Australian Government

Department of Health

PRICING FORUM 2017

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The basics

- **F1 formulary:**
  - Where new drugs are usually listed on the PBS.
  - Mostly on-patent medications.
- **F2 formulary:**
  - Multi branded medicines competition.
  - Mostly off-patent medications.
- **Combination Drugs List:**
  - Combination items contain at least two component drugs, where at least one is PBS listed.

Pricing in F1

- **A lower price offer.**
  - Flowed on through reference pricing to medicines considered to offer similar safety and efficacy.
- **One-off 5% statutory price reduction.**
  - Applies when a drug has been listed on F1 for 5 years.
- **Price increases.**
  - Pharmaceutical companies apply to increase the price of their medicines.
  - Available to both F1 and F2 medicines.

Price disclosure

- 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

Who?

- Who means you – the Authorised Representative for your company

What?

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).

When?

- 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)

How?

- Through a computer framework to the Department's contractors at Australian Healthcare Associates.

Back to – when?
When do you know?

- **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.

Weighted Average Disclosed Price (WADP) Calculation

Price Disclosure Legislation

National Health (Pharmaceutical Benefits) Regulations 1960

Part 6A describes Price Reduction and Price Disclosure

- Regulations 37C to 37T

National Health Act 1953

Part VII, Division 3B describes Price Disclosure

Two Weighted Average Disclosed Price (WADP) calculations performed

1) WADP calculation with all brand data

If drug and manner of administration (MoA) meets the

30 month clock

2) WADP calculation without originator brand data

The WADP calculation that results in the lowest price proceeds

30 Month Clock

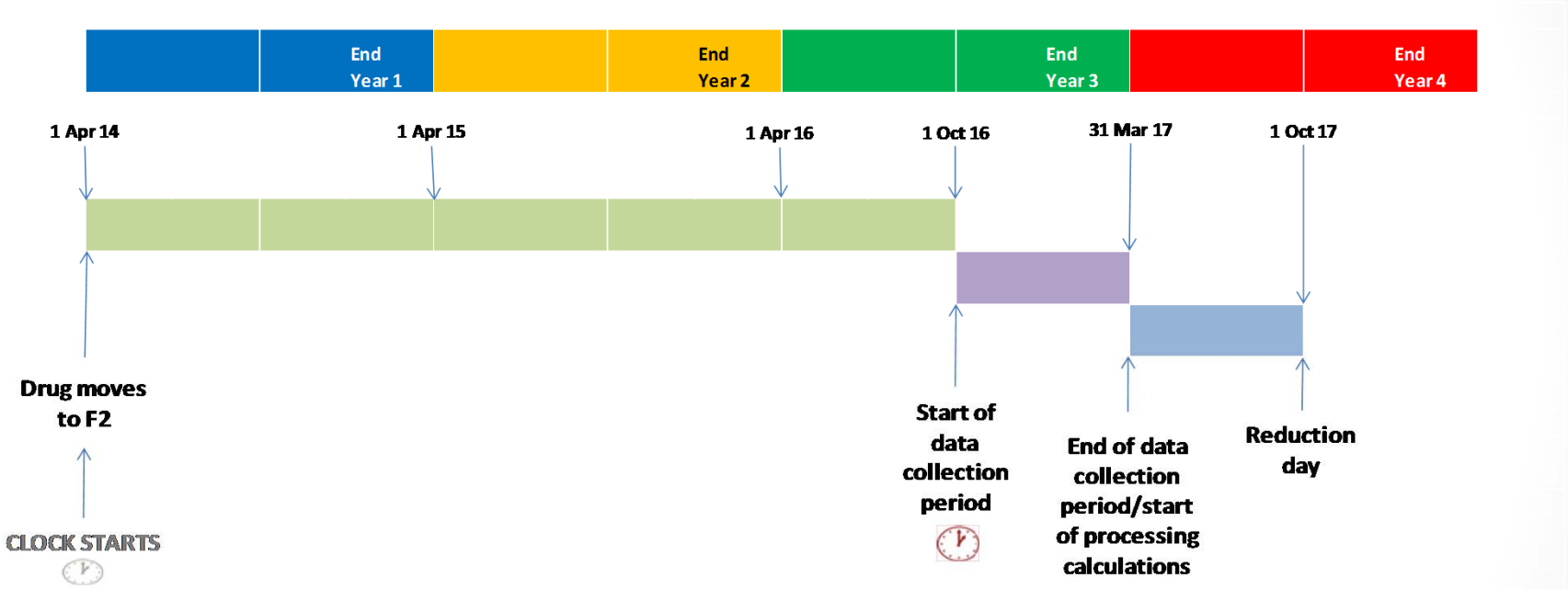
Intended to provide generic brands with an opportunity to compete before originator brand data is removed

To start the clock

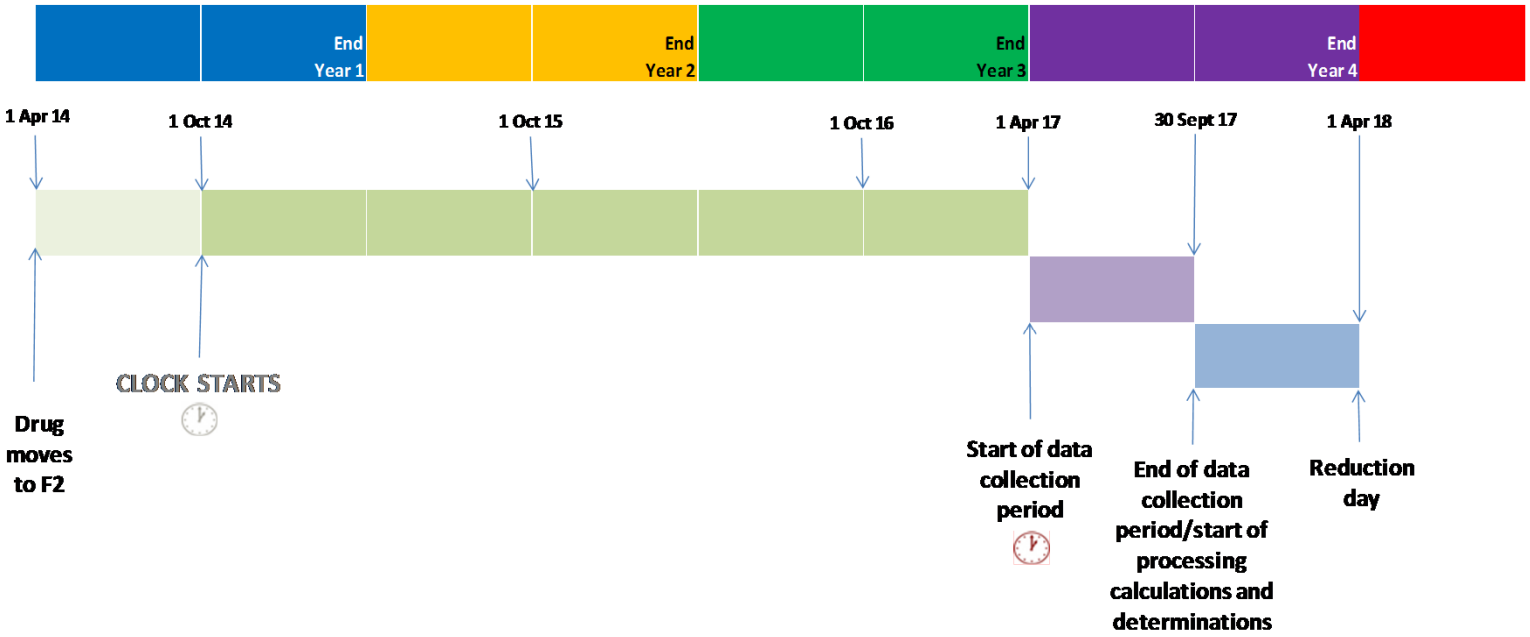
- **two or more brands of a pharmaceutical item that contain the same drug/MoA were on F2; or**
- **two or more bioequivalent or biosimilar brands that contain the same drug/MoA were on F2.**

List of brands for 2017 October Cycle will be published in April

Clock starts when drug moves to F2



Clock starts six months after drug moves to F2



Drug/MoA meets 30 Month Clock

Treatment of PIs of a drug/MoA

BUDDY RULE

Originator brand data will only be removed when there is a non-originator brand listed for the same month

Where the originator brand is the only brand of a PI, its data will not be removed

Buddy Rule
When is originator brand data removed?

- All pharmaceutical items have the same drug/MoA
- Brand 'O' = originator brand
- Brand 'G' = non-originator brand (does not have to be same brand)

Pharmaceutical Item 1

Oct	Nov	Dec	Jan	Feb	March
O	O	O	O	O	O
-	-	-	-	-	-

Result: <u>don't remove O</u> - no non-originator match for any month.

Pharmaceutical Item 2

Oct	Nov	Dec	Jan	Feb	March
O	O	O	O	O	O
G	G	G	G	G	G

Result: <u>remove O</u> – a non-originator match for each month.

Pharmaceutical Item 3

Oct	Nov	Dec	Jan	Feb	March
-	-	O	O	O	O
-	-	G	G	G	G

Result: <u>remove O</u>, originator brand 'start day' is first of December. There is a non-originator brand each month there is an originator brand.

Pharmaceutical Item 4

Oct	Nov	Dec	Jan	Feb	March
O	O	O	O	-	-
G	G	G	G	G	G

Result: <u>remove O</u>, there is a non-originator brand each month there is an originator brand.

Two Weighted Average Disclosed Price (WADP) calculations performed

1) WADP calculation with all brand data

If drug and manner of administration (MoA) meets the 30 month clock

2) WADP calculation without originator brand data

The WADP calculation that results in the lowest price proceeds

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

Data collection period: 1 October 2016 to 31 March 2017

Reduction day: 1 October 2017

STEPS

Step 1 - Net revenue for brand

Step 2 - Adjusted volume for brand

Step 3 - AEMP for brand of the pharmaceutical item

Step 4 - Disclosed price for brand

Step 5 - Price percentage difference of brand

Step 6 - Repeat steps 1 to 5 for each brand of the same pharmaceutical item

Step 7 - Total adjusted volumes of brands of the same pharmaceutical item

Step 8 - WAPD for the pharmaceutical item

Step 9 - Repeat steps 1 to 8 for each pharmaceutical item with related brands (e.g. different forms)

Step 10 - WAPD for all related brands with drug/manner of administration

Step 11 - WADP for each related listed brand of drug/manner of administration

10% Test - Compare WADP for brand with AEMP on relevant day

Pharmaceutical Item 1 - 10mg Capsule

- 2 brands (**Brand A®** & **Brand B® Originator**)

- Pricing Quantity (PQ) is 60 on the first day of each month in the data collection period

- AEMP is $100 on the first day of each month in the data collection period

Step 1—Net revenue (revenue minus incentive value)
Brand A® of 10mg Capsule
= $32,000 for 800 x packs of 60

Step 2—Adjusted volume for brand
PQ and pack size both 60: (800 × 60) ÷ 60 = volume of 800

Step 3—Average AEMP (AvgAEMP) for brand
Price for each month any brand of the PI listed ÷ months
= ($100+$100+$100+$100+$100+$100) ÷ 6 = $100

Step 4—Disclosed price for brand
(step 1 revenue ÷ step 2 volume)
= $32,000 ÷ 800 = $40

Step 5—Price percentage difference of brand
($100 AvgAEMP - $40 disclosed price) ÷ $100 = **60%**

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

Step 1—Net revenue
Brand B® (Originator brand)of 10 mg Capsule
=$60,000 for 600 x packs of 60

Step 2—Adjusted volume for brand
= (600 × 60) ÷ PQ of 60 = volume of 600

Step 3—AvgAEMP for brand (rounded)
= ($100+$100+$100+$100+$100+$100) ÷ 6 = $100

Step 4—Disclosed price for brand
= $60,000 ÷ 600 = $100

Step 5—Price percentage difference of brand
= ($100 - $100) ÷ $100 = **0%**

Step 7—Total adjusted volume for Pharmaceutical Item

= **Brand A®** 800 volume + **Brand B®** 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

$$= \frac{\text{Brand A® } (800 \times 60\%) + \text{Brand B® } (600 \times 0\%)}{\text{Total adjusted volume of brands of PI } (1{,}400)}$$

= **34.29% (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 tablet

- 2 brands (**Brand C®** & **Brand D®(Originator)**)
- PQ is 50 on the first day of each month in the data collection period
- AEMP is $120 on the first day of each month in the data collection period
- **Brand C®** delists on 1 March 2017

Brand C® of 20 mg tablet

Step 1—Net revenue

= $4,200 for 60 x packs of 50

Step 2 —Adjusted volume for brand

= (60 × 50) ÷ PQ of 50 = volume of 60

Step 3 — AvgAEMP (for brand)

= ($120+$120+$120+$120+$120+$120) ÷ 6 = $120

Step 4—Disclosed price for brand

= $4,200 revenue ÷ 60 volume = $70

Step 5—Price percentage difference of brand

= ($120 AvgAEMP - $70 disclosed price) ÷ $120 = **41.67%**

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

Brand D® (Originator) of 20 mg tablet

Step 1 - Net Revenue - $8,000 for 100 x packs of 50

Step 2 - Adjusted Volume - 100

Step 3 - AvgAEMP - ($120+$120+$120+$120+$120+$120) ÷ 6 = $120

Step 4 - Disclosed Price for Brand - $8,000 ÷ 100 = $80

Step 5 - Brand Price % Difference - ($120 - $80) ÷ $120 = **33.33%**

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

Step 8 - WAPD PI

$$= \frac{\textbf{Brand C®}\ (60 \times 41.67\%) + \textbf{Brand D®(Originator)}\ (100 \times 33.33\%)}{\text{Total adjusted volume of brands of PI(160)}}$$

= 36.46% (WAPD for PI)

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

a) Add together: (PI Total volume × AvgAEMP) of each PI.
= (1,400 × $100) + (160 × $120) = $159,200

b) Add together: (PI Total volume × AvgAEMP × PI WAPD) of each PI
= (1,400 × $100 × 34.29%) + (160 × $120 × 36.46%)
= $55,006.32

c) Divide (b) by (a) - % to 2 decimal places
= 55,006.32 ÷ 159,200.00

= 34.55% difference
(WAPD for drug/MoA)

Two Weighted Average Disclosed Price (WADP) calculations performed

1) WADP calculation with all brand data

If drug and manner of administration (MoA) meets the 30 month clock

2) WADP calculation without originator brand data

The WADP calculation that results in the lowest price proceeds

Pharmaceutical Item 1 - 10mg Capsule

- 2 brands (**Brand A®** & **Brand B® Originator**)

- Pricing Quantity (PQ) is 60 on the first day of each month in the data collection period

- AEMP is $100 on the first day of each month in the data collection period

Step 1—Net revenue (revenue minus incentive value)
Brand A® of 10mg Capsule
= $32,000 for 800 x packs of 60

Step 2—Adjusted volume for brand
PQ and pack size both 60: (800 × 60) ÷ 60 = volume of 800

Step 3—Average AEMP (AvgAEMP) for brand
Price for each month any brand of the PI listed ÷ months
= ($100+$100+$100+$100+$100+$100) ÷ 6 = $100

Step 4—Disclosed price for brand
(step 1 revenue ÷ step 2 volume)
= $32,000 ÷ 800 = $40

Step 5—Price percentage difference of brand
($100 AvgAEMP - $40 disclosed price) ÷ $100 = **60%**

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

Step 1—Net revenue
Brand B® (Originator brand) of 10 mg Capsule
=$60,000 for 600 x packs of 60

Step 2—Adjusted volume for brand
= (600 × 60) ÷ PQ of 60 = volume of 600

Step 3—AvgAEMP for brand (rounded)
= ($100+$100+$100+$100+$100+$100) ÷ 6 = $100

Step 4—Disclosed price for brand
= $60,000 ÷ 600 = $100

Step 5—Price percentage difference of brand
= ($100 - $100) ÷ $100 = **0%**

Step 7—Total adjusted volume for Pharmaceutical Item

= **Brand A®** 800 volume + ~~**Brand B®** 600 volume~~ = volume 800

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

$$= \frac{\textbf{Brand A®}\ (800 \times 60\%) + \sim\sim\textbf{Brand B®}\ (600 \times 0\%)\sim\sim}{\text{Total adjusted volume of brands of PI } (\sim\sim 1{,}400\sim\sim\ 800)}$$

= **60% (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 tablet

- 2 brands (**Brand C®** & **Brand D®(Originator)**)
- PQ is 50 on the first day of each month in the data collection period
- AEMP is $120 on the first day of each month in the data collection period
- **Brand C®** delists on 1 March 2017

Brand C® of 20 mg tablet

Step 1—Net revenue

= $4,200 for 60 x packs of 50

Step 2 —Adjusted volume for brand

= (60 × 50) ÷ PQ of 50 = volume of 60

Step 3 — AvgAEMP (for brand)

= ($120+$120+$120+$120+$120+$120) ÷ 6 = $120

Step 4—Disclosed price for brand

= $4,200 revenue ÷ 60 volume = $70

Step 5—Price percentage difference of brand

= ($120 AvgAEMP - $70 disclosed price) ÷ $120 = **41.67%**

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

Brand D® (Originator) of 20 mg tablet

Step 1 - Net Revenue - $8,000 for 100 x packs of 50

Step 2 - Adjusted Volume - 100

Step 3 - AvgAEMP - ($120+$120+$120+$120+$120+$120) ÷ 6 = $120

Step 4 - Disclosed Price for Brand - $8,000 ÷ 100 = $80

Step 5 - Brand Price % Difference - ($120 - $80) ÷ $120 = **33.33%**

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

Step 8 - WAPD PI

$$= \frac{\textbf{Brand C®}\ (60 \times 41.67\%) + \textbf{Brand D®(Originator)}\ (100 \times 33.33\%)}{\text{Total adjusted volume of brands of PI(160)}}$$

= 36.46% (WAPD for PI)

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

a) Add together: (PI Total volume × AvgAEMP) of each PI.
= (~~1,400~~ 800 × $100) + (160 × $120) = $99,200.00

b) Add together: (PI Total volume × AvgAEMP × PI WAPD) of each PI
= (~~1,400~~ 800 × $100 × 60%) + (160 × $120 × 36.46%)
= $55,000.32

c) Divide (b) by (a) - % to 2 decimal places
= 55,000.32 ÷ 99,200.00

= 55.44% difference
(WAPD for drug/MoA)

Two Weighted Average Disclosed Price (WADP) calculations performed

1) WADP calculation with all brand data = 34.55%

If drug and manner of administration (MoA) meets the 30 month clock

2) WADP calculation without originator brand data = 55.44%

Higher Step 10 drug/MoA WAPD is used in remainder of calculation

Higher Step 10 drug/MoA WAPD is used in remainder of calculation

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

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

Brand A® and **Brand B® (Originator)** 10 mg Capsule
= $100 – **55.44%** = $44.56 (ex-man WADP in legal instrument)

Brand C® 20 mg Tablet = no WADP – been delisted

Brand D® (Originator) 20 mg Tablet
= $120 –**55.44%** = $53.47 (ex-man WADP in legal instrument)

10% Test – to decide if the WADP is applied

10% test percentage = **AEMP** on day after end of data collection period (1 April 2017) **minus WADP**, expressed as a % of AEMP.

10 mg Capsule –**Brand A®** and **Brand B® (Originator)**
($90 - $44.56) ÷ $90 = 50.49%

Meets 10% Test - reduced to $44.56

[Price reduced from $100 to $90 on 1 April 2017 after end data collection on 31 March]

20 mg tablet – Brand C®: Delisted 1 April – no new price

20 mg tablet – Brand D® (Originator)
($110 - $53.47) ÷ $110 = 51.39%

Meets 10% test - reduced to $53.47

[Price reduced from $120 to $110 on 1 April 2017 after end data collection on 31 March]

Low Volume / Low Discount PIs

- New Regulation allows for ‘no reduction’ for certain pharmaceutical items with low volume and low discounting, even where other items with the same drug/MoA will take a reduction.
- If the ‘Low volume/Low Discount’ criteria is met, then the WADP is taken to be the current PBS price, which allows no reduction to occur during calculation.
- Operates at the pharmaceutical item level (including all listed brands of PI)
- First applied on 1 April 2016 reduction day
- Part of every cycle thereafter

Criteria

All must be met each cycle.

1. There is some volume of sales for the PI;
2. The 'total adjusted volume' for the particular PI is not more than 10% of the aggregated total adjusted volumes for all Pis for the drug/MoA (**Including originator brand data);**
3. The percentage discount calculated across all brands of the PI is no more than 3%;
4. There are no brands of the PI that are bioequivalent or biosimilar to brands of another PI that does not meet 1), 2) and 3) above; and
5. There is no advice from the Pharmaceutical Benefits Advisory Committee (PBAC) that the PI 'does not provide a significant improvement in efficacy or a reduction in toxicity over alternative therapies' (Sub-regulation 37SA(d)).

Pharmaceutical item (PI)	Example							
All Forms Contain Same Drug & MoA	**Form**	**Brand**	**Brand Volume**	**PI Volume** (Total volume across all brands of the pharmaceutical item)	**PI Discount** (weighted average percentage difference of all brands of the pharmaceutical item)	**Drug/MoA Discount** (Weighted average percentage difference across all PIs for the drug/MoA … assume same 10% test outcome)	**PI Volume not more than 10% of volume of all PIs for Drug/ MoA**	**Reduction?**
	Tablet 20 mg	A	2,500	19,500	15%	13.5%	No – 19,500 PI volume is more than 10% of 20,050 drug/MoA volume	**YES**
	Tablet 20 mg	B	17,000	19,500	15%	13.5%	No - see above	**YES**
	Tablet 1 mg	**C**	**550**	**550**	**2%**	**13.5%**	Yes - 550 PI volume is less than 10% of 20,050 drug/MoA volume	**NO** (no PBAC advice & no bioequiv PI)
	Caplet 60 mg	C	0	0	-	13.5%	N/A – nil volume	**YES** (no volume)

Questions and Answers

Contacts & More Information

- **Contacting the Department**

  Email: pricedisclosure@health.gov.au

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