



Australian Government
Department of Health and Ageing

Pharmaceutical Benefits Scheme Price Disclosure

Business Rules

July 2007

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Part I Preliminary

1 Purpose

The purpose of these rules is to provide details about 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.

The PBS Price Disclosure arrangements will commence on 1 August 2007.

2 Name of rules

These rules are the *PBS Price Disclosure Business Rules* (“*Business Rules*”).

3 Intended audience

These Business Rules are intended for use by:

- All relevant stakeholders including responsible persons for products supplied under the PBS and products listing on or intending to list on the PBS (generally pharmaceutical manufacturers); and
- The Department of Health and Ageing.

4 What is covered in this document?

This document covers:

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

5 Relevant legislation, policies and documents

Legislation governing these Business Rules is the *National Health Act 1953* and *National Health (Pharmaceutical Benefits) Regulations* (as amended).

Detailed procedures for price disclosure are published in the PBS Price Disclosure Procedural and Operational Guidelines document.

6 Definitions

Terms used in the Business Rules 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 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 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 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 manufacturer.

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.

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.

Collection period

Each data collection cycle consists of three 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.

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.

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.

7 Commencement

These rules commence on 1 August 2007.

Part II Price Disclosure Requirements

1 What is price disclosure?

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.

In order for this to happen, the Government requires responsible persons to provide information relating to the sales of those PBS listed drugs which are subject to the disclosure requirements.

This information may be used to determine the price which the Government pays for PBS listed drugs.

2 From what date does the price disclosure requirement take effect?

Price disclosure commences on:

- 1 August 2007 for drugs on F2A; and
- 1 January 2011 for drugs on F2 (including all drugs previously on F2A and F2T).

3 What triggers a mandatory price disclosure requirement?

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).

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.

New forms and strengths do not trigger disclosure requirements unless they are considered bioequivalent to an already listed brand.

If the responsible person of the new brand (that has triggered 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.

The responsible person does not disclose for forms and strengths that have a different manner of administration to the brand which triggered disclosure. 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.

4 How are combination items treated for price disclosure?

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.

Combination items will move to the F2 formulary (or F2A before 1 January 2011) upon listing of a new brand of the combination item that is bioequivalent or biosimilar to an existing brand. 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.

5 When and what information must be collected and submitted?

For each brand which is subject to price disclosure the responsible person is required to disclose monetary and non monetary information. This is required for all brands of all items of that drug with the same manner of administration and must be disclosed separately for each brand and each form and strength. This information will be used to calculate the weighted average disclosed price.

Brand specific information that responsible persons need to collect and submit

Responsible persons will need to **collect monthly** and **submit 3 monthly (except for the initial period which may include more or less than 3 months of data)** the following brand specific information:

- the sales revenue;
- the volume sold in units of brand; and
- the pack size that applies to the form and strength of the drug as supplied to pharmacists and wholesalers.

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.

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.

Responsible persons must begin collecting monthly data from the date of listing for mandatory brands and from the beginning of the month following the election to volunteer to disclose for voluntary brands. 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). Thereafter the responsible person is required to collect and submit three months of data each collection period. All data is required to be submitted within two calendar months from the day after the end of the collection period.

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

Responsible persons will also 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
- any other non-monetary incentives.

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.

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).

Responsible persons are not required to disclose data for all the incentives that they provide – only those which relate fully or in part to a brand which they are disclosing price information for.

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.

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 product for the reporting timeframe 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.

All amounts should be expressed in Australian dollars and be exclusive of GST.

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.

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)
- 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)

6 What sales are to be included?

Sales of PBS items to **public** hospitals must be **excluded** from the data submitted.

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 to the Department upon request.

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).

7 How does the responsible person submit the data?

Responsible persons are required to submit their data using the detailed templates provided by the Department. These, together with details of how to complete and submit them, will be sent to the responsible person by the Department.

8 What is the timeframe for submission of the information?

Responsible persons are required to submit **monthly data** within two calendar months from the day after the end of the collection period.

Responsible persons are required to submit **incentive data** within two calendar months from the day after the end of the annual incentive data collection cycle.

9 What are the three data collection cycles and when are they?

To comply with the price disclosure requirements, responsible persons will need to start collecting **monthly data** from the date of listing.

There are three annual collection cycles that all disclosed data must fit into. These cycles have start dates of:

- 1 September;
- 1 January; and
- 1 May.

All collection requirements are set to fit into one of three collection cycles. Each drug will fit into one of these three cycles. The new brand which triggers the price disclosure requirement will determine which cycle the drug fits into.

The collection cycle for **incentives data** will be 12 months for all cycles (i.e. the initial cycle and subsequent cycles). These cycles will have start dates of:

- 1 September;
- 1 January; and
- 1 May.

As monthly data should start being collected from the date of listing this may mean that the initial period exceeds 12 months. All data collected has to be submitted; however the Department will only use 12 months of data for each brand, disclosed, in the calculation of the weighted average disclosed price.

New brands following price disclosure

New brands of PBS items, where an existing brand is already subject to price disclosure requirements, will enter the existing collection cycle from the date of listing. These brands must collect monthly data from the date of listing and submit by the same dates as the brand that triggered disclosure. These brands must collect annual data from the month after listing and submit by the same dates as the brand that triggered disclosure.

10 What entity is responsible for meeting the disclosure requirements?

The responsible person is the entity that is subject to the disclosure requirements. Responsible person is a legal term and does not necessarily refer to an individual in many cases it will be a corporate entity such as a company.

11 What are the 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.*** The person signing the certification must also confirm that they are authorised to do so.

12 To whom is the information to be disclosed?

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

13 How will confidentiality be maintained over the responsible person's disclosed price information?

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.

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; and
- is generally available to the public.

To maintain confidentiality over the responsible person's disclosed price information, the Department will not make publicly available any information received from the responsible persons as a result of the disclosure. The Department will not divulge the result of the weighted average disclosed price calculations if those calculations do not result in a change to the approved ex-manufacturer price.

Part III Voluntary Price Disclosure

1 Who may voluntarily choose to be subject to the price disclosure requirements?

Once a new brand has triggered disclosure, any responsible person for 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.

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.

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.

2 What are the requirements regarding voluntary price disclosure?

The invitation to volunteer to disclose pricing information remains open and responsible persons may choose to accept it at any time. Responsible persons must officially accept the invitation by completing the *Notification of Voluntary Participation in the Pharmaceutical Benefits Scheme Price Disclosure Arrangements* form and by submitting it to the Department.

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.

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.

Disclosure becomes mandatory once responsible persons have volunteered to join the price disclosure arrangements.

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.

3 What are the timeframes regarding voluntary disclosure?

Once responsible persons have volunteered to join the price disclosure requirements they will be required to collect the information from the beginning of the following month from the date when they agreed to volunteer and they will fit into the collection cycle that has already been established when mandatory disclosure was triggered for that drug. For example, if they volunteered on 21 October 2007, they will start collecting data from the 1 November 2007.

This may mean that less than 12 months of their data is included in the initial calculation of the weighted average disclosed price.

Part IV Use of price disclosure information

1 How will the Department use the information?

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. This will then be used to determine whether a change to the approved ex-manufacturer price should occur.

Overview of the calculation

The disclosed information will firstly be used to calculate a weighted average price (WAP) for each form and strength of the drug. 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 drug (WA %) will then be calculated. Each form and strength of the drug will be weighted according to its PBS prescription volume and approved ex-manufacturer price. This weighting will be applied to each form and strength's weighted average percentage (WA %) to calculate an overall weighted average percentage for the drug. This will determine whether the approved ex-manufacturer price of each form and strength changes.

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

2 How will the Department calculate the weighted average disclosed price, weighted average percentage and price changes?

Once all disclosure information in relation to a strength or form of a brand (for purposes of these Business Rules it will be referred to as Brand A of drug Z) has been received from a responsible person, the Department will first:

Use the disclosed monthly data to:

- a) Add all of the monthly sales revenue earned for brand A to give a 12 month sales revenue figure for brand A (**S_A**).
- b) Add all the monthly volumes sold of brand A to give a 12 month volume figure for brand A (**V_A**). The volume will then be adjusted so that pack sizes are equivalent to the maximum quantity for dispensing in the *Schedule of Pharmaceutical Benefits*.

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

The Department will then calculate a 12 monthly net revenue figure (**R_A**) for brand A as follows:

$$R_A = S_A - I_A$$

Where **I_A** is the total incentive amount for brand A for the 12 month period as disclosed on the annual incentive data form.

For example:

For drug Z there may be 5 brands participating in price disclosure. Brands A, B and C which are available in a 20mg tablet and Brands A, D and E which are available in a 40mg tablet and Brands B and D which are available in a syrup.

The Department will calculate:

$$R_{A20}, R_{B20}, R_{C20} \text{ and } R_{A40}, R_{D40}, R_{E40}$$

Calculating the weighted average price

The weighted average disclosed price for the PBS item at a particular strength and form will be calculated using the following formula:

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

Where **R_B**, **R_C** through to **R_N** are the net revenues for each of the brands that have disclosed at the same strength and form.

This calculation is performed for each individual form and strength for all brands of the same manner of administration.

In some cases this will result in a range of weighted average prices (for the purpose of these Business Rules assume that we have calculated a weighted average price for three different strengths 1, 2 and 3- **WAP₁**, **WAP₂** and **WAP₃**).

Calculating the percentage difference

Each weighted average price for the PBS item will then be compared to the approved ex-manufacturer price (**B**) for the PBS item in that particular form and strength to calculate a percentage change.

The approved ex-manufacturer price minus the weighted average price will be divided by the approved ex-manufacturer price to calculate the percentage difference (**P**) in price for each strength and form.

$$\frac{B1 - WAP1}{B1} = P1$$

Calculating overall weighted average percentage difference

The Department will use annual data supplied by Medicare Australia relating to PBS prescription volumes for each strength and form of the drug (**Q**).

In the example, they will obtain volume data of drug Z for the 20mg and 40mg tablets and syrup.

The percentage change that will be applied across all forms and strengths is then calculated using the sum of each form and strength's percentage change in price multiplied by its prescription volume and approved ex-manufacturer price and then divided by the sum of each form and strength's prescription volume multiplied by the 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 (for example 15.6472%, will be rounded to 15.65%).

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

Providing that the weighted average percentage difference calculated is 10% or more, the approved ex-manufacturer price of each form and strength will be reduced by the weighted average percentage difference calculated above to give a Weighted Average Disclosed Price. This will become the new approved ex-manufacturer price.

However if the weighted average percentage calculated is less than 10%, then there will not be any change and the approved ex-manufacturer price will remain the same.

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.

3 How will the Department calculate the approved ex-manufacturer price?

The approved ex-manufacturer price will be calculated from the Approved Price to Pharmacists according to the parameters in the Fourth Community Pharmacy Agreement or its successor.

4 Why does the Department use the Medicare Australia prescription volume data?

The Department will use the Medicare Australia prescription volume data to weight the average percentage calculation. It is recognised that the Medicare Australia data does not capture all PBS dispensing (that is the under co-payment prescriptions). However the Medicare Australia data is the best and the most accurate data available for accessing PBS market share of PBS branded items across all forms and strengths of the same form of administration of a drug.

5 What is the minimum data that is required for the Department to proceed with the calculation?

The minimum data necessary to determine a weighted average disclosed price shall be 12 continuous months data from at least one responsible person in respect of at least one brand of one form/strength of the drug.

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.

Where a responsible person submits some but not all 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.

Part V Changes to pricing as a result of disclosure

1 When will price changes take place?

The price change will occur at one of two dates:

- 1 April; or
- 1 August.

If a price change is to occur, then a six month notice period is required. The change will occur at the first price change point after the expiration of the 6 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).

2 Which drugs will be affected by the change in price?

Any changes in price that result from price disclosure shall 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.

There will be no price flow-ons (that result from disclosure) across Therapeutic Groups. The drug that has been subject to price reductions based on price disclosure will be removed from the Therapeutic Group, and the remainder of the Therapeutic Group will operate as a Therapeutic Group (as before).

Price disclosure and mandatory 2% price reductions

For PBS items on F2A:

- Those items which have been subject to a price reduction from 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 “current” benchmark 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

In the event of price decreases 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.

3 In what circumstances will a price change not occur?

If the percentage difference calculated is less than 10%, there will be no change to the current approved ex-manufacturer price.

If the percentage difference would result in an increase to the current approved ex-manufacturer price, there will be no change to the current approved ex-manufacturer price.

4 Who will be notified of the change in price?

Whether a price change occurs or not, all responsible persons of that drug with the same manner of administration will be notified.

The Department will notify the industry six months before a price change is to occur.

Part VI Other

1 What are the expectations regarding compliance by the responsible persons?

It is expected that responsible persons will operate within an organisational framework and culture which supports compliance.

Responsible persons should practise good corporate governance and have appropriate systems in place to ensure compliance. They should maintain their financial records in accordance with applicable Australian Accounting Standards.

Responsible persons will be expected to develop a working knowledge of how the price disclosure process works. They will need to be aware of what their obligations are under the price disclosure arrangements and how it may affect their record keeping requirements.

They should ensure that appropriate methodologies for extracting and/or estimating data have been developed, are documented and applied in a consistent manner. A detailed audit trail will need to be documented and maintained so that data submitted can be traced to the underlying transactional records.

All documents, methodologies, detailed transactional records and any other documents relating to price disclosure arrangements must be kept for two years for each brand, starting from the end of the annual collection period for that drug.

2 What is considered to be non-compliance?

A responsible person can be considered to be non-compliant with the price disclosure requirements in a number of different ways. 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.

If a responsible person knows prior to the due date that they will be unable to comply, 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.

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.

3 What will be the consequences of non-compliance with disclosure requirements?

There are a range of actions that may be evoked for non-compliance by the responsible persons, including:

- Criminal penalties for:
 - Failure to comply with the price disclosure requirements;
 - Knowingly and/or recklessly providing false or misleading information
- Penalties of up to 60 penalty units for each offence;
- 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.

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 What are the dispute resolution arrangements?

Normal rights of review under administrative law will apply.

5 Are there any exemptions to the price disclosure arrangements?

Some PBS listed products 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 at www.health.gov.au/pbs

