Australian Government
Department of Health

2015 PBS Pricing Changes

Pricing Section
Pharmaceutical Evaluation Branch
4 March 2016

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PBS Statutory Pricing

- Today we are explaining the 2015 statutory pricing changes which were part of the Government's PBS Access & Sustainability Package
- Statutory price reductions, including price disclosure, are provided for in the *National Health Act 1953* (the Act) and the *National Health (Pharmaceutical Benefits) Regulations 1960*
- Statutory price reductions were first introduced through 2007 amendments to the Act
- Since then, there have been four major changes to the statutory pricing arrangements in 2010, 2012, 2014, and 2015

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Access and Sustainability Package – Pricing Changes

1. **F1 5%** - Products containing a drug that has been on the F1 formulary for at least 5 years will take a 5% statutory price reduction, which is also flowed on to Combination Drug List medicines
2. **F2 combination flow on** – F2 combination items will have price disclosure reductions to component ingredient drugs applied where this results in a lower price than direct application of price disclosure to the item
3. **Originator Removal** - Originator brand data is removed from the calculation of the weighted average disclosed price (WADP) for medicines listed on the F2 formulary for 3 years or more - where this results in a lower price than including originator data
4. **Low Volume / Low Discount** - Certain pharmaceutical items are excused from a price disclosure reduction

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PBS Basics – Pharmaceutical Item

- Pharmaceutical item is a specific combination of [drug, form, manner of administration](s84AB)

  eg: DrugA, 20 mg tablet, oral
- Form includes strength, formulation, presentation or other descriptor (s85(3))
  - Non-continuous formulation – 'form' generally refers to a single unit – 20 mg tablet
  - Continuous formulation – 'form' generally refers to a pack quantity - 120 mg/5 mL oral liquid, 100 mL

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PBS Basics – Brand of Pharmaceutical Item

Brand of Pharmaceutical Item

- Describes the branded product –
  eg: *Alpha* brand of *DrugA, tablet 20mg, oral*

- The *brand of pharmaceutical item* is also, for ready prepared products like those on formularies, the pharmaceutical benefit which is the thing subsidised under the Act (s84 definitions)

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PBS Basics – Responsible Person

Responsible person

- Legal person - usually a company. Supplies the brand of pharmaceutical item in Australia. (s84AF)

Authorised Representative

- Real person
  - nominated by responsible person re each brand of pharmaceutical item
  - represents the responsible person for agreements and formal correspondence

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PBS Basics – Bioequivalent or Biosimilar

- Often important for a listing or pricing decision. Eg, formulary allocation (s85AB), 16% reduction (s99ACB), some new price disclosure provisions (eg, reg37SA)
- A TGA statement is generally the basis for consideration of bioequivalence or biosimilarity
- The TGA consideration is at the molar dose level
- However, the Act refers to bioequivalence or biosimilarity of the legally listed brands of pharmaceutical item
- It is the rate and extent of absorption of the quantity of the product described in the 'brand of pharmaceutical item' that is relevant under the Act

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PBS Basics - Formulary

Formulary 1 (F1) (s85AB)

- For drugs that:
  - have no bioequivalent or biosimilar brands of pharmaceutical items (often referred to as being 'single branded'); and
  - are not part of a therapeutic group with another drug that has bioequivalent or biosimilar brands of pharmaceutical items; and
  - were not on F2 on the day before (ie, with one exception, no moving back to F1)

Formulary 2 (F2) (s85AB)

- For drugs that don't meet the F1 criteria, and are not on the Combination Drugs List. Often referred to as the multi-branded or generics formulary

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PBS Basics – Formulary (cont.)

Combination Drugs List (CDL) (ss85AB(5))

- For combination drugs where at least one of the components is PBS listed, and the combination drug has no bioequivalent or biosimilar brands (and is not in a therapeutic group with a drug that has bioequivalent or biosimilar brands). Often referred to as the single branded combination drug list

  For example:

  Adapalene with benzoyl peroxide is on F1 because it has no PBS listed component drug,

  alendronic acid with colecalciferol is on the CDL because at least one component is PBS listed.

- Formulary allocation is by legal instrument. The Combination Drugs List is administrative. Formulary or CDL allocation is available on our pricing webpage

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F1 5% Statutory Reduction

- A 5% reduction applies to the approved ex-manufacturer price of all brands of pharmaceutical items containing a drug when the drug has been on F1 for at least five years. (s99ACF & s99ACHA)
- New brands, new indications or new pharmaceutical items do not get a separate 5 year period. The 5 year period applies to the drug and the reduction will apply to all brands of pharmaceutical items with the drug
- 'Exempt items' are not exempt from the F1 5% reduction
- The first F1 5% reduction day is 1 April 2016. Reductions for drugs meeting the criteria over the next year will be applied each April, up to and including 1 April 2020. (s99ACHA)

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F1 5% Statutory Reduction (cont.)

- The *direct* price reduction to drugs that meet the '5 years on F1 criteria' applies by force of the Act. It is not discretionary and does not involve making a new price agreement. (s99ACF)
- If a new pharmaceutical item (eg, same drug with a different strength or formulation) lists after the 5% reduction day, it is listed at a price consistent with the reduced prices of the existing listings for the drug
- For new drugs seeking listing, the choice of comparator will continue to be assessed in the usual way. The price for the new drug will be considered taking account of the price of its comparator, including where the price is reduced by a F1 or flow-on reduction

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F1 5% Statutory Reduction (cont.)

- The F1 5% reduction is not flowed on by administrative reference pricing between drugs that are already on F1 or the combination drugs list.
- The pricing webpage has a Fact Sheet for F1 5% reductions that sets out the relevant F1 date 5 years before each reduction day. Affected drugs will be published each December for the next April reduction day
- The pricing webpage has the December 2015 list of all drugs affected by the 1 April 2016 F1 5% reduction day, including their pharmaceutical items that were PBS listed at the time of publication, and the 5% reduced ex-manufacturer price

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F1 5% Reduction – Flow-on to CDL

- The F1 5% reduction will be flowed on where the F1 drug is a component of another drug on the Combination Drugs List (CDL). (s99ACC)

  For example:

  DrugZ - on F1 taking 5% reduction

  DrugZwithA – on CDL

  Any brand of combination item that contains *DrugZwithA* will be considered for flow-on of the reduction

- The process for applying the F1 5% flow on is the same as for flow on reductions for the 16% 'first new brand' reduction and price disclosure reductions that have applied for some years (s99ACC)

- It is not necessary for the combination drug to have been listed for 5 years to take the flow-on reduction. This is also consistent with longstanding arrangements

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F1 5% Reduction – Flow-on to CDL

- The price agreement for brands of combination items containing the affected F1 component drug ceases to exist at the last moment of the day before the component drug takes its reduction (ss99ACC(2))

  For example: prices for brands of DrugZwithA cease at the end of 31 March 2016 because DrugZ is taking a F1 5% reduction on 1 April 2016

- A new price agreement can come into effect for the reduction day for the brand of combination item

- When deciding on a new price for the combination item, any 5% reduced prices for the F1 component drug have to be taken into account (ss99ACC(4B) – exception covered later)

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Pricing for Combination Products

- Combination products are usually, but not always, based on the sum of individual component prices at the time of listing (in accordance with PBAC guidelines). The same approach is used in flow-on pricing
- If there is cost effectiveness or other advice which has resulted in an uplift of the price over sum of components (or some other different pricing approach) that pricing approach will be reflected in the new price worked out taking account of the component price reduction

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Pricing for Combination Products (cont)

- Advice from the PBAC in relation to cost-effectiveness and relativity is taken into account on first listing and where considering administrative flow-ons:

  Example 1:

  enalapril maleate 20 mg plus hydrochlorothiazide 6 mg cost minimisation to

  enalapril maleate 20 mg and hydrochlorothiazide 12.5 mg as individual items

  Example 2:

  Rosuvastatin with ezetimibe cost-minimisation to

  atorvastatin with ezetimibe

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F1 5% flow-ons & s101(4AC)

- Any s101(4AC) advice from the PBAC (that the combination item provides a significant improvement in compliance, efficacy or reduction in toxicity over alternative therapies), may be considered by the pricing delegate. They may choose not to flow on all or some of the component drug reduction. (ss99ACC(4) and (4A)). A new price agreement is still needed, even if it confirms the old price
- The Department wrote to companies affected by April 2016 reductions in December 2015 seeking a PB11a form for a new price agreement, which was due in mid January 2016. A similar approach is expected each year
- If agreement cannot be reached on the new combination item price, advice can be sought from the PBAC regarding de-listing

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F1 5% - Example & Timeline

F1 Drug with New Indication & Combination Flow-on – April 2016 reduction.

Also available in the F1 5% Price Reduction Fact Sheet on the Pricing webpage.

DrugZ lists on PBS and is allocated to F1 formulary	1 January 2011
A new indication is listed on the PBS for a new or existing brand of pharmaceutical item containing drugZ	1 November 2015
List of F1 drugs subject to five per cent SPR on 1 April 2016 (and their indicative prices) published to PBS website (includes drugZ)	Mid-December 2015
Five year anniversary of drug Z being on F1	1 January 2016
Letters sent to responsible persons for combination items with drugZ+A on the CDL (which has the F1 component drugZ affected by the five per cent statutory price reduction) re new price	Published 18 December 2015 Will occur before mid-January each year
PB11a (request for new price agreement) due from responsible persons with affected combination items	Was due by mid January 2016 10 business days after letter
Five per cent statutory price reduction day for drugZ (including brand of pharmaceutical item with new indication), and flow-on reduction day for single brand combination items (with drugZ+A)	1 April 2016 (drug Z been listed for at least five years)

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F2 Combination Flow-On Reductions

- From 1 April 2016, where an F2 component drug in an F2 combination item takes a price disclosure reduction a flow-on reduction calculation will be done for the combination item. (s99ADHB).
- Price disclosure does not apply to legally determined 'exempt items', (s99ADHB & s85AH).
- The flow-on calculation must take into account the prices on reduction day for all related component drug and combination items. The calculation looks at reduced prices, not % reduction. (ss99ADHB(6))
- The flow-on calculations and processes will be similar to those discussed earlier and have been applied for some years for other statutory price reductions. The existing price will cease where a price disclosure reduction applies to a component drug, and a new price may be agreed or determined.(ss99ADBH(2) & (3))

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F2 Combination Flow-On Reductions

Example Calculation – with lower flow-on

DrugXwithY *– direct price disclosure outcome = 11%*
$75 less 11% = $66.75

DrugX *- price disclosure outcome = 40%*
$25 less 40% = $15

DrugY price in the combination is $50 (no reduction).

Flow on reduction: $15 + $50 = $65
Direct combo F2 reduction : $66.75
Flow on reduction applies

- If the pricing approach for a combination item allowed an uplift in price for cost effectiveness or there is some other pricing approach (such as no allowance in the price for one or more of the components) this will be reflected in the calculation.
- About 1/3 of the combination drugs on F2 are taking flow-on reductions on 1 April 2016.

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F2 Combination Flow-On Reductions

- If the flow-on calculation does not result in a lower price, and there would have been a direct price disclosure reduction for the F2 combination item, the new price agreement must reflect at least the direct price disclosure reduction. (s99ADBH(4))

  Example Calculation with lower direct reduction

  DrugXwithY
  Direct price disclosure outcome = 11%
  $75 less 11% = $66.75

  ***DrugX** - Price disclosure outcome = 15%*
  $25 less 15% = $21.25

  DrugY - Price in the combination is $50 (no price disclosure reduction).

  Flow on reduction = $21.25 + $50 = $71.25
  Direct combo F2 reduction = $66.75
  Direct reduction applies.

- Where a flow-on reduction applies, the Claimed Price for a product with a premium is reduced by the same percentage as the approved price is reduced – this is the same approach to reducing premiums that is used for direct reductions.

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F2 Combination Flow-On Reductions

- Any s101(4AC) advice from the PBAC (that the combination item provides a significant improvement in compliance, efficacy or reduction in toxicity over alternative therapies), may be considered by the pricing delegate when deciding whether the new price should be less than the existing price. (ss99ADHB(5)).

- A new price agreement is needed if an F2 component reduction occurs, even if it confirms the old price for the combination item.

- The Department wrote to affected companies in December 2015 seeking a PB11a form for a new price agreement, which was due in mid January 2016. A 10 working day turn-around is expected each cycle.

- If agreement cannot be reached on the new combination item price, advice can be sought from the PBAC regarding de-listing.

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F2 Combination Flow-On Catch-up

- If no F2 component drug price disclosure reduction occurs on either 1 April or 1 October 2016, then the price of each F2 component in an F2 combination will be considered for flow-on for 1 October 2016.
- This provision will ensure a link between F2 component and combination item prices, based on previous price disclosure reductions, even if the components are not taking reductions in April or October 2016.
- The flow-on calculation will be done the same way as if the F2 component were taking a reduction on the relevant reduction day. It will take into consideration the price of relevant components on the last reduction day when a reduction apply to the component.

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Price Disclosure

- **Overview of the Price Disclosure Process**
- **Low Volume / Low Discount** - Certain pharmaceutical items are excused from a price disclosure reduction
- **Originator Brand Removal** - Originator brand data is removed from the calculation of the weighted average disclosed price (WADP) for medicines listed on the F2 formulary for 3 years or more - where this results in a lower price than including originator data

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Price Disclosure Process Legislation

- *National Health (Pharmaceutical Benefits) Regulations 1960 , Part 6A* describes Price Reduction and Price Disclosure
  - Interpretation (37C to 37E)
  - Weighted Average Disclosed Price (37F to 37SA)
  - Information that must not be taken into account (37SB and 37SC – Originator brands)
  - Price disclosure requirements (37T)
- *National Health Act 1953*, Part VII, Division 3B describes Price Disclosure.

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Overview of Price Disclosure Process

- Every 6 months, information about supplies of PBS medicines on the F2 formulary (excluding public hospital sales) is required by law to be disclosed by RPs - legal 'Responsible Person' (supplying company). Data is provided to an independent Price Disclosure Data Administrator (PDDA).
- PDDA provides the electronic Price Disclosure Submission Utility (PDSU) to new RPs before their first data submission period.
- The PDSU is pre-populated with relevant brands of pharmaceutical items for each data period.
- The Authorised Representative for the RP must verify pre-populated brands and data before submission. Penalties exist for non-compliance.

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What is disclosed & used?

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

- Volume of sales
- Sales revenue
- Incentives, discounts or rebates (can be reported separately in the incentives field, netted off revenue or a combination of both)
- Data should *exclude* volume/revenue/incentives associated with sales to *public hospitals*

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Timetable for data disclosure

- Data is submitted twice per year between
  - 1 April and 12 May and
  - 1 October and 11 November.
- Data should accurately disclose supply in the previous 6 months.
- The Department uses calculations, quality assured by a third party, to prepare recommendations to the Minister's pricing delegate for the price disclosure legal determination and publication of reduction outcomes.
- There is intended to be a reduction day every 6 months (1 April and 1 October each year).

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Low volume and low discount

- First applies on the next reduction day - 1 April 2016
- Low volume/ low discount provision is contained in Regulation 37SA of the *National Health (Pharmaceutical Benefits) Regulations 1960*
- New Regulation allows for 'no reduction' for certain pharmaceutical items with low volume and low discounting, even where other items with the same drug and manner of administration (MoA) will take a reduction.
- If the 'no reduction' criteria is met, then the weighted average disclosed price is taken to be the current PBS price, which allows no reduction to occur during calculation.

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Low volume and low discount

'No reduction' criteria (37SA):

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

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Worked Examples

- Examples of new Regulation 37SA allowing for no reduction for a pharmaceutical item despite reductions for other items with the same drug and manner of administration.
- The figures in the example are for illustrative purposes – calculations are not intended to be an exact replica of method.

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Pharmaceutical item (PI)		Example 1						
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?**
Zeus / Oral	Tablet 20 mg	A	500	19,500	15%	13.5%	No – 19,500 PI volume is more than 10% of 20,050 drug/MoA volume	**YES**
Zeus / Oral	Tablet 20 mg	B	500	19,500	15%	13.5%	No - see above	**YES**
Zeus / Oral	Tablet 20 mg	C	1,500	19,500	15%	13.5%	No - see above	**YES**
Zeus / Oral	Tablet 20 mg	D	17,000	19,500	15%	13.5%	No - see above	**YES**
Zeus / Oral	Tablet 1 mg	C	50	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)
Zeus / Oral	Tablet 1 mg	D	500	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)
Zeus / Oral	Caplet 60 mg	C	0	0	-	13.5%	N/A – nil PI volume	**YES** (no volume)

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Pharmaceutical item (PI)		Example 2						
Drug / MoA	**Form**	**Brand**	**Brand Volume**	**PI Volume** (Total volume across all brands of the pharmaceutical item)	**PI Discount** (weighted average discount 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** (total drug/MoA volume = 357,500)	**Reduction?**
White / Oral	Tablet 20 mg	A	95,000	295,000	29.24%	24.84%	No – 295,000 PI volume is more than 10% of 357,500 drug/MoA volume	**YES**
White / Oral	Tablet 20 mg	B	200,000	295,000	29.24%	24.84%	No - see above	**YES**
White / Oral	Capsule 20 mg	B	22,500	22,500	2.69%	24.84%	Yes – 22,500 PI volume is less than 10% of 357,500 drug/ MoA volume	**YES – Tablet 20mg is bioequivalent**
White / Oral	Tablet 40 mg	A	25,000	35,000	21.10%	24.84%	Yes - 35,000 PI volume is less than 10% of 357,500 drug/MoA volume	**YES – PI discount is over 3%**
White / Oral	Tablet 40 mg	B	10,000	35,000	21.10%	24.84%	Yes - see above	Yes – see above
White / Oral	Tablet 40 mg (modified release)	B MR	5,000	5,000	1.02%	24.84%	Yes – 5,000 PI volume is less than 10% of 357,500 drug/MoA volume	**NO** (no PBAC advice & no bioequiv PI)

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Remove Originator

- Originator brand determination
- Originator brand removal
  - 30 Month Clock
  - Treatment of single branded pharmaceutical items
- First applies 1 October 2016 reduction day

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Originator Brand Determination

- *National Health Act 1953*, Part VII, Division 3B describes Price Disclosure
- Section 99ADB provides that the Minister (or delegate) may determine by legislative instrument that a brand of a pharmaceutical item that has a drug on F2 is an 'originator brand'.
- The first originator brand determination commenced on 1 October 2015. Amendments will be considered to add brands that move from F1 or CDL to F2 to the originator brand determination.
- At times it may be appropriate not to determine any originator brand, or to determine only one of multiple brands moving from F1 to F2, as an 'originator brand'.
- A copy of the originator brand determination is available on www.legislation.gov.au

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Examples of originator brands

- The policy for removal of originator brands from price disclosure calculations also includes all variants of the originator brand name.
- Any variants to the originator brand name will also be considered for addition to the 'originator brand' determination when they are listed on F2.
- Zovirax 200 mg and Zovirax 800 mg are both originator brands that contain the drug aciclovir.
- Amoxil and Amoxil Forte are both originator brands that contain the drug amoxicillin.

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Originator Brand Removal – 30 Month Clock

- The first calculations with and without the originator brand will be carried out at least three years after the drug was listed on the F2 formulary where 'F2/multi-branded criteria' are satisfied (30 Month Clock). The calculation that results in the lowest price will be used for the new PBS list price (ex-man price).
- F2/multi-branded criteria
  - 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.
- Generic brands will have had an opportunity to compete with the originator brand for at least 30 months on F2, prior to the start of the data collection period for the price disclosure cycle .
- A list of drug/MoAs that meet the 30 Month Clock will be published before the end of the data collection period.

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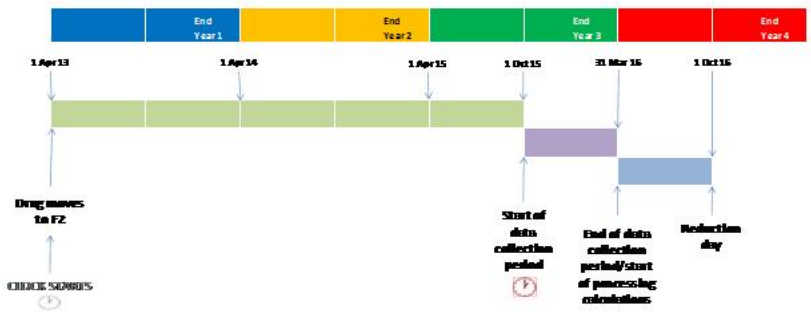
Originator Brand Removal – 30 Month Clock



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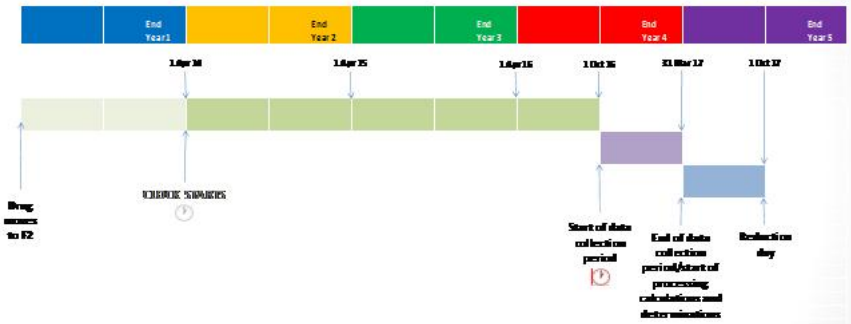
Originator Brand Removal – 30 Month Clock



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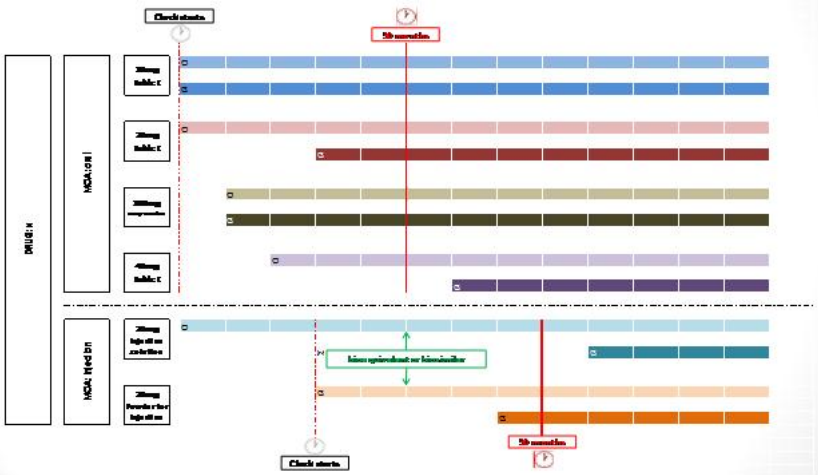
When the 30 Month Clock starts for a Drug/ MoA (37SC(1)(c))



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Originator Brand Removal – Treatment of single branded pharmaceutical items

- Originator brand data will not be removed for a pharmaceutical item unless there is a non-originator brand also listed for that pharmaceutical item for each of the months the originator brand is listed for the price disclosure cycle.
- Where the originator brand is the only brand of a pharmaceutical item, its data will not be removed.

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Once 30 month test has been met, when is originator brand data removed? (37SC(1)(a))

- All pharmaceutical items have the same drug and manner of administration
- Brand 'O' = originator brand
- Brand 'G' (or any other letter, for example H) = non-originator brand

Pharmaceutical Item 1

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

Result: don't remove O, no non-originator match for any month.

Pharmaceutical Item 2

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

Result: remove O, a non-originator match for each month.

Pharmaceutical Item 3

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

Result: remove O, 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	J	H	G	G

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

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Once 30 month test has been met, when is originator brand data removed? (37SC(1)(a))

- All pharmaceutical items have the same drug and manner of administration
- Brand 'O' = originator brand
- Brand 'G' (or any other letter, for example H) = non-originator brand

Pharmaceutical Item 5

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

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

Pharmaceutical Item 6

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

Result: don't remove O, there isn't a non-originator brand each month there is an originator brand.

Pharmaceutical Item 7

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

Result: don't remove O, there isn't a non-originator brand each month there is an originator brand.

Pharmaceutical Item 8

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

Result: don't remove O, there isn't a non-originator brand each month there is an originator brand.

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Timeline for first affected Remove Originator Price disclosure cycle

Date	Action
1 April 2013	Brands of a drug/MoA where the 30 month clock started on this day will be assessed as part of the first 'originator removal' cycle for the 1 October 2016 reduction day
1 October 2015	First originator brand determination commenced
1 October 2015 to 31 March 2016	Data collection period for first 'originator removal' cycle
1 April 2016 to 12 May 2016	Period for submission of data for first 'originator removal' cycle
Mid to late June 2016	Calculation outcomes for first 'originator removal' cycle published
1 October 2016	Reduction day for first 'originator removal' cycle

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Outcomes

- **By 3 months prior to reduction day**
  Legal determination (Legislation.gov.au) and summary of outcomes (PBS website) by pharmaceutical item.
- **By 2.5 months prior to reduction day**
  Indicative reduced prices: including ex-manufacturer price, price to pharmacy, premiums, and dispensed prices.
- **By 3 weeks prior to reduction day**
  Confirmation of prices
- **Reduction Day: 1 April or 1 October**

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Questions

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Contacts for more information

- **Contacting the Price Disclosure Data Administrator (PDDA)**
  Email: admin@pricedisclosure.com.au
  Telephone: 1300 336 062
- **Contacting the Department –Price Disclosure**
  Email: pricedisclosure@health.gov.au
  Telephone: (02) 6289 2303
- **Contacting the Department – Other pricing matters**
  Email: pbspricing@health.gov.au

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Useful resources

- The *National Health Act 1953*, *National Health (Pharmaceutical Benefits) Regulations 1960,* Weighted Average Disclosed Price Determination and Originator Brand Determination.
  www.legislation.gov.au
- The Price Disclosure Guidelines (currently being updated)
  http://www.pbs.gov.au/industry/pricing/price-disclosure-spd/price-disclosure-operational-guidelines-july-2014.pdf
- Drugs Subject to Price Disclosure list
  http://www.pbs.gov.au/info/industry/pricing/price-disclosure-spd/drugs-subject-to-price-disclosure
- Formulary Allocation List
  http://www.pbs.gov.au/info/industry/pricing/pbs-items/formulary-allocations

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