



Australian Government

Department of Health and Ageing

EXPANDED AND ACCELERATED PRICE DISCLOSURE

Sydney Workshop
Overview



Australian Government

Department of Health and Ageing

DoHA - EAPD TEAM

- Denise Woodward
- Nicola Stansfield
- Angela Peachey
- John-Paul Kelly
- Mish Patil
- Annette Honeyman
- Ros Jones
- Sandra Wang



Australian Government

Department of Health and Ageing

Service Provider

- Australian Healthcare Associates (AHA) have been selected by the department as the Service Provider for Expanded and Accelerated Price Disclosure
- AHA will be known as the Price Disclosure Data Administrators (PDDA)
- PDDA will be responsible for data collection and price disclosure related calculations.
- PDDA will provide a helpdesk facility to assist RP's with data submissions and cycle information.



Australian Government

Department of Health and Ageing

Price Disclosure Background

- Price disclosure requirements commenced in August 2007 for drugs in Part A of F2. (under Part VII of the *National Health Act 1953*).
- Responsible Persons are required under the Act to disclose information relating to the sales of drugs that are subject to Price Disclosure.
- From 1 December 2010, price disclosure was expanded to apply to all non exempt drugs on F2, and accelerated, removing the need to ‘trigger’ the price disclosure requirements, with a new brand listing.
- F2 drugs and manner of administrations new to Price Disclosure on 1 December 2010 have joined the first Main Cycle.



Australian Government

Department of Health and Ageing

Expanded and Accelerated Price Disclosure (EAPD)

- Drugs and manner of administrations which become subject to Price Disclosure after 1 December 2010 will join either one of the supplementary cycles or a subsequent main cycle, depending on the listing date.
- F2 drugs and manner of administrations already subject to Price Disclosure before 1 December 2010 have joined Transitional Cycles.



Australian Government

Department of Health and Ageing

‘Differences’

PD prior to 1 Dec and EAPD

	PD prior to 1 December	EAPD
Who is subject?	Part A of F2	All F2, non exempt items
Data for collection	• Sales revenue • Volume of sales • Incentives: type and value <i>* Excluding data for Public Hospital sales and exempt items</i>	Remains unchanged
Reporting periods	Quarterly reporting periods	Typically 6 month reporting periods.
Submit data to	Department of Health and Ageing	Price Disclosure Data Administrator
Submission due dates	2 months after the end of the collection period	6 weeks after end of reporting period



Australian Government

Department of Health and Ageing

Expanded and Accelerated Price Disclosure Cycles

The EAPD cycles consist of:

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



Australian Government

Department of Health and Ageing

Transitional Cycles

On 1 December 2010, three of the data collection cycles under the old price disclosure program were in progress (still in the data collection phase of the cycle). These cycles will become known as the Transitional Cycles.

Current Collection Period	Transitional Cycle
1 January – 31 December	1
1 May – 30 April	2
1 September – 31 August	3

Brands in the Transitional Cycles will then flow into the ongoing main cycle at the next available opportunity, with no gap in the data collection periods.



Australian Government

Department of Health and Ageing

Merging into the Main Cycle

Once a brand has completed the data collection period of either one of the *Transitional Cycles* or one of the *supplementary disclosure cycles* it will then merge into the next available main disclosure cycle, with no gap in the data collection periods.



Australian Government

Department of Health and Ageing

Drugs in Transitional Cycle 1

The following Drugs currently disclosing for the data collection period 1 January to 31 December will form part of Transitional Cycle 1.

Drug	Manner of Administration
Alendronic acid	Oral
Ceftriaxone	Injection
Cisplatin	Injection
Fluconazole	Oral
Fluconazole	Injection
Fludarabine	Injection
Levodopa with Carbidopa	Oral
Naltrexone	Oral
Risperidone	Oral
Topiramate	Oral
Vancomycin	Injection



Australian Government

Department of Health and Ageing

Transitional Cycle 1 to Main Cycle 2

Data collection period	Six month processing period	Reduction day
1 Jan 2010 – 30 Sept 2011	1 Oct 2011 – 31 March 2012	1 April 2012

Merge into main cycle

Data collection period	Six month processing period	Reduction day
1 Oct 2011 – 30 Sept 2012	1 Oct 2012 – 31 March 2013	1 April 2013



Australian Government

Department of Health and Ageing

Transitional Cycle 1

Drug = Cisplatin (last reduction Day 1 April 2011)

- Data collection 1 January 2010 to 30 Sept 2011
 - Data Processing 1 Oct 2011 to 31 March 2012
 - Reduction day 1 April 2012
- Move to main cycle two
- Data collection 1 Oct 2011 to 30 Sept 2012
 - Data Processing 1 Oct 2012 to 31 March 2013
 - Reduction Day 1 April 2013



Australian Government

Department of Health and Ageing

Drugs in Transitional Cycle 2

The following Drugs currently disclosing for the data collection period 1 May to 30 April will form part of Transitional Cycle 2.

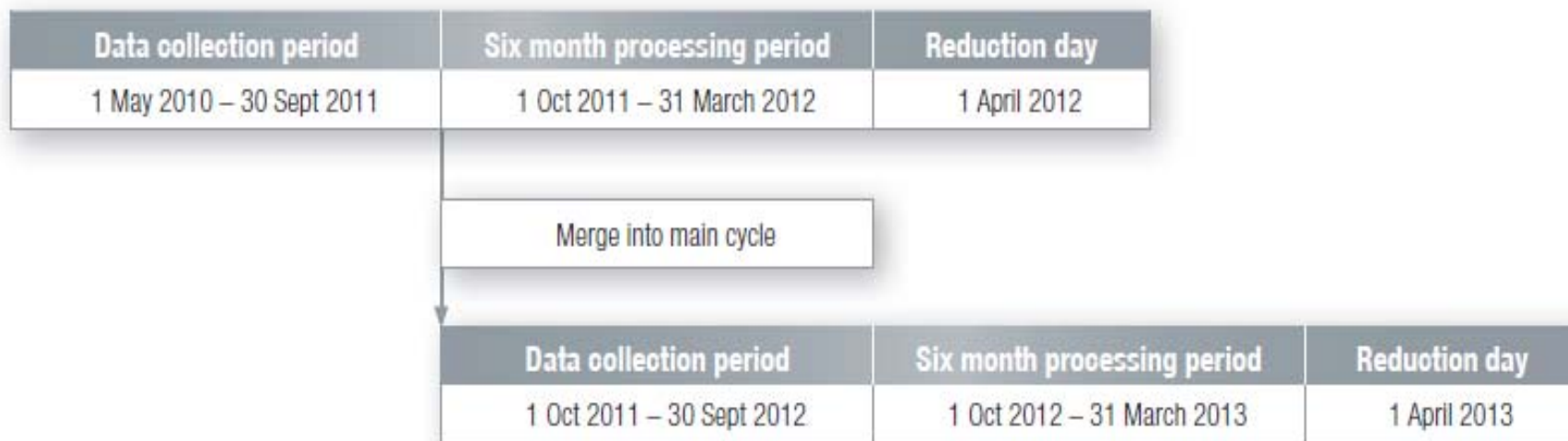
Drug	Manner of Administration
Carvedilol	Oral
Clopidogrel	Oral
Enalapril with hydrochlorothiazide	Oral
Gemcitabine	Injection
Irinotecan	Injection
Memantine	Oral
Paclitaxel	Injection
Sumatriptan	Oral
Vinorelbine	Injection



Australian Government

Department of Health and Ageing

Transitional Cycle 2 to Main Cycle 2





Australian Government

Department of Health and Ageing

Drugs in Transitional Cycle 3

The following Drugs currently disclosing for the data collection period 1 September to 31 August will form part of Transitional Cycle 3.

Drug	Manner of Administration
Alendronic acid with colecalciferol	Oral
Amisulpride	Oral
Azithromycin	Oral
Bicalutamide	Oral
Bisoprolol	Oral
Cabergoline	Oral
Cefalotin	Injection
Doxorubicin	Injection/Intravesical
Escitalopram	Oral
Famciclovir	Oral
Fosinopril with hydrochlorothiazide	Oral
Glucose	Injection
Levetiracetam	Oral

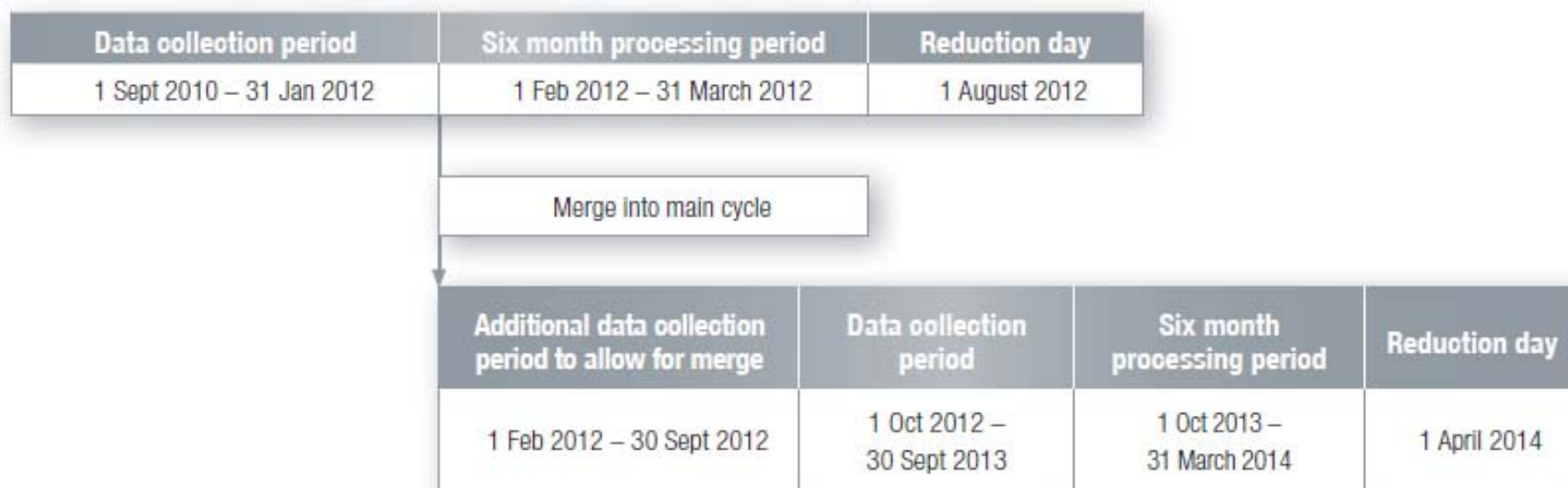
Drug	Manner of Administration
Meloxicam	Oral
Mitozantrone	Injection
Morphine	Oral
Ondansetron	Injection
Ondansetron	Oral
Oxaliplatin	Injection
Oxazepam	Oral
Oxybutynin	Oral
Perindopril with indapamide	Oral
Prochlorperazine	Oral
Sodium Chloride	Injection
Sodium Lactate Compound	Injection
Valproic acid	Oral



Australian Government

Department of Health and Ageing

Transitional Cycle 3 to Main Cycle 3

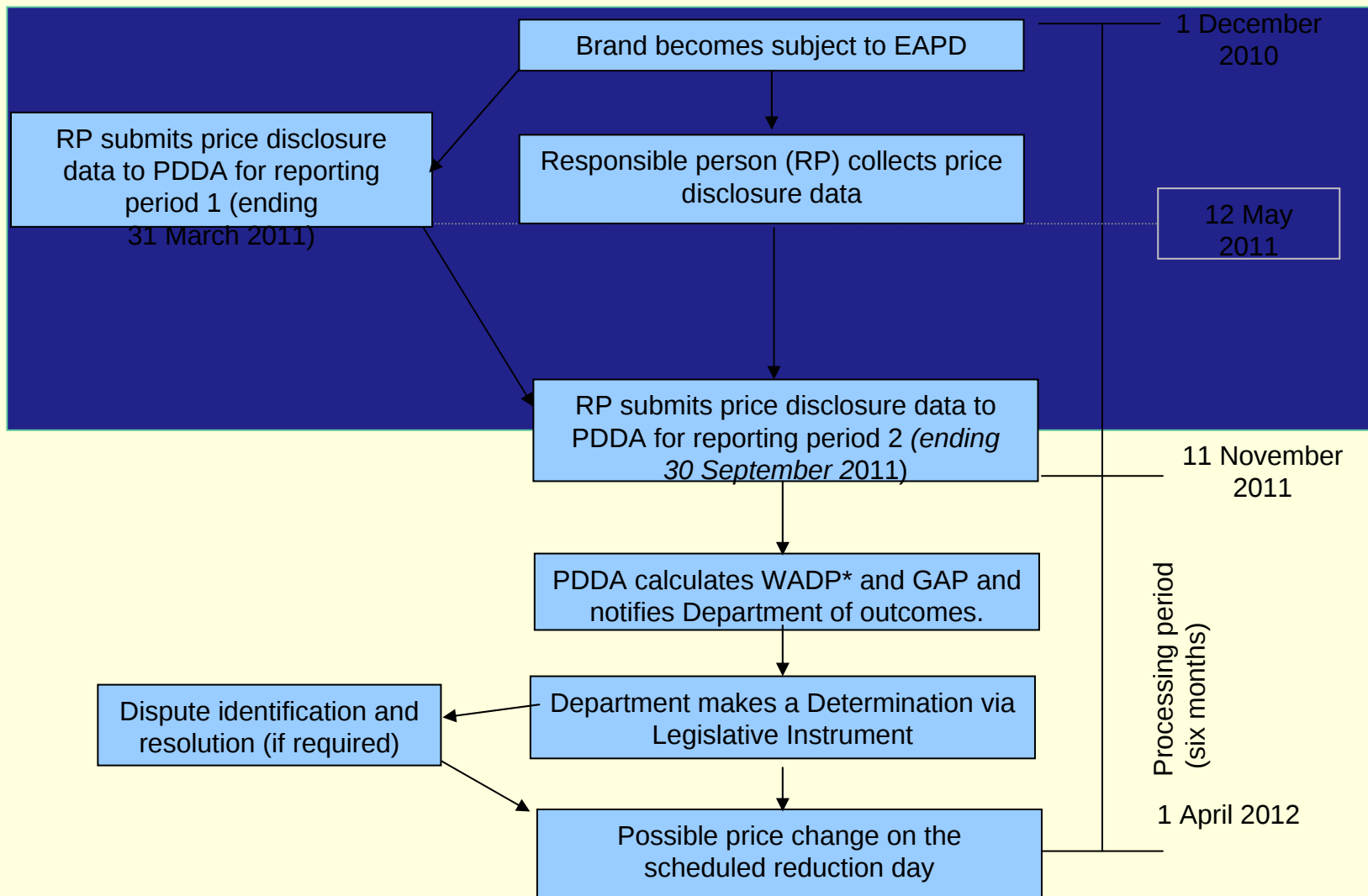




Australian Government

Department of Health and Ageing

Overview - *First Main Disclosure Cycle*





Australian Government

Department of Health and Ageing

Main Disclosure Cycles

Main cycle	Reporting period	Start date	End date	Submission Deadlines	Scheduled reduction day
First	1	1 December 2010	31 March 2011	12 May 2011	1 April 2012
	2	1 April 2011	30 September 2011	11 November 2011	
Subsequent	1	1 October*	31 March	12 May	1 April 2013
	2	1 April	30 September	11 November	

* if a brand lists on 1 July, 1 August or 1 September and is subject to EAPD for the first time it will join the subsequent main cycle proceeding these dates. Data collection for this brand will commence the date it becomes subject to EAPD.



Australian Government

Department of Health and Ageing

Interim Supplementary Disclosure Cycle

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

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



Australian Government

Department of Health and Ageing

Interim Supplementary Cycle

Drug A

- Data collection 1 January 2011 to 30 May 2012
 - Data Processing 1 June 2012 to 30 Nov 2012
 - Reduction day 1 December 2012
- Move to main cycle three
- Data collection 1 June 2012 to 30 Sept 2013
 - Data Processing 1 Oct 2012 to 31 March 2014
 - Reduction Day 1 April 2014



Australian Government

Department of Health and Ageing

Six Month Processing Period

Reduction Day



Data
Submission

- (6 Weeks)

Calculation and
Determination

- (5 Weeks)

Dispute Resolution

- (8 Weeks)

Data Transfer

- (6 Weeks min)



Australian Government

Department of Health and Ageing

Data for Submissions

Responsible persons must collect and submit the following brand specific data:

- 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.



Australian Government

Department of Health and Ageing

Data for Submissions

All sales revenue, volumes and incentives for all non exempt Medicines that contain an F2 Drug with a form, MOA and brand as determined under the Act – regardless of the possible dispensing circumstances.

- All pack sizes must be reported.
- Include Section 100 items.
- Exclude all public hospital sales.



Australian Government

Department of Health and Ageing

Data Submissions

- Data submissions are required 6 weeks after the end of a reporting period.
- Data is to be aggregated for the length of the reporting period.
- If you are reporting data of a new brand (for the first time), the first month of data should be reported separately.



Australian Government

Department of Health and Ageing

Data Submission by Month

Sales Revenue \$	Volume	Incentive Amount \$	Incentive Type	Pack size	Month
25 000	1000	1000	Rebate	20	Dec
30 000	1200	0		20	Jan
27 500	1125	1500	Rebate	20	Feb
15 000	750	1500	Rebate	20	March
30 000	1250	1200	Rebate	40	Dec
12 500	800	1000	Rebate	40	Jan
15 000	700	0		40	Feb
17 500	850	0		40	March



Australian Government

Department of Health and Ageing

Aggregated Data

Sales Revenue \$	Volume	Incentive Amount \$	Incentive Type	Pack Size	Dec-Mar
97 500	3 750	4 000	Rebate	20	Dec-Mar
75 000	3 600	2 200	Rebate	40	Dec-Mar



Australian Government

Department of Health and Ageing

Aggregated Data

New brand

Sales Revenue \$	Volume	Incentive Amount \$	Incentive Type	Pack Size	Dec-Mar
25 000	1 000	1 000	Rebate	20	Dec
72 500	2 750	3 000	Rebate	20	Jan - March
30 000	1 250	1 200	Rebate	40	Dec
45 000	2 350	1 000	Rebate	40	Jan - March



Australian Government

Department of Health and Ageing

Weighted Average Disclosed Price (WADP) Calculation

- PDDA will use the data submission for each brand of a specific drug to calculate a WADP for all brands of that drug that have the same manner of administration.
- The Department will use this information to determine whether a price reduction will occur.



Australian Government

Department of Health and Ageing

Guaranteed Adjustment Proportion (GAP) Calculation

- A guaranteed 23% price reduction which will only apply to the *first* Main Disclosure Cycle.
- If the Average Unadjusted Price Reduction is less than 23%, the GAP calculation generates new unadjusted price reductions through an iterative process that forces the unadjusted price reductions towards 23%.
- Drugs whose unadjusted price reduction is calculated to be less than 10% will not be effected by the GAP calculation.
- As part of the GAP calculation no brand will have its price reduced below the lowest disclosed price for the item.



Australian Government

Department of Health and Ageing

Possible Outcomes

If the unadjusted price reduction is:

$\geq 10\%$, the approved ex-manufacturer price is reduced to the weighted average disclosed price (or the GAP-adjusted ex-manufacturer price, if applicable)

$< 10\%$, the approved ex-manufacturer price remains the same



Australian Government

Department of Health and Ageing

Scheduled Reduction Days

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



Australian Government

Department of Health and Ageing

Non compliance

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

These include the following:

- The Responsible Person did not submit any data when required to do so;
- The Responsible Person submitted partial and/or incomplete data;
- The Responsible Person submitted inaccurate data; and
- The Responsible Person submitted all required data, however, it was late.



Australian Government

Department of Health and Ageing

Penalties for non compliance

There are a range of actions that may be evoked for non compliance by the responsible persons.

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.



Australian Government

Department of Health and Ageing

Quality Outcomes

The Department is taking appropriate measures to ensure the accuracy and reliability of the EAPD process. The Department is implementing the following processes:

- Data collection and price disclosure WADP and GAP calculations are to be performed by PDDA
- The systems developed by PDDA for the WADP and GAP calculation to undergo quality assurance checks by a third party, Pitcher Partners.
- Individual WADP and GAP calculations to undergo quality assurance checks by Pitcher Partners.
- Data submissions to undergo reasonableness checks and trend analysis by PDDA.



Australian Government

Department of Health and Ageing

Quality of Data

The accuracy of the WADP and GAP calculations are reliant on the accuracy of data submissions, Responsible Person data submissions must be accompanied by a declaration from the Responsible Person's Authorised Representative.

Confirmation reports of data submissions will continue to be provided to Responsible Persons.

Responsible Persons should check that the data in the confirmation report is consistent with the data provided in their submission, this is the data that will be used in the WADP and GAP calculations.



Australian Government

Department of Health and Ageing

National Health Act and Regulations

- More information is available on the PBS website www.pbs.gov.au
- Regulations at www.comlaw.gov.au
- If you have any further questions regarding EAPD:
 - email the Department of Health and Ageing eapd@health.gov.au
 - call the EAPD Enquiry Line (02) 6289 2303



Australian Government

Department of Health and Ageing

Legislative Instrument - Determination

The department will make a determination via legislative instrument of the ‘new’

ex - manufacturer price based on WADP and GAP (if applicable) calculations.

- The department will alert RP's that the determination has been made via www.pbs.gov.au
- The determination can be view via www.comlaw.gov.au
- The department will post a copy of the determination on www.pbs.gov.au



Australian Government

Department of Health and Ageing

Q & A