Australian Government
Department of Health and Ageing

Expanded and Accelerated Price Disclosure What's new? What's different?

	Price disclosure prior to 1 December 2010	EAPD
Who is subject	• Mandatory for any new brand that lists on F2A on or after 1 August 2007, if it is bioequivalent or biosimilar to an existing brand; and • Responsible Persons who elect to voluntarily disclose for a brand, where another brand of the same drug and manner of administration are subject to PD.	Mandatory for all drugs listed on the F2 Formulary of the PBS.[1] Responsible Persons that have NOT elected to voluntarily disclose for brands of drugs subject to disclosure will now have to disclose for these brands. (see www.pbs.gov.au)
	Brands of items that are listed as Exempt items, as determined under section 84AH of the *National Health Act 1953*, are **not** subject to Price Disclosure.	Remains unchanged.
Data for collection and submission	Data to be collected: • The sales revenue for the brand; • the volume of the brand sold; • the kind of incentives (if any); and • the value of the incentives given for the brand.	Remains unchanged.
	Data should be **excluded** in relation to: • Sales of Exempt items as determined under section 84AH of the *National Health Act 1953*; and • Sales to Public hospitals.	Remains unchanged.

[1] This includes all drugs previously on F2A and F2T.

Disclosure Cycles	There are three collection cycles with start dates of: • 1 January; • 1 May; and • 1 September of each year. The 1 May and the 1 September cycle are 23 months in length with the 1 January cycle is 27 months in length.	The EAPD disclosure cycles include: • first main disclosure cycle; • the interim supplementary disclosure cycle; • subsequent main disclosure cycles; • 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 period 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 cycles will be no less than 18 months, consisting: • a data collection period of at least 12 months (made up of at least two six month reporting periods); and • a six month processing period.
Data submission	Submitted to the Department	Submitted to the Service Provider.
	Data is submitted quarterly.	Data is submitted six monthly[2].
	Data submitted as follows: • data is submitted quarterly, each quarterly report has a month by month break down of data. This data must be submitted within **two calendar months** after the end of the reporting period; and • annual incentives data for the full 12 month data collection must be submitted within **two calendar months** after the end of the annual data collection cycle. Data can be submitted: • electronically (CD/DVD); or • in writing.	Data submitted as follows: • Sales revenue, volume and incentive data is to be submitted six monthly, with no requirement for data to be reported monthly unless reporting for a new brand. Data must be submitted within **six weeks** of the end of the reporting period. Data will be submitted electronically via direct input or transfer of a data file (Excel, or XML) to the Service Provider[3].

[2] Excluding the *First* Main Cycle commencing 1 December 2010 which will have a reporting period after the first 4 months and then six monthly.

[3] This may involve downloading software provided by the Service Provider.

WADP[4] Calculation	WADP calculation as prescribed in the *National Health (Pharmaceutical Benefits) Regulations* 1960.	Remains unchanged.
		However, if in the *first* main disclosure cycle the guaranteed saving of 23% is not achieved via the application of the WADP then the **Guaranteed Adjustment Proportion (GAP) calculation** will be applied to all drugs whose weighted average percentage difference was equal to or greater than 10%. The GAP will proportionally reduce the price of these drugs until an average saving of 23% is achieved across all of F2 (no drug will have its price reduced below the lowest disclosed price).
Notification	Department makes a legal determination of the price reduction via legislative instrument.	Remains unchanged.
	Industry is notified in writing of price reductions **six months** prior to a scheduled Price Disclosure reduction day.	The price change will occur on the first reduction day after the Department has made the determination. 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. Responsible Persons will be able to access this information via the Legislative instrument on the Comlaw website.
Prescribed reduction days	• 1 April; and • 1 August of each year.	• 1 April; • 1 August; and • 1 December of each year.

[4] Weighted Average Disclosed Price.