

# PBS Price Disclosure

Including 2014 Simplified Price Disclosure Amendments

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Overview & Management

• Information about sales of PBS medicines on the F2 formulary is disclosed by pharmaceutical companies to an independent Price Disclosure Data Administrator (PDDA) every 6 months.

• The PDDA uses the data collected to calculate weighted average disclosed prices for groups of medicines with the same drug and manner of administration.

• Method in the *National Health (Pharmaceutical Benefits) Regulations 1960 (Regs 37F to 37S)*.

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Overview & Management (cont.)

• When the disclosed price calculated over a data collection period is at least 10% below the PBS price, the ex- manufacturer PBS price is reduced.

[s99ADH of *National Health Act 1953*]

• The PDDA contacts companies new to price disclosure just before their first data submission period to provide the electronic Price Disclosure Submission Utility (PDSU).

• Companies need to know their brand has an F2 drug and be prepared to submit data.

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Overview & Management (cont.)

• The PDSU is pre-populated with relevant brands of pharmaceutical items for each data period.

• The Authorised Representative for the legal ‘responsible person’ (supplying company) must verify pre-populated brands and data before submission. Penalties for non- compliance.

• The Department uses PDDA calculations, quality assured by a third party, to prepare the price disclosure legal determination and publish outcomes.

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Start Dates

• Price Disclosure is for brands of F2 drugs.

• Generally multi-branded drugs. Can be single branded.

• **Where the drug is new to F2**

• existing brand (usually moving from F1 or combo list) –

starts price disclosure from the day the drug is on F2

• new brand on day drug moves to F2 – starts price disclosure from listing date

• **Where the drug is already on F2**

• New brand – starts price disclosure from listing date

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How do I know a drug is on F2

• Legal instrument - drug moves to F2 when bioequivalent or biosimilar brand lists for drug, or a drug in therapeutic group.

Currently  *National Health (Listed drugs on F1 or F2) Determination 2010 (No. PB 93 of 2010)* latest

Helpful documents for checking F2 and price disclosure status:

• Formulary Allocation List – check monthly

<http://www.pbs.gov.au/info/industry/pricing/pbs-items/formulary-allocations>

• Drugs Subject to Price Disclosure list – check monthly [http://www.pbs.gov.au/info/industry/pricing/price-disclosure-spd/drugs-subject-to- price-disclosure](http://www.pbs.gov.au/info/industry/pricing/price-disclosure-spd/drugs-subject-to-price-disclosure)

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When to disclose data?

• In the 6 weeks after every 31 March ( by 12 May) and

30 September (by 11 November).

• Data is for previous 6 months (or less if brand not listed or drug not F2 for the whole 6 months).

• Calculation is done once a drug/MoA has been on F2 for at least 6 months.

• The Price Disclosure Guidelines give details about how the first cycle works (can be longer than 6 months)

Current Guidelines - see pages 12-16 & 19-20. [http://www.pbs.gov.au/industry/pricing/price-disclosure-spd/price-disclosure-](http://www.pbs.gov.au/industry/pricing/price-disclosure-spd/price-disclosure-operational-guidelines-july-2014.pdf)

[operational-guidelines-july-2014.pdf](http://www.pbs.gov.au/industry/pricing/price-disclosure-spd/price-disclosure-operational-guidelines-july-2014.pdf) 7

What is Disclosed & Used?

**For each pack size of each brand of every form/strength:**

• Volume of sales

• Sales Revenue (taking account of any rebates related to the sales)

• Incentives for sales – value and type

• Exclude public hospital sales

• The calculation uses data for all months in the data collection period, except for data disclosed for the first month of PBS listing.

• There is intended to be a reduction day every 6 months (1 April

and 1 October each year). 8

Publishing Outcomes & Prices

<http://www.pbs.gov.au/info/industry/pricing/price-disclosure-spd>

• **By 3 months prior to reduction** day (e.g., mid to late June for

October) – Legal determination and summary of outcomes.

• **By 2.5 months prior to reduction** day (e.g., by mid July for October) – Indicative reduced prices: ex-manufacturer, dispensed prices with fees and mark-ups, and premiums.

These prices generally remain correct for reduction day, but could change with an intervening price or listing change – e.g., change to pricing quantity adjusts new AEMP. Price to pharmacy currently not available in indicative prices – working toward it.

• **3 – 4 weeks prior to reduction** day (e.g., by 2nd week of Sept for October) – Confirmation of prices, including ex-manufacturer, 9 price to pharmacy, premiums, and dispensed prices.

**WorkedExample**

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**Scenario -** Brands of two pharmaceutical items with the same drug and manner of administration (drug/MoA)

**Data collection period:** 1 October to 31 March

**Pharmaceutical Item 1 - 10mg Capsule**

• 2 brands (**Dionysius®** & **Cronus®)**

• Pricing Quantity (PQ) is 60 for each month in the 6 month period

• AEMP is $110 for 2 months, then $92.50 for the next 4 months (e.g., December price change in Oct. to March collection period)

• This sample item shows a basic calculation with the impact of

a price change during the data collection period, a new brand 11

listing, and a disclosed price above ex-manufacturer price.

**Step 1—Net revenue (revenue – incentive value) Dionysius® - New** brand of 10mg capsule

= $50,000 for 800 x 60 pack (excluding first month)

**Step 2—Adjusted volume for brand**

PQ and pack size both 60: (800 × 60) ÷ 60 = volume of 800

**Step 3—av.AEMP for brand** (rounded)

Price for each month any brand of the item listed ÷ months

= ($110+$110+$92.50+$92.50+$92.50+$92.50) ÷ 6 = $98.33

**Step 4—Disclosed price for brand**

(step 1 revenue ÷ step 2 volume)

= $50,000 ÷ 800 = $62.50

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**Step 5—Price percentage difference of brand**

($98.33 av.AEMP - $62.50 disclosed price) ÷ $98.33 = 36.44%

**Step 6—Repeat steps 1 to 5 for each brand of the same**

**Pharmaceutical Item**

**Step 1—Net revenue**

**Cronus®** brand 10 mg capsule

=$66,000 for 600 x 60 pack

**Step 2—Adjusted volume for brand**

= (600 × 60) ÷ PQ of 60 = volume of 600

**Step 3—av.AEMP for brand** (rounded)

= ($110+$110+$92.50+$92.50+$92.50+$92.50) ÷ 6 = $98.33

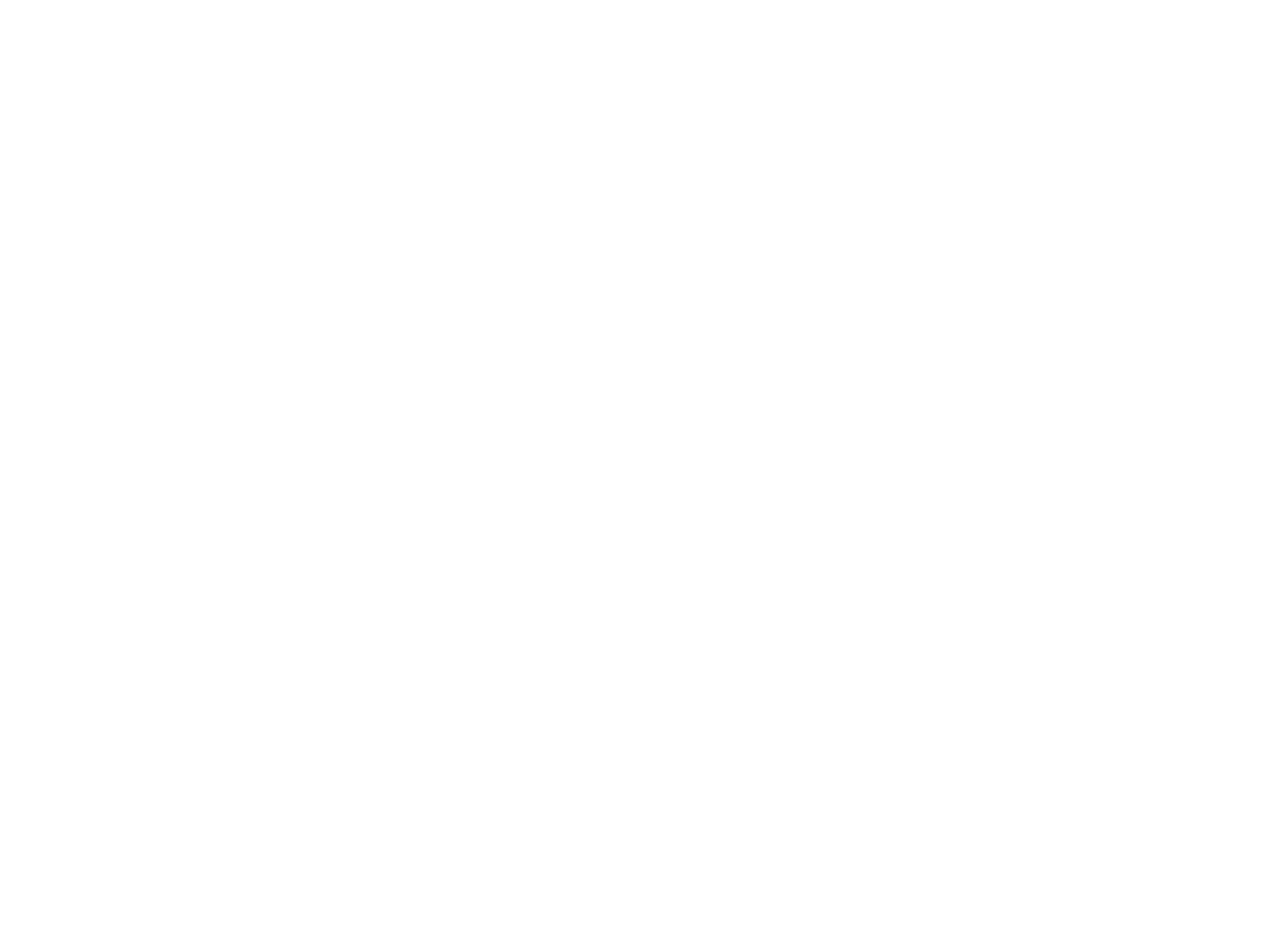
**Step 4—Disclosed price for brand**

= $66,000 ÷ 600 = $110 = over $98.33 = adjust to $98.33

**Step 5—Price percentage difference of brand** 13

= ($98.33 - $98.33) ÷ $98.33 = 0%

**Step 7—Total adjusted volume for Pharmaceutical Item (PI)**



= **Dionysius®** 800 volume + **Cronus®** 600 volume = volume 1,400

**Step 8—Weighted average percentage difference (WAPD) for PI** Add together: (adj. volume for brand × brand % difference) of each brand of PI ÷ (total volume for PI), % to 2 decimal places

= **Dionysius®** (800 × 36.44%) + **Cronus®** (600 × 0%) Total adjusted volume of brands of PI (1,400)

= 20.82% (WAPD for PI - 10 mg capsule)

**Step 9—Repeat steps 1 to 8 for each pharmaceutical item with related brands (each different form with same drug/MoA)**

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**Pharmaceutical Item 2 - 20mg SR tablet**

• 2 brands (**Dionysius®** & **Zeus®**)

• PQ is 50 for the first 2 months, then 100 for the next 4 months

• AEMP is $60 for the first 2 months, then $120 for the next 4 months

• One brand ( **Zeus®**) delists on 1 April (day after end of data collection)

• This sample item shows a change in pricing quantity during the data collection period and that no determination is made

for a delisted brand. 15

**Dionysius®** brand 20 mg SR tablet

**Step 1—Net revenue**

= $35,000 for 1000 x 50 pack

**Step 2 —Adjusted volume for brand**

Adjust volume to PQ on last day data collection period (100)

= (1,000 × old PQ of 50) ÷ new PQ of 100 = volume of 500

**Step 3 — av.AEMP (for brand), with adjustment for PQ**

AEMP for first 2 months adjusted to PQ on final day (100)

= ($60 ÷ 50) × 100 = 120 ($120+$120+$120+$120+$120+$120) ÷ 6 = $120

**Step 4—Disclosed price for brand**

= $35,000 revenue ÷ 500 volume = $70

**Step 5—Price percentage difference of brand** 16

= ($120 av.AEMP - $70 disclosed price) ÷ $120 = 41.67%

**Zeus®** brand 20 mg SR tablet

|  |  |  |
| --- | --- | --- |
| **Step** | **1** | **- Net Revenue** - $32,000 for 400 x 100 pack |
| **Step** | **2** | **- Adjusted Volume** - 400 |
| **Step** | **3** | **- av.AEMP** - ($120+$120+$120+$120+$120+$120) ÷ 6 = $120 |
| **Step** | **4** | **- Disclosed Price for Brand** - $32,000 ÷ 400 = $80 |
| **Step** | **5** | **- Brand Price % Difference** - ($120 - $80) ÷ $120 = 33.33% |

20 mg SR Pharmaceutical Item WAPD

**Step 7 - Total adjusted volume for PI (20mg)** = 500 + 400 = 900

**Step 8 - WAPD**

= **Dionysius®** (500 × 41.67%) + **Zeus®**(400 × 33.33%)

Total adjusted volume of brands of PI(900)

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= 37.96% (WAPD for PI)

**Step 10—WAPD for all related brands (for drug/MOA)**

a) Add together: (PI Total volume × av.AEMP) of each PI.

= (1,400 × $98.33) + (900 × $120) = $245,662.00

b) Add together: (PI Total volume × av.AEMP × PI WAPD) of each PI

= (1,400 × $98.33 × 20.82%) + (900 × $120 × 37.96%)

= $69,658.03

c) Divide (b) by (a) - % to 2 decimal places

= 69,658.03 ÷ 245,662.00

= 28.36% difference (WAPD for drug/MoA)

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**Step 11—Weighted average disclosed price (WADP) for listed brands of drug/MOA**

(av.AEMP)-(WAPD for drug/MoA) = WADP, to 2 decimal places.

**Dionysius®** and **Cronus®** 10 mg

= $98.33 – 28.36% = $70.44 (ex-man WADP in legal instrument)

**Dionysius®** 20 mg

= $120 – 28.36% = $85.97 (ex-man WADP in legal instrument)

**Zeus®** 20 mg = no WADP – been delisted

**Step 11 adjustment** - Adjust legal instrument WADP for any

change in PQ between last day of data collection period and next

day (e.g., from 31 March to 1 April) – no PQ change in this 19

scenario.

**10% Test – to decide if the WADP is applied**

10% test percentage **\*** = **AEMP** on day after end of data collection period **minus WADP** in legal instrument, expressed as a % of AEMP.

**10 mg capsule** – **Dionysius®** and **Cronus®**

($80 - $70.44) ÷ $80 = 11.95%

Meets 10% Test - reduced to $70.44**#**

[Price reduced from $92.50 to $80 on 1 April after end data collection on 31 March]

**20 mg SR tablet – Dionysius®** ($110 - $85.97) ÷ $110 = 21.85% Meets 10% test - reduced to $85.97 **#**

[Price reduced from $120 to $110 on 1 April after end data collection on 31 March]

**20 mg SR tablet – Zeus®** : Delisted 1 April – no new price

**\*** *Known as the unadjusted price reduction in the legislation* 20

**#** *unless other listing /pricing changes occur (e.g., price already became lower, or a change in listings / PQs)*

Contacts & More Information

• **Contacting the Price Disclosure Data Administrator (PDDA)**

Email: [admin@pricedisclosure.com.au](mailto:admin@pricedisclosure.com.au)

Telephone: 1300 336 062

• **Contacting the Department**

Email: [pricedisclosure@health.gov.au](mailto:pricedisclosure@health.gov.au)

Telephone: (02) 6289 2303

• The **Price Disclosure Guidelines** (current July 2014):

[http://www.pbs.gov.au/industry/pricing/price-disclosure-spd/price- disclosure-operational-guidelines-july-2014.pdf](http://www.pbs.gov.au/industry/pricing/price-disclosure-spd/price-disclosure-operational-guidelines-july-2014.pdf)

• The *National Health Act 1953*, *National Health*

*(Pharmaceutical Benefits) Regulations 1960* and Weighted 21

Average Disclosed Price Determinations: [www. comlaw. gov.au](http://www.comlaw.gov.au/)