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EXPANDED AND ACCELERATED PRICE DISCLOSURE

Overview of procedural and operational
requirements for Responsible Persons



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Introduction

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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 will be expanded to apply to all drugs non exempt drugs on F2.
- From 1 December 2010, price disclosure will also be accelerated, removing the need to ‘trigger’ the price disclosure requirements, with a new brand listing.



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Expanded and Accelerated Price Disclosure (EAPD)

- All non exempt Drugs on the F2 of the PBS are subject to Price Disclosure as of 1 December 2010.
- F2 drugs and manner of administrations new to Price Disclosure on 1 December 2010 will join the Main Cycle.
- 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 will join Transitional Cycles.



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Differences between PD prior to 1 Dec and EAPD

	PD prior to 1 December	EAPD
Who is subject?	Part A of F2	All F2
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	Service Provider
Submission due dates	2 months after the end of the collection period	6 weeks after end of reporting period



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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.



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Brands which were subject to Price Disclosure before 1 December 2010

On the commencement date of EAPD, three of the current Price Disclosure data collection cycles will be in progress:

- 1 January – 31 December
- 1 May – 30 April
- 1 September – 31 August



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Transitional Cycles

On 1 December 2010, three of the data collection cycles under the current price disclosure program will be 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.



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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



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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



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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

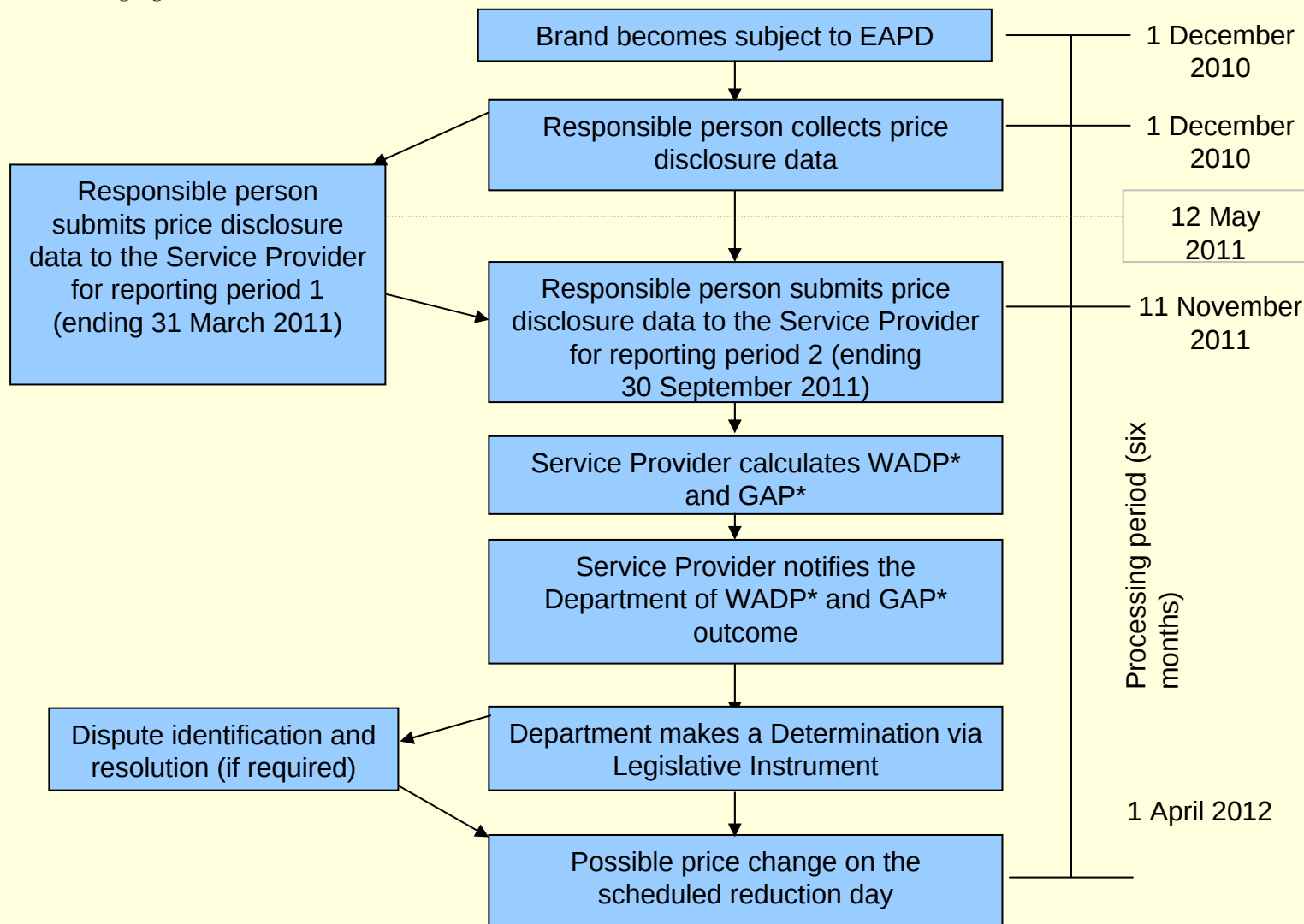
Drug	Manner of Administration
Meloxicam	Oral
Mitozantrone	Injection
Morphine	Oral
Ondansetron	Injection
Ondansetron	Oral
Oxaliplatin	Injection
Oxazepam	Oral
Oxybutynin	Oral
Perindopril with indapamide	Oral
Prochlorperazine	Oral
Sodium Chloride	Injection
Sodium Lactate Compound	Injection
Valproic acid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



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EAPD – First Main Disclosure Cycle





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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.



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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).



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Supplementary Disclosure Cycles A

Reporting period	Start date	End date	Submission Deadlines	Scheduled reduction day
1	1 November – 1 February*	31 March	12 May	1 August
2	1 April	30 September	11 November	
3	1 October	31 January	14 March	

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



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Supplementary Disclosure Cycles B

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

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



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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.



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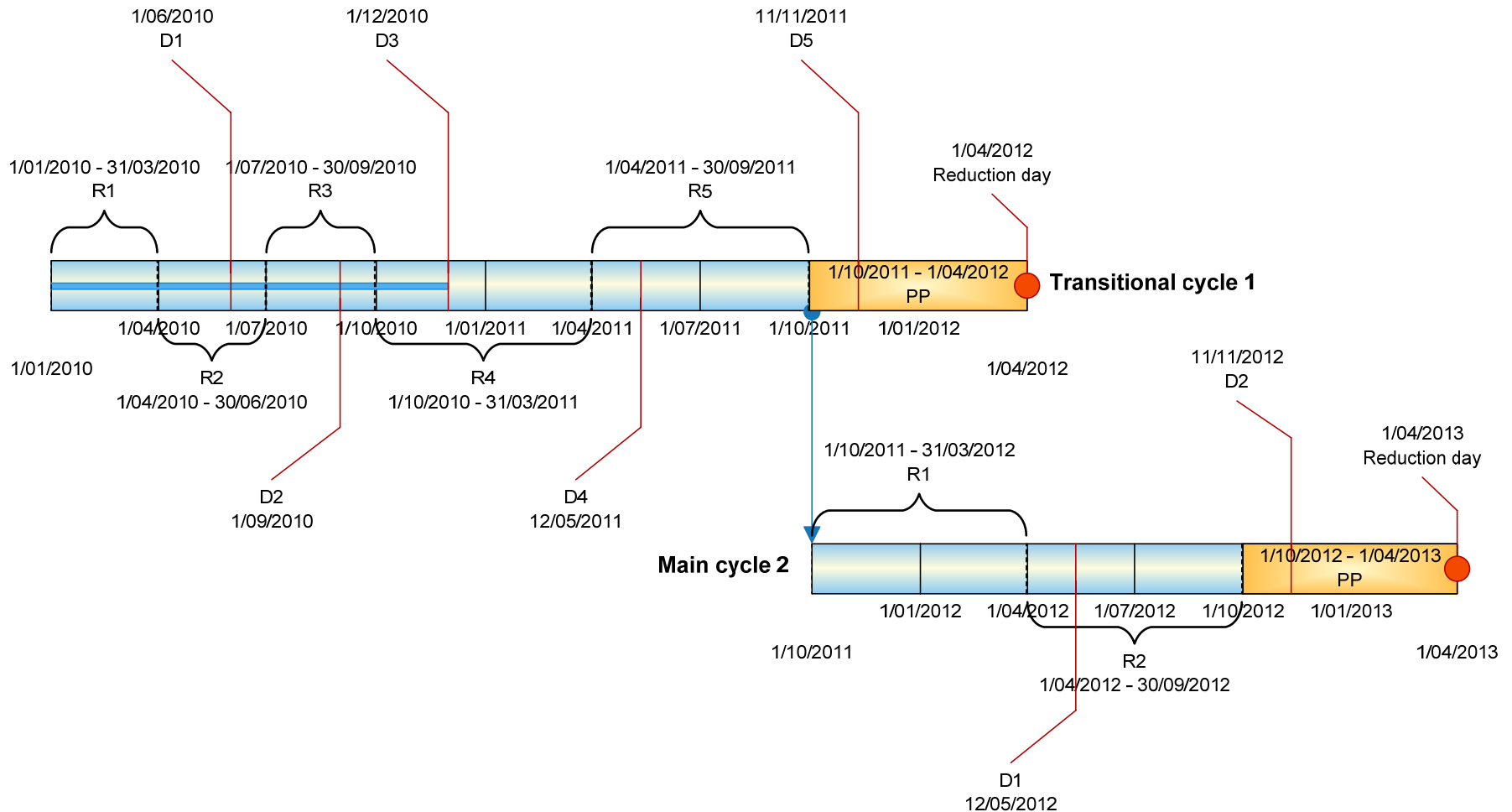
Transitional Cycle 1 to Main Cycle 2

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

Transitional Cycle 1 to Main Cycle 2

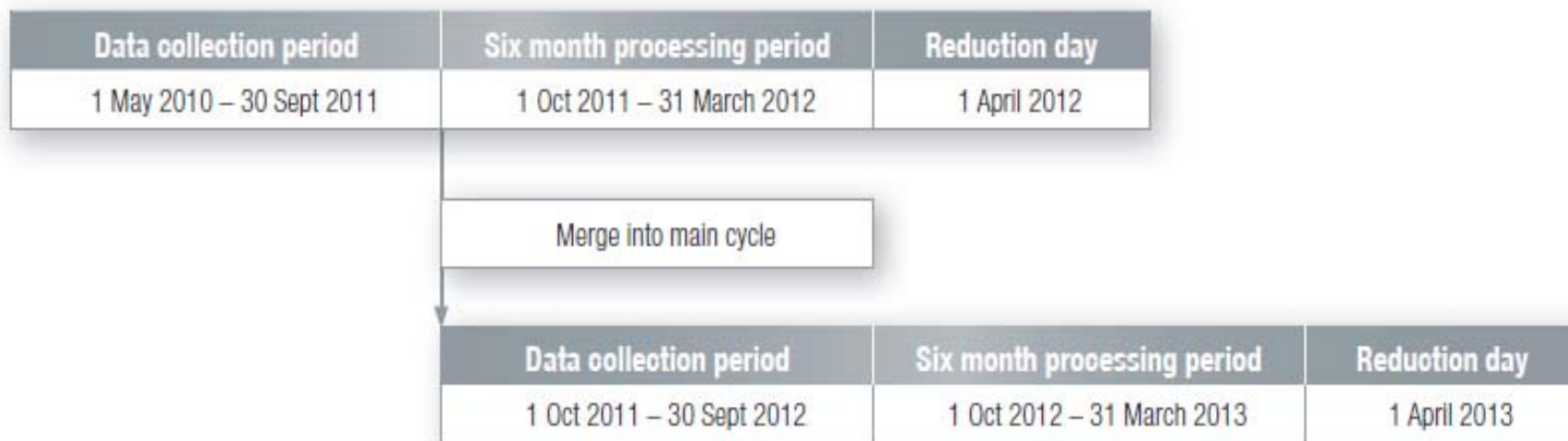




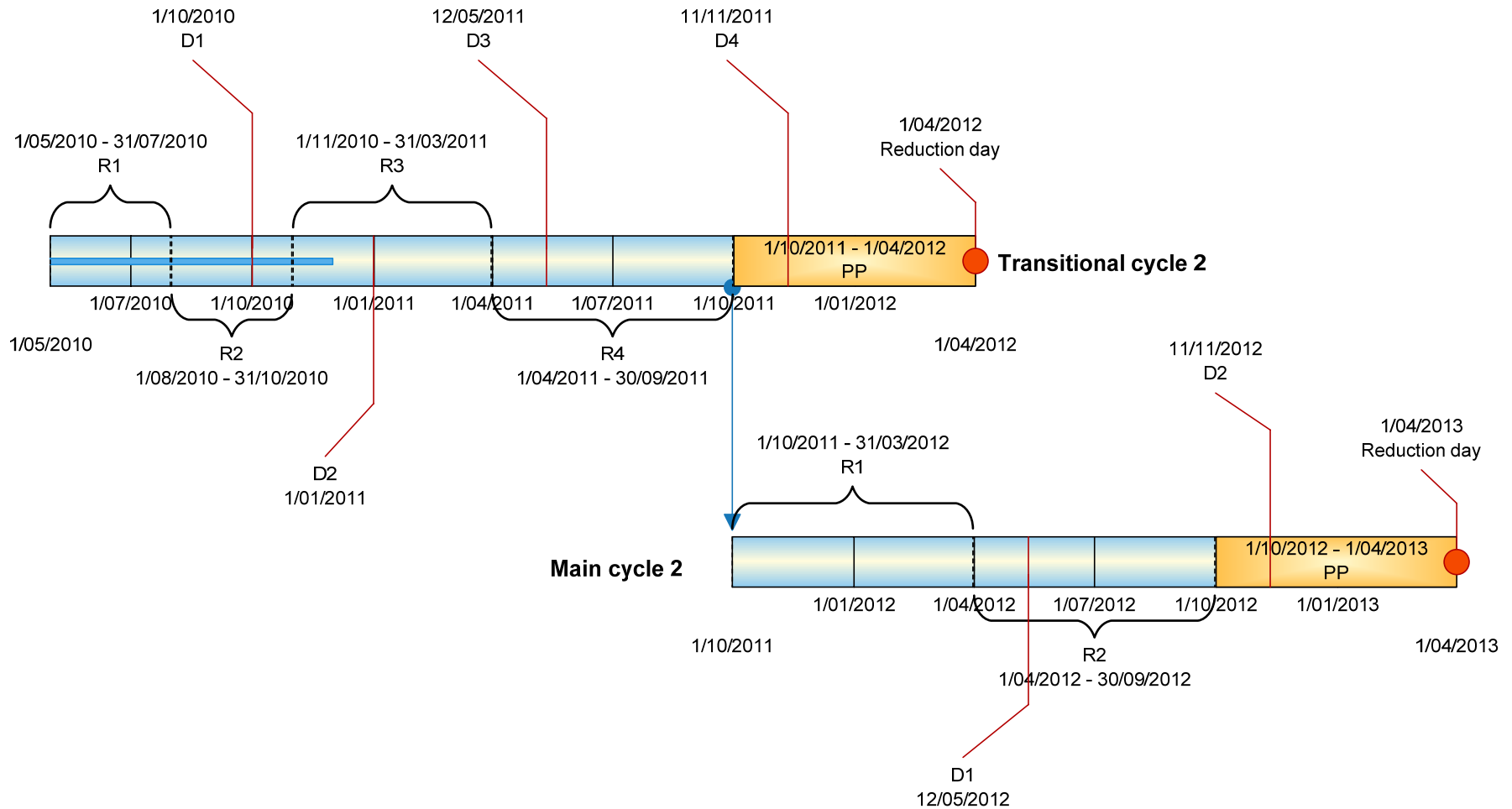
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Transitional Cycle 2 to Main Cycle 2



Transitional Cycle 2 to Main Cycle 2

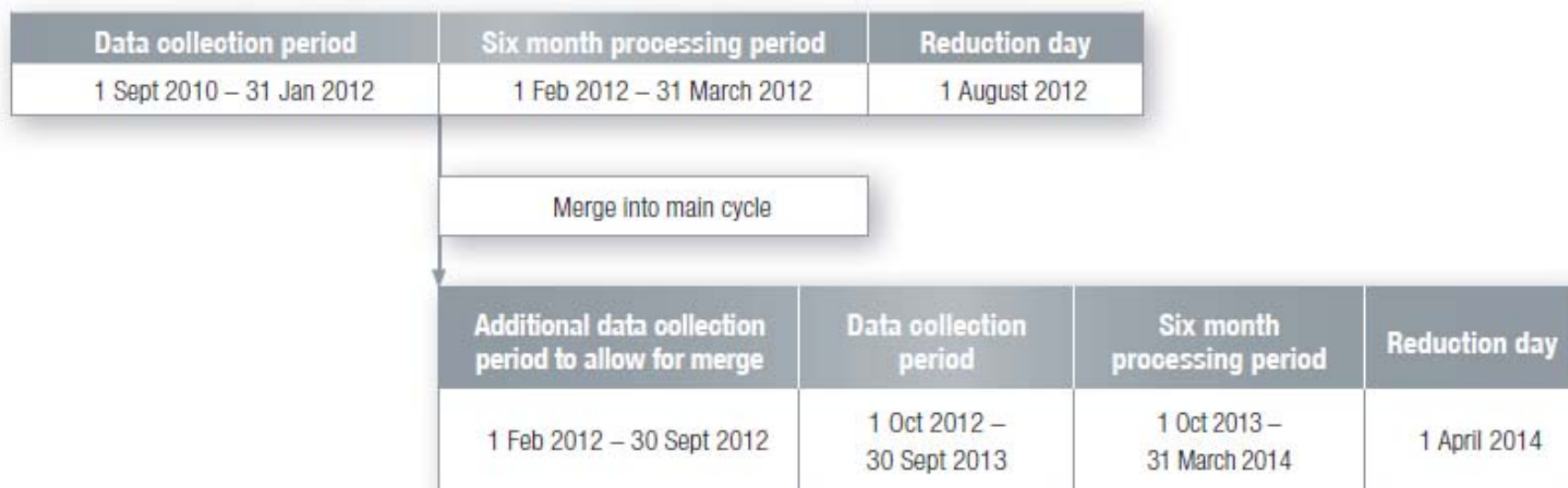




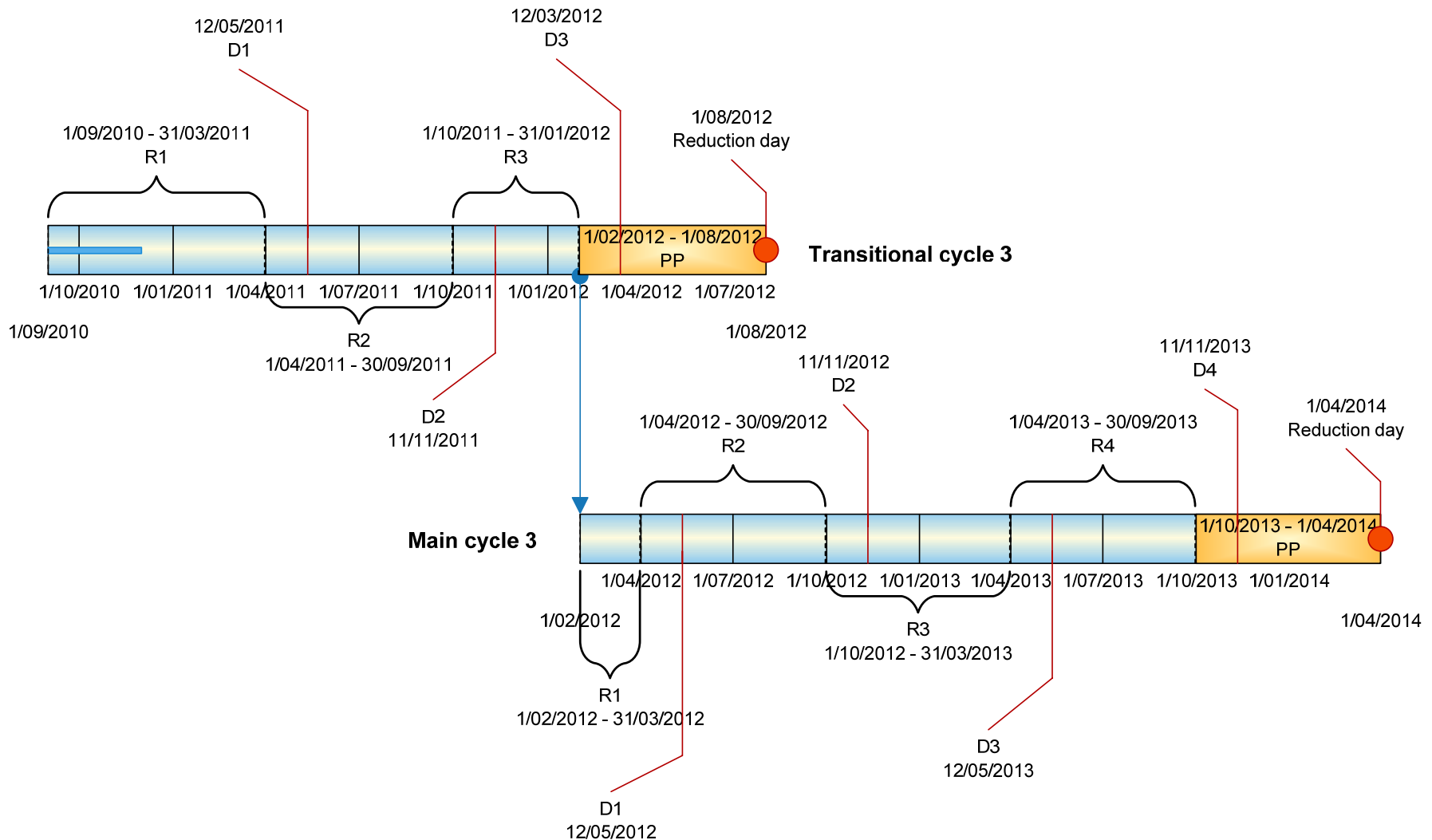
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Transitional Cycle 3 to Main Cycle 3



Transitional Cycle 3 to Main Cycle 3





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What data must be collected?

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.



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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.



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Submitting 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.



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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.



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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.



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Weighted Average Disclosed Price (WADP) Calculation

- The Service Provider 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.



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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.
- No brand will have its price reduced below the lowest disclosed price for the item.



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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



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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.



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PDWG

As part of the price disclosure working group the Department, together with industry have been working to develop a dispute resolution process for handling disputes which may arise due to EAPD.

The process will provide guidance for both industry and the Department, allowing a streamlined approach to addressing and resolving disputes.



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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 to be outsourced to an independent service provider.
- The systems developed by the independent service providers for the WADP and GAP calculation to undergo quality assurance checks by a third party.
- Individual WADP and GAP calculations to undergo quality assurance checks by a third party
- Data submissions to undergo reasonableness checks and trend analysis by independent service provider



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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 sent to Responsible Person's

Responsible 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.



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Q & A



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Further Questions?

- 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