



Expanded and Accelerated Price Disclosure Quick Reference Guide

Purpose

This document provides an overview of requirements under the Pharmaceutical Benefits Scheme (PBS) Expanded and Accelerated Price Disclosure (EAPD).

This document can be read in conjunction with the Expanded and Accelerated Price Disclosure Procedural and Operational Guidelines which will be available on the [PBS website](#) by 26 November 2010.

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.

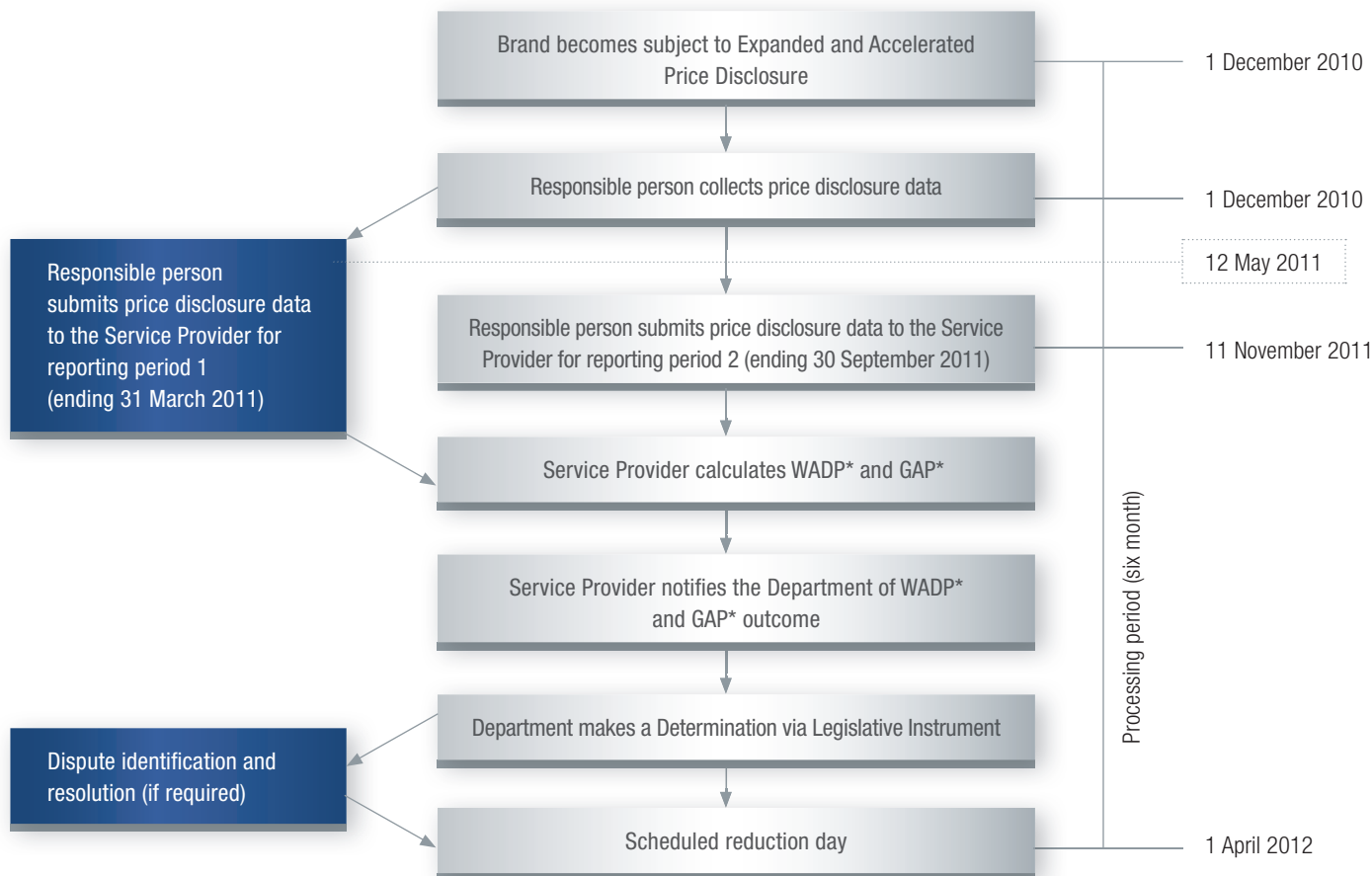
Under price disclosure, companies submit sales information to the department, and, based on this information, the price the Australian Government pays is adjusted to reflect more closely the price at which the medicines are supplied.

What is Expanded and Accelerated Price Disclosure (EAPD)?

EAPD commences on 1 December 2010 and is an extension of the price disclosure program. EAPD will include mandatory disclosure for all sales of non exempt medicines on F2 (see www.pbs.gov.au).

Medicines under price disclosure arrangements prior to 1 December 2010 will continue to disclose under transitional arrangements.

Expanded and Accelerated Price Disclosure process¹ 'First Main Disclosure Cycle'



¹ Based on the first main disclosure cycle commencing 1 December 2010
 * GAP – Guaranteed Adjustment Proportion calculation applies to first main cycle only
 * WADP – Weighted Average Disclosed Price calculation

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Data Collection

What data must be collected?

Responsible persons must collect and submit the following brand specific data in line with EAPD requirements:

- the sales revenue for the brand;
- the volume of the brand sold, based on the number of packs sold;
- the kind of incentives (if any) given for the brand for the reporting period; and
- the value of the incentives given for the brand for the reporting period.

NOTE:

- Sales for Exempt items should be excluded.
- Data relating to sales of PBS items to public hospitals must be excluded from the data submitted. 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)

A list of exempt items is available on the [PBS website](#).

Data collection cycles

The EAPD cycles consist of:

- *first* Main Disclosure Cycle, (this is the only cycle that the Guaranteed Adjustment Proportion calculation will be applied to);
- the Interim Supplementary Disclosure Cycle;
- *Subsequent* Main Disclosure Cycles;
- Supplementary Disclosure Cycles A; and
- Supplementary Disclosure Cycles B.

With the exception of the *first* Main Disclosure Cycle each EAPD cycle will be no less than eighteen months and will consist of:

- a data collection period of at least 12 months; and
- a six month processing period.

For more information see **Fact Sheet 1: Expanded and Accelerated Price Disclosure Cycles**.

Transitional Cycles

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 of the cycle). These cycles will become known as the Transitional Cycles.

For more information see **Fact Sheet 2: Transitional Cycles**.

Data Submission

When to submit data

Data submissions collected for each EAPD cycle must be submitted within six weeks after the end of each of the reporting periods.

How to submit data

The Responsible Person must submit data to the Service Provider. Data submissions will be submitted electronically via direct input or transfer of a data file (Excel or XML) to the Service Provider.

NOTE:

Data submissions must be accompanied by the EAPD Declaration signed by the Responsible Person's Authorised Representative as nominated to the Department.

Managing incorrect data or errors

The Service Provider will process all submissions and send a Submission Confirmation Report to the Responsible Person's Authorised Representative.

The Authorised Representative should check the confirmation report thoroughly to ensure that the information is accurate and complete.

If an error is identified the Responsible Person must resubmit the data for the brand of drug as soon as possible. Once submitted, the Service Provider will repeat the confirmation process.

The accuracy of data submissions provided to the service provider is extremely important, data submissions form the basis for the Weighted Average Disclosed Price (WADP) calculation and for the first main disclosure cycle the Guaranteed Adjustment Proportion calculation. Authorised Representatives are urged to take the necessary steps to ensure data supplied to the service provider is true and correct.

- ² The first main disclosure cycle commencing 1 December 2010 will be 16 months, based on a 10 month data collection period (made up of one 4 month and one six month reporting period) and a six month processing period.
- ³ The Department will be able to provide more information about the Service Provider once the tender process has been completed.
- ⁴ This may involve downloading software provided by the Service Provider. More information will be provided relating to this process as soon as possible.

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Calculation

The Service Provider will use the submitted 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 use this information to determine whether a price reduction will occur.

Possible Outcomes

If the weighted average percentage difference is:

- $\geq 10\%$, the approved ex-manufacturer price of each PBS item will be reduced by the weighted average percentage difference to give a weighted average disclosed price.
- $< 10\%$, there is no price change and the approved ex-manufacturer price remains the same.

NOTE:

- The scheduled reduction days for EAPD are:
 - 1 April;
 - 1 August; and
 - 1 December.
- A price reduction will occur on the first scheduled reduction day after the Department has legally determined (via legislative instrument) the price reductions.

Guaranteed Adjustment Proportion (GAP) Calculation

For the first main disclosure cycle, if the guaranteed average saving of a 23% price reduction across all non exempt F2 drugs that become subject to price disclosure on 1 December 2010 is not achieved via the application of the WADP calculation, then the Guaranteed Adjustment Proportion (GAP) calculation will be applied to all drugs whose weighted average percentage was equal to or greater than 10%.

The GAP will proportionally reduce the price of drugs (with a weighted average percentage equal to or greater than 10%) until an average saving of 23% is achieved across non exempt F2 drugs that become subject to price disclosure on 1 December 2010.

The GAP calculation may need to be performed more than once to achieve the guaranteed average savings of 23%.

If a drug reaches its lowest disclosed price (the disclosed price is the price at which the Responsible Person sells the drug, it is calculated from the sales, volume and incentive data provided by the Responsible Person) it will be reduced to that price, and removed from any further iterations of the GAP calculation.

NOTE:

- The guaranteed 23% price reduction will only apply to the first main price disclosure cycle.
- Drugs whose weighted average percentage is calculated to be less than 10% are not included in the GAP calculation.
- No drug will have its price reduced below the lowest disclosed price.

Compliance

Responsible Persons should be aware that there are penalties for non-compliance with the EAPD requirements. For further information regarding A Compliance Culture see the **Expanded and Accelerated Price Disclosure Procedural and Operational Guidelines**.

Compliance requirements are consistent with Price Disclosure policy prior to 1 December 2010.

Further Reference Material

For more information refer to:

- Expanded and Accelerated Price Disclosure Procedural and Operational Guidelines
- Fact Sheet 1: Expanded and Accelerated Price Disclosure Cycles
- Fact Sheet 2: Expanded and Accelerated Price Disclosure Transitional Cycles
- Pharmaceutical Benefits Scheme (PBS) website: www.pbs.gov.au
- *National Health Act 1953*: www.comlaw.gov.au

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 or call the EAPD Inquiry Line on (02) 6289 2303.

⁵ Expanded and Accelerated Price Disclosure Procedural and Operational Guidelines will be available on www.pbs.gov.au by 26 November 2010.

⁶ As above