been triggered will fit into the existing collection cycle.
57. Each data collection cycle consists of four quarterly collection periods. The first data collection period always commences on the 1st day of the data collection cycle and may include more than three months data. Subsequent quarters consist of three months of data.

The table below illustrates the first data collection cycle for all listing dates of trigger brands up to 1 August 2008. Data submission dates are also included and discussed further below.

Table – Data collection cycles

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

Commencement of data collection after disclosure has been triggered

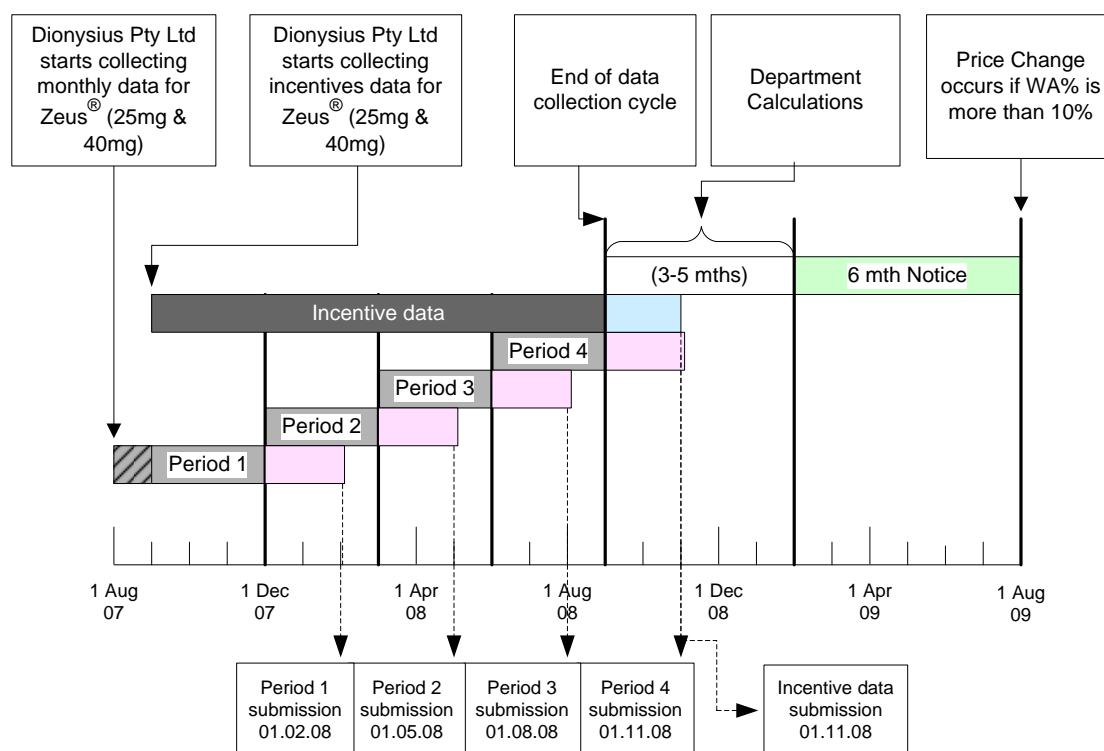
58. New brands that voluntarily disclose after the start of the first data collection cycle must collect monthly and annual data from the 1st day of the month following the date they agreed to voluntarily disclose. Brands that voluntarily disclose before the start of the first data collection cycle begin collecting monthly data from the 1st day of the month following the date they agreed to voluntarily disclose and annual data on the first day of the first data collection cycle.
59. New brands of PBS items that are already subject to disclosure must collect monthly data from the date of listing. Only data (both monthly and annual) from the first month after the date of listing will be used in a calculation of a weighted average disclosed price.






Submission

Timeframe for submission of the information

60. Responsible persons are required to submit monthly information within two calendar months from the day after the end of the collection period.
61. As data collection must commence on the date of listing, the initial submission for the brand that initially triggered disclosure will always consist of more than three months of data. All data collected has to be submitted; however the Department will not use more than 12 months of data in the calculation of the weighted average disclosed price.
62. When a new or existing brand joins an existing collection cycle, the initial submission of data for that brand may cover a period of less than three months.
63. All annual incentive data must be submitted within two calendar months from the day after the end of the annual incentive data collection cycle. The initial submission of annual incentive data may cover a period of less than 12 months for brands that did not initially trigger disclosure.

EXAMPLE – Timeframes for collection and submission of the required information for Dionysius Pty Ltd



-  = Any data collected prior to the commencement of the first data collection cycle will not be used in calculations" Note: this may cover more than 1 month
-  = Each period (1 to 4) represents the collection period of monthly data
-  = Represents the submission period (2 calendar months) for monthly data to be submitted to the Department
-  = Represents the submission period (2 calendar months) for incentives data to be submitted to the Department
-  = required 6 month notice period before the price change

Timeframes regarding voluntary disclosure

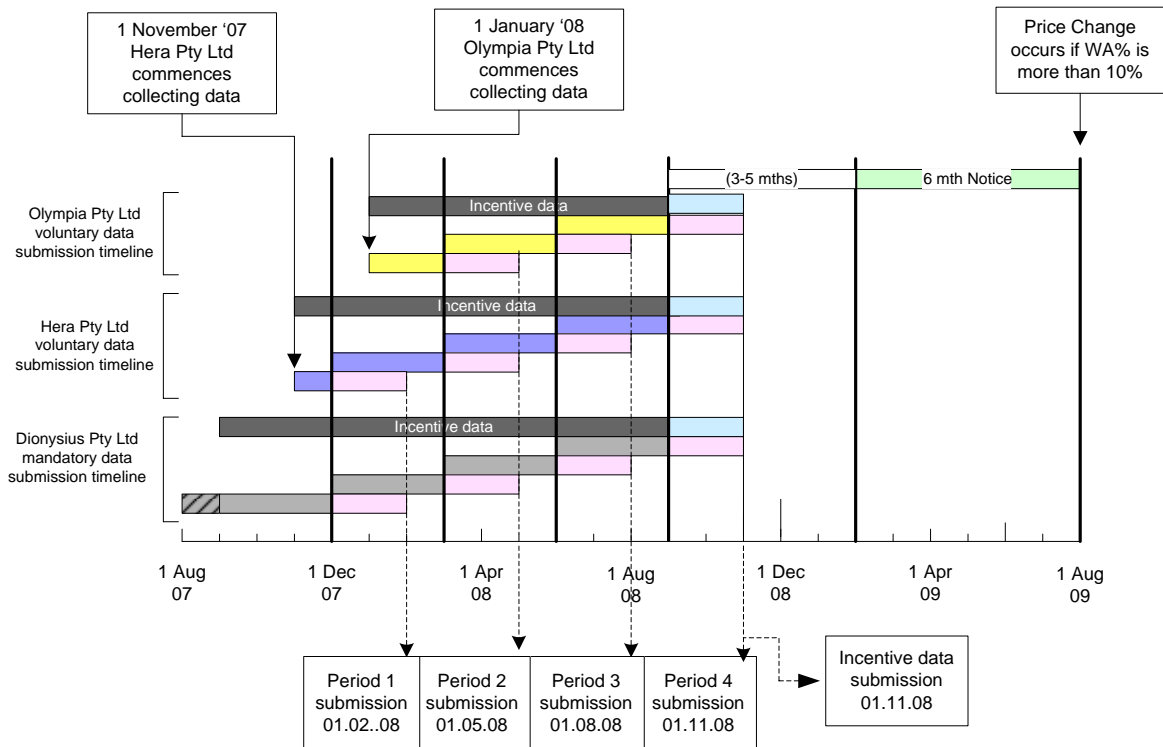
64. Once responsible persons have volunteered to join the price disclosure requirements they will be required to collect the information from the beginning of the month following the date they volunteer.
65. The submitted data will fit into the collection cycle that has already been established when mandatory disclosure was triggered for the manner of administration for that drug.
66. This may mean that less than 12 months of data for that brand is included in the initial calculation of the weighted average disclosed price.

EXAMPLE – Timeframes for collection and submission of the required information for Hera Pty Ltd, Olympia Pty Ltd and Dionysius Pty Ltd

Hera Pty Ltd volunteers to disclose price information for IRIS® on 21 October 2007 and it will need to start collecting data from 1 November 2007.

Olympia Pty Ltd volunteers to disclose price information on 5 December 2007 and will need to start collecting data from 1 January 2008

THE PRICE DISCLOSURE LIFE CYCLE



- = Any data collected prior to the commencement of the first data collection cycle will not be used in calculations* Note: this may cover more than 1 month
- = Each period (1 to 4) represents the collection period of monthly data
- = Represents the submission period (2 calendar months) for monthly data to be submitted to the Department
- = Represents the submission period (2 calendar months) for incentives data to be submitted to the Department
- = required 6 month notice period before the price change

Certification requirements

When a responsible person submits the price disclosure information to the Department, the Chief Executive Officer (or his or her authorised delegate) is required to certify to the Department in accordance with the certification procedures, that ***I have caused reasonable reviews of the information to be done. To the best of my knowledge and belief, the information is true, complete and accurate***, as of the date it is submitted and in accordance with the business rules.

EXAMPLE – CEO of Dionysius Pty Ltd signing Responsible person’s Declaration

4. Responsible Person’s Declaration

4.1. I,

(1) (Name of person signing) _____

(2) (Title of person signing) _____

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.

Signed by: CEO Dionysius Pty Ltd _____

Date: 31 October 2008 _____

Calculation

The entity responsible for calculations

67. 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

68. Responsible persons are responsible for performing two types of calculations:
 - Calculations relating to collection and submission of monthly data; and
 - Calculations relating to collection and apportioning of cost of any brand and non-brand specific incentives relating to the brand for which disclosure has been triggered.
69. Calculations may also be required to remove information relating to sales to public hospitals from the data sets.
70. 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.
71. 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

72. 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 collection and apportioning of cost of any brand and non-brand specific incentives relating to the brand.

73. Responsible persons are responsible for the collection and calculations relating to apportioning of cost of any brand and non-brand specific incentives to the brand, using their own methodologies.

The following example demonstrates how a responsible person may wish to apportion non-brand specific incentives across two products.

EXAMPLE - Annual Incentive Data for Zeus® (as submitted by Dionysius Pty Ltd)

Sale Incentives Provided	Total Cost of Incentives relating to the Sale of products (\$)	Total Sales Revenue (across all products) (\$)	I ₂₅
bonus stock	nil	nil	-
bundling discounts	nil	nil	-
cash discounts	500,000	10,000,000	112,252
charge backs	500,000	8,500,000	132,062
co-operative advertising	nil	nil	-
competitions	nil	nil	-
computer hardware and software	nil	nil	-
conference attendance	nil	nil	-
coupons	nil	nil	-
free or reduced price-services	nil	nil	-
goods in kind	nil	nil	-
grants	nil	nil	-
hospitality	nil	nil	-
in-store merchandising	nil	nil	-
loyalty rebates	150,000	4,500,000	74,835
prompt payment discounts	nil	nil	-
share offers	nil	nil	-
stock replacement programs	nil	nil	-
up-front payments	nil	nil	-
volume discounts	250,000	6,000,000	93,544
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	653,084	2,245,049	653,084
any other monetary incentives	nil	nil	-
the monetary value of any other in kind incentives	nil	nil	-

E.g. For loyalty rebates:

$$\frac{TC_{loyalty\ rebates}}{TR_{loyalty\ rebates}} \times S_{Z25} = I_{z25\ loyalty\ rebates} \quad \frac{150,000}{4,500,000} \times 2,245,049 = 74,835$$

S_{Z25} = Sales Revenue for Zeus 25 mg tablet, I_{Z25} = Incentives for Zeus 25mg tablet, TC= Total Cost of incentives for all products to which the incentives relate; TR= Total Sales Revenue of all products to which the incentives relate.

In this example, the same calculations are carried out for volume discounts, cash discounts and charge backs.

EXAMPLE – Calculating a Total Incentive Amount for Zeus® 25 and Zeus® 40

$$I_{z25 \text{ loyalty rebates}} + I_{Z25 \text{ volumediscunts}} + I_{Z25 \text{ cashdiscunts}} + I_{Z25 \text{ charg ebacks}} + I_{Z25 \text{ brandspecificrebates}} = I_{Z25}$$

$$I_{Z25} = 1,065,777$$

$$I_{Z40} = 1,294,121$$

Department's calculations

Overview of the calculation of the price change

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

The disclosed information will firstly be used to calculate a weighted average price (WAP) for each form and strength of the drug with the same manner of administration. These WAPs will then be compared to the approved ex-manufacturer price for each form and strength of the drug. For each form and strength, the percentage difference between the WAP and the approved ex-manufacturer price will be calculated.

The weighted average percentage difference for the manner of administration of the drug (WA %) will then be calculated. The weighting for each form and strength of the drug will be based on its annual PBS prescription volume. This weighting will be applied to each form and strength's weighted average percentage (WA %) to calculate an overall weighted average percentage for the manner of administration of the drug. This will determine whether the approved ex-manufacturer price of each form and strength changes.

If the overall WA % **for the manner of administration of the drug** is 10% or more, then all the approved ex-manufacturer prices for all brands of that drug with the same manner of administration will change. Each approved ex-manufacturer price will decrease by WA%.

-
74. Once all disclosure information in relation to a strength or form of a brand has been received from a responsible person, the Department will perform steps one to five as specified below:

Step 1

The Department will define the group for disclosure calculations.

75. This includes all items for which price has been disclosed (on both a voluntary or mandatory basis) within a particular manner of administration of the drug.

Step 2

Calculate the net revenue for each brand within the group

From the information provided by each responsible person, the Department will calculate the net revenue from each brand (R_{brand}) by taking the 12 month Sales Revenue (S_{brand}) and subtracting the the 12 month Incentive values (I_{brand}).

$$R_{\text{brand}} = S_{\text{brand}} - I_{\text{brand}}$$

S_{brand} is totalled from the responsible person's quarterly data submissions for the whole collection cycle.

I_{brand} is taken from the responsible person's annual data submission for the whole collection cycle.

76. The Department will calculate the net revenue for each brand within the group by using the disclosed monthly data to:
- Sum all of the monthly sales revenue earned for the brand to give a 12 month sales revenue figure for the brand (R_{Brand}) (note that any data collected prior to the commencement of the first data collection cycle and any data relating to the first month after listing for mandatory brands will not be used in any calculations).

EXAMPLE – Calculation of a 12 month sales revenue figure

Tablet Zeus 25mg		
	Sales Revenue Earned (\$)	Volume Sold
August	185,610	7,225
September	185,764	7,231
October	185,353	7,215
November	182,527	7,206
December	180,037	7,578
January	182,399	7,100
February	182,630	7,109
March	185,122	7,105
April	196,606	7,653
May	197,736	7,697
June	194,679	7,008
July	186,175	7,247
August	186,021	7,241
TOTAL	2,245,049	87,390

First month of data is excluded from the calculation data

$S_{Z25} = 2,245,049$

THE PRICE DISCLOSURE LIFE CYCLE

- b. Sum all the monthly volumes sold of the brand to give a 12 month volume figure for the brand (V_{Brand}). The Department will then convert the volumes so that pack sizes are equivalent to the maximum quantity for dispensing in the *Schedule of Pharmaceutical Benefits*.

EXAMPLE- Calculation of 12 monthly volumes sold for Zeus[®] 25 mg

Tablet Zeus [®] 25mg		
	Gross Sales Revenue Earned (\$)	Volume Sold
August	185,764	7,231
September	185,764	7,231
October	185,353	7,215
November	182,527	7,206
December	180,037	7,578
January	182,399	7,100
February	182,630	7,109
March	185,122	7,105
April	196,606	7,653
May	197,736	7,697
June	194,679	7,008
July	186,175	7,247
August	186,021	7,241
TOTAL	2,245,049	87,390

Volume of Zeus[®] sold per month

$V_{Z25} = 87,390$

- c. The Department will have the disclosed 12 month incentive data figure for each brand as provided by responsible persons in their annual incentive forms (I_{Brand}).

EXAMPLE - Annual Incentive Data for Zeus[®] 25 mg (as submitted by Dionysius Pty Ltd)

Sale Incentives Provided	Indicate (✓) which incentives are used
bonus stock	
bundling discounts	
cash discounts	✓
charge backs	✓
co-operative advertising	
competitions	
computer hardware and software	
conference attendance	
coupons	
free or reduced price-services	
goods in kind	
grants	
hospitality	
in-store merchandising	
loyalty rebates	✓
prompt payment discounts	
share offers	
stock replacement programs	
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	

Indicates which incentives Dionysius Pty Ltd use

Please provide total proportion of costs (in dollars) of brand and non-brand specific incentives relating to the drug specified in this form:

$I_{225} = \$ 1,065,777$

\$ 1,065,777

77. The same steps will be repeated for **all brands** within the group which have disclosed.
78. The Department will then calculate a 12 monthly net revenue figure (R_{Brand}) for each disclosed brand as follows:

$$R_{\text{Brand}} = S_{\text{Brand}} - I_{\text{Brand}}$$

EXAMPLE – Calculating 12 monthly net revenue figure for Zeus® 25

$$R_{Z25} = S_{Z25} - I_{Z25}$$

$$R_{Z25} = 2,245,049 - 1,065,777$$

$$R_{Z25} = 1,179,272$$

79. The same steps will be repeated for all brands which have disclosed and for all forms and strengths with the same manner of administration which have disclosed.

EXAMPLE- Calculating 12 monthly net revenue figure for Zeus® 40

$$R_{Z40} = S_{Z40} - I_{Z40}$$

$$R_{Z40} = 3,495,907$$

EXAMPLE – Data collected and calculated from all Responsible Persons disclosing price information

Data Collected and Calculated from all Responsible Persons						
Manufacturer	Brand Name	Mandatory Disclosure OR Voluntary	Strength	Form	R ₂₅	V ₂₅
Dionysius Pty Ltd	Zeus®	Mandatory	25 mg	Tablet	1,179,272	87,390
Hera Pty Ltd	Iris®	Voluntary		Tablet	869,542	67,284
Olympia Pty Ltd	Ares®	Voluntary		Tablet	764,158	45,326
Manufacturer	Brand Name	Mandatory Disclosure OR Voluntary	Strength	Form	R ₄₀	V ₄₀
Dionysius Pty Ltd	Zeus®	Mandatory	40 mg	Tablet	3,495,907	184,632
Hera Pty Ltd	Iris®	Voluntary		Tablet	1,683,471	107,736
Olympia Pty Ltd	Ares®	Voluntary		Tablet	1,931,543	87,632

Step 3

Calculation of the weighted average price for each form and strength

80. The Department will calculate the weighted average price for each form and strength by using the following formula:

$$\text{Weighted Average Price (WAP)} = \sum \frac{R_A + R_B + R_C + \dots R_N}{V_A + V_B + V_C + \dots V_N}$$

81. Where R_B , R_C and R_N are the net revenues for each of the brands that have disclosed at the same form and strength and V_B , V_C and V_N are the volumes supplied for each of the brands by the responsible person.
82. This calculation is performed for each individual form and strength of the same manner of administration. In some cases this will result in a range of weighted average prices for the drug.

EXAMPLE – Weighted average price calculation for the PBS item

$$WAP_{25mg} = \sum \frac{R_{Z25} + R_{I25} + R_{A25}}{V_{Z25} + V_{I25} + V_{A25}}$$

$$WAP_{25mg} = \sum \frac{1,179,272 + 869,542 + 764,158}{87,390 + 67,284 + 45,326}$$

$$WAP_{25mg} = \$14.06$$

Using the same methodology as above, the WAP for 40mg can also be calculated. WAP shown below

$$WAP_{40mg} = \$18.71$$

Step 4

Calculation of the percentage difference for each form and strength

83. The weighted average price for each form and strength will then be compared to the approved ex-manufacturer price (**B1**) for that form and strength to calculate a percentage difference (**P1**).
84. The approved ex-manufacturer price minus the weighted average price will be divided by the approved ex-manufacturer price to calculate the percentage difference (**P1**) in price for each form and strength.

$$P_1 = \frac{B_1 - WAP_1}{B_1}$$

EXAMPLE - Calculating the percentage change of Zeus[®] 25mg and 40mg

Approved ex-manufacturer price for 25mg = \$22.95
 Approved ex-manufacturer price for 40mg = \$28.35

$$P_{25mg} = \frac{B_{25mg} - WAP_{25mg}}{B_{25mg}}$$

$$P_{25mg} = \frac{22.95 - 14.06}{22.95} = 38.74\%$$

$$P_{25mg} = 38.74\% \quad P_{40mg} = 34.00\%$$

Step 5**Calculation of the weighted average percentage price difference for the group**

85. The Department will then use data supplied by Medicare Australia relating to PBS prescription volumes, for each form and strength of the drug which has disclosed, to calculate the weighted average percentage price difference for the drug.
86. The Medicare Australia data will be adjusted so that one pack is equivalent in size to the maximum quantity for dispensing of that PBS item within the *Schedule of Pharmaceutical Benefits*.

EXAMPLE – PBS prescription volumes and Approved Ex-Manufacturer Price for Zeus[®] 25mg and 40mg

PBS prescription volume for 25 mg = 295,000 (Q25)
 PBS prescription volume for 40 mg = 465,000 (Q40)

Approved Ex-manufacturer Price for 25 mg = \$22.95
 Approved Ex-manufacturer Price for 40 mg = \$28.35

87. The percentage difference that may be applied across all forms and strengths is then calculated using the sum of each disclosed form and strength's percentage difference in price multiplied by its PBS prescription volume and approved ex-manufacturer price and then divided by the sum of each disclosed form and strength's PBS prescription volume multiplied by approved ex-manufacturer price using the following formula:

Average Weighted Percentage difference (WA %) =

$$\sum \frac{(P_1 \cdot Q_1 \cdot B_1) + (P_2 \cdot Q_2 \cdot B_2) + \dots + (P_n \cdot Q_n \cdot B_n)}{(Q_1 \cdot B_1) + (Q_2 \cdot B_2) + \dots + (Q_n \cdot B_n)}$$

The percentage change will be rounded to two decimal places (e.g. 15.6472% will be rounded to 15.65%).

EXAMPLE - Weighted average Percentage difference for all strengths and forms of PBS Item

$$WA\%_{all} = \sum \frac{(P_1 \cdot Q_1 \cdot B_1) + (P_2 \cdot Q_2 \cdot B_2) + \dots + (P_n \cdot Q_n \cdot B_n)}{(Q_1 \cdot B_1) + (Q_2 \cdot B_2) + \dots + (Q_n \cdot B_n)}$$

$$WA\%_{all \text{ products}} = \sum \frac{(38.7\% \times 295,000 \times \$22.95) + (34.0\% \times 465,000 \times \$28.35)}{(295,000 \times \$22.95) + (465,000 \times \$28.35)} = 35.61\%$$

The percentage difference WA% is 35.61 %.

How will the weighted average percentage difference affect the approved ex-manufacturer price

88. If the weighted average percentage difference is 10% or more, the approved ex manufacturer price of each PBS item will be reduced by this weighted average percentage difference above to give a Weighted Average Disclosed Price. This will become the new approved ex-manufacturer price.
89. However if the weighted average percentage difference is less than 10% then there will not be any price change and the approved ex-manufacturer price will remain the same.
90. Any changes to the approved ex-manufacturer price will flow through to the Approved Price to Pharmacists according to the parameters in the Fourth Community Pharmacy Agreement or its successor.

EXAMPLE- Price change effect on Delphy oral products

	25mg TABLET	40mg TABLET
Approved Ex-manufacturer Price	\$22.95	\$28.35
Reduction of 35.61%	\$(8.17)	\$(10.10)
New Approved Ex-manufacturer Price	\$14.78	\$18.25

THE PRICE DISCLOSURE LIFE CYCLE

Minimum data required for the Department to be able to calculate a weighted average disclosed price

91. 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.
92. Non-compliance by a responsible person will not prohibit the Department from proceeding with the calculation providing that the minimum data requirement stated above has been met.
93. 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.

Changes to Price as a Result of Disclosure

Notification of the change in price

94. The Department will formally notify industry of a price change six months before a price change will occur.
95. Whether a price change occurs or not, all responsible persons of that drug with the same manner of administration will be formally notified of the outcome.

When will price changes take place?

96. The price change will occur at one of two dates:
 - 1 April; or
 - 1 August.
97. The change will occur at the first price change point after the expiration of the six month notice period (but not before 1 August 2009 for drugs on F2A or, 1 August 2012 for drugs on F2T before 1 January 2011).

Drugs that will be affected by the change in price

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

EXAMPLE - Calculation for Delphy including different forms and strengths for the same manner of administration

If Delphy also had a 25mg LIQUID and a 40mg CAPSULE the following flow of calculations would have occurred:

Manner of Administration - ORAL
Forms of the Drug - 25mg Tablet 40 mg Tablet
 25mg Liquid 40 mg Capsule

Approved ex-manufacturer Price

25mg Tablet \$ 22.95 40 mg Tablet \$ 28.35
 25mg Liquid \$ 38.14 40 mg Capsule \$ 31.57

Percentage difference in price for each form and strength (P)

25mg Tablet 38.74% 40 mg Tablet 34.00%
 25mg Liquid 16.21% 40 mg Capsule 29.30%

PBS Volume Sale (Q)

25mg Tablet 295,000 40 mg Tablet 465,000
 25mg Liquid 59,000 40 mg Capsule 139,500

$$WA\%_{all\ products} = \frac{(P_{25T} \cdot Q_{25T} \cdot B_{25T}) + (P_{25L} \cdot Q_{25L} \cdot B_{25L}) + (P_{40T} \cdot Q_{40T} \cdot B_{40T}) + (P_{40C} \cdot Q_{40C} \cdot B_{40C})}{(Q_{25T} \cdot B_{25T}) + (Q_{25L} \cdot B_{25L}) + (Q_{40T} \cdot B_{40T}) + (Q_{40C} \cdot B_{40C})}$$

$$WA\%_{all\ products} = \frac{(38.74\% \times 295,000 \times \$22.95) + (16.21\% \times 59,000 \times \$38.14) + (34.00\% \times 465,000 \times \$28.35) + (29.30\% \times 139,500 \times \$31.57)}{(295,000 \times \$22.95) + (59,000 \times \$38.14) + (465,000 \times \$28.35) + (139,500 \times \$31.57)}$$

$$WA\%_{all\ products} = 32.92\%$$

Price change for different Forms and Strengths

	25mg TABLET	25mg LIQUID	40mg TABLET	40mg CAPSULE
Approved Ex-Manufacturer Price	\$22.95	\$38.14	\$28.35	\$31.57
Reduction of 32.92%	\$(7.56)	\$(12.56)	\$(9.33)	\$(10.39)
New Approved Ex-Manufacturer Price	\$15.39	\$25.58	\$19.02	\$21.18

* However, if Delphy also had a cream, the cream would not be affected by the price change due to the cream being a different form of administration (not oral). Only Delphy products administered orally are subject to the price change.

Price disclosure and Therapeutic Groups

99. There will be no price flow-ons (that result from disclosure) to other drugs within a Therapeutic Group. The drug that has been subject to price reductions as a result of price disclosure will be removed from the Therapeutic Group.

Price disclosure and mandatory 2% price reductions

100. For PBS items on F2A:
 - Those items which have been subject to a price reduction due to price disclosure will not be subject to any remaining 2 % price reductions;
 - In the event of a 2% mandatory 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 collection cycle.

Price disclosure and other price reductions

101. 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 collection cycle.

Circumstances when a price change will not occur

102. There will be no change to the approved ex-manufacturer price if the weighted average percentage difference calculated is less than 10%.
103. If the weighted average percentage change price 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.

3

Compliance Guidelines

A compliance culture

104. It is expected that responsible persons will operate within an organisational framework and culture which supports compliance.
105. They should practise good corporate governance and have appropriate systems in place.
106. Their financial records are expected to be maintained in accordance with applicable Australian Accounting Standards.
107. 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.
108. Serious penalties apply for non compliance with price disclosure requirements. Responsible persons should develop a working knowledge of how the price disclosure process works. Responsible persons will need to make themselves aware of their obligations under the price disclosure arrangements and how these affect their record keeping and reporting requirements.
109. 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.
110. 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.

111. 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

112. 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;
 - The responsible person submitted all required data, however, it was late.
113. 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;
 - any action which the Department now intends to take and the timeframes for that action.
114. 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 14 calendar days.
115. If a responsible person knows prior to the due date that it will be unable to comply, then the responsible person should notify the Department 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.
116. 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

117. 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
 - 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.
118. 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 price disclosure 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.

4

Security Arrangements for Commercial-in-Confidence Material

Confidentiality of the responsible person's disclosed price information

119. The Department considers all information submitted by responsible persons to be commercial-in-confidence, and recognises the responsible person's expectation that commercial-in-confidence information will be protected from inadvertent, unintended or improper disclosure.
120. 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.

5

Related Information

Where to go for other related information

- Regulations and Determinations are available online from the Federal Register of Legislative Instruments – www.frli.gov.au
- The *National Health Act 1953* is available at www.comlaw.gov.au
- www.health.gov.au
- www.health.gov.au/pbsreform
- www.pbs.gov.au
- Training manuals and other information will be available.

6

Appendices

Appendix A Monthly Data Form

Appendix B Annual Incentive Data Form

Appendix C Voluntary Submission Form

Appendix A

Monthly Data Form



Australian Government
Department of Health and Ageing

Monthly Data Form

1. Responsible Person's Details

1.1 Responsible Person:

2. PBS Item

2.1. Manufacturer's Code:

2.2. Drug Name:

2.3. Brand Name:

2.4. Strength:

2.5. Form of Manufacture:

2.6. Manner of Administration:

3. Monthly Data

3.1 Collection Period: 3.2 Period: of

3.3 Date to be submitted by:

3.4 Please provide monthly data in the below table:

	Month/Year	Month/Year	Month/Year	Month/Year
Sales revenue earned				
Volume in units				

Data should be:

- Expressed in Australian dollars;
- Rounded to the nearest whole dollar; and
- Exclusive of GST.

COMMERCIAL IN CONFIDENCE

4. Responsible Person's Declaration

- 4.1. I, _____
(1) (Name of person signing) _____
(2) (Title of person signing) _____

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.

Signed by: _____

Date: _____

5. Contact Details

- 5.1 Person who completed this form:
- 5.2 Position:
- 5.3 Contact Telephone Number:
- 5.4. Contact E-mail address:



Appendix B

Annual Incentive Data Form



Australian Government
Department of Health and Ageing

Annual Incentives Data Form

1. Responsible Person's Details

1.1 Responsible Person:

2. PBS Item

2.1. Drug Name:

2.2. Brand Name:

2.2. Manufacturer's Code:

2.3. Manner of Administration:

2.4. Form of Manufacture:

2.5. Strength:

3. Incentive Data

3.1 Collection Period:

3.2. Date to be submitted by:

Brand specific rebates and discounts already disclosed on the monthly data forms are not required to be disclosed again here.

Sale Incentives Provided	Indicate (✓) which incentives are used
bonus stock	
bundling discounts	
cash discounts	
charge backs	
co-operative advertising	
competitions	
computer hardware and software	
conference attendance	
coupons	
free or reduced price-services	
goods in kind	
grants	
hospitality	
in-store merchandising	
loyalty rebates	
prompt payment discounts	
share offers	

COMMERCIAL IN CONFIDENCE

Sale Incentives Provided	Indicate (✓) which incentives are used
stock replacement programs	
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	

Please provide total proportion of costs (in dollars) of brand and non-brand specific incentives relating to the drug specified in this form:

Please provide details of the nature of any incentives disclosed above under the categories of

“Any other monetary incentives”
“Any other non- monetary incentives”

Data should be:

- Expressed in Australian dollars;
- Rounded to the nearest whole dollar; and
- Exclusive of GST.

4. Responsible Person’s Declaration

4.1. I, (1) (Name of person signing) _____
(2) (Title of person signing) _____

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.

Signed by: _____

Date: _____

5. Contact Details

5.1 Person who completed this form:

5.2 Position:

5.3 Contact Telephone Number:

5.4. Contact Email address:

Appendix C

Voluntary Submission Form



Australian Government
Department of Health and Ageing

**Notification of Voluntary
Participation in the
Pharmaceutical Benefits
Scheme Price Disclosure Arrangements**

Voluntary price disclosure is an 'opt-in' process; however once you have decided to disclose voluntarily you will be bound by the price disclosure arrangements and cannot later 'opt-out' of the arrangements.

Please note that disclosure becomes mandatory once you have volunteered to join the price disclosure arrangements.

1. Responsible Person's Details

1.1 Responsible Person:

2. PBS Item

2.1. Drug Name:

2.2. Manner of Administration:

Please note that the Price Disclosure Arrangements will apply to all forms and strengths of the drug with the same manner of administration.

Brand name	Form of Manufacture	Strength	Pack size	Manufacturer's Code

COMMERCIAL IN CONFIDENCE

3. Responsible Person's Declaration

3.1. I, (1) (Name of person signing) _____
(2) (Title of person signing) _____

declare:

- (i) that I am authorised by the Responsible Person named in this disclosure to make this declaration on its behalf;
- (ii) that the Responsible Person hereby consents to voluntarily disclose the prices of the PBS Drug referred to in this notification in accordance with the provisions of the Pharmaceutical Benefits Scheme (PBS) Price Disclosure Arrangements;
- (iii) that the Responsible Person has read the PBS Price Disclosure Arrangements and agrees to be bound by them;
- (iv) that the Responsible Person understands that its disclosure obligations in relation to the PBS Drug referred to in this notification are continuous and ongoing and that it cannot at any time opt –out of the Price Disclosure Arrangements.

I confirm that the Responsible Person will start collecting price data from the beginning of the next month and will submit this data in accordance with the PBS Price Disclosure Business Rules and the applicable legislation.

Signed by: _____

Date: _____