



## 1. What is Price Disclosure?

Price disclosure is a key component of the PBS reforms package, having commenced in August 2007. The price disclosure program progressively reduces the price of some PBS medicines which are subject to competition, ensuring better value for money from these medicines.

Under price disclosure, companies submit sales information to the Department, and, based on this information, the price the Australian Government pays is adjusted to reflect more closely the price at which the medicines are supplied.

In order for this to happen, 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 is used to determine the price which the Government pays for PBS listed drugs.

## 2. What is Expanded and Accelerated Price Disclosure (EAPD)?

Under the EAPD arrangements all non-exempt drugs listed on the F2 Formulary of the PBS will be subject to EAPD. This will mean that all F2 drugs will be treated in the same way and a new brand will no longer be required to trigger price disclosure.

## 3. Who will have to comply with EAPD?

Commencing 1 December 2010, all Responsible Persons with a non exempt drug on F2 will have to comply with the EAPD provisions. Drugs currently subject to price disclosure will continue to disclose under transitional arrangements (see: [Fact Sheet 2: Transitional Cycles](#)).

## 4. When does EAPD commence?

EAPD commences on 1 December 2010. As of this date Responsible Persons are required to collect data in line with EAPD requirements.

## 5. What are the EAPD cycles?

The EAPD cycles consist of:

- *first* Main Disclosure Cycle;
- *subsequent* Main Disclosure Cycles;

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

The *first* Main Disclosure Cycle will be 16 months in total, consisting of:

- a data collection period of 10 months, made up of two reporting periods the first reporting period will be four months with second reporting period being six months in length; and
- a six month processing period

All other EAPD cycles will be no less than eighteen months, allowing for a data collection period of at least 12 months and a six month processing period.

The inclusion of one *Interim Supplementary Disclosure Cycle* will allow new F2 drug listings occurring after 1 December 2010 and before 1 July 2011, to have a disclosure cycle of at least eighteen months. The brand would then move to the next available data collection period in a Main Disclosure Cycle (i.e. commencing in 2012).

The *Supplementary Disclosure Cycles A and B* allow new F2 drug listings occurring after 1 December 2010, where the drug and/or manner of administration or the manner of administration first becomes subject to EAPD requirements, to have a disclosure cycle of at least eighteen months. The brand would then move to the next available data collection period in a Main Disclosure Cycle (see [Fact Sheet 1: Expanded and Accelerated Price Disclosure Cycles](#)).

There will also be three data collection cycles under the price disclosure program in progress prior to 1 December 2010 (still in the data collection phase of the cycle). These cycles will become known as the Transitional Cycles.

## 6. What are Transitional Cycles?

On commencement of EAPD, three of the data collection cycles under the price disclosure program prior to 1 December 2010, will be in progress (still in the data collection phase). For the list of drugs subject to Transitional Cycles see [Fact Sheet 2: Transitional Cycles](#).

Transitional arrangements will apply to allow these three cycles to adopt the new processes and provisions of EAPD (see: [Fact Sheet 2: Transitional Cycles](#)).

### 7. Who is the 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.

### 8. What data must be collected and submitted?

Responsible Persons must collect and submit brand specific data in line with EAPD requirements. Sales revenue, volume and incentive data must be collected for relevant reporting periods and submitted within 6 weeks of the end of a reporting period.

### 9. How does the Responsible Person submit the data?

The Responsible Person must submit EAPD data to the Service Provider electronically (see: Expanded and Accelerated Quick Reference Guide).

### 10. What is the timeframe for the collection and submission of data?

EAPD data collection and submission timeframes for each disclosure cycle are outlined in: Fact Sheet 1: Expanded and Accelerated Price Disclosure Cycles.

All EAPD data (including sales revenue, volume and incentives data) will be required to be submitted, by a Responsible Person, from the day the listed brand becomes subject to EAPD, in six monthly\* reporting periods, within six weeks of the end of each reporting period.

#### NOTE:

A reporting period of less than six months may occur where there is a need to allow for brands new to EAPD or movement from a Supplementary Disclosure Cycle to the Main Disclosure Cycle.

### 11. How will the data be used?

The Service Provider will use the disclosed data relating to a specific drug to calculate a weighted average disclosed price (WADP) for all forms and strengths of that drug that have the same manner of administration. The Department will then use this information to determine whether a price reduction should occur.

### 12. What is the GAP calculation?

The GAP calculation guarantees an overall saving of at least 23% across the medicines involved in the *first* Main Disclosure Cycle of EAPD price reductions.

If the average unadjusted price reduction, in the *first* Main Disclosure Cycle, is less than 23%, the price reductions (which were based on the WADPs) are adjusted accordingly until the average unadjusted price reduction is at least 23%.\*

The GAP-adjusted reductions are then used, in place of the unadjusted price reductions, to reduce the applicable approved ex-manufacturer price of each brand. The result is the adjusted approved ex-manufacturer price.

#### NOTE:

When applying the GAP, no drug will be reduced below the lowest disclosed price.

### 13. Which drugs will be included in the GAP calculation?

All brands in the *first* Main Disclosure Cycle commencing on 1 December 2010 will be included in the GAP (see Fact Sheet 1: Expanded and Accelerated Price Disclosure Cycles). The GAP calculation will only occur in the *first* Main Disclosure Cycle.

### 14. When will price reductions take place?

There will be three scheduled reduction days each year:

- 1 April;
- 1 August; and
- 1 December.\*

#### NOTE:

1 December is an additional reduction day, which did not exist under the previous Price Disclosure arrangements.

### 15. Which drugs will be affected by the price reductions?

Price reductions will occur for all forms and strengths of a drug that have the same manner of administration for which a weighted average percentage difference equal to or greater than 10% has been calculated.

### 16. In what circumstances will a price reduction not occur?

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

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

### 17. Who will be notified of the reductions?

It will no longer be a legal obligation that the Department writes to all Responsible Persons with information in relation to any price disclosure related price reductions.

The Department will make a determination via Legislative Instrument which is published on [ComLaw](#).

### 18. To whom will the data be disclosed? How will confidentiality be maintained?

The EAPD data is to be provided to the service provider.

The Department and the service provider consider all information submitted by Responsible Persons to be commercial-in-confidence, and recognises the Responsible Persons' expectation that commercial-in-confidence information will be protected from inadvertent, unintended or improper disclosure.

In accordance with its legal responsibilities the Department and the service provider will treat all information received from the Responsible Person as confidential and will not disclose that information to any person without the prior consent of the Responsible Person (which consent will not be unreasonably withheld), except where the confidential information:

- is required, or authorised, to be disclosed by law;
- 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.

To maintain confidentiality over the Responsible Person's disclosed price information the Department and the service provider will not make publicly available any information received from the Responsible Persons as a result of the disclosure. The Department and the service provider 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.

#### NOTE:

Sales, volume and incentive data will only be used for the purposes of the Expanded and Accelerated Price Disclosure program.

### 19. How can I receive updates about EAPD

Up-to-date information about the Expanded and Accelerated Price Disclosure arrangements will be made available on the PBS Website [www.pbs.gov.au](http://www.pbs.gov.au).

### 20. What if I have further questions?

If you have any further questions regarding the Expanded and Accelerated Price Disclosure arrangements please email the Department of Health and Ageing at [eapd@health.gov.au](mailto:eapd@health.gov.au) or call the EAPD Inquiry Line on (02) 6289 2303.