



WELCOME – PBS PRICING FORUM

OVERVIEW

Housekeeping matters

- How is the Department structured?
- PBD is now TAAD – what does this mean for you?

Strategic Agreement – pricing matters

- An overview of what is in it and where implementation is up to

Price negotiations

- The process and guidance

Price disclosure

- Overview and discussion on how it is expected to work post Agreement implementation

Q&A



Departmental Structure

OVERVIEW:

- Responsible Minister
- Secretary of the Department
- Deputy Secretary – looks after Groups of Divisions
- First Assistant Secretary – looks after ‘Divisions’
- Assistant Secretary – looks after ‘Branches’
- Director – looks after ‘Sections’
- Assistant Director – looks after “Sub-Sections/ Sub-Teams”
- Departmental Officer



PBD to TAAD – the Technology Assessment and Access Division

Four branches

- Pharmacy and Insurance Branch – headed by Julianne Quaine
- Office of Health Technology – Assessment Branch – headed by Tracey Duffy
- Office of Health Technology – Policy Branch – headed by Louise Clarke
- Policy and Pricing Branch – headed by Lisa La Rance



PBD to TAAD – the Technology Assessment and Access Division

Temporary acting arrangements

- Penny Shakespeare is acting as Deputy Secretary of the Health Benefits Group (which includes TAAD)
- Ann Smith will be acting as First Assistant Secretary of TAAD



What does the new “TAAD” mean for you?

- The person that you regularly talk to is unlikely to have changed
- The mailing addresses that you send information to have not changed
- David Nott = new and special
- Penny Lovell = everything else
- And...the PB11a news is...



Strategic Agreement

- Still working through the implementation details.
- Legislation will be required for those changes discussed here today.
- **Key aspects are:**
 - Anniversary reductions to F1 drugs – 5 years, 10 years, 15 plus years
 - Increase of 16% price to 25% reduction on listing of first generic
 - New presentation rules
 - Ministerial discretion
 - Price disclosure threshold change



Anniversary Reductions to F1 medicines

- Current 5 Year Anniversary 5% reduction extended to 2022
- New reductions:
 - 10 Year Anniversary 10% reduction
 - 15 Year Anniversary 5% reduction
- “Catch up” reduction 1 June 2018 :
 - One-off 10% - F1 medicines listed since 1 June 2008;
 - A further, one-off 5% - F1 medicines listed before on or before 1 June 2003.
- After the initial 1 June 2018 “catch-up”, 10 year and 15 year F1 SPRs will occur on 1 April each year from 2019 to 2021.



'First generic' reduction - change from 16% to 25%

- Currently:
 - Listing of the first generic brand of a medicine triggers 16% reduction to all brands of that medicine
- From 1 October 2018:
 - The reduction will be 25%
- Reverts back to 16% on 30 June 2022



'First generic' reduction - New Presentation Rules

- Currently:
 - Any new brand that is bioequivalent/biosimilar to an existing brand is considered a first generic and triggers the reduction.
 - This includes new presentations listed by the same manufacturer of the existing brand
- From the date legislation takes effect:
 - Prior to 5th Anniversary of listing of a drug, new presentations listed by the same manufacturer of the existing brand will not trigger.
 - From 5th to 10th Anniversary, the Minister has discretion not to trigger
 - From the 10th Anniversary onwards, new presentations will trigger.



Ministerial Discretion

- Currently:
 - There is no Ministerial discretion for ‘anniversary’ or ‘first generic’ price reductions.
- From the date legislation takes effect:
 - The Minister will have discretion to reduce or not apply price reductions.



Arrangements

- Following passage of legislation the Department will:
 - Release a list F1 medicines and ‘catch up’ anniversary price reductions to take effect on 1 June 2018 and subsequent anniversary reduction days.
 - Provide details on Ministerial Discretion arrangements.



Australian Government
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PBS INFORMATION SESSION

PBS PRICING & MANAGED ACCESS

Technology Assessment & Access
Division

David Nott



Overview

- PBAC functions and outcomes
- Post-PBAC process related to what is required to list on the PBS, including the following:
 - Price negotiation based on PBAC recommendation
 - Estimates agreement
 - Deeds-based arrangements
- Other pricing matters – reference pricing
- Further information and contacts



PBAC functions and Government decision

- Assessment of comparative effectiveness, comparative safety, comparative cost effectiveness.
- Two main approaches
 - as “acceptably cost-effective” OR
 - on a “cost-minimisation” basis.
- The Government cannot list a medicine on the PBS without a recommendation from the PBAC under legislation.
- Final decisions on any listings of medicines and vaccines are taken by the Government.

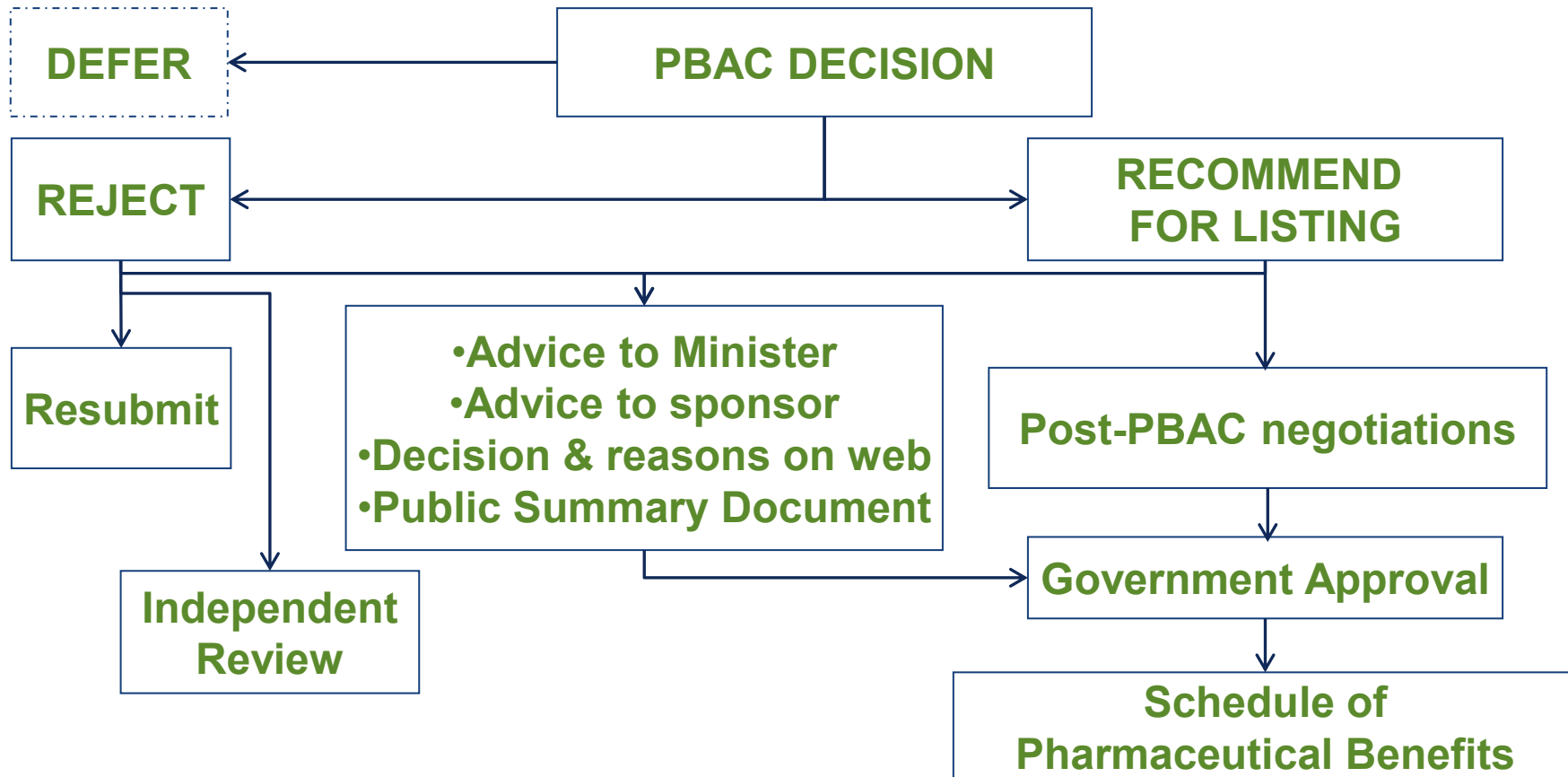


PBAC outcomes

- Recommend
 - Cost-minimisation (no price advantage)
 - Acceptable cost-effectiveness (price advantage)
 - Other factors influential (eg “rule of rescue”)
- Reject
 - Incremental cost-effectiveness ratio (ICER) unacceptably high
 - Poor quality of evidence
 - High level of uncertainty
 - Concerns about usage beyond restriction
 - Other concerns
- Deferral
 - Other information requested by the PBAC (including on price)
 - Parallel process - missing TGA Delegate’s Overview
- This information is made publicly available on the PBS website

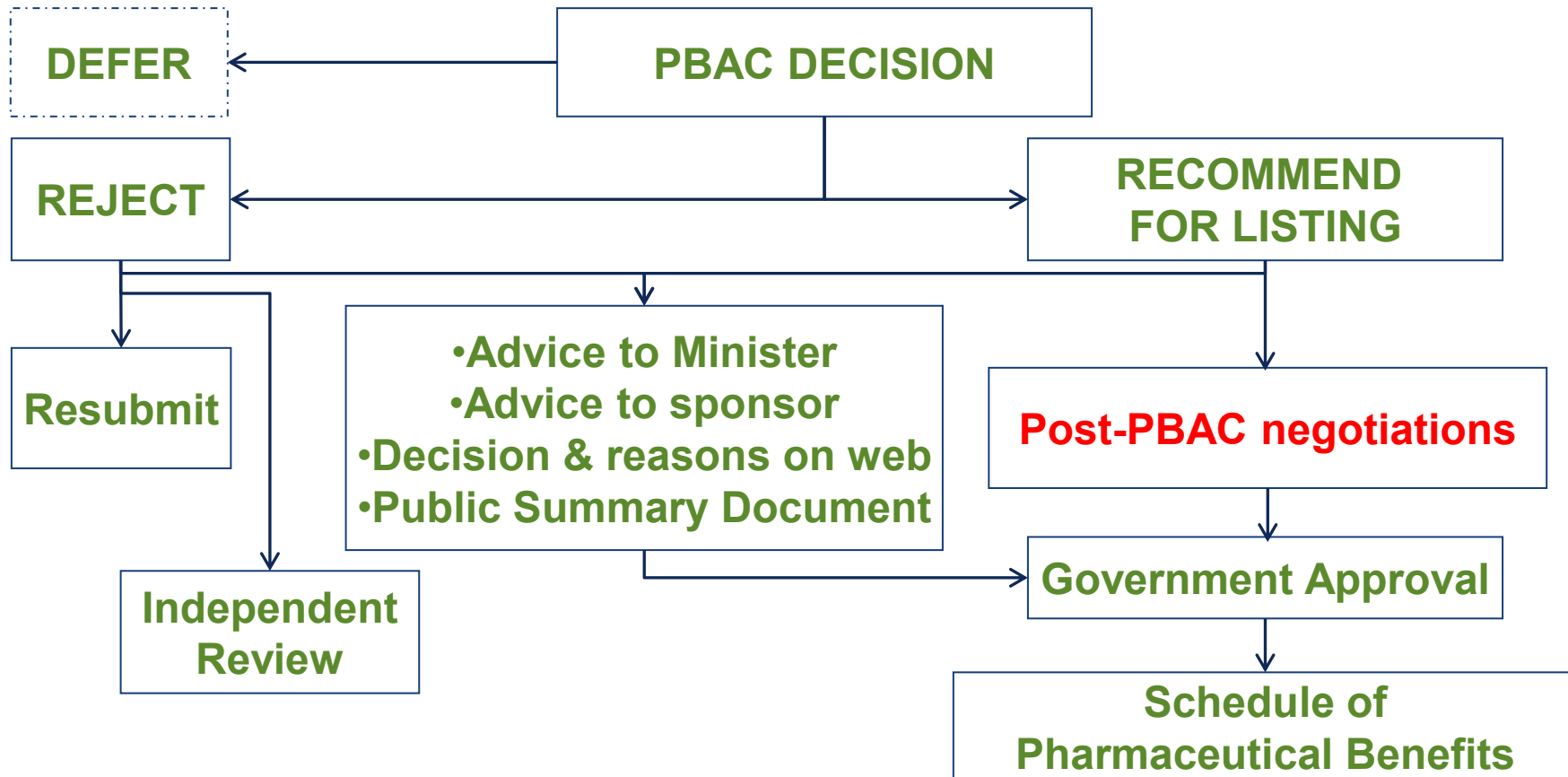


Post-PBAC Process





Post-PBAC Process





Post-PBAC negotiations

- Check listing documentation requirements and provide where necessary.
- Finalisation of restrictions with the HTA team (Office of Health Technology Assessment Branch).
- Establish in-principle pricing agreement.
- Reach agreement on estimates of utilisation and costings.
- Entering into Deeds of Agreement for risk-sharing or special pricing arrangements (where required).
- **Note:** Department relies on **sponsors** to keep matters progressing (get in contact once you have your PBAC outcomes, keep in touch as post-PBAC discussions progress)



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Pricing based on cost-effectiveness

- Health-based reason to justify a price premium for the proposed medicine over the comparator.
- Extent and nature of health gain will justify price increase
 - May include cost offsets (ie MBS)
- Submission of the following:
 - PB11a – request for approved ex-manufacturer price
 - PB11b – cost of goods
 - Supporting documentation of the updated cost-effective methodology (usually in the format of an Excel model)
- Proposals must be consistent with recommendations of PBAC as reflected in the ratified minutes.



Pricing based on cost-minimisation

- No health-based reason to justify a price premium for the proposed medicine over its comparator.
- Price may be set by the cheapest alternative medicine.
- Determine equi-effective dosing where applicable.
- Submission of the following:
 - PB11a – request for approved ex-manufacturer price
 - PB11b – cost of goods (if not already listed)
 - Supporting documentation of the updated cost-minimisation methodology consistent with recommendations made by PBAC (usually in the format of an Excel model)
- Where a recommended comparator has a Deed based arrangement (ie SPA or RSA) – necessary undertakings of confidentiality must first be completed prior to the release of any information.



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Costing pathways

- Cost over \$20m in any of the future years
 - Cabinet
- Cost under \$20m in all future years
 - Minister
- Any save
 - Minister
- Nil financial impact
 - Departmental delegate



Timelines post PBAC

- Agreement with
 - Department of Health – price
 - Department of Health – estimates
 - Portfolio agencies
 - Department of Finance – 10 weeks before listing
 - Department of Health – RSA and/or SPA
- Approved by Minister or Cabinet
- Announced by Minister



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Deeds based arrangements – SPA

- 2 broad types - Special Pricing Arrangements (SPA) and Risk Sharing Arrangements (RSA)
- Deeds of Agreement - established between the Government and the sponsor of a medicine.
- Deed must be in place prior to the date of listing (or change) of a medicine on the PBS.

SPAs

- Gives effect to a Published v Effective price – to allow Australia to have access to medicines at lower prices without affecting the price for the product in other global markets.
- The lower effective price generally involves the Department recovering a percentage of the Commonwealth Expenditure through an agreed rebate.
- SPAs are currently acquitted on a quarterly basis.
- SPA deeds are entered into at the discretion of the Minister (or delegate) – SPA criteria may be provided to sponsors upon request.
- The existence of SPAs on the PBS is made publicly known, however the content of the individual arrangement is confidential and commercially privileged information.



Deeds based arrangements – RSA

RSAs

- Put into place by the Department to manage any uncertainties relating to cost effectiveness, expected utilisation and overall cost that may be identified through the PBAC process.
- Examples of the types of uncertainties that are addressed by RSAs include but are not limited to:
 - Number of eligible patients;
 - Potential use in non-cost effective populations; (i.e. outside the PBS listing)
 - Potential for dose escalation beyond that expected in the submission;
 - Potential for use beyond disease progression, for a longer duration than is cost-effective or in non-responding patients that is not cost effective; and
 - Risk of use in combination or in addition to current therapy rather than replacing existing therapies.
 - Potential for future data gathering (ie Managed Entry)



Deeds based arrangements – RSA

- RSAs are generally financial-based and involves the Department recovering a percentage of Commonwealth Expenditure once an agreed amount or Subsidisation Cap has been exceeded.
- Caps are calculated based on:
 - effective DPMQ less an average patient co-payment
 - Agreed estimates of utilisation across the forward years (usually 5)
- RSAs are generally reconciled annually.
- The existence of a RSA on the PBS is currently not made publicly known.



Deeds based arrangements – more info

- SPA

- For more information around whether a comparator medicine has a SPA - consult the therapeutic relativity sheets and the Note in the Schedule text
- <http://www.pbs.gov.au/info/industry/pricing/pbs-items/therapeutic-relativity-sheets>

- RSA and managed access

- For more information and a standard template - visit PBS Website
- <http://www.pbs.gov.au/pbs/industry/listing/elements/deeds-agreement>

Keep in mind:

- Deeds are contracts between the Commonwealth and sponsors and are thus all individually negotiated and agreed to.
- The Commonwealth may from time to time take a view on how it may wish to manage certain matters within the individual contracts and negotiate with sponsor/s to that end.
 - Zero-lag rebates



Other pricing matters

- Reference pricing
 - Linking medicines considered to be of similar efficacy and safety.
 - PBAC advice **may** be sought relating to interchangeability of medicines.
 - Policy applies in F1 medicines only.
 - Strategic Agreement changes – department has extended notification period to 20 business days for initial response.
- Sponsors do not need to wait for a PBAC outcome to discuss pricing with the Department:
 - Pre-PBAC
 - Price offers
 - Pricing policy



Contact and further information

- For PBAC Guidelines (cost-effectiveness, cost-minimisation requirements) <https://pbac.pbs.gov.au/>
- For listing requirements <http://www.pbs.gov.au/info/industry/listing/elements/>

- For Post-PBAC pricing neg't – pbspricing@health.gov.au
- For Utilisation and Costings – PBS.Estimates@health.gov.au
- For Deeds-based arrangements – RSA@health.gov.au



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PRICE DISCLOSURE



OVERVIEW

- **Legislation**
- **Who, What, How, When..**
- **Weighted Average Disclose Price Calculation**
 - 30 Month Clock
 - Buddy Rule
 - 10% Test
- **CHANGES**
 - New threshold – 30%
 - When it applies
 - When it reverts to 10%
- **Further information and contacts**
- **Questions**



Price Disclosure Legislation

National Health Act 1953

Part VII, Division 3B describes Price Disclosure

National Health (Pharmaceutical Benefits) Regulations 2017

Part 7, Division 2 describes Price Reduction and Price Disclosure

- Regulations 67 to 85

Changes will be provided by amendments to the Act



What drugs are subject to Price Disclosure

- **All brands of drugs on F2 are subject to Price Disclosure**
 - Generally multi-branded drugs (can be single branded)
- **Drugs new to F2**
 - Subject to price disclosure from the day the drug moves to F2
- **Where the drug is already on F2**
 - New brand lists – subject to price disclosure from listing date



What is disclosed?

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

- **Volume** of sales
 - Sales **Revenue** (taking account of any rebates related to those sales)
 - **Incentives** given in relation to the brand – value and type
-
- **Excluding supplies to public hospitals**



How is data disclosed?

Through the **Price Disclosure Submission Utility** (PDSU) to the Department's **Price Disclosure Data Administrator** (PDDA) which is Australian Healthcare Associates

PDDA will provide the electronic **PDSU** to new companies before their first data submission period



When is data disclosed?

- In the **6 weeks** after every 31 March (**by 12 May**) and 30 September (**by 11 November**)
- Data is for the previous 6 months (or less if brand is not listed or drug is not F2 for the whole 6 months)
- Calculation is done once a drug and manner of administration (MoA) has been on F2 for at least 6 months
- The Price Disclosure Guidelines provide details about how the first data collection period works (can be longer than 6 months)



Once all data has been submitted

The PDDA will undertake:

- **Data Analysis**
- **Data Queries**
- Perform the **Weighted Average Disclosed Price (WADP) calculation** in accordance with Act and Regulations
- Perform the **Unadjusted Price Reduction (10% test)**
- **WORKED EXAMPLE**



Weighted Average Disclosed Price Calculation

Two WADP calculations performed

1) with all brand data

If drug/MoA meets 30 Month Clock

2) without originator brand data

The WADP calculation that results in the lowest price will be used to calculate the **Unadjusted Price Reduction (10% test)**



30 Month Clock

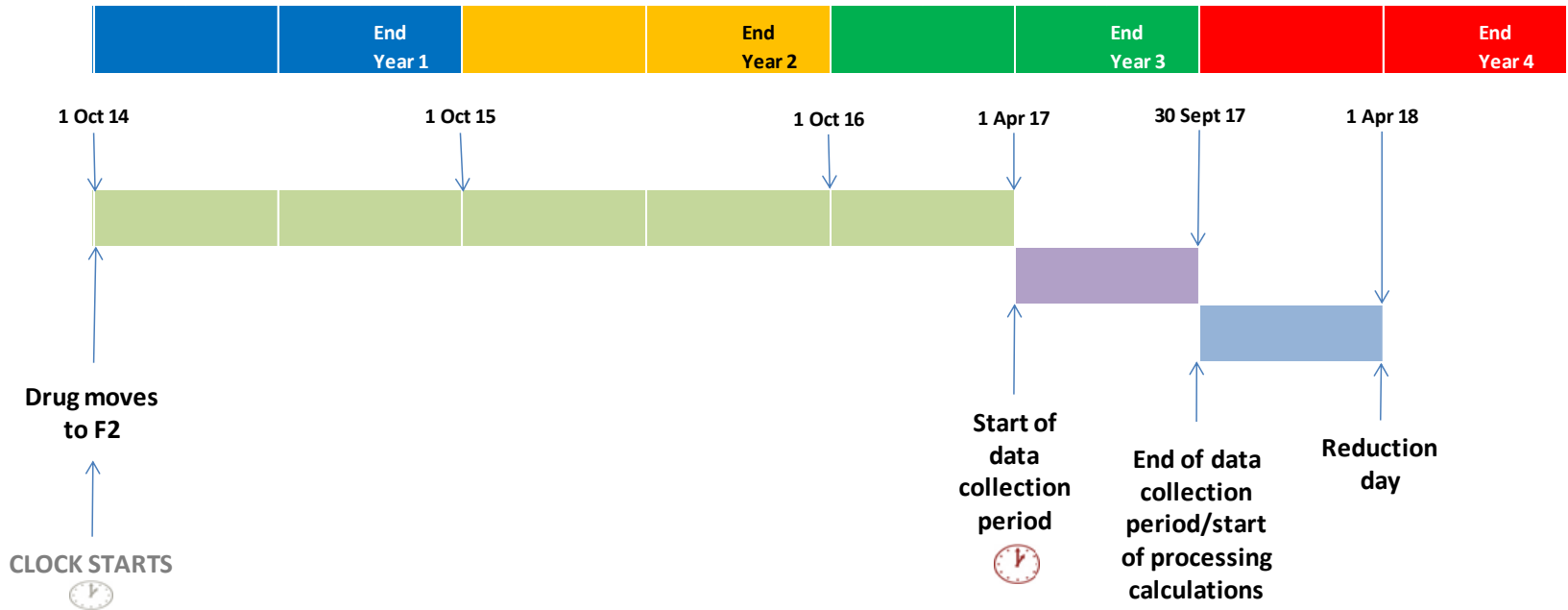
Intended to provide generic brands with an opportunity to compete before originator brand data is removed from the calculation

To start the clock

- two or more brands of a pharmaceutical item (particular form/strength) 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.



30 Month Clock Example





Buddy Rule

- Drug/MoA meets **30 Month Clock**
- Originator brand data will **only be removed** if for each month of the data collection period where an originator brand is listed, there is a non-originator brand also listed
- Where the originator brand is the only brand of a particular form/strength, its **data will not be removed**



Buddy Rule Examples

- All forms/strengths 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: don't remove O - no non-originator match for any month.

Pharmaceutical Item 3

| Oct | Nov | Dec | Jan | Feb | March |
|-----|-----|-----|-----|-----|-------|
| - | - | O | O | O | O |
| - | - | G | G | 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 2

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

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

Pharmaceutical Item 4

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

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



Unadjusted Price Reduction (10% test)

- Remaining calculation steps are performed
- WADP is calculated
- **No changes up to this step**

10% Test

- The WADP is compared to the PBS price and if the difference is at least 10%, the ex-manufacturer price is reduced to the WADP on the reduction day
- **This is where the new change comes into the equation**



The Changes

- **30% Unadjusted Price Reduction (30% test)**
 - where a drug has been subject to two remove originator calculations (generally seven cycles)
- **Increase from 10% to 30%**
- **Revert to 10%** if a drug takes a 30% or greater reduction in **two consecutive** price disclosure cycles



Who will be subject to the 30% test?

- **42 Month Clock**
- This approach will also capture drug/MoAs:
 - that meet the 30 Month Clock but **NOT** the Buddy Rule
 - do **NOT** have an Originator Brand determined



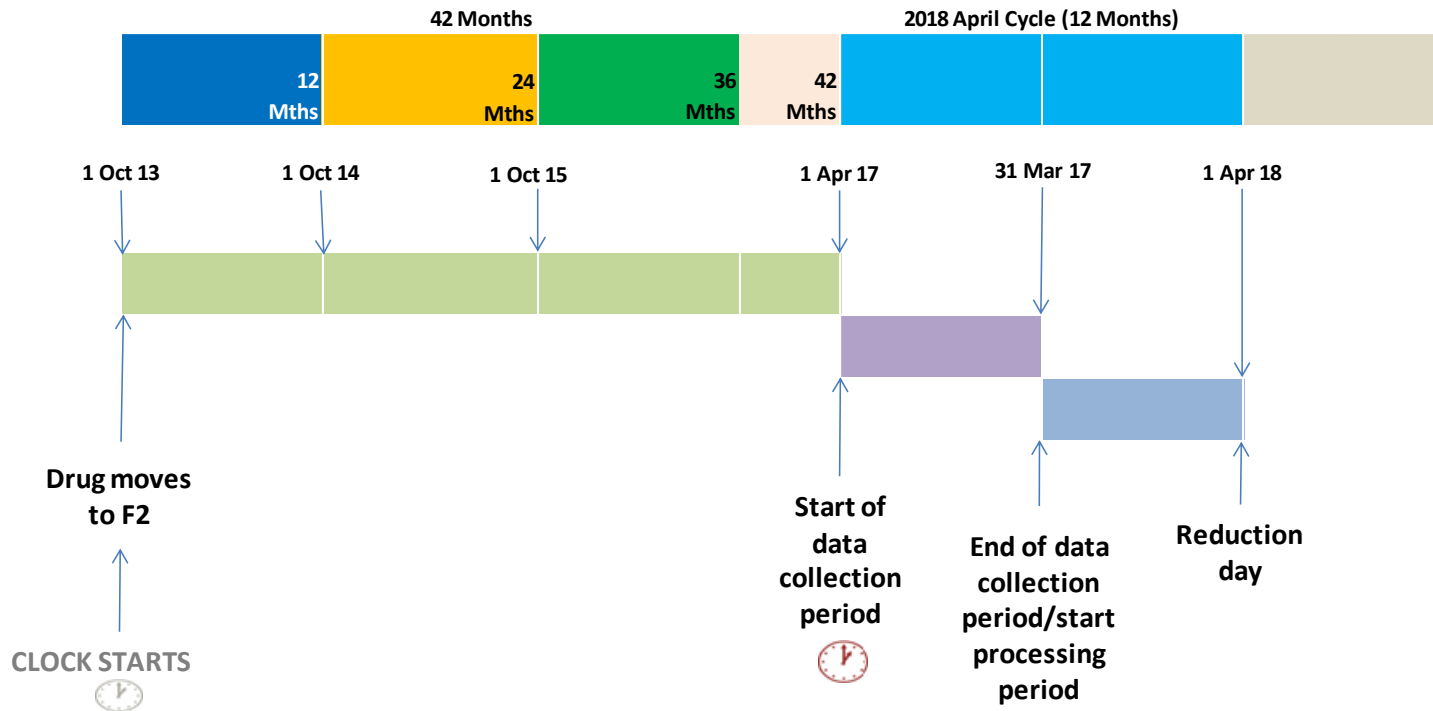
42 Month Clock

- Identify drugs that will be subject to 30% test
- Extension of 30 Month Clock (operates the same way)
- 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.

222/375 drug/MoAs meet **42 Month Clock** for the **2018 April Cycle**



42 Month Clock Example





30% Test - How long will this last?

Outcomes will continue to be monitored by the Department and PDDA

30% test will continue until it is breached in **TWO CONSECUTIVE** calculations

Reverts to 10% the calculation after



Impact of Changes on YOU

- What do you have to do differently? **Nothing**
- Timelines for data disclosure **do not change**



Notification of Outcomes

- **No changes to timeframes**
- **Outcomes updated** to indicate what threshold your drug/MoA was subject too
- **Dispute Resolution Administrative Process** remains the same
 - Encourage companies to contact the Team to discuss concerns prior to formally registering a dispute



Sustainability Reviews

- **Short term approach**
- Undertaken until legislative change could be made
- Existing processes may be utilised:
 - Price increase request
 - Delisting from the PBS



Further Information

- www.PBS.gov.au
- Price Disclosure Web Page
- Pricing of PBS Items Web Page



Contacts

- Contacting the Department
- Email: pricedisclosure@health.gov.au
- Telephone: (02) 6289 2303

- Email: pbspricing@health.gov.au

- Contacting the Price Disclosure Data Administrator (PDDA)
- Email: admin@pricedisclosure.com.au
- Telephone: 1300 336 062



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Questions
