Australian Government

Department of Health

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)*.

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.

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.

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

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

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-operational-guidelines-july-2014.pdf

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).

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, price to pharmacy, premiums, and dispensed prices.

Worked Example

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 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

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
= ($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

$$= \frac{\text{Dionysius® } (800 \times 36.44\%) + \text{Cronus® } (600 \times 0\%)}{\text{Total adjusted volume of brands of PI } (1{,}400)}$$

= 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)

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.

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

= ($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

$$= \frac{\textbf{Dionysius®}\ (500 \times 41.67\%) + \textbf{Zeus®}(400 \times 33.33\%)}{\text{Total adjusted volume of brands of PI}(900)}$$

= 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)

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 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*

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

  Telephone: 1300 336 062

- **Contacting the Department**

  Email: 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

- The *National Health Act 1953*, *National Health (Pharmaceutical Benefits) Regulations 1960* and Weighted Average Disclosed Price Determinations: www.comlaw.gov.au