Fact Sheet
Pharmaceutical Benefits Scheme (PBS) Reform

1. Introduction

The purpose of this paper is to provide further detail about the PBS reform measures and associated implementation timeframe in addition to that released on 16 November 2006. Further details about the reforms will be released by the Department from time to time as they become available.

2. Background

The Government is making changes to the Pharmaceutical Benefits Scheme (PBS) to give Australians continued access to new and expensive medicines while ensuring the PBS remains affordable into the future.

The reforms comprise a range of inter-connected measures:

- Changes to the pricing of PBS listed medicines;
- Pharmacy and pharmaceutical wholesaler compensation arrangements;
- Streamlined authority approvals for some medicines; and
- Establishment of an access to medicines working group.

The Government is also considering a generic medicines awareness campaign.

It is timely to introduce these changes, with the PBS entering a phase of lower, more stable growth and with the knowledge that patents for over 100 drugs will be expiring in the next ten years. These changes will make the PBS an even stronger system with the government paying less for certain medicines without increasing the cost to patients.

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3. Measures

3.1. Changes to the Pricing of PBS listed medicines

3.1.1 Creation of formularies

From 1 August 2007, PBS medicines will be listed on two separate formularies:

- Formulary 1 (F1) will comprise single brand medicines. However, it will not contain single brand medicines which are interchangeable at the patient level[1] with multiple brand medicines[2]; and
- Formulary 2 (F2) will comprise multiple brand medicines and any single brand medicines which are interchangeable with multiple brand medicines at the patient level.

A medicine will be classified into only one formulary. If one formulation or strength of a medicine has multiple brands, then the entire molecule will be listed on the F2 formulary,

[1] Medicines in the following groups have been recommended by the Pharmaceutical Benefits Advisory Committee (PBAC) and determined by the Minister to be interchangeable at the patient level: ACE inhibitors, angiotensin II receptor antagonists, calcium channel blockers, H2 receptor antagonists, proton pump inhibitors and the HMG Coenzyme A reductase inhibitors (pravastatin & simvastatin only).

[2] Medicines will move from F1 to F2A from time to time, as new brands of F1 medicines are listed on the PBS and competition for the supply of those medicines commences.

even if multiple brands are not available in other formulations or strengths of that medicine. Formulary lists as at 1 December 2006 were distributed to stakeholders on 20 December 2006.

Over the counter medicines subsidised through the PBS will be separately flagged and distributed across the formularies subject to the same pricing arrangements as apply within each formulary.

3.1.2 Ongoing price links

- There will be no ongoing price links across medicines listed on F1 and those listed on F2. Attachment A provides examples of how current reference pricing groups will apply when the formularies take effect.
- Reference pricing will continue to apply between medicines that are linked within reference pricing groups on F1.
- Reference pricing will continue to apply within Therapeutic Group Premium (TGP) groups and across different brands of the same medicine listed on F2.

3.1.3 Pricing mechanisms

3.1.3.1 Price disclosure

Over time, medicines listed on F2 will move to a system of price disclosure where the price that the Government pays will reflect more closely the actual price at which the medicine is being sold.

A transitional pricing arrangement will apply to F2 with two sub-formularies being created:

- Formulary 2A (F2A) will comprise medicines that did not attract significant trading terms to pharmacy at 1 October 2006 (i.e. less than 25%).
- Formulary 2T (F2T) will comprise medicines that did attract significant trading terms to pharmacy at 1 October 2006 (i.e. 25% or more).

3.1.3.2 All medicines on F2A

Medicines on F2A will be subject to the following pricing arrangements:

- Staged price reductions of 2% per year for three years will apply commencing on 1 August 2008.
- The 12.5% price reduction policy will continue to apply, where relevant.
- Price reductions for medicines on F2A will apply to all brands, forms and strengths of that medicine and to products that are interchangeable with that medicine.
- Price disclosure:
  - Suppliers listing a new brand on or after 1 August 2007 must agree to disclose the actual market price as a condition of listing. Staged price reductions for that medicine will apply until such time as the price of the medicine is based on the disclosed price.
  - The first price reductions resulting from disclosure will take effect from 1 August 2009. Price reductions will reflect the weighted average disclosed price. (refer Section 3.1.5)
  - Pricing based on disclosure will then continue on an annual cycle.

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3.1.3.3 All medicines on F2T

Medicines on F2T will be subject to the following pricing arrangements:

- A one-off 25% mandatory price reduction will apply on 1 August 2008.
- The 12.5% price reduction policy will continue to apply, where relevant.
- Price reductions for medicines on F2T will flow on to all brands, forms and strengths of that medicine and to medicines that are interchangeable with that medicine.
- For a defined list of patented medicines on F2T, the 25% price reduction will be phased over the remaining patent life.
- Price disclosure:
  - Suppliers listing a new brand on or after 1 January 2011 must agree to disclose the actual market price as a condition of listing.
  - The first price reductions resulting from disclosure will take effect from 1 August 2012. Price reductions will reflect the weighted average disclosed price. (refer Section 3.1.5)
  - Pricing based on disclosure will then continue on an annual cycle.

3.1.3.4 F1 medicines entering F2 after 1 August 2007

- Medicines moving from F1 will, as a general rule, join the F2A formulary.
- The 12.5% price reduction policy will continue to apply, where relevant.
- Staged price reductions of 2% will apply as per F2A up to and including 1 August 2010.
- Price disclosure:
  - Suppliers listing a new brand on or after 1 August 2007 must agree to disclose the actual market price as a condition of listing.
  - The first price adjustments resulting from disclosure will take effect from 1 August 2009. Price reductions will reflect the weighted average disclosed price.
  - Pricing based on disclosure will then continue on an annual cycle.

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3.1.4 Price disclosure

The following principles will apply:

1. Price disclosure arrangements will be triggered by the listing of a new brand of a listed medicine on or after 1 August 2007 (F2A) and on or after 1 January 2011 (F2T).
2. Unless a 12.5% or 2% price reduction applies, the initial listing price of the new brand will be the same price as other brands of that medicine. However, it will be a requirement of listing that the supplier of the new brand agrees to disclose to the Department of Health and Ageing the actual price at which they sell that brand to wholesalers and/or pharmacies.
3. All other suppliers of that medicine (brands, forms and strengths) will be invited to volunteer to disclose the prices at which they sell their medicine.

3.1.5 Calculation of the weighted average price

The following principles will apply:

1. For the purposes of calculating the weighted average disclosed price, the disclosed price will be the ex-manufacturer price, i.e. excluding the wholesaler mark-up.
2. Price reductions as a result of price disclosure arrangements will reflect the weighted average disclosed price.
3. Calculation of the weighted average disclosed price will exclude the first month of data following listing, although these data will still be collected. This is to ensure that the initial period of market competition does not unduly influence the weighted average.
4. The submission of price data to the Department will be at a specified time (expected to be on a quarterly basis).
5. The weighted average disclosed price will not apply if the required price reduction is less than 10% of the current PBS ex-supplier price.
6. If the reduction is greater than 10%, the weighted average disclosed price will become the government subsidy price for that medicine.
7. All suppliers will be advised of any price reduction six months before the price change takes effect.

An example of how price disclosure would work is at Attachment B.

3.1.6 Guarantee supply

It is anticipated that legislation will protect supply by requiring the suppliers of new brands of medicines listing on the PBS to guarantee to supply for a minimum period and imposing penalties if they fail to meet this commitment.

3.2. Pharmacy and wholesaler support arrangements

Pharmacists will be provided assistance to adjust to the new arrangements. This will take the form of:

- An incentive of $1.50 to dispense a substitutable, premium-free medicine. This applies only to PBS subsidised medicines. Under-co-payment medicines and private scripts will not be eligible for this payment.
- An incentive of 40c for each prescription processed using PBS Online; and
- Increases in pharmacy mark ups and dispensing fees.

Additional funding of $69 million over three years will be added to the Community Services Obligation (CSO) Funding Pool to compensate pharmaceutical wholesalers for the impact on the wholesale margin resulting from the new pricing arrangements. Wholesalers are eligible to access the CSO Funding Pool if they can demonstrate that they meet specified service standards.

3.3. Streamlining authority approvals for some medicines

From 1 July 2007 the PBS-listed medicines that require an authority approval prior to prescribing will be separated into two categories:

1. Medicines that require approval from Medicare Australia prior to prescribing.

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- This category will include medicines for short term use, Section 100 medicines, requests for increased quantities and those medicines with an increased potential for misuse, abuse or adverse effects, such as narcotic medicines.

2. Medicines where the prescriber will not have to obtain approval from Medicare Australia prior to prescribing.
   - This will not negate the need for the prescriber to ensure that patients receiving such medicines meet the prescribing requirements as specified by the Pharmaceutical Benefits Advisory Committee (PBAC) and specified in the PBS Schedule.
   - This will apply to medicines for the treatment of long term chronic conditions (such as diabetes and osteoporosis) where the patient and doctor are both very familiar with the condition and medication. Medicare Australia will undertake education and monitoring to ensure doctors are aware of the changes.

A list of PBS medicines and item codes for which the streamlined authority arrangements will apply was distributed to stakeholders on 20 December 2006.

3.4. Access to medicines working group

A Medicines Australia and Department of Health and Ageing working group will be set up to consider issues regarding timely and appropriate access to new medicines for the PBS. The working group will establish a work plan and performance indicators for its work and report against these indicators. Other relevant bodies, such as the Therapeutic Goods Administration and the PBAC will be involved as required. The first meeting of this group is expected to take place in April 2007.

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3.5. Generic medicines awareness campaign

The Government is considering a public awareness campaign to promote the use of generic medicines. The campaign is expected to comprise print, radio and television advertisements, which promote the safety, health and economic aspects of generic medicines. It would focus in particular on high users of the PBS, including concession card holders and those with chronic, long term conditions.

The campaign would commence in late 2007 or early 2008 and continue until 2009-10.

4. Implementation

4.1 Stakeholder engagement

The Department of Health and Ageing will establish a stakeholder reference group as a forum for providing updates to stakeholders on implementation progress and as a forum for seeking feedback on a range of issues.

The stakeholder reference group comprises representation from the Australian Medical Association, the Australia Self Medication Industry, the Generic Medicines Industry Association, Medicines Australia, the National Pharmaceutical Services Association, the Pharmacy Guild of Australia and the Pharmaceutical Society of Australia. The first meeting of this group took place on 19 December 2006.

4.2 Next steps

The Department of Health and Ageing will manage the implementation of the reforms in

conjunction with other government agencies and key stakeholder groups. Key issues to be addressed in the implementation process will be:

- Amendments to the *National Health Act 1953* by 1 July 2007.
- Development of information for industry, pharmacies, wholesalers and prescribers on the new arrangements.
- Finalisation and publication of F1 and F2 lists.
- Finalisation and publication of authority-required medicines that will be covered by the new streamlined process.
- Development of procedural guidelines outlining price disclosure requirements, an IT system to collect this information, and training for industry on these requirements.
- Redesign of Medicare Australia systems and prescribing and dispensing software to conform to the new requirements.
- Formation of the Medicines Australia – Department of Health and Ageing working group.
- Development and implementation of a generic medicines awareness campaign.

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Attachment A

Examples of how current reference pricing groups will be split across formularies[3]

Reference Pricing Group L01 (1) – Antineoplastic agents (for the treatment of cancers):

Medicines in group	Formulary
Paclitaxel	F2A
Vinorelbine tartrate	F2A
Docetaxel	F1
Doxorubicin	F1
Gemcitabine	F1
Pemetrexed	F1
Topotecan	F1

Reference Pricing Group N06 (3) – Psychoanaleptics (for the treatment of depression):

Medicines in group	Formulary
Citalopram hydrobromide	F2T
Fluoxetine hydrochloride	F2T
Fluvoxamine maleate	F2T
Mirtazapine	F2T
Moclobemide	F2T
Paroxetine hydrochloride	F2T
Sertraline hydrochloride	F2T
Escitalopram oxalate	F1
Reboxetine mesilate	F1

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[3] Schedule of Pharmaceutical Benefits, August 2006

Attachment B

Example of how price disclosure would operate

Note: Assumes drug with single item code, and all manufacturers disclosing price information. Other disclosure scenarios (eg. where only one manufacturer discloses price information) will result in different actions.

Price disclosure - example

1. Single brand medicine, PBS price (ex-manufacturer price) is $100, originator sells with no discount – no disclosing brands

PBS Price	Manufacturer	Actual supply price	Share of volume
$100.00	Originator	$100.00	100%

2. New brand enters after patent expiry, with disclosure a condition of listing.
New brand offers 30% discount to pharmacy and secures 20% of volume.
In this scenario the originator also elects to disclose.

PBS price	Manufacturer	Actual supply price	Share of volume
$100.00	Originator	$100.00	80%
	New brand	$70.00	20%
		WAP	**$94.00**
		price difference	6.0%
		Action:	no price reduction

Weighted average pricing (WAP) is less than 10% below ex-manufacturer price, so there is no price reduction.

3. New brand gains 40% market share with 30% discounts to pharmacy

PBS price	Manufacturer	Actual supply price	Share of volume
$100.00	Originator	$100.00	60%
	New brand	$70.00	40%
		WAP	**$88.00**
		price difference	12.0%
		Action:	price reduction

The WAP is 12% below the ex-manufacturer price, so a price reduction is triggered.

4. New brand gains 50% market share with 50% discounts to pharmacy

PBS price	Manufacturer	Actual supply price	Share of volume
$100.00	Originator	$100.00	50%
	New brand	$50.00	50%
		WAP	**$75.00**
		price difference	25.0%
		Action:	price reduction

The WAP is 25% below the ex-manufacturer price, so a price reduction is triggered.

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DETERMINATION OF PRICES FOR PBS LISTED DRUGS

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DETERMINATION OF PRICES FOR PBS LISTED DRUGS

1. OVERVIEW

The National Health Act (the Act) provides the legislative basis for determining the prices of the pharmaceuticals that are subsidised by the Australian Government. The Act requires the Pharmaceutical Benefits Advisory Committee (PBAC) to consider the cost of a drug as well as its efficacy and toxicity. The Schedule of Pharmaceutical Benefits lists the drugs that are available through the Pharmaceutical Benefits Scheme (PBS) and includes their subsidised price.

The Act specifies that a drug may not be subsidised on the PBS, unless the PBAC has recommended listing.

The PBAC bases its recommendations for listing on the evaluation of information provided by a drug's suppliers. The PBAC's two main bases for recommending listing are:

- **cost-effectiveness** – where a drug has been demonstrated to provide additional benefits over current therapies, but at a higher cost; or, for drugs with no alternatives, where the benefits are considered worth the cost; or

- **cost-minimisation** – for a drug that is considered to provide similar health outcomes for similar costs compared to a drug already listed on the PBS.

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In this context, cost-effectiveness and cost-minimisation are economic terms which describe the basis of the PBAC's listing recommendations.

Listing recommendations based on cost-effectiveness support the Australian Government's policy of paying a higher price for a drug only if that drug provides additional benefits over other available drugs. Hence the provisions of the Act indicate that the PBAC can only recommend listing a drug that is more costly than a current therapy, if that drug provides a significant improvement in efficacy or reduction in toxicity.

Drugs that the PBAC recommends on a cost-minimisation basis are subject to reference pricing (see Section 2.2) which means that the price of a drug to be listed, is referenced to the price of a similar drug (or drugs) already listed on the PBS. Such drugs are seen as forming a reference pricing group. Drugs referenced to one another are detailed in the Pharmaceutical Benefits Pricing Authority's (PBPA's) Therapeutic Relativity Sheets.

Reference pricing groups usually consist of drugs with the same pharmacological action and usually treat similar conditions. However, some reference pricing groups include drugs with different modes of action (see Section 3.2). A list of current reference pricing drug categories based on the information in the Therapeutic Relativity Sheets is at Attachment A.

There are a number of ways that the price of a listed drug can be adjusted after its initial listing. If the price of a drug in a reference pricing group is reduced below the current benchmark price, the prices of the other drugs in that group should be reduced accordingly (see Section 2.2 and Section 3.1).

Prices of some listed drugs are adjusted through the application of the Weighted Average Monthly Treatment Cost (WAMTC) methodology, which is a particular form of reference pricing (see Section 3.2). Prices of drugs that are subject to WAMTC adjustment are no longer adjusted using the dosage relativities set out in the Therapeutic Relativity Sheets. There are currently seven groups of drugs whose prices are adjusted relative to each other according to the WAMTC methodology. Two of these groups have drugs from more than one therapeutic grouping in the PBS schedule.

Drugs in some reference pricing groups are eligible to have a price premium, which the consumer pays. The Government continues to pay the base subsidised price (i.e. the benchmark price) for drugs that have such a price premium applied (see Section 4).

2. DETERMINATION OF PRICE AT THE TIME OF PBS LISTING

Before a drug can be listed on the PBS, the PBAC must recommend listing.

The PBAC usually recommends a drug for listing on the basis of either 'cost-effectiveness' or 'cost-minimisation'. These terms are explained below.

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2.1 Pricing of drugs recommended on basis of cost-effectiveness

The PBAC considers that a drug is of acceptable incremental 'cost-effectiveness' if the benefits that the drug provides over its main comparator(s), justifies a price higher than that of the comparator(s).

Drugs that are listed on the basis of cost-effectiveness are not directly subject to reference pricing. s47C s47C However, the pricing of some drugs recommended on a cost-effectiveness basis may be linked to that of a cost-minimised drug. For example, drug A is considered cost effective against cost B, and pricing is based upon the price of drug B plus an additional 40%. As the price of the cost-minimised drug changes, so may that of the other higher priced drug.

Aprepritant is an example of a drug that has been listed on a cost-effectiveness basis. It was shown to provide additional benefits in effectiveness that were considered to be of substantial clinical importance, at an acceptable additional cost.

When a drug might be used in a range of clinical settings but the PBAC considers it cost-effective for one of those purposes only, the recommendation will restrict subsidy to that one condition.

For a cost-effectiveness listing, the PBPA normally determines the price by using the 'cost plus' method.

The listing price is based on the cost of manufacture and margin on those costs. This margin can vary and is determined on a case-by-case basis. A margin of around 30% is usually considered reasonable, but higher margins may be recommended for low volume

products (e.g. cost to the PBS of $50,000 per annum or less) and lower margins may be recommended for high volume products.

The cost plus method uses cost data from the sponsor. Costs may consist of manufacturing costs including landed cost, packaging, drug content, quality assurance, plant and equipment, manufacturing overheads and Therapeutic Goods Administration (TGA) fees. A range of other costs can sometimes be also included. For example, in one case, the PBPA recognised the cost of setting up a patient registry to monitor how the drug was used, as a legitimate cost for providing the drug to consumers.

Perhexiline maleate tablet and terbutaline injection are examples of products for which the 'cost plus' method is used.

2.2 Cost-minimisation - reference pricing

A 'cost-minimisation' recommendation can be made where the PBAC considers a drug to be of similar safety and efficacy to a currently listed drug. The PBAC guidelines describe the therapeutic claim as 'no worse than' its main comparator. A drug listed on the basis of a cost-minimisation recommendation, forms part of a reference pricing drug group.

When making cost-minimisation recommendations the PBAC gives advice to the PBPA about equi-effective doses of the new drug and its comparator. This advice is indicated in the PBPA Therapeutic Relativity Sheets.

An example of a cost-minimisation recommendation is:

> "*bicalutamide 50mg daily was accepted on a cost-minimisation basis compared to flutamide 250mg three times daily*"

In this case, the reference pricing group would be flutamide, bicalutamide and any other drug already cost minimised to flutamide.

Drugs within a reference pricing group are priced at the same level by the PBPA. In practice this means that the lowest priced brand or drug, sets the benchmark price for the other brands of that drug and/or the other drugs within the same reference pricing group.

For example, naratriptan was recommended on the basis that 2.5 mg naratriptan was equi-effective to a dose of 50 mg sumatriptan. Both have the same dispensed price which is $26.70 for:

- 4 x 2.5 mg naritriptan tablets; and
- 4 x 50 mg sumatriptan tablets.

Reference pricing groups usually consist of drugs from the same ATC therapeutic sub-group (see below). Although some reference pricing groups are made up of drugs from more than one therapeutic sub-group.

A list of current reference pricing categories, based on the PBPA Therapeutic Relativity Sheets, is at Attachment A.

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Where a new drug is offered at a price that is lower than the existing benchmark, the subsidy prices of other drugs in the reference pricing group should reduce. However, under certain conditions, suppliers can charge a price that is higher than the subsidy price by adding a brand premium or therapeutic group premium (see Section 4).

2.3 Pricing different strengths of the same drug

The guidelines for new strengths of already listed drugs indicate that as a general rule, the pricing of half strength formulations is at two-thirds to 70% of the full strength. For example, a new 10 mg tablet would be priced at about two-thirds of the existing 20 mg tablet. Likewise, a double strength is usually one and two-thirds times the price of the single strength. There are no general guidelines for other strength ratios.

These guidelines do not apply in all cases. For example, there can be 'flat' pricing for expensive drugs where history indicates pricing of the different strengths is based on the same price per mg (or gram or unit etc).

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2.4 Pricing combination products

A combination product is a product that is made up of more than one chemical entity. The pricing of combination products is usually based on the sum of the individual components, at price to pharmacist level. Advice from the PBAC in relation to relativity is also taken into account.

For example, the combination tablet containing enalapril maleate 20 mg plus hydrochlorothiazide 6 mg was recommended on a cost-minimisation basis compared with enalapril maleate 20 mg and hydrochlorothiazide 12.5 mg as individual items.

Where a new combination product contains a component at a strength that is not already listed as a separate item (e.g., 100 mg-2.5 mg but where the listed items are 100 mg and 5 mg), the guidelines applying to new strengths of listed drugs may be invoked. For example,. the price of the 100 mg-5 mg strength would be the sum of the prices of the listed components and the price of the 100 mg-2.5 mg formulation would be the sum of the price to pharmacist for the 100 mg and two-thirds of the price of the 5 mg listing.

2.5 Drugs equal for pricing purposes but with different listed dispensed prices

Often drugs considered equal for pricing purposes do have the same dispensed price in the PBS schedule. However, there are a number of scenarios which will result in the dollar value of two equi-effective drugs not being the same. Such scenarios include the six listed below which are explained in more detail, with examples, in Attachment B:

– The dosage relativity recommended by PBAC does not reflect the tablet strengths (B1).

– Two or more reference priced drugs are available in different pack sizes (B2).

– Two or more reference priced drugs are available in different numbers of strengths (B3).
– Price differences resulting from rounding (B4).
– The ratio of prices between strengths is different (B5).
– One drug may be worth different amounts for different indications (B6).

3. HOW PRICES OF ALREADY LISTED DRUGS ARE ADJUSTED

There are a number of ways that the price of a listed drug can be adjusted after its initial listing on the PBS at the original listing price.

3.1 Adjustment in accordance with price movements in the therapeutic group

Whenever the price of a drug in a reference pricing group is reduced below the current benchmark price, the subsidised prices of the other drugs in that group should be reduced accordingly. The reduction in price is based on the policy that the price of equi-effective doses of two comparable drugs should be the same.

Sometimes it is not practical to set the prices of equi-effective doses of drug to be exactly the same. In these cases the closest approximation to equal prices for equi-effective doses is applied (See Section 2.5).

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3.2 Weighted average monthly treatment cost (WAMTC)

Weighted Average Monthly Treatment Cost (WAMTC) methodology is a particular form of reference pricing, and when used replaces the pricing based on the dosage relativity of the PBPA's Therapeutic Relativity Sheets. In theory, any group of two or more drugs recommended by the PBAC for listing on a cost-minimisation basis would be eligible to form a WAMTC group, but the methodology is generally confined to more complex groups. New WAMTC groups are formed by the PBPA provided the PBAC has no objection that such a group be formed.

The aim of the WAMTC methodology is to adjust pricing of drugs that have been accepted by the PBAC as being therapeutically similar, so that their cost to the Government, exclusive of brand or therapeutic group premiums (see Section 4), is the same.

The simpler form of reference pricing is usually based on the therapeutic relativities of drugs, from clinical trials, as presented to the PBAC at the time of submission (ie 20 mg of drug X was deemed equivalent to 30 mg of drug Y). Price is then generally determined on this basis. However, the WAMTC methodology is more complex and is intended to account for different usage practices in the market place rather than the formal clinical trial situation. Using sample data on prescribing behaviours and data on script volumes, a weighted average daily (and thus monthly) cost of treatment can be obtained.

All drugs listed under the Therapeutic Group Premium (TGP) Policy (see Section 4.2) are automatically subject to pricing reviews using WAMTC. In addition, some WAMTC groups

include drugs from more than one therapeutic sub-group (eg CCBs and SSRIs plus in the Table below).

Drugs listed in TGP groups have been accepted by the PBAC as being interchangeable at the patient level because they all act by the same mechanism and have all been accepted as being of similar effectiveness and having similar adverse effects.

Drugs listed in a non-TGP WAMTC group (and any other group of drugs considered equal for pricing purposes) are not necessarily substitutable at the individual patient level, as they may not act by the same mechanism. However, since they are considered to provide the same health outcomes on a population basis, they are combined into a single reference pricing group.

There are currently seven groups of drugs whose prices are adjusted according to WAMTC methodology. These are listed in the table below.

WAMTC groups

WAMTC Group	Drugs in WAMTC Group	ATC Group	Items excluded	Review*
Angiotensin converting enzyme (ACE) inhibitors	captopril, enalapril, fosinopril, lisinopril, perindopril, quinapril, ramipril, trandolapril	C09		Apr
HMG Coenzyme A reductase inhibitors (Statins)	atorvastatin, pravastatin, simvastatin	C10	fluvastatin	Apr
Angiotensin II receptor antagonists (ATRAs)	candesartan, eprosartan, irbesartan, telmisartan	C09		Apr
Calcium channel blockers (CCBs)	amlodipine, felodipine, lercanidipine, nifedipine, diltiazem	C08		Apr
Antidepressants: Selective serotonin reuptake inhibitors (SSRIs) plus	citalopram, escitalopram, fluoxetine, fluvoxamine, mirtazapine, moclobemide, reboxetine, paroxetine, sertraline	N06	venlafaxine	Aug
H_2-receptor antagonists (H_2RAs)	cimetidine, ranitidine, nizatidine, famotidine	A02		Dec
Proton pump inhibitors (PPIs)	esomeprazole, lansoprazole, omeprazole, pantoprazole, rabeprazole	A02	esomeprazole tablet 40mg	Dec

*This is the month in each year that the PBPA considers the review results. Secretariat starts reviews several weeks before a PBPA meeting.

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4. SPECIAL PATIENT CONTRIBUTIONS

Special pharmaceutical benefits arrangements allow a sponsor to charge a higher price to the consumer for a PBS item, than the Australian Government is prepared to subsidise. Patients pay the extra charge together with the usual patient co-payment.

The three different types of these arrangements are described below.

4.1 Brand Premium Arrangements

The benchmark price is the price of the lowest priced brand for that form of the drug. This benchmark price is determined by the PBPA.

Sponsors of alternative brands may charge a brand premium for s47C **form and strength of** s47C **drug only where there is an alternative brand of that same form and strength of the drug** s47C **at the benchmark price**. Different brands of the same drug are indicated in the Schedule by having like superscripts next to the brand name for a particular drug form and strength (for example "[a] Poly-Tears" and "[a] Tears Naturale").

The level of the premium is a matter for the sponsor of that brand. The amount of the premium is payable by the patient in addition to the patient co-payment.

The rationale for this approach to brand premiums is to ensure that consumers always have access to at least one brand of every s47C drug, available at the benchmark price. Pharmacists are permitted to offer a consumer a cheaper brand of the same drug if a drug with a brand premium is prescribed (provided the prescriber has not vetoed this).

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4.2 Therapeutic Group Premium (TGP) Arrangements

The Therapeutic Group Premium (TGP) policy was introduced on 1 February 1998. This policy applies to a sub-set of the therapeutic groups (described in Section 2.2). These groups are known as the Therapeutic Group Premium (TGP) groups.

TGP groups consist of drugs considered clinically similar and interchangeable on an individual patient basis. Currently there are four TGP groups consisting of chemical entities with the same mode of action in the same pharmacological group, accepted on a cost-minimisation basis and with drugs which are considered similar at an individual patient level. TGP groups are selected by the Minister and are automatically subject to reference pricing using the WAMTC methodology

The policy provides that, while the Australian Government only subsidises to the level of the lowest priced drug, suppliers of the other drugs are allowed to set additional premiums to be paid by patients, as long as certain conditions are met.

Under the TGP policy, the supplier of a particular formulation or strength of a drug in a TGP group can have a therapeutic group premium, s47C **there is a drug available at the benchmark price in the group as a whole.**

At present there are four TGP groups which have been constructed on PBAC advice, based on therapeutic interchangeability at the individual consumer level:

- H_2-receptor antagonists (cimetidine, ranitidine nizatidine, famotidine)

- Angiotensin converting enzyme (ACE) inhibitors (captopril, enalapril, fosinopril, lisinopril, perindopril, quinapril, ramipril, trandolapril)

- HMG Coenzyme A reductase inhibitors (statins) (atorvastatin, pravastatin, simvastatin) (*Note that fluvastatin is excluded from this group for WAMTC purposes but is affected by its outcomes through relativity with simvastatin)*

- Dihydropyridine-derivative calcium channel blockers – CCBs (amlodipine, felodipine, lercanidipine, nifedipine).
  (Note that these four drugs plus diltiazem form a WAMTC group through diltiazem's relativity to the other drugs).

The products in these groups have their prices reviewed using the WAMTC methodology. At least one drug from the group will set the therapeutic benchmark price. While the subsidy price for the alternate drugs in the group will be at the same level as the benchmark price, sponsors of the alternate drugs may charge a TGP if they so desire. Currently, three of the four TGP groups have drugs with TGPs.

The premium and co-payment are paid by the patient. The rationale for this approach is the same as for brand premiums, which is to ensure that patients always have access to one product in each of these groups, at the benchmark price. However, unlike brand premiums, pharmacists are not permitted to offer another drug within the same therapeutic group. Only the prescriber may choose between drugs within a therapeutic group

The HIC allows prescribers to seek exemption from the premium for their patients if:

- adverse effects occur with all of the base-priced drugs;
- drug interactions occur with all of the base-priced drugs;
- drug interactions are expected to occur with all of the base-priced drugs; or
- the transfer to a base-priced drug would cause patient confusion resulting in problems with compliance.

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4.3 Other Special Patient Contribution Arrangements

These special patient contribution arrangements can apply to any PBS item but to date have only been applied to 'unique' items, where there is no alternative listed on the PBS. This type of arrangement occurs when the sponsor requests a higher price than the Australian Government is willing to accept, and the Australian Government is prepared to subsidise up to a certain level only.

The patient pays the 'special patient contribution' (the difference between the Australian Government dispensed price and the sponsor's requested dispensed price) in addition to the patient co-payment.

The arrangements are rarely used. They have been applied in only three instances in the last five years. At present they apply in only one instance (bleomycin injection).

ATTACHMENT A

REFERENCE PRICING GROUPS

Groups with additions due to 1 April 2005 listings – additions in *italics*

Items added
Emtricitabine – addition to group 91
Pemetrexed Disodium Heptahydrate – addition to group 46
Tenofovir DisoproxilFumarate – addition to group 91

New group added
Group 101 (section 100 items)
Bosentan Monohydrate;
Iloprost Trometamol

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No.	ATC Group	Drugs (Declaration Wording)	Circumstances	Comments on Relativities
DRUGS FOR ACID RELATED DISORDERS				
1.	A02	Aluminium Hydroxide – Dried with Magnesium Hydroxide Aluminium Hydroxide – Dried with Magnesium Trisilicate and Magnesium Hydroxide Sodium Alginate with Calcium Carbonate and Sodium Bicarbonate		The two aluminium hydroxide products historically priced the same; the third product was listed as deserving a 'small' advantage over the other two.
2.	A02	Cimetidine Cimetidine Hydrochloride Famotidine Nizatidine Ranitidine Hydrochloride		A TGP group

No.	ATC Group	Drugs (Declaration Wording)	Circumstances	Comments on Relativities
3.	A02	Esomeprazole Magnesium Trihydrate Lansoprazole Omeprazole Omeprazole Magnesium Pantoprazole Sodium Sesquihydrate Rabeprazole Sodium		A WAMTC group
4.	A02	Esomeprazole Magnesium Trihydrate and Clarithromycin and Amoxycillin Trihydrate Omeprazole and Clarithromycin and Amoxycillin Trihydrate		Listed on a cost minimisation basis.
ANTIEMETICS AND ANTINAUSEANTS				
5.	A04	Dolasetron Mesylate Granisetron Hydrochloride Ondansetron Ondansetron Hydrochloride Dihydrate Tropisetron Hydrochloride		The other three recommended on a cost minimisation basis versus ondansetron by the PBAC; PBPA agreed to a small premium for ondansetron over tropisetron due to the formers use associated with radiotherapy (in addition to chemotherapy) and use in children.
LAXATIVES				
6.	A06	Bisacodyl Docusate Sodium with Bisacodyl		Historically these two have always been the same price.
7.	A06	Bisacodyl Sorbitol with Sodium Citrate and Sodium Lauryl Sulfoacetate	Refers to enema formulations	Historically have been considered as alternatives.
ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS				
8.	A07	Diphenoxylate Hydrochloride with Atropine Sulfate Loperamide Hydrochloride		Historically the two items have been priced similarly.
9.	A07	Hydrocortisone Acetate Mesalazine	Refers to rectal foam or suppository formulations	Mesalazine suppository recommended on cost minimisation basis versus hydrocortisone foam.
10.	A07	Olsalazine sodium Mesalazine		Historically the two drugs have been seen as alternatives.
DIGESTIVES, INCL. ENZYMES				
11.	A09	Pancreatic Extract Pancrelipase		The different brands are inter-related.

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No.	ATC Group	Drugs (Declaration Wording)	Circumstances	Comments on Relativities
DRUGS USED IN DIABETES				
12.	A10	Insulin – Isophane Insulin – Neutral Insulin - Neutral with Insulin – Isophane		All human insulins have been priced the same per unit.
13.	A10	Insulin Aspart Insulin Lispro Insulin Aspart with Insulin Aspart Protamine Suspension Insulin Lispro with Insulin Lispro Protamine Suspension		Insulin aspart was recommended on a cost minimisation basis versus insulin lispro. (But these are priced higher than the previous group.)
14.	A10	Glibenclamide Glipizide		The relationship between glibenclamide, glipazide and gliclazide has been reviewed by the PBAC. Data were available to demonstrate gliclazide had an advantage over glibenclamide but there was a lack of data for glipazide.
15.	A10	Gliclazide Glimepiride		The PBAC recommended glimepiride on a cost minisation basis versus sulfonylureas. The PBPA accepted a comparison versus gliclazide.
16.	A10	Pioglitazone Hydrochloride Rosiglitazone Maleate		Pioglitazone was recommended for listing on a cost minimisation basis versus rosiglitazone.
ANTITHROMBOTIC AGENTS				
17.	B01	Dalteparin Sodium Enoxaparin Sodium		The two drugs were accepted as equivalent.
18.	B01	Alteplase Reteplase Tenecteplase		Retiplase and tenectiplase were both recommended cost minimised versus alteplase.
19.	B01	Abciximab Eptifibatide Acetate		Eptifibitide was recommended cost minimised verus abciximab.
BETA BLOCKING AGENTS				
20.	C07	Oxprenolol Hydrochloride Propranolol Hydrochloride		Historically have been viewed as comparable.
21.	C07	Atenolol Metoprolol Tartrate		Historically have been viewed as comparable, but with a premium over the previous group).

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No.	ATC Group	Drugs (Declaration Wording)	Circumstances	Comments on Relativities
22.	C07	Bisoprolol Fumarate Carvedilol Metoprolol Succinate		Bisoprolol and metoprolol tartrate ere both recommended cost minimised versus carvedilol.
CALCIUM CHANNEL BLOCKERS				
23.	C08	Amlodipine Besylate Diltiazem Hydrochloride Felodipine Lercanidipine Hydrochloride Nifedipine		WAMTC group. Amlodipine Besylate; Felodipine; Lercanidipine Hydrochloride; & Nifedipine form a TGP group
AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM				
24.	C09	Captopril Enalapril Maleate Fosinopril Sodium Lisinopril Perindopril Erbumine Quinapril Hydrochloride Ramipril Trandolapril		TGP group. (Assuming the ACE and ATRA groups remain separated.)
25.	C09	Candesartan Cilexetil Eprosartan Mesylate Irbesartan Telmisartan		WAMTC group. (Assuming the ACE and ATRA groups remain separated.)
SERUM LIPID REDUCING AGENTS				
26.	C10	Atorvastatin Calcium Fluvastatin Sodium Pravastatin Sodium Simvastatin		Atorvastatin, pravastatin and simvastatin are a TGP group. Fluvastatin was recommended with pricing based on its ability to lower LDL cholesterol compared to simvastatin.
27.	C10	Fenofibrate Gemfibrozil		Fenofibrate recommended cost minimised versus gemfibrozil.

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No.	ATC Group	Drugs (Declaration Wording)	Circumstances	Comments on Relativities
CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS				
28.	D07	Betamethasone Valerate Betamethasone Dipropionate Methylprednisolone Aceponate Mometasone Furoate Triamcinolone Acetonide		Betamethasone dipropionate was accepted by the PBAC as providing a modest advantage over betamethasone valerate and triamcinolone acetonide. Mometasone was cost minimised versus betamethasone dipropionate and methylprednisolone aceponate cost minimised versus mometasone.
OTHER GYNECOLOGICALS				
29.	G02	Bromocriptine Mesylate Cabergoline		Cabergoline was accepted on a cost minimisation basis versus bromocriptine.
SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM				
30.	G03	Levonorgestrel Levonorgestrel with Ethinyloestradiol Norethisterone with Ethinyloestradiol Norethisterone with Mestranol Norethisterone	Formulations for use as oral contraceptives	All of the oral contraceptives are considered equivalent for pricing purposes.
31.	G03	Oestradiol Valerate Oestriol Oestrogens-Conjugated Piperazine Oestrone Sulfate		All of the drugs are considered as alternatives (oestrogens for HRT).
32.	G03	Testosterone Testosterone Enanthate Testosterone Propionate with Testosterone Phenylpropionate and Testosterone Isocaproate Testosterone Propionate with Testosterone Phenylpropionate Testosterone Isocaproate and Testosterone Decanoate	Subcutaneous implant and injection formulations	Historically testosterone esters injections and testosterone enanthate injection have been considered equivalent. Testosterone implants were recommended on a cost minimisation basis versus testosterone injections.

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No.	ATC Group	Drugs (Declaration Wording)	Circumstances	Comments on Relativities
33.	G03	Oestradiol Oestradiol and Oestradiol with Norethisterone Acetate Oestradiol Hemihydrate Oestradiol Hemihydrate and Oestradiol Hemihydrate with Norethisterone Acetate Oestradiol Hemihydrate with Norethisterone Acetate	By transdermal administration	All of the listed transdermal patches have been listed on a cost minimisation basis.
34.	G03	Oestradiol and Oestradiol with Dydrogesterone Oestradiol and Oestradiol with Norethisterone Acetate Oestradiol Hemihydrate with Norethisterone Acetate Oestradiol Valerate and Oestradiol Valerate with Cyproterone Acetate Oestrogens-Conjugated and Oestrogens-Conjugated with Medroxyprogesterone Acetate Oestrogens-Conjugated with Medroxyprogesterone Acetate	By oral administration	All of the oral HRT formulations have been listed on a cost minimisation basis.
35.	G03	Follitropin Alfa Follitropin Beta		Follitropin alfa and follitropin beta are accepted as equivalent.
36.	G03	Danazol Gestrinone		Gestrinone was recommended on the basis of similar safety and efficacy to danazol.
UROLOGICALS				
37.	G04	Oxybutynin Hydrochloride Propantheline Bromide		Oxybutynin hydrochloride was recommended on the basis that it deserved a small premium over propantheline bromide.
CORTICOSTEROIDS FOR SYSTEMIC USE				
38.	H02	Betamethasone Acetate with Betamethasone Sodium Phosphate Triamcinolone Acetonide		Historically these two injections have been viewed as alternatives.

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No.	ATC Group	Drugs (Declaration Wording)	Circumstances	Comments on Relativities
39.	H02	Prednisolone Prednisone		Historically these two drugs have been viewed as alternatives.
ANTIBACTERIALS FOR SYSTEMIC USE-				
40.	J01	Dicloxacillin Sodium Flucloxacillin Sodium		Dicloxacillin was recommended on a cost minimisation basis versus flucloxacillin.
41.	J01	Amoxycillin Trihydrate Cephalexin Amoxycillin Trihydrate with Water-Purified BP Cephalexin with Water-Purified BP		The PBAC has advised, that as used in clinical practice cephalexin should be viewed as clinically equivalent to amoxicillin.
42.	J01	Amoxycillin Trihydrate with Potassium Clavulanate Cefaclor Monohydrate Cefuroxime Axetil		The PBAC has accepted that cefaclor has similar efficacy to amoxycillin with clavulanate. Cefuroxime was recommended on a cost minimisation basis versus Ceclor.
43.	J01	Cefotaxime Sodium Ceftriaxone Sodium		Since listing cefotaxime and ceftriaxone have been accepted as alternatives.
44.	J01	Clarithromycin Erythromycin Erythromycin Ethyl Succinate Roxithromycin		Erythromycin has been accepted as being clinically equivalent to erythromycin ethyl succinate. Roxithromycin was recommended on the basis that it offered a small advantage over erythromycin. Clarithromycin was recommended on the basis of cost minimisation versus roxithromycin.
ANTIVIRALS FOR SYSTEMIC USE				
45.	J05	Aciclovir Famciclovir Valaciclovir Hydrochloride		Famciclovir was recommended as being equivalent to acyclovir. Valaciclovir was accepted on the basis of equivalence to acyclovir.
ANTINEOPLASTIC AGENTS				
46.	L01	Docetaxel Paclitaxel *Pemetrexed Disodium Heptahydrate* Gemcitabine Hydrochloride Vinorelbine Tartrate	For use in non-small cell lung cancer	Paclitaxel was recommended on a cost minimisation basis versus docetaxel and gemcitabine Vinorelbine was recommended as being of similar safety and efficacy to pactitaxel. *Pemetrexed was recommended on a cost minimisation basis versus docetaxel.*

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No.	ATC Group	Drugs (Declaration Wording)	Circumstances	Comments on Relativities
47.	L01	Etoposide Etoposide Phosphate		The two drugs have been accepted as being equivalent.
48.	L01	Irinotecan Hydrochloride Trihydrate Oxaliplatin		Oxaliplatin was recommended on a cost minimisation basis versus irinotecan.
ENDOCRINE THERAPY				
49.	L02	Goserelin Acetate; Leuprorelin Acetate		Goserelin and leuprorelin are seen as equivalent.
50.	L02	Bicalutamide; Flutamide; Nilutamide		Bicalutamide was recommended on a cost minimisation basis versus flutamide. Nilutamide was recommended on a cost minimisation basis versus flutamide.
51.	L02	Anastrozole; Exemestane; Letrozole		Anastrozole was recommended on a cost minimisation basis versus letrozole. Exemestane was recommended on a cost minimisation basis versus anastrozole and letrozole.
52.	L02	Tamoxifen Citrate; Toremefine Citrate		Toremefine was recommended on a cost minimisation basis versus tamoxifen.
IMMUNOSTIMULANTS				
53.	L03	Interferon Alfa-2a Interferon Alfa-2b		The two drugs have been accepted as equivalent.
54.	L03	Interferon Beta-1a Interferon Beta-1b Glatiramer Acetate		Interferon beta-1a (Avonex®) was presented on a cost minimisation basis versus interferon beta-1b (Betaferon®). Glatiramer was accepted on a cost minimisation basis versus interferon beta-1a and interferon beta-1b. Rebif® brand of interferon beta-1a was accepted on a cost minimisation basis versus Avonex® and Betaferon®.
55.	L04	Adalimumab Anakinra Etanercept Infliximab		Infliximab was recommended on a cost minimisation basis versus etanercept. Adalimumab was recommended on a cost minimisation basis versus etanercept. Anakinra was accepted as being less effective than etanercept but of acceptable cost effectiveness compared to the other drugs in patients unresponsive to the other drugs.

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No.	ATC Group	Drugs (Declaration Wording)	Circumstances	Comments on Relativities
ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS				
56.	M01	Diclofenac Sodium Diflunisal Ibuprofen Indomethacin Ketoprofen Naproxen Naproxen Sodium Piroxicam Sulindac Tiaprofenic Acid		All of the older NSAIDs are considered to be of similar safety and efficacy (and have been a WAMTC group in the past).
DRUGS FOR TREATMENT OF BONE DISEASES				
57.	M05	Calcitriol; Disodium Etidronate and Calcium Carbonate		Disodium etidronate and calcium carbonate was listed as being equivalent to calcitriol.
58.	M05	Alendronate Sodium; Raloxifene Hydrochloride; Risedronate Sodium		Raloxifene was recommended on a cost minimisation basis versus alendronate. Risedronate was recommended on a cost minimisation basis versus alendronate.
ANALGESICS				
59.	N02	Naratriptan Hydrochloride; Sumatriptan Succinate; Zolmitriptan		Naratriptan was recommended on a cost minimisation basis versus sumatriptan. Zolmitriptan was recommended on a cost minimisation basis versus sumatriptan.
60.	N02	Morphine Sulfate; Oxycodone Hydrochloride		Oxycodone was recommended on a cost minimisation basis versus morphine.
61.	N02	Pethidine Hydrochloride; Tramadol Hydrochloride		Tramadol was recommended on the basis of similar safety and efficacy compared to pethidine.

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No.	ATC Group	Drugs (Declaration Wording)	Circumstances	Comments on Relativities
ANTIEPILEPTICS				
62.	N03	Gabapentin; Lamotrigine; Levetiracetam; Oxcarbazepine; Tiagabine Hydrochloride; Topiramate; Vigabatrin		All of these anti-epileptic drugs have been accepted on a cost minimisation basis (and a WAMTC group was proposed at one stage).
ANTI-PARKINSON DRUGS				
63.	N04	Levodopa with Benserazide Hydrochloride; Levodopa with Carbidopa		These two drugs are considered equivalent.
64.	N04	Entacapone; Pergolide Mesylate		Entacapone was recommended on a cost minimisation basis versus pergolide.
PSYCHOLEPTICS				
65.	N05	Flupenthixol Decanoate; Fluphenazine Decanoate; Haloperidol Decanoate; Zuclopenthixol Decanoate		All of these injections are considered equivalent.
66.	N05	Nitrazepam; Temazepam		The PBAC has advised that the two drugs should be seen as equivalent.
67.	N05	Aripiprazole; Olanzapine		Aripiprazole was recommended on a cost minimisation basis versus olanzapine.
68.	N05	Amisulpride; Quetiapine Fumarate; Risperidone		Amisulpride was recommended on a cost minimisation basis versus risperidone. Quetiapine was recommended on a cost minimisation basis versus risperidone.
PSYCHOANALEPTICS				
69.	N06	Amitriptyline Hydrochloride; Imipramine Hydrochloride		These two drugs are considered equivalent.
70.	N06	Dothiepin Hydrochloride; Doxepin Hydrochloride		These two drugs are considered equivalent (but have a premium over the previous group).

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No.	ATC Group	Drugs (Declaration Wording)	Circumstances	Comments on Relativities
71.	N06	Citalopram Hydrobromide; Escitalopram Oxalate; Fluoxetine Hydrochloride; Fluvoxamine Maleate; Mirtazapine; Moclobemide; Paroxetine Hydrochloride; Reboxetine Mesilate; Sertraline Hydrochloride		WAMTC group.
72.	N06	Donepezil Hydrochloride; Galantamine Hydrobromide; Rivastigmine Hydrogen Tartrate		Donepezil and rivastigmine are considered to be of similar effectiveness and toxicity. Galantamine was recommended on a cost minimisation basis versus donepezil.
OTHER NERVOUS SYSTEM DRUGS				
73.	N07	Acamprosate Calcium; Naltrexone Hydrochloride		Naltrexone was recommended on a cost minimisation basis versus acamprosate.
ANTIPROTOZOALS				
74.	P01	Quinine Bisulfate; Quinine Sulfate		The two salts have always been seen as equivalent.
DRUGS FOR OBSTRUCTIVE AIRWAYS DISEASE				
75.	R03	Salbutamol Sulfate; Terbutaline Sulfate		The two drugs are seen as equivalent.
76.	R03	Nedocromil Sodium; Sodium Cromoglycate		Nedocromil was accepted as being equivalent to sodium cromoglycate.
77.	R03	Eformoterol Fumarate Dihydrate; Salmeterol Xinafoate		Eformoterol was accepted as being equivalent to salmeterol.
78.	R03	Beclomethasone Dipropionate; Budesonide; Fluticasone Propionate		Fluticasone was accepted as beiung equivalent to budesonide and beclomethasone.
OPHTHALMOLOGICALS				
79.	S01	Ciprofloxacin Hydrochloride; Gentamicin Sulfate; Ofloxacin; Tobramycin		Gentamycin and tobramycin were listed as being equivalent. Ciprofloxacin and ofloxacin were accepted as being equivalent to gentamycin/tobramycin.

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No.	ATC Group	Drugs (Declaration Wording)	Circumstances	Comments on Relativities
80.	S01	Dexamethasone; Fluoromethalone; Fluoromethalone Acetate		The three drugs are considered alternatives.
81.	S01	Betaxolol Hydrochloride; Levobunolol Hydrochloride; Timolol Maleate		Following a review, the PBAC advised that betaxolol and timolol should be considered equivalent. Levobunilol was accepted as being of similar safety and efficacy to timolol.
82.	S01	Lodoxamide Trometamol; Sodium Cromoglycate		Lodoxamide was recommended on a cost minimisation basis versus sodium cromoglycate.
83.	S01	Brimonidine Tartrate; Brinzolamide; Dorzolamide Hydrochloride		Brimonidine has been accepted as being no worse than brinzolamideor dorzolamide.
84.	S01	Bimatoprost; Latanoprost; Travoprost		Bimatoprost and travaprost were recommended on a cost minimisation basis versus latanoprost.
85.	S01	Carbomer 974; Carbomer 980; Carmellose Sodium; Hypromellose 2900 with Dextran 70;	Refers to eye drops in unit dose presentations	These have all been accepted on a cost minimisation basis.
86.	S01	Carbomer 980; Carmellose Sodium; Hypromellose; Hypromellose with Carbomer 980; Hypromellose 2900 with Dextran 70; Polyethylene Glycol 400 with Propylene Glycol; Polyvinyl Alcohol	Refers to eye drops in multi-dose presentations	Following a review, the PBAC has advised that all these items should be viewed as equivalent.
OTOLOGICALS				
87.	S02	Dexamethasone Sodium Metasulfobenzoate with Framycetin Sulfate and Gramicidin; Triamcinolone Acetonide with Neomycin Sulfate, Gramicidin and Nystatin		Historically, these have been considered as alternatives.

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No.	ATC Group	Drugs (Declaration Wording)	Circumstances	Comments on Relativities
VARIOUS				
88.	V04	Glucose Indicator-Blood	All types	All of these items are seen as alternatives.
SECTION 100 ITEMS				
89.		Filgrastim Lenograstim Pegfilgrastim		Lenograstim was recommended on a cost minimisation basis versus filgrastim. Pegfilgrastim was recommended on a cost minimisation basis versus filgrastim.
90.		Amprenavir Atazanavir Sulfate Fosamprenavir Calcium Indinavir Sulfate Nelfinavir Mesylate Ritonavir Saquinavir Saquinavir Mesylate		All of these protease inhibitors have been accepted on a cost minimisation basis.
91.		Abacavir Sulfate Didanosine *Emtricitabine* Lamivudine Stavudine Stavudine with Water – Purified BP *Tenofovir DisoproxilFumarate* Zidovudine		Stavudine was recommended on a cost minimisation basis versus zidovudine. Zidovudine is considered of similar effectiveness compared to didanosine. Abacavir was recommended on a cost minimisation basis versus other NRTIs eg. lamivudine. *Emtracitabine was recommended on a cost minimisation basis versus lamivudine.* *For use as first line therapy, tenofovir was recommended on a cost minimisation basis versus stavudine and zidovudine.*
92.		Delavirdine Mesylate; Efavirenz; Nevirapine		Delavirdine was recommended on a cost minimisation basis versus nevirapine. Efavirenz was recommended on a cost minimisation basis versus NNRTIs eg nevirapine.
93.		Cidofovir; Foscarnet Sodium; Ganciclovir	Formulations for intravenous infusion	Cidofovir was recommended on a cost minimisation basis versus gabciclovir Foscarnet was presented as having comparable efficacy to ganciclovir.

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No.	ATC Group	Drugs (Declaration Wording)	Circumstances	Comments on Relativities
94.		Botulinum Toxin Type A Purified Neurotoxin Complex; Clostridium Botulinum Type A Toxin-Haemagglutinin Complex		Dysport® brand of botulinum toxin was accepted as being equivalent to Botox® brand.
95.		Somatropin	All presentations	All growth hormone brands are considered equivalent.
96.		Darbepoetin Alfa; Epoetin Alfa		Darbepoetin was recommended on a cost minimisation basis versus epoetin.
97.		Lanreotide Acetate; Octreotide Acetate		Lanreotide acetate was recommended on a cost minimisation basis versus octreotide
98.		Disodium Pamidronate Zoledronic Acid		Zoledronic acid was recommended on a cost minimisation basis versus disodium pamidronate.
99.		Ribavirin and Peginterferon Alfa-2a; Ribavirin and Peginterferon Alfa-2b		Pegasys RBV® was recommended on a cost minimisation basis versus Pegatron®.
100.		Sirolimus; Tacrolimus		Sirolimus was recommended as being no worse than tacrolimus.
101.		*Bosentan Monohydrate*; *IloprostTrometamol*		*Iloprost was recommended on a cost minimisation basis versus bosentan.*

Note: these groupings are based upon the relativities between medicines as outlined in the PBPA's Therapeutic Relativity Sheets. For further information refer (http://www.health.gov.au/internet/wcms/publishing.nsf/Content/health-pbs-general-pricing-therelativity.htm)

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ATTACHMENT B

EXAMPLES WHERE DRUGS ARE CONSIDERED EQUAL FOR PRICING PURPOSES BUT THEIR LISTED DISPENSED PRICES ARE DIFFERENT

While there are situations where two drugs considered equal for pricing purposes do have the same dispensed price in the PBS schedule, there are a number of scenarios which will result in the dollar value of two equi-effective dugs not being the same. Six such situations are set out in detail below.

B.1 The dosage relativity recommended by PBAC does not reflect the tablet strengths

Example: Aripiprazole was recommended on the basis that 23.1 mg aripirazole = 16.3 mg olanzapine, but aripiprazole comes in tablets of 10 mg, 15 mg, 20 mg and 30 mg and olanzapine in strengths of 2.5 mg, 5 mg, 7.5 mg and 10 mg. None of the tablet strengths are in a ratio of 23.1:16.3 and thus none of the dispensed prices will be the same.

In this situation, pricing is based on comparing the nearest strengths using the PBAC-advised dosage relativity.

30 x olanzapine 7.5 mg (225 mg of drug) has price to pharmacist of $149.42.
30 x 10 mg aripiprazole is equivalent to 212 mg olanzapine (300 ÷ 23.1 x 16.3).
30 x 10 mg aripiprazole are worth $140.79 ($149.42 ÷ 225 x 212).

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B.2 Two or more reference priced drugs are available in different pack sizes

Example: Olanzapine wafer formulation was listed on the basis of equivalence to the tablet formulation. The wafer formulations are packaged in 28s whereas the tablets are packaged in 30s.

Olanzapine wafer 10 mg = the price to pharmacist for 30 x 10 mg tablets multiplied by 28/30 $207.54 ÷ 30 x 28 = $193.70.

B.3 Two or more reference priced drugs are available in different numbers of strengths

Example: Sertraline was recommended on the basis that 50 mg of this drug was equi-effective to 20 mg fluoxetine. However, sertraline comes in strengths of 50 mg and 100 mg and fluoxetine in 20 mg only. 100 mg of sertraline may not be the same as 2 x 20 mg fluoxetine (different dose-response curves) and pricing of double strength tablet is often less than twice the single strength.

B.4 Price differences resulting from rounding

Example: Olanzapine has had two across-the-board reductions since listing. Due to rounding, the prices to pharmacist for the10 mg tablet and the 10 mg wafer are no longer exactly in the ratio of 30:28.

Tablet 10 mg: original price to pharmacist $207.54 x 0.96 (4% reduction) = $199.238 which is rounded up to $199.24.
Wafer 10 mg: original price to pharmacist $193.70 x 0.96 = $185.952 which is rounded down to $185.95.
$199.24 : $185.92 = 30:27.99.

B.5 Ratio of prices between strengths different

Example: Two drugs regarded as equal for pricing purposes may each have three strengths. The middle strength could be the same but the ratio between the three strengths of each drug may be different. Overall, the average cost of the drug across all patients may be the same.

Drug X: 10 x 10 mg = $100; 10 x 20 mg = $150; and 10 x 40 mg = $225
Drug Y: 10 x 30 mg = $90; 10 x 60 mg = $150.00; and 10 x 120 mg = $250.

B.6 One drug may be worth different amounts for different indications

Example: The drugs clarithromycin and roxithromycin have been listed on a cost-minimisation basis when used for the treatment of respiratory tract infections (actually listed as unrestricted benefits). Clarithromycin is also used in the treatment of mycobacterium avium complex in AIDS patients, where its 'worth' is higher.

The resultant price for clarithromycin is weighted according to use between the two situations and would thus appear to be at a higher price for its unrestricted listing.

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INTRODUCTION

The 2007 legislative reforms introduced statutory price reductions (SPRs) (in sections 99ACB and 99ACD of the *National Health Act 1953* ('the Act')) to apply when the first bioequivalent or biosimilar brand listed on the Pharmaceutical Benefits Scheme (PBS).

Amendments to these provisions in 2018, arising out of a Strategic Agreement with Medicines Australia, allow a more flexible application of new brand SPRs, including through the introduction of instances of Ministerial discretion. The Act now provides an avenue for Sponsors[1] of drugs listed on the F1 formulary to list "new presentations" of existing listed PBS medicines in certain circumstances without being required to offer a lower price and triggering an SPR.

The new provisions are intended to enable Sponsors of F1 listed medicines to list new presentations of those medicines, subject to certain conditions, without necessarily triggering an SPR. Where the Minister has discretion not to apply an SPR, the exercise of that power is likely to take into account that the Government intends to encourage user-friendly presentations that support better health outcomes and/or quality of life, which might not be available when a medicine is first added to the PBS.

An extract from the legislation is at Appendix 1.

An extract from the Strategic Agreement with Medicines Australia, is at Appendix 2.

What is a "new presentation"?

The new provisions are intended to encourage innovation that contributes to better outcomes for patients. The Government does not intend to incentivise new formulations of existing drugs which will simply delay or reduce brand competition.

New presentations[2] of existing brands of pharmaceutical items include, for example:

(a) a medicine presented as an auto-injector instead of the existing presentation which consists of a vial and a syringe;
(b) a medicine which is presented as an effervescent tablet instead of the existing presentation which is a capsule; and
(c) a medicine which is presented in an inhaler device that does not need to be primed before each dose, compared to an inhaler device that needs to be primed before each dose.

Changes to medicines which do not amount to new presentations include, for example, new flavours, shapes or colours.

[1] 'Sponsor' has the same meaning in this guidance material as Responsible Person. The term 'Sponsor' is used to align with the Pharmaceutical Benefits Advisory Committee Guidelines.
[2] The new presentations to which this guideline applies are presentations that can be considered bioequivalent to a currently listed pharmaceutical item for the purposes of the *National Health Act 1953*. See also Section 4.1 of the Procedure guidance for listing medicines on the Pharmaceutical Benefits Scheme for information on the evidence required for different types of new listing applications. http://www.pbs.gov.au/industry/listing/procedure-guidance/files/procedure-guidance-listing-medicines-on-the-pbs.pdf

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The Minister's powers to make determinations to include new forms (under section 85(3)) or brands (under section 85(6)) and to agree prices (under section 85AB) are currently delegated to specified Departmental officers.

Whether a new pharmaceutical item is a new presentation of an existing item is a matter that will be considered by the Department before, or in conjunction with, the decision whether to agree the price and to determine the form and brand of the new item.

HOW TO APPLY FOR LISTING

Step 1 - You must make a submission to the PBAC to list the new pharmaceutical item and follow the processes for listing as set out in the PBAC Guidelines.

Step 2 - This will depend on how long the *drug* in the existing listed brand has been listed on the PBS, and the date on which the Sponsor proposes the new pharmaceutical item be added to the PBS.

Noting that Sponsors listing new presentations can only avoid an SPR if the new listing occurs within a specified time period after the date the existing drug was declared to be a pharmaceutical benefit, Sponsors are encouraged to apply sufficiently in advance of the proposed listing date.

A. If the proposed listing date is within 5 years of the drug being listed on the PBS then:

- The Sponsor must make a separate application to the Department asking that the Department recognise the new item as a new presentation.

The information in that application should include:

a) the date that the drug in the pharmaceutical item was first PBS listed;
b) a statement that the company is the Sponsor for both the existing listed item and the new item; and
c) an explanation, and evidence (if applicable), as to why the new item is a new presentation.

Sponsors must send the application to PBSSPR@health.gov.au at the same time as the submission to PBAC.

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What next?

If the item is a new presentation:

- The Sponsor will be notified within three weeks of the conclusion of the PBAC meeting.
- The new item and the existing item will both remain in F1 until the drug no longer meets the F1 criteria.
- Sponsors must make a formal price offer with the same Approved Ex Manufacturer Price (AEMP) as the existing listed item to proceed with the new listing.

If the item is not a new presentation:

- The Department will notify the Sponsor within three weeks of the conclusion of the PBAC meeting of why the new item is not a new presentation within the meaning of the Act.
- Sponsors will be given an opportunity to provide further information to the Department before a final assessment is made.

- If the item is not a new presentation, the listing can only proceed if the Sponsor offers a lower price in accordance with sections 99ACB and 99ACD of the Act.

B. If the proposed listing date is between 5 to 10 years after the drug was listed on the PBS:

- Sponsors must ask:
  (1) the Department to recognise the new item as a new presentation; and

  (2) the Minister to exercise the discretion not to apply the SPR and not to move the drug from F1 to F2.

The information in the application to the Department and Minister should include:

a) the date that the drug in the pharmaceutical item was first PBS listed;
b) a statement that the company is the Sponsor for both the existing listed brand and the new item;
c) an explanation, and evidence (if applicable) as to why the new item is a new presentation; and
d) an explanation as to why the Ministerial discretion should be exercised, setting out any matters that the Sponsor considers are relevant to the decision.

Sponsors must send this application to PBSSPR@health.gov.au at the same time as submitting an application to the PBAC.

Please note that even if a new item is a new presentation, the Minister still has to consider whether or not to trigger the SPR and move the drug to F2.

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What next?

If the item is a new presentation, it will then be assessed for Ministerial discretion.

If the item is not a new presentation:

- The Department will notify the Sponsor within three weeks of the conclusion of the PBAC meeting of why the new item is not a new presentation within the meaning of the Act.
- Sponsors will be given an opportunity to provide further information to the Department before a final assessment is made.
- If the item is not a new presentation, the listing can only proceed if the Sponsor offers a lower price in accordance with sections 99ACB and 99ACD of the Act.

What will be considered when making a decision to exercise discretion?

The Act states that the Minister may consider:

a) Any advice given by the PBAC;
b) Any information provided by the Sponsor; and
c) Any other matter the Minister considers relevant.

Some (but not all) of the other matters that the Minister considers relevant may include:

- the pricing history of the medicine;
- clinical aspects, including but not limited to whether the medicine is clinically needed on the PBS and whether the new presentation provides advantages for patients;

- the potential impact of the listing on future brand competition (and therefore PBS expenditure) in relation to the drug; and
- other financial impacts on the PBS if the discretion is exercised.

What next?

<u>If the Minister decides to exercise the discretion not to apply the SPR:</u>

(a) The Department will notify the Sponsor of the decision within six[3] weeks of the conclusion of the PBAC meeting.
(b) The Sponsor will need to make a formal price offer with the same AEMP as the existing listing for the new listing to proceed.
(c) The Minister (or delegate) will include the brand of pharmaceutical item in a Notifiable Instrument published on the Federal Register of Legislation and the drug will remain in F1 until whichever of the following events occurs first:
   - A new brand of the same pharmaceutical item is listed by a different Sponsor;
   - The drug in the pharmaceutical item no longer satisfies the F1 criteria; or
   - The tenth anniversary of the drug in the pharmaceutical item being on F1 is reached.

   If one of these events occur, the drug will move from F1 to F2 and the applicable SPR will apply.

<u>If the indicative Ministerial decision is not to exercise the discretion:</u>

(d) The Department will notify the Sponsor of the outcome of its request for Ministerial discretion, and brief reasons why the Minister is not inclined to exercise the discretion, within six weeks[4] of the publication of the PBAC outcomes.
(e) Sponsors will be given an opportunity to provide further information to the Department before the Minister makes a final decision about whether to exercise the discretion.
(f) If the Minister's final decision is not to exercise the discretion, the listing can only proceed if the Sponsor offers a lower price in accordance with sections 99ACB and 99ACD of the Act.

C. If it is after 10 years of the existing drug listing on the PBS:

- No exemptions apply. The Sponsor will need to offer a lower AEMP in accordance with sections 99ACB and 99ACD of the Act and the new item will cause the drug to be moved to F2 and the SPR to apply.

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[3] Noting this may be longer if (a) the Department's initial assessment is that the new item is not a new presentation, but that assessment is changed after the Sponsor provides further information or (b) the Minister elects to exercise the discretion personally.
[4] Noting that this may be longer if the Minister elects to exercise the discretion personally.

The Act sets out the legislative basis for the Minister's discretionary power.

99ACB 16% price reduction for new brands of pharmaceutical items that are not combination items

When section applies to new brands

(1) Subject to subsections (2), (3), (3A) and (3B), this section applies to a brand (the ***new brand***) of a pharmaceutical item (the ***trigger item***) that is not a combination item if:

(a) a determination under subsection 85(6) comes into force in relation to the new brand of the trigger item on a day (the ***determination day***); and

(b) on the day before the determination day, the new brand of the trigger item was not a listed brand of the trigger item; and

(c) on the day before the determination day:

(i) a brand (the ***existing brand***) of a pharmaceutical item (the ***existing item***) was a listed brand of the existing item; and

(ii) the new brand of the trigger item is bioequivalent or biosimilar to the existing brand of the existing item; and

(iii) the trigger item and existing item have the same drug and manner of administration.

Note: For the purposes of paragraph (c), the new brand and the existing brand may be the same brand, or the trigger item and the existing item may be the same pharmaceutical item.

Circumstances in which section does not apply

(2) This section does not apply in relation to the new brand of the trigger item if:

(a) the trigger item is in a class of pharmaceutical items to which a 12.5% or 16% administrative price reduction has applied; or

(b) another pharmaceutical item that has the same drug and manner of administration as the new brand of the trigger item is in a class of pharmaceutical items to which a 12.5% or 16% administrative price reduction has applied; or

(c) if the drug that is in the trigger item is in a therapeutic group—a pharmaceutical item that:

(i) has another drug that is in that group; and

(ii) has the same manner of administration as the new brand of the trigger item;

is in a class of pharmaceutical items to which a 12.5% or 16% administrative price reduction has applied.

(3) This section does not apply in relation to the new brand of the trigger item if:

(a) any of the following has applied:

(i) subsection (1);

(ii) subsection 99ACF(1) or (2) because of item 1 of the table in section 99ACF;

in relation to:

(b) the new brand, or another listed brand, of the trigger item; or

(c) a listed brand of another pharmaceutical item that has the same drug and manner of administration as the new brand of the trigger item; or

(d) if the drug that is in the trigger item is in a therapeutic group—a listed brand of a pharmaceutical item that:

(i) has another drug that is in that group; and

(ii) has the same manner of administration as the new brand of the trigger item.

Note: For the purposes of subparagraph (a)(i), subsection (1) is taken not to have applied in relation to a brand of a pharmaceutical item in some cases: see section 99AEI.

(3A) This section does not apply in relation to the new brand of the trigger item if:

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(a) the new brand of the trigger item is a new presentation of an existing listed brand of a pharmaceutical item; and

(b) the determination day in relation to the new brand of the trigger item is on or before the fifth anniversary of the drug in the pharmaceutical item being on F1; and

(c) the responsible person for the new brand of the trigger item is the same person as the responsible person for the existing listed brand of the pharmaceutical item; and

(d) either of the following apply:

(i) there is not another brand of the pharmaceutical item that has the drug that is a listed brand;

(ii) the drug is not on F2.

(3B) This section does not apply in relation to the new brand of the trigger item if:

(a) the new brand of the trigger item is a new presentation of an existing listed brand of a pharmaceutical item; and

(b) the Minister has made a determination under section 99ACBA in relation to the new brand of the trigger item; and

(c) the determination under section 99ACBA has not ceased to have effect.

…

99ACBA Ministerial determination—brand of pharmaceutical item that is not a combination item is not a new brand

(1) If:

(a) a brand of a pharmaceutical item (the ***trigger item***) is not a combination item; and

(b) the brand of the trigger item:

(i) is not a listed brand of the trigger item; and

(ii) is a new presentation of an existing listed brand of a pharmaceutical item; and

(c) the Minister is satisfied that the determination day in relation to the brand of the trigger item is to be after the fifth anniversary, and before the tenth anniversary, of the drug in the pharmaceutical item being on F1;

the Minister may determine, by notifiable instrument, that the brand of the trigger item is not a new brand for the purposes of section 99ACB.

(2) If the Minister makes a determination under this section in relation to the brand of the trigger item, it must be made before the determination day in relation to the brand of the trigger item.

(3) In making a determination, the Minister may have regard to:

(a) any advice given by the Pharmaceutical Benefits Advisory Committee; and

(b) any information provided by the responsible person for the brand of the trigger item; and

(c) any other matter that the Minister considers relevant.

(4) A determination made under this section ceases to have effect on whichever is the earliest of the following:

(a) the day that another brand of the pharmaceutical item becomes a listed brand;

(b) the day that the drug in the pharmaceutical item does not satisfy all of the criteria for F1;

(c) the tenth anniversary of the drug in the pharmaceutical item being on F1.

(5) In this section:

determination day has the same meaning as in paragraph 99ACB(1)(a).

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When section applies to new brands

(1) Subject to subsections (1A), (2) and (3), this section applies to a brand (the ***new brand***) of a pharmaceutical item (the ***trigger combination item***) that is a combination item if:

(a) a determination under subsection 85(6) comes into force in relation to the new brand of the trigger combination item on a day (the ***determination day***); and

(b) on the day before the determination day, the new brand of the trigger combination item was not a listed brand of the trigger combination item; and

(c) on the day before the determination day:

(i) a brand (the ***existing brand***) of a pharmaceutical item (the ***existing item***) was a listed brand of the existing item; and

(ii) the new brand of the trigger combination item is bioequivalent or biosimilar to the existing brand of the existing item; and

(iii) the drug in the trigger combination item and existing item contain the same component drugs; and

(iv) the trigger combination item and the existing item have the same manner of administration.

Note: For the purposes of paragraph (c), the new brand and the existing brand may be the same brand, or the trigger combination item and the existing item may be the same pharmaceutical item.

Circumstances in which section does not apply to new brands

(1A) This section does not apply in relation to the new brand of the trigger combination item if:

(a) the trigger combination item is in a class of pharmaceutical items to which a 12.5% or 16% administrative price reduction has applied; or

(b) another combination item that has the same drug and manner of administration as the new brand of the trigger combination item is in a class of pharmaceutical items to which a 12.5% or 16% administrative price reduction has applied; or

(c) if the drug in the trigger combination item is in a therapeutic group—a combination item that:

(i) has another drug that is in that group; and

(ii) has the same manner of administration as the new brand of the trigger combination item;

is in a class of pharmaceutical items to which a 12.5% or 16% administrative price reduction has applied.

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(2) This section does not apply in relation to the new brand of the trigger combination item if subsection (1) or section 99ACE has applied in relation to:

(a) the new brand, or another listed brand, of the trigger combination item; or

(b) a brand of another combination item that:

(i) has a drug that contains the same component drugs as the new brand of the trigger combination item; and

(ii) has the same manner of administration as the new brand of the trigger combination item; or

(c) if the drug in the trigger combination item is in a therapeutic group—a combination item that:

(i) has another drug that is in that group; and

(ii) has the same manner of administration as the new brand of the trigger combination item.

Note: For the purposes of this subsection, subsection (1) is taken not to have applied in relation to a brand of a pharmaceutical item in some cases: see section 99AEI.

(3) This section does not apply in relation to the new brand of the trigger combination item if:

(a) all of the following apply:

(i) the new brand of the trigger combination item is a new presentation of an existing listed brand of a pharmaceutical item;

(ii) a declaration under subsection 85(2) is in force in relation to the drug in the pharmaceutical item;

(iii) the determination day in relation to the new brand of the trigger combination item is on or before the fifth anniversary of the declaration under subsection 85(2) being made;

(iv) the responsible person for the new brand of the trigger combination item is the same as the responsible person for the existing listed brand of the pharmaceutical item;

(v) the drug is not on F2; or

(b) all of the following apply:

(i) the new brand of the trigger combination item is a new presentation of an existing listed brand of a pharmaceutical item;

(ii) the Minister has made a determination under section 99ACEA in relation to the new brand of the trigger combination item;

(iii) the determination under section 99ACEA has not ceased to have effect.

…

99ACEA Ministerial determination—brand of pharmaceutical item that is a combination item is not a new brand

(1) If:

(a) a brand of a pharmaceutical item (the ***trigger combination item***) is a combination item; and

(b) the brand of the trigger combination item is a new presentation of an existing listed brand of a pharmaceutical item; and

(c) a declaration under subsection 85(2) is in force in relation to the drug in the pharmaceutical item; and

(d) the Minister is satisfied that the determination day in relation to the brand of the trigger combination item is after the fifth anniversary, and before the tenth anniversary, of the declaration under subsection 85(2) being made;

the Minister may determine, by notifiable instrument, that the brand of the trigger combination item is not a new brand for the purposes of section 99ACD.

(2) If the Minister makes a determination under this section in relation to the brand of the trigger combination item, it must be made before the determination day in relation to the brand of the trigger combination item.

(3) In making a determination, the Minister may have regard to:

(a) any advice given by the Pharmaceutical Benefits Advisory Committee; and

(b) any information provided by the responsible person for the brand of the trigger combination item; and

(c) any other matter that the Minister considers relevant.

(4) A determination made under this section ceases to have effect on whichever is the earliest of the following:

(a) the tenth anniversary of the declaration under subsection 85(2) being made;

(b) the day that the drug is on F2.

(5) In this section:

determination day has the same meaning as in paragraph 99ACD(1)(a).

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5. Savings measures from new price policies

5.1 F1 Statutory Price Reductions

5.1.1 The Commonwealth will seek amendments to the act to:

(a) extend the current one-off 5 per cent Statutory Price Reduction that applies to brands of pharmaceutical items on the F1 formulary once the drug has been listed on the PBS for 5 years, to include new reduction dates on 1 April 2021 and 1 April 2022;

(b) apply a further one-off Statutory Price Reduction of 10 per cent to brands of pharmaceutical items on the F1 formulary once the drug has been listed on the PBS for at least 10 years; and

(c) apply an additional one-off 5 per cent Statutory Price Reduction to brands of pharmaceutical items on the F1 formulary once the drug has been listed on the PBS for at least 15 years.

5.1.2 The one-off 10 per cent Statutory Price Reductions described in clause 1.1.1(b) are intended to initially apply on 1 June 2018 (and will be applied on each subsequent 1 April up to and including 1 April 2021) to each brand of pharmaceutical item with a drug on the F1 formulary once the drug has been listed on the PBS for 10 years on or prior to that reduction day.

5.1.3 The additional one-off 5 per cent Statutory Price Reductions described in clause 1.1.1(c) are intended to initially apply on 1 June 2018 (and will be applied on each subsequent 1 April up to and including 1 April 2021) to each brand of pharmaceutical item with a drug on the F1 formulary once the drug has been listed on the PBS for 15 years on or prior to that reduction day.

5.1.4 The intent of clauses 1.1.1(b) and 1.1.1(c) is that brands of pharmaceutical items that have been listed on the PBS for fifteen years or more as of 1 June 2018 will receive a one-off 10 per cent Statutory Price Reduction followed by a one-off 5 per cent Statutory Price Reduction on the same day.

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5.2 Price reductions applicable at the entry of first new brand of a pharmaceutical item

The Commonwealth will seek amendments to the act to increase, from 16 per cent to 25 per cent, the Statutory Price Reduction applicable at the entry of the first new brand of a pharmaceutical item (**First New Brand**). The amendments to the Act described in this clause 5.2 are intended to commence on 1 October 2018, and will apply until the end of the Term. Following the end of the Term, the Statutory Price Reduction applying due to the entry of the First New Brand will revert to 16%.

5.3 Effective prices

5.3.1 Only reductions in the effective price of a medicine will be calculated for the purpose of the process described in clause 5.8.

5.3.2 This means that for the purpose of determining eligibility for discretion to not apply a Statutory Price Reduction (or to reduce a Statutory Price Reduction), a change in the published price that does not impact the effective price is not included.

5.4 Indications

5.4.1 Where drugs in brands of pharmaceutical item have received amended listings (for example, listing of new indications) following their first listing and remain in the F1 formulary, any 5 per cent (whether at 5 years or 15 years since listing on the PBS) or 10 per cent Price Reductions will continue to be calculated from the date on which the drug in that brand of pharmaceutical item was first listed on the PBS. The 5 per cent or 10 per cent Price Reductions will be applied to the price of the brands of pharmaceutical item as at the relevant reduction day when the drug has been listed on the PBS for 5 or 10 or 15 years and is on the F1 formulary, as applicable.

5.4.2 Where a new indication is added that results in the introduction of a weighted price for the drug, or a reduction in weighted price, this reduction will be excluded for the purposes of determining eligibility for the discretion to not apply Statutory Price Reductions described in clause 5.8.

5.5 Reference pricing of 5% or 10% Statutory Price Reductions

5.5.1 Where a 5 per cent (whether at 5 years or 15 years since listing on the PBS) or 10 per cent Statutory Price Reduction has been applied to a brand of pharmaceutical item containing a drug (**Reduced Drug**), pharmaceutical items containing other drugs which may be linked to the Reduced Drug for pricing purposes will not be reference priced against the Reduced Drug in respect of the 5 per cent or 10 per cent Statutory Price Reduction for the Reduced Drug.

5.5.2 Clause 5.5.1 does not prevent the application of other reference pricing changes to the Reduced Drug and other related drugs that are not related to a F1 Statutory Price Reduction.

5.6 Combination items

5.6.1 Where a drug on the single brand combination drug list has a component drug that is not PBS listed, the applicable F1 Statutory Price Reduction will be applied to that component drug on the same day it would have otherwise applied had the component drug been listed on the PBS on the same day as the combination item (for 5 years, 10 years or 15 years, as applicable).

5.6.2 Clause 5.5.1 does not prevent F1 Statutory Price Reductions being applied to component drugs being flowed on to combination items on the single brand combination drugs list.

5.6.3 For the purposes of clause 5.8, flow on price reductions to combination items will be accounted for in the discretion applied at the time of anniversary Statutory Price Reductions and when a new combination brand lists.

5.7 F1 price reductions effect on new listings

5.7.1 Subject to the remainder of this clause 5.7, new listing applications can request a price adjustment where:

(a) The new drug will be listed on the PBS in F1; or

(b) The drug in F1 has its listing on the PBS extended to a new consumer population or with changes in its PBS restriction,

on a cost-minimisation basis, by comparison with a medicine on the F1 formulary that has already taken a 5 per cent (whether at 5 or 15 years since listing) or 10 per cent Statutory Price Reduction (**Existing Items**).

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5.7.2 At the request of the applicant, the listing medicine will not have the 5 per cent or 10 per cent Statutory Price Reduction which has been applied to the existing items used to calculate the listing medicine's price when it:

(a) is listed on the PBS; or

(b) has its listing on the PBS extended.

5.7.3 The processes described in clauses 5.7.1 and 5.7.2 are not intended to limit the requirement in the Act that the Minister must agree or determine the price at which a drug in F1 is listed on the PBS or has its listing on the PBS extended.

5.7.4 The processes described in clauses 5.7.1 and 5.7.2 are intended to only apply where the PBAC determined comparator is in F1 and has been subject to either of the 5 per cent Statutory Price Reductions (whether at 5 years and/or at 15 years since listing) or a 10 per cent Statutory Price Reduction. The PBAC will continue to consider medicines against the appropriate comparator in accordance with PBAC guidelines and regardless of the comparator's formulary.

5.7.5 Where a medicine's listing price has been agreed or determined in accordance with the processes described in clauses 5.7.1 and 5.7.2, it is the intention that such medicines will be subject to an administrative Price Reduction at the end of the Term. The Price Reduction of the medicine at the end of the Term will be equivalent to the percentage by which the PBS listing price, or extended listing price, of that medicine exceeded the Existing Item's price at the time of the medicine's listing on the PBS, or extension of listing on the PBS, except that any Price Reduction of the medicine at the end of the Term should be reduced to reflect any Statutory Price Reductions in respect of the medicine that occurred during the Term.

5.7.6 The process for, and basis upon which, the Price Reduction described in clause 5.7.5 will be achieved will be agreed between the Commonwealth and the relevant responsible person at the time of the listing, or extension of the listing, of the medicine. This may include the Minister requiring the relevant responsible person to enter into a deed of agreement with the Commonwealth to achieve this outcome, which should include how price reductions taken during the term of the deed of agreement will be managed at the end of the Term.

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5.8 Discretion to apply Statutory Price Reductions

5.8.1 The amendments to the Act described in clause 5.8.3 are intended to allow the Minister the discretion to not apply a Statutory Price Reduction (or to reduce a Statutory Price Reduction) where a medicine has already been subject to disproportionately large price decline since listing.

5.8.2 Without limiting the Minister's discretion under the Act, the intention is that the medicines described in clause 5.8.3:

(a) that have already taken a price reduction since 1 January 2016 (**Start Date**) that is less than the full applicable Statutory Price Reduction, will not be subject to the full Statutory Price Reductions and will only be subject to partial Statutory Price Reductions calculated by subtracting the earlier Price Reductions (expressed in dollars) from the applicable Statutory Price Reduction (expressed in dollars); or

(b) that have already had a larger Price Reduction since the Start Date (expressed in dollars) than would arise under the applicable Statutory Price Reduction

(expressed in dollars) will not be subject to the applicable Statutory Price Reduction.

5.8.3 The Commonwealth will seek amendments to the Act to allow the Minister the discretion to not apply a Statutory Price Reduction, or to apply a lower Statutory Price Reduction, in circumstances where brands of pharmaceutical items have since the Start Date:

(a) already taken a Price Reduction as a result of the application of the Reference Pricing Policy;

(b) triggered a reduction under the Reference Pricing Policy resulting in a Price Reduction for other medicines; or

(c) already taken an administrative price reduction as a result of the application of existing pricing policies.

5.8.4 At the time of the application of the Statutory Price Reduction applicable at the 5, 10 or 15 year anniversary since listing, the calculation will be the Statutory Price Reduction level minus the total price reductions taken prior to that anniversary. If the total price reductions are greater than the Statutory Price Reduction otherwise due, the relevant Statutory Price Reduction will not occur.

5.8.5 At the time of the application of the Statutory Price Reduction arising due to the entry of the First New Brand as defined in clause 5.2 (**Relevant Reduction**), previous Price Reductions for the medicine will be taken into account as follows:

(a) If the previous Price Reductions are equivalent to 40 per cent or more of the original price of the medicine, the Relevant Reduction will not occur;

(b) If the previous Price Reductions are equivalent to between 15 and 40 per cent of the original price of the medicine, the Relevant Reduction is to be calculated as a dollar figure equal to 40 per cent of the original price of the medicine less the total Price Reductions, expressed in dollars, in relation to that medicine since listing such that the overall reduction does not exceed 40 per cent of the original price of the medicine; and

(c) If the previous Price Reductions are equivalent to 15 per cent or less of the original price of the medicine, then the Relevant Reduction will still be the full 25 per cent Statutory Price Reduction.

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5.9 New presentations

5.9.1 The Commonwealth will seek amendments to the Act[5] so that for drugs on the F1 formulary, where the same responsible person lists a new presentation of the drug:

(a) Prior to, or on, the fifth anniversary of listing, the new presentation will not be defined as a 'new brand' for the purposes of sections 99ACB or 99ACD of the Act;

(b) From the fifth anniversary to the tenth anniversary of listing, the new presentation may, at the discretion of the minister, be defined as a 'new brand' for the purposes of sections 99ACB or 99ACD of the Act, as applicable; and

(c) On and from the tenth anniversary of the listing, this new presentation will be a 'new brand' for the purposes of sections 99ACB or 99ACD of the Act, as applicable.

[5] The parties acknowledge that the arrangements described in this clause 5.9 may be implemented in the Act without changes being made to the sections of the Act specified in this clause 5.9.

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5.9.2 In exercising the discretion referred to in clause 5.9.1(b), the minister may rely on advice from the PBAC and other relevant considerations including provision of required information from the responsible person.

5.10 Clarification in respect of arrangements

Nothing in this clause 5 is intended to limit:

5.10.1 The ability of the Commonwealth or the Minister to accept or implement, and flow through Reference Pricing Policy based Price Reductions or Price Reductions as a result of a price offer by responsible persons;

5.10.2 The operation of Departmental processes that enable responsible persons to seek increases or decreases in the price of medicines; or

5.10.3 The operation of Departmental processes that enable responsible persons to apply for exemption from reductions in the price of pharmaceutical items resulting from the application of Statutory Price Reductions. For the avoidance of doubt, the Department will continue to consider exemption applications from responsible persons, for example where the viability of continued supply may be compromised by price reductions.

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Australian Government
Department of Health

MINISTERIAL DISCRETION GUIDANCE MATERIAL FOR STATUTORY PRICE REDUCTIONS

Introduction

The purpose of this Guidance Material is to assist an Authorised Representative who, on behalf of a Responsible Person, is considering making a request to the Minister for Health (or the Minister's delegate)[1], for the exercise of Ministerial Discretion in relation to Statutory Price Reductions (SPRs) that apply under Division 3A of Part VII of the *National Health Act 1953* (Cth) (**the Act**).

Information about SPRs that apply under Division 3A of Part VII of the Act is at Appendix 1. For further information about SPRs please consult the relevant sections in the Act and the Explanatory Memorandum. An extract from the Act for the Minister's discretionary powers in relation to SPRs is at Appendix 2. An extract from the Strategic Agreement with Medicines Australia is at Appendix 3.

This Material is intended to provide guidance on the types of information and the matters that may be considered relevant to the exercise of discretion. It should not be used as a basis for legal interpretation and is not intended to limit the Minister's powers conferred by the Act.

The Minister and the Australian Government accept no responsibility arising from use of, or reliance on, this document.

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Ministerial Discretion

The Act provides for Ministerial Discretion powers to reduce or not apply SPRs under Division 3A of Part VII of the Act by notifiable instrument.

Ministerial Discretion ensures that the prices of important Pharmaceutical Benefits Scheme (PBS) listed medicines will not be allowed to be reduced below what is needed to secure supply for Australian patients.

[1] All references to the Minister are also a reference, if applicable, to the Minister's delegate.

Statutory Price Reductions that Allow for Ministerial Discretion

The Act provides for Ministerial Discretion powers to reduce or not apply SPRs under Division 3A of Part VII of the Act (Table 1).

Table 1: Statutory Price Reductions that allow for Ministerial Discretion

Type of SPR	Description	Section/s of the Act
Anniversary price reductions	Anniversary reductions apply to F1 medicines on the fifth, tenth and fifteenth anniversary of a drug being listed on the PBS. Refer to Appendix 1, Part 1.	99ACHB, 99ACJA, 99ACKA, 99ACKB and 99ACF Refer to Appendix 2, Part 1.
First new brand reductions	A statutory price reduction is applied to existing PBS-listed products when the first new brand (the trigger item) that is bioequivalent or biosimilar and has the same manner of administration as an existing item lists on the PBS. The reduction that applies is 25% off the current AEMP, or a reduction to bring the price to 60% off the earliest of the 1 January 2016 or the date of listing AEMP. All related brands that have the same drug and manner of administration as the trigger item, will also have their AEMPs reduced by the same percentage reduction. Refer to Appendix 1, Part 2.	99ACB, 99ACD and 99ACR Refer to Appendix 2, Part 2
Catch-up price reductions	On 1 April 2023, catch-up price reductions will apply to brands of any drugs that have been listed on the PBS for fifteen years or more and have not taken a price disclosure reduction. The size of catch-up price reductions will vary depending on previous SPRs that have applied to the pharmaceutical item and will be up to a maximum of 36.82%. Refer to Appendix 1, Part 3.	99ACN Refer to Appendix 2, Part 3.
Combination flow-on price reductions	From 1 July 2022, SPRs automatically "flow-on" to combination items. This occurs by reducing a combination item where a listed component in the combination item is subject to a SPR. Refer to Appendix 1, Part 4.	99ACC and 99ADHB Refer to Appendix 2, Part 4.
New presentations (5 – 10 years)	Where there is a "new presentation"[2] of an existing medicine that has been listed on the PBS for 5 to 10 years, the Responsible Person can apply for Ministerial Discretion to not apply first new brand reductions for the purposes of section 99ACB and 99ACD of the Act. Refer to Appendix 1, Part 5.	99ACBA and 99ACEA Refer to Appendix 2, Part 5.

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[2] Refer to the New Presentation guidance material for more information about making a new presentation request - https://www.pbs.gov.au/industry/pricing/ministerial-discretion/New-Presentation-Ministerial-Discretion-Guidance.pdf

What will be considered when making a decision to exercise discretion?

Guidance is provided on the types of information and the matters that might be considered relevant to the exercise of discretion in cases where a Responsible Person would like to request not to apply, or to reduce the amount of the SPRs outlined in Table 1. This guidance is not intended to limit the Minister's powers conferred by the Act.

The Minister **must** take into account what the Approved Ex-Manufacturer Price (**AEMP**) would otherwise be if they do not exercise discretion (i.e., what the new price would be if the full reduction applied) and **may** take into account any other matter that they consider relevant.

Other matters that the Minister may consider relevant may include:

1. **The pricing history of the medicine**, including, but not limited to, whether:
   a) the medicine has taken significant price reductions since 1 January 2016
   b) the medicine has taken significant price reductions as a result of actions of the Responsible Person (such as through self-initiated price reductions to list new indications), or of the actions of other Responsible Persons (such as through a reference pricing exercise)
   c) the medicine has previously been granted Ministerial Discretion
   d) the medicine has previously been subject to a price increase.

2. **Clinical and viability aspects of the medicine**, including but not limited to, whether:
   a) the medicine is clinically needed[3] on the PBS, taking into consideration factors such as:
      i. if the medicine is identified on the World Health Organization's Model Lists of Essential Medicines
      ii. any new or existing advice from the PBAC or clinical experts
      iii. if there is a therapeutic alternative available on the PBS
      iv. if there are other available brands of the medicine on the PBS
      v. whether the therapeutic alternatives and/or other available brands will be able to meet market demand.
   b) a further reduction to the price will:
      i. impact the viability[4] of continued PBS supply; and
      ii. lead to the medicine being de-listed from the PBS if discretion is not granted.

3. **Financial impacts**, including:
   a) The financial impact on the PBS if discretion is granted
   b) The financial impact on the PBS if the medicine was delisted
   c) The financial impacts on consumers if discretion is granted
   d) The financial impacts on consumers if the medicine is delisted.

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[3] Where required, clinical advice will be sought to determine clinical need, such as from a medical advisor or the Pharmaceutical Benefits Advisory Committee (PBAC).
[4] Refers to any impacts a price reduction may have on a company's ability to continue supplying the product and/or operating in Australia.

Note: it is not necessary for all matters listed above to be addressed in a request for Ministerial Discretion nor is it necessary for the Minister to consider all of these matters when deciding whether or not to exercise discretion. It remains open to Responsible Persons to submit any other reasons why discretion should be exercised, where that matter is not listed above.

Making a request

The request must be made through the Health Products Portal (**HPP**) under 'list management service requests' which includes completing cost of goods information. Requests are cost recovered and current fees are listed on the PBS website.

Provision of additional material that is relevant to the request is not a requirement but may assist in determining whether discretion should be exercised. Examples of additional material that may be relevant include, but are not limited to:

Additional material relating to clinical need:

- PBAC or clinical advice;
- evidence of the medicine's place in the clinical pathway, such as if it is used in patients who have failed prior treatments; and
- whether the medicine is for a specific and/or vulnerable patient community.

Additional material relating to viability:

- the Responsible Person's plans for the listing should discretion not be granted;
- cost of goods information outlining where a reduction may take the price below this amount;
- commercial and fiscal viability including economies of scale, gross margins of the Listed Brand, and the impact on the company's domestic and/or global revenue;
- available information on historical shortages or discontinuations of brands of the pharmaceutical item; and
- whether following de-listing because of non-viability, target patient groups would have the capacity to pay for the medicine.

Other material:

- availability and prices of alternative brands, products and treatments;
- prices of items when supplied privately in Australia and in comparable overseas markets; and
- reliability of information provided by the Responsible Person including certification by independent third party.

The Department has responsibility for managing all aspects of requests made to the Minister. The Department will provide the Minister with the submission together with a summary of the request and a recommendation in relation to the exercise of discretion. All submissions will be treated as commercial-in-confidence. Giving false or misleading information is a serious offence.

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Application timeframes

1. 1 April 2023 reductions (catch-up reductions and anniversary reductions)

A list of medicines subject to reductions occurring on 1 April 2023 (catch-up reductions and anniversary reductions), and the indicative AEMP, will be made available on the PBS website on 1 July 2022 (refer to Table 2).

Combination items that contain a component item that is subject to a catch-up or anniversary reduction will be subject to a flow-on price reduction on the same date (Refer to Appendix 1, Part 4). Combination items are subject to the same Ministerial Discretion timeframes outlined in Table 2.

Table 2: Ministerial Discretion application timeframes for 1 April 2023 reductions

Date	Milestone
1 Jul 2022	Publication of indicative list of medicines subject to 1 April 2023 reductions
	Ministerial Discretion applications open
29 Jul 2022	Closing date for Ministerial Discretion applications
10 Oct 2022	**Indicative** Ministerial Discretion outcomes[5]
25 Oct 2022	Closing date for sponsors to submit additional information
15 Nov 2022	Sponsors notified of **final** Ministerial Discretion outcomes
15 Jan 2023	Closing date for delisting request (1 April 2023)[6]
1 Apr 2023	Reduction Day

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2. Anniversary price reductions occurring from 1 April 2024

A list of medicines subject to anniversary price reductions, and the indicative AEMP, will be made available on the PBS website from 1 August in the previous year before the 1 April reduction date (refer to Table 3). The closing date for Ministerial Discretion applications for anniversary price reductions is 11 September in the previous year before the 1 April reduction date (refer to Table 3).

Combination items that contain a component item that is subject to an anniversary reduction will be subject to a flow-on price reduction on the same date (Refer to Appendix 1, Part 4). Combination items are subject to the same Ministerial Discretion timeframes outlined in Table 3.

[5] Responsible Persons will be provided with opportunity to submit further information.

[6] Some delist requests may require PBAC consideration therefore a 1 April 2023 delist date cannot be guaranteed.

Table 3: Ministerial Discretion application timeframes for anniversary price reductions

MD application close	Indicative MD outcome	Additional information due	Final MD outcome	Closing date for delist requests[1]	Reduction date
30 business days	*30 business days*	*10 business days*	*20 business days*	*24 business days*	*~77 business days*
11 Sept 2023	23 Oct 2023	6 Nov 2023	4 Dec 2023	15 Jan 2024	1 Apr 2024
11 Sept 2024	23 Oct 2024	6 Nov 2024	4 Dec 2024	15 Jan 2025	1 Apr 2025
11 Sept 2025	23 Oct 2025	6 Nov 2025	4 Dec 2025	15 Jan 2026	1 Apr 2026
11 Sept 2026	23 Oct 2026	6 Nov 2026	4 Dec 2026	15 Jan 2027	1 Apr 2027

[1]*Some delist requests may require PBAC consideration therefore a 1 April 2023 delist date cannot be guaranteed.*
Note: business days indicate the amount of time available for each party to complete the activity.

3. First new brand reductions

Responsible Persons of originator medicines subject to first new brand reductions will be notified within five business days from the Department receiving the application to list the new brand. In some instances where the medicine is subject to a Deed of Agreement it may not be possible to notify the new AEMP within five business days. In these instances, Responsible Persons will be notified that an application has been received within five business days and will be notified of the new AEMP as soon as possible. The closing date for Ministerial Discretion applications will be 15 business days after the closing date for Responsible Persons to submit a new brand application (refer to Table 4).
Combination items that contain a component item that is subject to the first new brand reduction will be subject to the flow-on price reduction on the same date (Refer to Appendix 1, Part 4). Combination items are subject to the same Ministerial Discretion timeframes outlined in Table 4.

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Table 4: Ministerial Discretion application timeframes for First New Brand reductions

FNB application close	Originator notification	MD application close	Indicative MD outcome	Additional information due	Final MD outcome[1]	Reduction date
	5 business days	*10 business days*	*20 business days*	*5 business days*	*10 business days*	
1 Feb 2023	7 Feb 2023	21 Feb 2023	21 Mar 2023	28 Mar 2023	11 Apr 2023	1 Jun 2023
31 Mar 2023	11 Apr 2023	26 Apr 2023	17 May 2023	24 May 2023	7 Jun 2023	1 Aug 2023
1 Jun 2023	8 Jun 2023	22 Jun 2023	20 Jul 2023	27 Jul 2023	10 Aug 2023	1 Oct 2023

[1] *Late delisting requests may be considered for a delist on the reduction date following notification of the final MD.*
Note: business days indicate the amount of time available for each party to complete the activity.

4. New presentations (5 – 10 years)

Listing a "new presentation"[7] of an existing medicine that has been listed on the PBS for 5 to 10 years allows the Responsible Person to apply for Ministerial Discretion to not apply first new brand reductions for the purposes of section 99ACB and 99ACD of the Act.

Table 5: Ministerial Discretion application timeframes for new presentations (5-10 years)

Submit intent to apply	Submit pricing offer package	MD closing date	MD indicative outcome	Additional information due	MD final outcome	Requested listing date
	5 business days	***10 business days***	***20 business days***	***5 business days***	***10 business days***	
1 Feb 2023	7 Feb 2023	21 Feb 2023	21 Mar 2023	28 Mar 2023	11 Apr 2023	1 Jun 2023
31 Mar 2023	11 Apr 2023	26 Apr 2023	17 May 2023	24 May 2023	7 Jun 2023	1 Aug 2023
1 Jun 2023	8 Jun 2023	22 Jun 2023	20 Jul 2023	27 Jul 2023	10 Aug 2023	1 Oct 2023

Note: business days indicate the amount of time available for each party to complete the activity.

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[7] Refer to the New Presentation guidance material for more information about making a new presentation request - https://www.pbs.gov.au/industry/pricing/ministerial-discretion/New-Presentation-Ministerial-Discretion-Guidance.pdf

Outcome of request

The Department will, in accordance with the timeframes outlined above:

a) notify the Responsible Person of the indicative decision via the HPP
b) where the indicative Ministerial decision is not to exercise the discretion, a summary of reasons will be provided and the Responsible Person will be given an opportunity to provide further information to the Department (via the HPP) before the Minister makes a final decision about whether to exercise the discretion
c) notify the Responsible Person of the final outcome.

Where Ministerial discretion is exercised, the outcome will also be published on the Federal Register of Legislation in a Notifiable Instrument, as required by the legislation, before the reduction day.

If Ministerial Discretion is not exercised

The following options remain available to the Responsible Person through the HPP:

a) Request a price increase
b) Request a Brand Price Premium
c) Request the product to be delisted from the PBS.

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APPENDIX 1: Background on Statutory Price Reductions

1. Anniversary Price Reductions (5, 10, 15 year)

- Under section 99ACF of the Act, the Minister can exercise Ministerial Discretion in relation to the anniversary reductions which occur depending on the length of time a medicine has been listed on the Pharmaceutical Benefits Scheme (**PBS**).
- The price reduction applied will be capped at 60 per cent off (or 40 per cent of) the Listed Brand's AEMP on 1 January 2016 or the AEMP at a later date of listing.
- Table 6 outlines the anniversary price reductions that commence from 1 April 2023.

Table 6: Anniversary price reductions

Listing duration	Reduction that applies	Section/s of the Act	Price reduction days
At least 5 years but less than 10 years	5%	99ACHB	1 April 2023 1 April 2024 1 April 2025 1 April 2026 1 April 2027
At least 10 years but less than 15 years	5%	99ACJA	1 April 2023 1 April 2024 1 April 2025 1 April 2026 1 April 2027
15 years or more	26.1%	99ACKA	1 April 2023 1 April 2024 1 April 2025 1 April 2026
	30%	99ACKB	1 April 2027

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2. First New Brand Reductions

- Under sections 99ACB, 99ACD and 99ACR of the Act a statutory price reduction is applied to existing PBS-listed products when the first new brand (the trigger item) that is bioequivalent or biosimilar and has the same manner of administration as an existing item lists on the PBS. The reduction that applies is 25% off the current AEMP, or a reduction to bring the price to 60% off the earliest of the 1 January 2016 or the date of listing AEMP. Refer to Table 7.
- All brands that have the same drug and manner of administration as the trigger item, will also have their AEMPs reduced by the same percentage reduction.
- The price reduction applied will be capped at 60 per cent off (or 40 per cent of) the Listed Brand's AEMP on 1 January 2016 or the AEMP at a later date of listing.
- Where the existing brand has an effective price, please refer to clause 9.4.2 of the Strategic Agreement.
- Refer to the First New Brand Policy that will be available on the PBS website from 1 July 2022 for more detailed information.

Table 7: First new brand reductions

Reduction off AEMP since 1 January 2016 or later date of listing	Reduction that applies to both the existing and new brand
60 % or more	0%
>35% and <60%	Reduced price is equal to 40% of the 1 January 2016 or date of listing AEMP.
<35%	25%

3. Catch-Up Reductions

- On 1 April 2023, catch-up price reductions will apply in accordance with section 99ACN of the Act to brands of any drugs that have been listed on the PBS for fifteen years or more that have not taken a price disclosure reduction.
- The size of catch-up price reductions will vary depending on previous statutory price reductions and will be up to a maximum of 36.82%. The catch-up reductions will be calculated in accordance with the formula outlined in section 99ACN(2) of the Act.
- The price reduction applied will be capped at 60 per cent off the Listed Brand's AEMP on 1 January 2016 or the AEMP at a later date of listing.

4. Combination Flow-on Reductions

- A combination item is a pharmaceutical item that has a drug that contains at least two other drugs, at least one of which is listed on the PBS.
- Under sections 99ACC and 99ADHB of the Act, statutory price reductions "flow-on" to combination items.
- Under section 99ACC of the Act, on the reduction day[8], the AEMP of the **single** brand of the combination is reduced in accordance with section 65A of the Regulation[9] (refer to Appendix 4).
- Under section 99ADHB of the Act, on the reduction day, the AEMP of the **existing** brand of the combination item is reduced in accordance with section 85A[10] the regulations (refer to Appendix 4).

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[8] Sections 65A and 85A, as inserted by Schedule 1 to the *National Health (Pharmaceutical Benefits) Amendment (2021 Measures No. 1) Regulations 2021*, apply in relation to reduction days occurring on or after 1 July 2022.
[9] National Health Act 1953 National Health (Pharmaceutical Benefits) Amendment (2021 Measures No. 1) Regulations 2021
[10] National Health Act 1953 National Health (Pharmaceutical Benefits) Amendment (2021 Measures No. 1) Regulations 2021

5. New Presentations of medicines that have been PBS listed for 5 – 10 years

- "New presentation" provisions under the Act (sections 99ACBA, and 99ACEA) provide an avenue for Responsible Persons of existing brands of listed pharmaceutical items, to list new presentations of those medicines[11].
- This is intended to encourage innovation that contributes to better outcomes for patients and not to incentivise new formulations of existing drugs which will simply delay or reduce brand competition.
- If a proposed listing date is within 5 years of the drug being listed on the PBS, the Responsible Person must make an application to the Department asking that the Department recognise the new item as a new presentation.
- If the proposed listing date is between 5 to 10 years after the drug was listed on the PBS, listing a "new presentation" of an existing listed PBS medicine would enable the Responsible Person to apply for Ministerial Discretion to not apply first new brand reductions for the purposes of section 99ACB, and 99ACD. In this case the Responsible Person must request:
  (1) the Department to recognise the new item as a new presentation[12]; and
  (2) the Minister to exercise the discretion not to apply the SPR and not to move the drug from F1 to F2.
- A new presentation that is listed within 5 years of the initial PBS listing will not be defined as a new brand for the purposes of sections 99ACB or 99ACD of the Act. For example, if drug X has been listed on the PBS within 5 years, recognising drug X as new presentation would entail **not** triggering any price reduction under sections 99ACB, and 99ACD of the Act.
- Recognising a new item with a proposed PBS listing date of 5 to 10 years as a new presentation does not necessarily require the Minister to not trigger the SPR; the Minister would still have to consider whether or not to apply first new brand reductions for the purposes of section 99ACB, and 99ACD for the new presentation.

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[11] To apply for a new presentation listing, refer to https://www.pbs.gov.au/industry/pricing/ministerial-discretion/New-Presentation-Ministerial-Discretion-Guidance.pdf
[12] To apply for a new presentation listing, refer to https://www.pbs.gov.au/industry/pricing/ministerial-discretion/New-Presentation-Ministerial-Discretion-Guidance.pdf

APPENDIX 2: Excerpts from the *National Health Act 1953* (Cth)

1. Anniversary price reductions

99ACHB 5% statutory price reduction for drugs on F1—fifth anniversary

(1) This section applies to a brand of a pharmaceutical item on a 5% price reduction day if:
- (a) the drug in the pharmaceutical item is on F1 on the 5% price reduction day; and
- (b) the 5% price reduction day is on or after the fifth anniversary of the drug being a listed drug; and
- (c) subsection 99ACR(4) has not applied to the brand of the pharmaceutical item; and
- (d) on or before the 5% price reduction day, the approved ex-manufacturer price of the brand of the pharmaceutical item has not been reduced:
  - (i) under subsection 99ACF(1) or (2); or
  - (ii) because of repealed section 99ACE or repealed section 99ACH; or
  - (iii) under section 99ACQ; or
  - (iv) under subsection 99ACR(3).

(2) In this section, each of the following is a ***5% price reduction day***:
- (a) 1 April 2023;
- (b) 1 April 2024;
- (c) 1 April 2025;
- (d) 1 April 2026;
- (e) 1 April 2027.

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99ACJA 5% statutory price reduction for drugs on F1—tenth anniversary

(1) This section applies to a brand of a pharmaceutical item on a 5% price reduction day if:
- (a) the drug in the pharmaceutical item is on F1 on the 5% price reduction day; and
- (b) the 5% price reduction day is on or after the tenth anniversary of the drug being a listed drug; and
- (c) the approved ex-manufacturer price of the brand of the pharmaceutical item has not been previously reduced under subsection 99ACF(1) or (2) because of:
  - (i) item 3 in the table in section 99ACF; or
  - (ii) item 3A in the table in section 99ACF; or
  - (iii) item 5 in the table in section 99ACF;
  - (iv) item 7 in the table in section 99ACF; and
- (d) subsection 99ACR(4) has not applied to the brand of the pharmaceutical item; and
- (e) on or before the 5% price reduction day, the approved ex-manufacturer price of the brand of the pharmaceutical item has not previously been reduced:
  - (i) because of repealed section 99ACE or repealed section 99ACH; or
  - (ii) under section 99ACQ; or
  - (iii) under subsection 99ACR(3).

(2) In this section, each of the following is a ***5% price reduction day***:
- (a) 1 April 2023;
- (b) 1 April 2024;
- (c) 1 April 2025;
- (d) 1 April 2026;

(e) 1 April 2027.

99ACKA 26.1% statutory price reduction for certain drugs—15th anniversary

(1) This section applies to a brand of a pharmaceutical item on a 26.1% price reduction day if:

(a) the 26.1% price reduction day is on or after the 15th anniversary of the drug in the pharmaceutical item being a listed drug; and

(b) the approved ex-manufacturer price of the brand of the pharmaceutical item has not been previously reduced under subsection 99ACF(1) or (2) because of:

(i) item 4 in the table in section 99ACF; or

(ii) item 4A in the table in section 99ACF; or

(iii) item 6 in the table in section 99ACF; or

(iv) item 8 in the table in section 99ACF; and

(c) the approved ex-manufacturer price of the brand of the pharmaceutical item has not been previously reduced on or before the 26.1% reduction day:

(i) because of section 99ACB or 99ACD; or

(ii) because of repealed section 99ACE or repealed section 99ACH; or

(iii) under section 99ACQ; or

(iv) under subsection 99ACR(3); and

(d) subsection 99ACR(4) has not applied to the brand of the pharmaceutical item on or before the 26.1% price reduction day; and

(e) the pharmaceutical item is not an exempt item.

Note: See also section 99ACG..

(2) In this section, each of the following is a ***26.1% price reduction day***:

(a) 1 April 2023;

(b) 1 April 2024;

(c) 1 April 2025;

(d) 1 April 2026.

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99ACKB 30% statutory price reduction for certain drugs—15th anniversary

(1) This section applies to a brand of a pharmaceutical item on the 30% price reduction day if:

(a) the 30% price reduction day is on or after the 15th anniversary of the drug in the pharmaceutical item being a listed drug; and

(b) the approved ex-manufacturer price of the brand of the pharmaceutical item has not been previously reduced under subsection 99ACF(1) or (2) because of:

(i) item 4 in the table in section 99ACF; or

(ii) item 4A in the table in section 99ACF; or

(iii) item 6 in the table in section 99ACF; or

(iv) item 8 in the table in section 99ACF; and

(c) the approved ex-manufacturer price of the brand of the pharmaceutical item has not been reduced on or before the 30% reduction day:

(i) because of section 99ACB or 99ACD; or

(ii) because of repealed section 99ACE or repealed section 99ACH; or

(iii) under section 99ACQ; or

(iv) under subsection 99ACR(3); and

(d) subsection 99ACR(4) has not applied to the brand of the pharmaceutical item on or before the 30% price reduction day; and

(e) the pharmaceutical item is not an exempt item.

Note: See also section 99ACG.

(2) In this section, the ***30% price reduction day*** is 1 April 2027.

99ACF Statutory price reductions

Reduction equal to percentage etc.

(1) Subject to sections 99ACG and 99ADHC, if:

(a) a section or subsection referred to in column 2 of the table in this subsection applies to a listed brand of a pharmaceutical item on a day specified in the section or subsection (the ***reduction day***); and

(b) subsection (2) does not apply to the listed brand of the pharmaceutical item on the reduction day; and

(c) on the day before the reduction day, an approved ex-manufacturer price was, or one or more claimed prices were, in force for the listed brand of the pharmaceutical item;

then, subject to subsections (1A), (2A) and (3), the approved ex-manufacturer price is, and (if applicable) each of the claimed prices are, taken to be reduced, on the reduction day, by the percentage or method specified in column 3 of the table for the section or subsection referred to in column 2.

Statutory price reductions table

Item	Section or subsection	Percentage or method
2	99ACHA	5%
2A	99ACHB	5%
3	99ACJ	10%
3A	99ACJA	5%
4	99ACK	5%
4A	99ACKA	26.1%
4B	99ACKB	30%
5	99ACL(1)	10%
6	99ACL(2)	(a) first, 10%; and (b) second, using the price worked out under paragraph (a), by 5%
7	99ACM	5%
8	99ACN	The percentage referred to in paragraph 99ACN(1)(c)
9	99ACP	1.48%

Note: Subsection (1) does not apply if there is no determination under subsection 85(6) in respect of the pharmaceutical item in force on the specified day (whether or not the determination was revoked following a request by the Responsible Person for the pharmaceutical item).

Reduction cap

(1A) If:

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(a) the approved ex-manufacturer price of a listed brand of a pharmaceutical item is to be reduced under subsection (1) because of an item in the table in subsection (1); and

(b) apart from this subsection, the reduced approved ex-manufacturer price would be less than the amount (the ***capped price***) equal to:

(i) 40% of the approved ex-manufacturer price of a listed brand of the pharmaceutical item on 1 January 2016; or

(ii) if subparagraph (i) does not apply—40% of the original approved ex-manufacturer price of the first listed brand of the pharmaceutical item;

the approved ex-manufacturer price of the listed brand of the pharmaceutical item is taken to be reduced under subsection (1) because of that item to an amount equal to the capped price.

(1B) If the approved ex-manufacturer price mentioned in subparagraph (1A)(b)(i) or (ii) is by reference to a different pricing quantity than the pricing quantity on the reduction day, the approved ex-manufacturer price mentioned in that subparagraph is taken to be the amount that the approved ex-manufacturer price would have been had the pricing quantity been the same as the pricing quantity on the reduction day.

Reduction more than percentage

(2) This subsection applies if:

(a) a section or subsection referred to in column 2 of the table in subsection (1) applies to a listed brand of a pharmaceutical item on a reduction day; and

(b) subject to subsection (2A), on the reduction day, the approved ex manufacturer price of the listed brand of the pharmaceutical item does not exceed:

(i) the approved ex manufacturer price of the brand of the pharmaceutical item in force on the day before the reduction day, reduced by more than the percentage or method specified in column 3 of the table for the section or subsection referred to in column 2; or

(ii) if subsection (1A) would have applied to the brand of the pharmaceutical item if paragraph (1)(b) were disregarded—the capped price of the brand of the pharmaceutical item that would be worked under subsection (1A) if paragraph (1)(b) were disregarded; and

(c) if, on the day before the reduction day and on the reduction day, a determination under subsection 85B(3) was in force in relation to a particular pack quantity of the listed brand of the pharmaceutical item—the claimed price for that pack quantity of the brand of the pharmaceutical item does not exceed the claimed price for the same pack quantity of the brand of the pharmaceutical item in force on the day before the reduction day, reduced by more than the percentage or method specified in column 3 of the table for the section or subsection referred to in column 2.

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Apportioning if pricing quantity changes

(2A) If the pricing quantity of the listed brand of the pharmaceutical item on the day before the reduction day is different from the pricing quantity of the listed brand of the pharmaceutical item on the reduction day, then, for the purposes of subsection (1) and paragraph (2)(b), the approved ex-manufacturer price of the listed brand of the pharmaceutical item on the day before the reduction day is taken to be the amount worked out as follows:

$$\frac{\text{AEMP1}}{\text{PQ1}} \times \text{PQ2}$$

where:

AEMP1 means the amount that was the approved ex-manufacturer price of the listed brand of the pharmaceutical item on the day before the reduction day.

PQ1 means the pricing quantity of the listed brand of the pharmaceutical item on the day before the reduction day.

PQ2 means the pricing quantity of the listed brand of the pharmaceutical item on the reduction day.

Ministerial discretion not to apply, or to reduce, statutory price reduction

(3) In relation to a listed brand of a pharmaceutical item, the Minister may, by notifiable instrument, determine that:

(a) the approved ex-manufacturer price is, or (if applicable) one or more claimed prices are, not to be reduced under a provision mentioned in an item of the table in subsection (1) (the ***specified provision***) in relation to a particular reduction day; or

(b) the approved ex-manufacturer price is, or (if applicable) one or more of the claimed prices are, to be reduced by a lower percentage than would otherwise apply under a provision mentioned in an item of the table in subsection (1) (the ***specified provision***) in relation to a particular reduction day

(3A) In making a determination in relation to the application of an item of the table in subsection (1):

(a) the Minister must take into account what the approved ex-manufacturer price, and (if applicable) each of the claimed prices, of the listed brand of the pharmaceutical item would otherwise be under this section in relation to the particular reduction day if a determination were not made; and

(b) the Minister may take into account any other matter that the Minister considers relevant.

(3B) If the Minister makes a determination in relation to a specified provision, the approved ex-manufacturer price is, and (if applicable) each of the claimed prices are, not to be further reduced under that specified provision on any reduction day that occurs after the reduction day specified in the determination made under subsection (3).

Section does not limit Minister's powers

(4) This section does not limit the Minister's powers, on or after the reduction day, to make:

(a) further price agreements; or

(b) further determinations under section 85B;

for the listed brand of the pharmaceutical item.

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2. First new brand reductions

99ACB First new brand price reductions for brands of pharmaceutical items that are not combination items

When section applies to new brands

(1) Subject to subsections (2), (3), (3A) and (3B), this section applies to a brand (the ***new brand***) of a pharmaceutical item (the ***trigger item***) that is not a combination item if:

(a) a determination under subsection 85(6) comes into force in relation to the new brand of the trigger item on a day (the ***determination day***); and

(b) on the day before the determination day, the new brand of the trigger item was not a listed brand of the trigger item; and

(c) on the day before the determination day:

(i) a brand (the ***existing brand***) of a pharmaceutical item (the ***existing item***) was a listed brand of the existing item; and

(ii) the new brand of the trigger item is bioequivalent or biosimilar to the existing brand of the existing item; and

(iii) the trigger item and existing item have the same drug and manner of administration.

Note: For the purposes of paragraph (c), the new brand and the existing brand may be the same brand, or the trigger item and the existing item may be the same pharmaceutical item.

Circumstances in which section does not apply

(2) This section does not apply in relation to the new brand of the trigger item if:

(a) the trigger item is in a class of pharmaceutical items to which a 12.5%, 16% or 25% administrative price reduction has applied; or

(b) another pharmaceutical item that has the same drug and manner of administration as the new brand of the trigger item is in a class of pharmaceutical items to which a 12.5%, 16% or 25% administrative price reduction has applied; or

(c) if the drug that is in the trigger item is in a therapeutic group—a pharmaceutical item that:

(i) has another drug that is in that group; and

(ii) has the same manner of administration as the new brand of the trigger item;

is in a class of pharmaceutical items to which a 12.5%, 16% or 25% administrative price reduction has applied; or

(d) on the day before the determination day:

(i) the approved ex-manufacturer price of a listed brand of the existing item on 1 January 2016; or

(ii) if subparagraph (i) does not apply—the original approved ex-manufacturer price of the first listed brand of the existing item;

has, by virtue of previous price reductions, been reduced by 60% or more.

(2A) If the approved ex-manufacturer price mentioned in subparagraph (2)(d)(i) or (ii) is by reference to a different pricing quantity than the pricing quantity on the day before the determination day, the approved ex-manufacturer price mentioned in that subparagraph is taken to be the amount that the approved ex-manufacturer price would have been had the pricing quantity been the same as the pricing quantity on the day before the determination day.

(3) This section does not apply in relation to the new brand of the trigger item if:

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(a) any of the following has applied:

(i) subsection (5) or (5A);

(ia) a determination under paragraph (6A)(b);

(ib) subsection 99ACF(1) or (2) because of item 4A, 4B or 8 in the table in subsection 99ACF(1);

(ii) subsection 99ACF(1) or (2) because of repealed section 99ACH;

(iii) repealed subsection 99ACF(2AB) or (2AC);

(iv) section 99ACQ;

(v) subsection 99ACR(3) or (4);

in relation to:

(b) the new brand, or another listed brand, of the trigger item; or

(c) a listed brand of another pharmaceutical item that has the same drug and manner of administration as the new brand of the trigger item; or

(d) if the drug that is in the trigger item is in a therapeutic group—a listed brand of a pharmaceutical item that:

(i) has another drug that is in that group; and

(ii) has the same manner of administration as the new brand of the trigger item.

Note: For the purposes of subparagraph (a)(i), subsections (5) and (5A) of this section are taken not to have applied in relation to a brand of a pharmaceutical item in some cases: see section 99AEI and subsection (6B) of this section.

(3A) This section does not apply in relation to the new brand of the trigger item if:

(a) the new brand of the trigger item is a new presentation of an existing listed brand of a pharmaceutical item; and

(b) the determination day in relation to the new brand of the trigger item is on or before the fifth anniversary of the drug in the pharmaceutical item being on F1; and

(c) the Responsible Person for the new brand of the trigger item is the same person as the Responsible Person for the existing listed brand of the pharmaceutical item; and

(d) either of the following apply:

(i) there is not another brand of the pharmaceutical item that has the drug that is a listed brand;

(ii) the drug is not on F2.

(3B) This section does not apply in relation to the new brand of the trigger item if:

(a) the new brand of the trigger item is a new presentation of an existing listed brand of a pharmaceutical item; and

(b) the Minister has made a determination under section 99ACBA in relation to the new brand of the trigger item; and

(c) the determination under section 99ACBA has not ceased to have effect.

First new brand price reduction

(4) The Minister:

(a) may, under section 85AD, make a price agreement for the new brand of the trigger item; and

(b) must not make a determination under section 85B in relation to the new brand of the trigger item.

(4A) If, on the day before the determination day:

(a) the approved ex-manufacturer price of a listed brand of the existing item on 1 January 2016; or

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(b) if paragraph (a) does not apply—the original approved ex-manufacturer price of the first listed brand of the existing item;

has, by virtue of previous price reductions, been reduced by:

(c) 35% or less, subsection (5) applies; and

(d) more than 35% but less than 60%, subsection (5A) applies.

Note: If previous price reductions have been 60% or more, see paragraph (2)(d).

(4B) If the approved ex-manufacturer price mentioned in paragraph (4A)(a) or (b) is by reference to a different pricing quantity than the pricing quantity on the day before the determination day, the approved ex-manufacturer price mentioned in that paragraph is taken to be the amount that the approved ex-manufacturer price would have been had the pricing quantity been the same as the pricing quantity on the day before the determination day.

(5) Subject to subsections (6) and (6A), the agreed price of the new brand of the trigger item that comes into force on the determination day must not exceed the approved ex-manufacturer price, on the day before the determination day, of the existing brand of the existing item, reduced by 25%.

(5A) Subject to subsections (6) and (6A), the agreed price of the new brand of the trigger item that comes into force on the determination day must not exceed:

(a) 40% of the approved ex-manufacturer price of a listed brand of the existing item on 1 January 2016; or

(b) if paragraph (a) does not apply—40% of the original approved ex-manufacturer price of the first listed brand of the existing item.

(5B) If the approved ex-manufacturer price mentioned in paragraph (5A)(a) or (b) is by reference to a different pricing quantity than the pricing quantity on the day before the determination day, the approved ex-manufacturer price mentioned in that paragraph is taken to be the amount that the approved ex-manufacturer price would have been had the pricing quantity been the same as the pricing quantity on the day before the determination day.

Apportioning if pricing quantity changes

(6) If the pricing quantity of the existing brand of the existing item on the day before the determination day is different from the pricing quantity of the existing brand of the existing item on the determination day, then, for the purposes of subsections (5) and (5A), the approved ex-manufacturer price of the existing brand of the existing item on the day before the determination day is taken to be the amount worked out as follows:

$$\frac{\text{AEMP1}}{\text{PQ1}} \times \text{PQ2}$$

where:

AEMP1 means the amount that was the approved ex-manufacturer price of the existing brand of the existing item on the day before the determination day.

PQ1 means the pricing quantity of the existing brand of the existing item on the day before the determination day.

PQ2 means the pricing quantity of the existing brand of the existing item on the determination day.

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Ministerial discretion not to apply, or to reduce, statutory price reduction

(6A) The Minister may, by notifiable instrument, determine that:

(a) the agreed price of the new brand of the trigger item that comes into force on the determination day is to be equal to the approved ex-manufacturer price, on the day before the determination day, of the existing brand of the existing item; or

(b) the agreed price of the new brand of the trigger item that comes into force on the determination day must not exceed the approved ex-manufacturer price, on the day before the determination day, of the existing brand of the existing item, reduced by a lower percentage than would otherwise result from the operation of subsection (5) or (5A) in relation to the determination day.

(6B) If the Minister makes a determination under paragraph (6A)(a), subsections (5) and (5A) are taken not to have applied to the trigger item.

(6C) In making a determination under subsection (6A):

(a) the Minister must take into account what the agreed price of the new brand of the trigger item would otherwise be under this section in relation to the particular determination day if a determination were not made; and

(b) the Minister may take into account any other matter that the Minister considers relevant.

Section does not limit Minister's powers

(7) This section does not limit the Minister's powers, after the determination day, to make:

(a) further price agreements; or

(b) determinations under section 85B;

for the new brand of the trigger item.

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99ACD First new brand price reductions for brands of combination items

When section applies to new brands

(1) Subject to subsections (1A), (2) and (3), this section applies to a brand (the ***new brand***) of a pharmaceutical item (the ***trigger combination item***) that is a combination item if:

(a) a determination under subsection 85(6) comes into force in relation to the new brand of the trigger combination item on a day (the ***determination day***); and

(b) on the day before the determination day, the new brand of the trigger combination item was not a listed brand of the trigger combination item; and

(c) on the day before the determination day:

(i) a brand (the ***existing brand***) of a pharmaceutical item (the ***existing item***) was a listed brand of the existing item; and

(ii) the new brand of the trigger combination item is bioequivalent or biosimilar to the existing brand of the existing item; and

(iii) the drug in the trigger combination item and existing item contain the same component drugs; and

(iv) the trigger combination item and the existing item have the same manner of administration.

Note: For the purposes of paragraph (c), the new brand and the existing brand may be the same brand, or the trigger combination item and the existing item may be the same pharmaceutical item.

Circumstances in which section does not apply to new brands

(1A) This section does not apply in relation to the new brand of the trigger combination item if:

(a) the trigger combination item is in a class of pharmaceutical items to which a 12.5%, 16% or 25% administrative price reduction has applied; or

(b) another combination item that has the same drug and manner of administration as the new brand of the trigger combination item is in a class of pharmaceutical items to which a 12.5%, 16% or 25% administrative price reduction has applied; or

(c) if the drug in the trigger combination item is in a therapeutic group—a combination item that:

(i) has another drug that is in that group; and

(ii) has the same manner of administration as the new brand of the trigger combination item;

is in a class of pharmaceutical items to which a 12.5%, 16% or 25% administrative price reduction has applied; or

(d) on the day before the determination day:

(i) the approved ex-manufacturer price of a listed brand of the existing item on 1 January 2016; or

(ii) if subparagraph (i) does not apply—the original approved ex-manufacturer price of the first listed brand of the existing item;

has, by virtue of previous price reductions, been reduced by 60% or more.

(1B) If the approved ex-manufacturer price mentioned in subparagraph (1A)(d)(i) or (ii) is by reference to a different pricing quantity than the pricing quantity on the day before the determination day, the approved ex-manufacturer price mentioned in that subparagraph is taken to be the amount that the approved ex-manufacturer price would have been had the pricing quantity been the same as the pricing quantity on the day before the determination day.

(2) This section does not apply in relation to the new brand of the trigger combination item if a listed provision (see subsection (2A)) has applied in relation to:

(a) the new brand, or another listed brand, of the trigger combination item; or

(b) a brand of another combination item that:

(i) has a drug that contains the same component drugs as the new brand of the trigger combination item; and

(ii) has the same manner of administration as the new brand of the trigger combination item; or

(c) if the drug in the trigger combination item is in a therapeutic group—a combination item that:

(i) has another drug that is in that group; and

(ii) has the same manner of administration as the new brand of the trigger combination item.

Note: For the purposes of this subsection, subsections (5) and (5A) of this section are taken not to have applied in relation to a brand of a pharmaceutical item in some cases: see section 99AEI and subsection (7B) of this section.

(2A) For the purposes of subsection (2), ***listed provision*** means:

(a) subsection (5) or (5A); or

(b) a determination under paragraph (7A)(b); or

(c) subsection 99ACF(1) or (2) because of item 4A, 4B or 8 in the table in subsection 99ACF(1); or

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(d) section 99ACQ; or
(e) subsection 99ACR(3) or (4); or
(f) repealed section 99ACE.

(3) This section does not apply in relation to the new brand of the trigger combination item if:
(a) all of the following apply:
(i) the new brand of the trigger combination item is a new presentation of an existing listed brand of a pharmaceutical item;
(ii) a declaration under subsection 85(2) is in force in relation to the drug in the pharmaceutical item;
(iii) the determination day in relation to the new brand of the trigger combination item is on or before the fifth anniversary of the declaration under subsection 85(2) being made;
(iv) the Responsible Person for the new brand of the trigger combination item is the same as the Responsible Person for the existing listed brand of the pharmaceutical item;
(v) the drug is not on F2; or
(b) all of the following apply:
(i) the new brand of the trigger combination item is a new presentation of an existing listed brand of a pharmaceutical item;
(ii) the Minister has made a determination under section 99ACEA in relation to the new brand of the trigger combination item;
(iii) the determination under section 99ACEA has not ceased to have effect.

First new brand price reduction

(4) The Minister:
(a) may, under a price agreement, agree an agreed price for the new brand of the trigger combination item that comes into force on the determination day; and
(b) must not make a determination under section 85B for the new brand of the trigger combination item.

(4A) If, on the day before the determination day:
(a) the approved ex-manufacturer price of a listed brand of the existing item on 1 January 2016; or
(b) if paragraph (a) does not apply—the original approved ex-manufacturer price of the first listed brand of the existing item;

has, by virtue of previous price reductions, been reduced by:
(c) 35% or less, subsection (5) applies; and
(d) more than 35% but less than 60%, subsection (5A) applies.

Note: If previous price reductions have been 60% or more, see paragraph (1A)(d).

(4B) If the approved ex-manufacturer price mentioned in paragraph (4A)(a) or (b) is by reference to a different pricing quantity than the pricing quantity on the day before the determination day, the approved ex-manufacturer price mentioned in that paragraph is taken to be the amount that the approved ex-manufacturer price would have been had the pricing quantity been the same as the pricing quantity on the day before the determination day.

(5) Subject to subsections (7) and (7A), the agreed price of the new brand of the trigger combination item that comes into force on the determination day must not exceed the

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approved ex-manufacturer price, on the day before the determination day, of the existing brand of the existing item, reduced by 25%.

(5A) Subject to subsections (7) and (7A), the agreed price of the new brand of the trigger combination item that comes into force on the determination day must not exceed:

(a) 40% of the approved ex-manufacturer price of a listed brand of the existing item on 1 January 2016; or

(b) if paragraph (a) does not apply—40% of the original approved ex-manufacturer price of the first listed brand of the existing item.

(5B) If the approved ex-manufacturer price mentioned in paragraph (5A)(a) or (b) is by reference to a different pricing quantity than the pricing quantity on the day before the determination day, the approved ex-manufacturer price mentioned in that paragraph is taken to be the amount that the approved ex-manufacturer price would have been had the pricing quantity been the same as the pricing quantity on the day before the determination day.

Apportioning if pricing quantity changes

(7) If the pricing quantity of the existing brand of the existing item on the day before the determination day is different from the pricing quantity of the existing brand of the existing item on the determination day, then, for the purposes of subsections (5) and (5A), the approved ex-manufacturer price of the existing brand of the existing item on the day before the determination day is taken to be the amount worked out as follows:

$$\frac{\text{AEMP1}}{\text{PQ1}} \times \text{PQ2}$$

where:

AEMP1 means the amount that was the approved ex-manufacturer price of the existing brand of the existing item on the day before the determination day.

PQ1 means the pricing quantity of the existing brand of the existing item on the day before the determination day.

PQ2 means the pricing quantity of the existing brand of the existing item on the determination day.

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Ministerial discretion not to apply, or to reduce, statutory price reduction

(7A) The Minister may, by notifiable instrument, determine that:

(a) the agreed price of the new brand of the trigger combination item that comes into force on the determination day is to be equal to the approved ex-manufacturer price, on the day before the determination day, of the existing brand of the existing item; or

(b) the agreed price of the new brand of the trigger combination item that comes into force on the determination day must not exceed the approved ex-manufacturer price, on the day before the determination day, of the existing brand of the existing item, reduced by a lower percentage than would otherwise result from the operation of subsection (5) or (5A) in relation to the determination day.

(7B) If the Minister makes a determination under paragraph (7A)(a), subsections (5) and (5A) are taken not to have applied to the trigger combination item.

(7C) In making a determination under subsection (7A) :

(a) the Minister must take into account what the agreed price of the new brand of the trigger combination item would otherwise be under this section in relation to the particular determination day if a determination were not made; and

(b) the Minister may take into account any other matter that the Minister considers relevant.

Section does not limit Minister's powers

(8) This section does not limit the Minister's powers, after the determination day, to make:

(a) further price agreements; or

(b) determinations under section 85B;

for the new brand of the trigger combination item.

99ACR Flow-on of first new brand price reductions to related brands

(1) This section applies to a brand (the ***related brand***) of a pharmaceutical item (a ***related item***) mentioned in subsection (2) if:

(a) subsection 99ACB(5) or (5A) or 99ACD(5) or (5A) has applied to the agreed price for a brand (the ***new brand***) of a pharmaceutical item (the ***new item***); and

(b) that price comes into force on a day (the ***reduction day***); and

(c) on the day before the reduction day, the related brand of the related item was a listed brand of the related item; and

(d) the related item is not an exempt item.

Note: See also section 99ACG.

(2) For the purposes of this section, a related brand of a related item is any of the following:

(a) a listed brand of another pharmaceutical item that has the same drug and manner of administration as the new item;

(b) if the drug in the new item is in a therapeutic group—a listed brand of a pharmaceutical item that:

(i) has another drug that is in that group; and

(ii) has the same manner of administration as the new brand of the new item.

(3) Subject to subsections (4) and (6), on the reduction day, the approved ex-manufacturer price, and (if applicable) the claimed price, of the related brand of the related item is taken to be reduced by a percentage equal to the percentage by which the agreed price for the new brand was reduced as a result of the application of the subsection mentioned in paragraph (1)(a).

(4) Subsection (3) does not apply to the related brand of the related item if:

(a) on the reduction day, the approved ex-manufacturer price of the related brand of the related item does not exceed the approved ex-manufacturer price of the related brand of the related item in force on the day before the reduction day, reduced by more than the percentage required under subsection (3); and

(b) if there is an applicable claimed price of the related brand of the related item—on the reduction day, the claimed price of the related brand of the related item does not exceed the claimed price of the related brand of the related item in force on the day before the reduction day, reduced by more than the percentage required under subsection (3).

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Apportioning if pricing quantity changes

(5) If the pricing quantity of the related brand of the related item on the day before the reduction day is different from the pricing quantity of the related brand of the related item on the reduction day, then, for the purposes of subsection (3) and paragraph (4)(a), the approved ex-manufacturer price of the related brand of the related item on the day before the reduction day is taken to be the amount worked out using the following formula:

$$\frac{\text{AEMP1}}{\text{PQ1}} \times \text{PQ2}$$

where:

AEMP1 means the amount that was the approved ex-manufacturer price of the related brand of the related item on the day before the reduction day.

PQ1 means the pricing quantity of the related brand of the related item on the day before the reduction day.

PQ2 means the pricing quantity of the related brand of the related item on the reduction day.

Ministerial discretion not to apply, or to reduce, flow-on price reduction

(6) In relation to the related brand of the related item, the Minister may, by notifiable instrument, determine that:

(a) the approved ex-manufacturer price, and (if applicable) the claimed price, is not to be reduced under subsection (3) in relation to a particular reduction day; or

(b) the approved ex-manufacturer price, and (if applicable) the claimed price, is to be reduced by a lower percentage than would otherwise apply under subsection (3) in relation to a particular reduction day.

(7) If the Minister makes a determination under paragraph (6)(a), subsection (3) is taken not to have applied to the related brand of the related item.

(8) In making a determination under subsection (6):

(a) the Minister must take into account what the approved ex-manufacturer price, and (if applicable) the claimed price, of the related brand of the related item would otherwise be under this section in relation to the particular reduction day if a determination were not made; and

(b) the Minister may take into account any other matter the Minister thinks is relevant.

Section does not limit Minister's powers

(9) This section does not limit the Minister's powers, on or after the reduction day, to make:

(a) further price agreements; or

(b) determinations under section 85B;

for the related brand of the related item.

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3. Catch-up price reductions

99ACN Catch-up price reduction for certain drugs—15th anniversary

(1) This section applies to a brand of a pharmaceutical item on the catch-up price reduction day if:

(a) the 15th anniversary of the drug in the pharmaceutical item being a listed drug was on or before 1 April 2022; and

(b) the pharmaceutical item is not an exempt item; and

(c) on the catch-up price reduction day, the percentage worked out using the formula in subsection (2) is greater than zero.

Note: See also section 99ACG.

(2) The formula mentioned in paragraph (1)(c) is:

$$100\% - \frac{63.18\%}{\text{Product of differential percentages}}$$

where:

product of differential percentages means:

(a) if there has been only one previous price reduction under this Division—the differential percentage for that price reduction; or

(b) if there have been 2 or more previous price reductions under this Division—the product of the differential percentages for those previous price reductions; or

(c) if there have not been any previous price reductions under this Division—100%.

Note 1: The effect of the formula is that, following the application of the price reduction which applies as a result of this section and item 8 of the table in section 99ACF(1), the cumulative impact of price reductions under this Division, applied successively, will be 36.82%. For example, if the brand of the pharmaceutical item has been subject to a 5% previous price reduction under this Division followed by a 16% previous price reduction under this Division, the product of the differential percentages will be (100% - 5%) x (100% - 16%) = 79.80%, and the percentage worked out using the formula will be 100% - 63.18%/79.80% = 20.83%.

Note 2: For rounding of the percentage worked out using the formula, see subsection (5).

(3) For the purposes of this section, ***previous price reduction under this Division*** has the meaning given by section 99ACNA.

(4) For the purposes of this section, the ***differential percentage*** for a previous price reduction under this Division means the difference between 100% and the previous price reduction under this Division.

(5) The percentage worked out using the formula in subsection (2) is to be calculated to 2 decimal places (rounding up if the third decimal place is 5 or more).

(6) In this section, the ***catch-up price reduction day*** is 1 April 2023.

99ACNA Catch-up price reduction for certain drugs—meaning of *previous price reduction under this Division*

(1) For the purposes of the application of section 99ACN to a brand (the ***relevant brand***) of a pharmaceutical item, ***previous price reduction under this Division*** means:

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(a) a reduction, on or before the catch-up price reduction day, in the approved ex-manufacturer price of the relevant brand or another brand of the pharmaceutical item under this Division (expressed as a percentage) (other than a reduction attributable to section 99ACN); or

(b) in the case of a reduction, on or before the catch-up price reduction day, in the approved ex-manufacturer price of the relevant brand or another brand of the pharmaceutical item under subsection 99ACF (2)—the reduction in the approved ex-manufacturer price of the relevant brand or the other brand of the pharmaceutical item (expressed as a percentage) that would have occurred under subsection 99ACF (1) if paragraph (b) of that subsection were disregarded; or

(c) in the case of a reduction, on or before the catch-up price reduction day, in the approved ex-manufacturer price of the relevant brand or another brand of the pharmaceutical item under subsection 99ACR (4)—the reduction in the approved ex-manufacturer price of the relevant brand or the other brand of the pharmaceutical item (expressed as a percentage) that would have occurred under subsection 99ACR (3) if subsection 99ACR(4) did not apply; or

(d) a 12.5% administrative price reduction that applied, on or before the catch-up price reduction day, to the relevant brand or another brand of the pharmaceutical item.

(2) For the purposes of this section:

(a) a reduction in the agreed price of a brand of the pharmaceutical item is taken to be a reduction in the approved ex-manufacturer price of the brand of the pharmaceutical item; and

(b) a reduction in the determined price of a brand of the pharmaceutical item is taken to be a reduction in the approved ex-manufacturer price of the brand of the pharmaceutical item; and

(c) a reduction before 1 October 2012 in the approved price to pharmacists (within the meaning of this Part as it stood before 1 October 2012) of a brand of the pharmaceutical item is taken to be a reduction in the approved ex-manufacturer price of the brand of the pharmaceutical item.

(3) A reference in this section to the approved ex-manufacturer price of a brand of a pharmaceutical item being reduced under subsection 99ACR (4) is to be read as a reference to that subsection applying to the brand of the pharmaceutical item.

(4) A reference in this section to this Division includes this Division as in force at any time before the commencement of this section.

(5) In this section, the ***catch-up price reduction day*** is 1 April 2023.

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4. Combination flow-on price reductions

99ACC Price reductions for single brands of combination items

When section applies

(1) This section applies if:

(a) subsection 85AB(5) applies to the drug in a combination item; and

(b) there is only one listed brand (the ***single brand***) of the combination item; and

(c) there is an approved ex-manufacturer price for the single brand of the combination item; and

(d) any of the following apply:

(i) if the drug in the combination item contains only one listed component drug—that listed component drug becomes subject to a statutory price reduction on a day (the ***reduction day***); or

(ii) if the drug in the combination item contains 2 or more listed component drugs—one of the listed component drugs becomes subject to a statutory price reduction on a day (the ***reduction day***); or

(iii) if the drug in the combination item contains 2 or more listed component drugs—2 or more of the listed component drugs become subject to a statutory price reduction on the same day (the ***reduction day***); and

(e) on the reduction day, or on the day before that day, no listed brand of another combination item that has a drug that contains the same component drugs as the combination item:

(i) is bioequivalent or biosimilar to the single brand of the combination item; and

(ii) has the same manner of administration as the single brand of the combination item.

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Price reduction

(2) Subject to subsections (5A), (5C) and (5E), on the reduction day, the approved ex-manufacturer price of the single brand of the combination item is taken to be reduced in accordance with a method prescribed by the regulations.

(3) Different methods may be prescribed by the regulations for different classes of combination items.

(4) Subsection (3) does not limit subsection 33(3A) of the *Acts Interpretation Act 1901*.

(5) Subject to subsections (5A) and (5C), if the approved ex-manufacturer price of the single brand of the combination item is reduced under subsection (2), then, on the reduction day, the claimed price (if any) of the single brand of the combination item is taken to be reduced by a percentage equal to the percentage by which the approved ex-manufacturer price of the single brand of the combination item is reduced under subsection (2).

Reduction cap

(5A) If:

(a) the approved ex-manufacturer price of the single brand of the combination item is to be reduced under subsection (2); and

(b) apart from this subsection, the reduced approved ex-manufacturer price would be less than the amount (the ***capped price***) equal to:

(i) 40% of the approved ex-manufacturer price of a listed brand of the combination item on 1 January 2016; or

(ii) if subparagraph (i) does not apply—40% of the original approved ex-manufacturer price of the first listed brand of the combination item;

the approved ex-manufacturer price of the single brand of the combination item is taken to be reduced under subsection (2) to an amount equal to the capped price.

(5B) If the approved ex-manufacturer price mentioned in subparagraph (5A)(b)(i) or (ii) is by reference to a different pricing quantity than the pricing quantity on the reduction day, the approved ex-manufacturer price mentioned in that subparagraph is taken to be the amount that the approved ex-manufacturer price would have been had the pricing quantity been the same as the pricing quantity on the reduction day.

Ministerial discretion not to apply, or to reduce, statutory price reduction

(5C) In relation to the single brand of the combination item, the Minister may, by notifiable instrument, determine that:

(a) the approved ex-manufacturer price, and (if applicable) the claimed price, is not to be reduced under subsection (2) or (5), as the case requires, in relation to a particular reduction day; or

(b) the approved ex-manufacturer price, and (if applicable) the claimed price, is to be reduced by a lower percentage than would otherwise apply under subsection (2) or (5), as the case requires, in relation to a particular reduction day.

(5D) In making a determination under subsection (5C):

(a) the Minister must take into account what the approved ex-manufacturer price, and (if applicable) the claimed price, of the single brand of the combination item would otherwise be under this section in relation to the particular reduction day if a determination were not made; and

(b) the Minister may take into account:

(i) any advice given to the Minister under subsection 101(4AC) in relation to the combination item; and

(ii) any other matter the Minister thinks is relevant.

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(5E) If the Minister makes a determination under subsection (5C), the approved ex-manufacturer price of the single brand of the combination item is not to be further reduced under this section on any reduction day that occurs after the reduction day specified in the determination made under subsection (5C).

Section does not limit Minister's powers

(5F) This section does not limit the Minister's powers, on or after the reduction day, to make:

(a) further price agreements; or

(b) determinations under section 85B;

for the single brand of the combination item.

Subject to statutory price reduction etc.

(6) The following provisions have effect:

(a) a listed component drug contained in a drug in a combination item becomes ***subject to statutory price reduction*** if section 99ACB or 99ACQ or subsection 99ACR(3)

or (4) or section 99ADH, has applied to a listed brand of a pharmaceutical item that:

(i) has the listed component drug; and

(ii) has the same manner of administration as the combination item;

(b) whichever provision mentioned in paragraph (a) applied, that provision applies to the listed component drug contained in the drug in the combination item in the same way as that provision applies to the listed brand of the pharmaceutical item that:

(i) has the listed component drug; and

(ii) has the same manner of administration as the combination item;

(c) a listed component drug contained in a drug in a combination item becomes ***subject to statutory price reduction*** if subsection 99ACF(1) or (2) because of an item in the table in section 99ACF has applied to a listed brand of a pharmaceutical item that has the listed component drug;

(d) whichever provision mentioned in paragraph (c) applied, that provision applies to the listed component drug contained in the drug in the combination item in the same way as that provision applies to the listed brand of the pharmaceutical item that has the listed component drug.

*Modified meaning of the **same manner of administration***

(7) For the purposes of subsection (6), a combination item whose drug contains a listed component drug has the same manner of administration as another pharmaceutical item that has (or whose drug contains) the listed component drug if the manner of administration set out in a determination under subsection 85(5) for the combination item, to the extent that the manner of administration relates to the listed component drug:

(a) if the other pharmaceutical item is not a combination item—is the same as the manner of administration set out in a determination under subsection 85(5) for the other pharmaceutical item; or

(b) if the other pharmaceutical item is another combination item—is the same as the manner of administration set out in a determination under subsection 85(5) for the other combination item, to the extent that the manner of administration relates to the listed component drug.

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99ADHB Flow on price reductions for brands of combination items

When section applies

(1) This section applies if:

(a) there is an approved ex-manufacturer price (the ***existing price***) in force for a brand (the ***existing brand***) of a combination item; and

(b) the combination item is not an exempt item; and

(c) the combination item has a drug on F2; and

(d) a brand of a pharmaceutical item (the ***non-combination item***) that is not a combination item has a drug (the ***common drug***) that is in the combination item; and

(e) the combination item has the same manner of administration as the non-combination item; and

(f) on a day (the ***reduction day***) after the day the existing price came into force for the existing brand of the combination item, section 99ADH applied to the brand of the non-combination item.

Note: The meaning of ***the same manner of administration*** is modified for the purposes of this section by subsection (7).

Price reduction

(2) Subject to subsections (6) and (6B), on the reduction day, the approved ex-manufacturer price of the existing brand of the combination item is taken to be reduced in accordance with a method prescribed by the regulations.

(3) Different methods may be prescribed by the regulations for different classes of combination items.

(4) Subsection (3) does not limit subsection 33(3A) of the *Acts Interpretation Act 1901*.

(5) Subject to subsection (6), if the approved ex-manufacturer price of the existing brand of the combination item is reduced under subsection (2), then, on the reduction day, the claimed price (if any) of the existing brand of the combination item is taken to be reduced by a percentage equal to the percentage by which the approved ex-manufacturer price of the existing brand of the combination item is reduced under subsection (2).

Ministerial discretion not to apply, or to reduce, statutory price reduction

(6) In relation to the existing brand of the combination item, the Minister may, by notifiable instrument, determine that:

(a) the approved ex-manufacturer price, and (if applicable) the claimed price, is not to be reduced under subsection (2) or (5), as the case requires, in relation to a particular reduction day; or

(b) the approved ex-manufacturer price, and (if applicable) the claimed price, is to be reduced by a lower percentage than would otherwise apply under subsection (2) or (5), as the case requires, in relation to a particular reduction day.

(6A) In making a determination under subsection (6):

(a) the Minister must take into account what the approved ex-manufacturer price, and (if applicable) the claimed price, of the existing brand of the combination item would otherwise be under this section in relation to the particular reduction day if a determination were not made; and

(b) the Minister may take into account:

(i) any advice given to the Minister under subsection 101(4AC) in relation to the combination item; and

(ii) any other matter the Minister thinks is relevant.

(6B) If the Minister makes a determination under subsection (6), the approved ex-manufacturer price of the existing brand of the combination item is not to be further reduced under this section on any reduction day that occurs after the reduction day specified in the determination made under subsection (6).

Section does not limit Minister's powers

(6C) This section does not limit the Minister's powers, on or after the reduction day, to make:

(a) further price agreements; or

(b) determinations under section 85B;

for the existing brand of the combination item.

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*Modified meaning of the **same manner of administration***

(7) For the purposes of this section, the existing brand of the combination item has the same manner of administration as a pharmaceutical item that is not a combination item (the ***non-combination item***) if the manner of administration set out in a determination under subsection 85(5) for the combination item, to the extent that the manner of administration relates to the common drug, is the same as the manner of administration set out in a determination under subsection 85(5) for the non-combination item.

Section does not limit Minister's powers

(13) This section does not limit the Minister's powers, after the reduction day, to make further price agreements or determinations under section 85B in relation to the existing brand of the combination item.

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5. New presentation (5 – 10 years)

99ACBA Ministerial determination—brand of pharmaceutical item that is not a combination item is not a new brand

(1) If:

(a) a brand of a pharmaceutical item (the ***trigger item***) is not a combination item; and

(b) the brand of the trigger item:

(i) is not a listed brand of the trigger item; and

(ii) is a new presentation of an existing listed brand of a pharmaceutical item; and

(c) the Minister is satisfied that the determination day in relation to the brand of the trigger item is to be after the fifth anniversary, and before the tenth anniversary, of the drug in the pharmaceutical item being on F1;

the Minister may determine, by notifiable instrument, that the brand of the trigger item is not a new brand for the purposes of section 99ACB.

(2) If the Minister makes a determination under this section in relation to the brand of the trigger item, it must be made before the determination day in relation to the brand of the trigger item.

(3) In making a determination, the Minister may have regard to:

(a) any advice given by the Pharmaceutical Benefits Advisory Committee; and

(b) any information provided by the Responsible Person for the brand of the trigger item; and

(c) any other matter that the Minister considers relevant.

(4) A determination made under this section ceases to have effect on whichever is the earliest of the following:

(a) the day that another brand of the pharmaceutical item becomes a listed brand;

(b) the day that the drug in the pharmaceutical item does not satisfy all of the criteria for F1;

(c) the tenth anniversary of the drug in the pharmaceutical item being on F1.

(5) In this section:

determination day has the same meaning as in paragraph 99ACB(1)(a).

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99ACEA Ministerial determination—brand of pharmaceutical item that is a combination item is not a new brand

(1) If:

(a) a brand of a pharmaceutical item (the ***trigger combination item***) is a combination item; and

(b) the brand of the trigger combination item is a new presentation of an existing listed brand of a pharmaceutical item; and

(c) a declaration under subsection 85(2) is in force in relation to the drug in the pharmaceutical item; and

(d) the Minister is satisfied that the determination day in relation to the brand of the trigger combination item is after the fifth anniversary, and before the tenth anniversary, of the declaration under subsection 85(2) being made;

the Minister may determine, by notifiable instrument, that the brand of the trigger combination item is not a new brand for the purposes of section 99ACD.

(2) If the Minister makes a determination under this section in relation to the brand of the trigger combination item, it must be made before the determination day in relation to the brand of the trigger combination item.

(3) In making a determination, the Minister may have regard to:

(a) any advice given by the Pharmaceutical Benefits Advisory Committee; and

(b) any information provided by the Responsible Person for the brand of the trigger combination item; and

(c) any other matter that the Minister considers relevant.

(4) A determination made under this section ceases to have effect on whichever is the earliest of the following:

(a) the tenth anniversary of the declaration under subsection 85(2) being made;

(b) the day that the drug is on F2.

(5) In this section:

determination day has the same meaning as in paragraph 99ACD(1)(a).

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APPENDIX 3: Excerpts from the Strategic Agreement with Medicines Australia

9. Statutory Price Reductions

9.1 Outline

9.1.1 As at the date of this Agreement, Division 3A of Part VII of the Act provides for Statutory Price Reductions.

9.1.2 The parties agree that the Commonwealth will seek amendments to the Act[13] to commence from 1 July 2022 to:

(a) continue or modify (or both) Statutory Price Reductions on the basis set out in clauses 9.2, 9.3 and 9.4.1;

(b) reflect the arrangements set out in clauses 9.5 and 9.6; and

(c) make consequential changes to Divisions 3A and 3B of Part VII of the Act to implement the modified Statutory Price Reductions and other arrangements described in this clause 9.

9.2 Amendments to Statutory Price Reductions

9.2.1 The percentage reductions for the Statutory Price Reductions in Table 2 that applied prior to this Agreement will be modified as per the new percentage under this Agreement set out in Table 2 and will apply on the corresponding reduction days specified in Table 2 during the Term.

9.2.2 The Statutory Price Reduction mechanisms described in this clause will apply until the end of the Term.

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Table 2: Amendments to SPRs

Section	Description	Percentage prior to this Agreement[14]	New percentage under this Agreement	Reduction day(s)
99ACHA	One off price reduction on 5th anniversary of the drug being a Listed Drug	5%	5%	1 April 2023 1 April 2024 1 April 2025 1 April 2026 1 April 2027
99ACJ	One off price reduction on 10th anniversary of drug being a Listed Drug	10%	5%	1 April 2023 1 April 2024 1 April 2025 1 April 2026 1 April 2027

[13] If necessary, amendments may also be sought to the *National Health Amendment (Pharmaceutical Benefits—Budget and Other Measures) Act 2018* (Cth).

[14] Nothing in this Agreement modifies any Statutory Price Reduction already provided for in the Act, unless and until the Act is amended to do so.

Section	Description	Percentage prior to this Agreement[14]	New percentage under this Agreement	Reduction day(s)
99ACK	One off price reduction on 15th anniverary of drug being a Listed Drug (if before any first new brand price reduction)	5%	26.1%	1 April 2023 1 April 2024 1 April 2025 1 April 2026
			30%	1 April 2027
99ACB 99ACD 99ACE 99ACF 99ACH	First new brand price reduction (if before 15th anniversary of drug being a Listed Drug)	25% up to a maximum of 40% off the earliest of 1 January 2016 or date of listing AEMP until 30 June 2022. 16% thereafter	25% up to a maximum of 60% off the earliest of 1 January 2016 or date of listing AEMP[15],	The listing of the first new brand

9.3 Catch-up reductions

9.3.1 On 1 April 2023, a catch-up reduction of 5% will apply to Listed Brands that have a Listed Drug that has had its 10th anniversary of listing on the PBS between 1 May 2021 and 1 April 2022.

9.3.2 On 1 April 2023, a catch-up reduction will apply to all Listed Brands that have a Listed Drug that has been listed for 15 years or more, and have not taken a Price Disclosure reduction (under Division 3B of the Act), such that the sum of Statutory Price Reductions (including catch-ups) the Listed Brand has been subject to after these catch-up reductions, applied successively, will total 36.82%.[16] Examples of the catch-up percentages are set out in the Table at Appendix 1.

9.3.3 Listed Brands with a Listed Drug that move to the F2 formulary after 1 August 2022, and prior to the 15th anniversary of that Listed Drug being listed, will be subject to a 1.48% reduction on the 15th anniversary of that Listed Drug being listed if no Price Disclosure reduction has applied.

9.4 Cap on Statutory Price Reductions

9.4.1 Without limiting clauses 9.4.2 or 9.5.2 or the Minister's discretion under the Act, the Commonwealth will seek to amend the Act to provide that Statutory Price Reductions will not take Approved Ex-Manufacturer Price(s) for Listed Brands of Pharmaceutical Items below 40% of their Approved Ex-Manufacturer Price(s) on 1 January 2016 or later date of listing on the PBS.

[15] This will not limit application of the Commonwealth policy whereby the Commonwealth will seek a price from the responsible person for the first new brand that is not more than the Effective Price of the originator brand on 1 January 2016 or later date of listing reduced by 25%, subject to the 60% cap on Statutory Price Reductions specified in clause 9.4.

[16] For clarity, where a Listed Brand has already had a price reduction exceeding 36.82%, the price of such Listed Brands will not be increased under these catch-ups.

9.4.2 Without limiting clause 9.5.2 or the Minister's discretion under the Act, the Commonwealth will continue its existing policy[17] for agreeing prices of the First New Brand where the originator brand of a Pharmaceutical Item (**Existing Brand**) has or had an Effective Price, subject to the new 60% cap. To list a First New Brand in this circumstance:

(a) the Responsible Person for the First New Brand will be expected to offer an Approved Ex-Manufacturer Price for the First New Brand that is not more than a price that is 25% lower than the Effective Price for the Existing Brand;

(b) where the Approved Ex-Manufacturer Price of the First New Brand that is 25% lower than the Effective Price of the Existing Brand would be below 40% of the Effective Price of the Existing Brand on 1 January 2016 or later date of listing on the PBS, the Responsible Person for the First New Brand will be expected to offer an Approved Ex-Manufacturer Price for the First New Brand that is not more than 40% of the Effective Price of the Existing Brand on 1 January 2016 or later date of listing on the PBS; or

(c) where the Effective Price of the Existing Brand is already below 40% of the Effective Price on 1 January 2016 or later date of listing on the PBS, the Responsible Person for the First New Brand will be expected to offer an Approved Ex-Manufacturer Price that is equal to the current Effective Price of the Existing Brand.

9.4.3 By no later than July 2022 the Commonwealth will publish on the pbs.gov.au website a detailed statement of its First New Brand price reduction policy as updated as a result of this Agreement.[18]

9.5 Price reduction mechanism

9.5.1 The Commonwealth will seek to amend the Act to provide that all price reductions under Division 3A and Division 3B of the Act occur through a legislated mechanism without the need for the Minister and Responsible Person for the Listed Brand to enter into a new price agreement under section 85AD of the Act.

9.5.2 The Commonwealth will seek to amend the Act so that where a Listed Brand of a Pharmaceutical Item (**Existing Brand**) has an Effective Price, and the First New Brand of the Pharmaceutical Item that is bioequivalent or biosimilar to the Existing Brand (**New Brand**) is listed, the Approved Ex-Manufacturer Price of the Existing Brand will automatically adjust to be equal to the Approved Ex-Manufacturer Price of the New Brand without the need for the Minister and

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[17] As at the date of this Agreement, it is Commonwealth policy that the Responsible Person for the First New Brand agree an Approved Ex-Manufacturer Price that is not more than the Effective Price of the existing brand reduced by 25%. As at the date of this Agreement, if the Effective Price reduced by 25% would be lower than 60% of the Effective Price of the Existing Brand on 1 January 2016 or later date of listing on the PBS, the Responsible Person for the First New Brand is expected to agree an AEMP not more than 60% of the effective price on 1 January 2016 or later date of listing on the PBS. Under this policy, if the Effective Price is already lower than 60% of the Effective Price of the Existing Brand on 1 January 2016 or later date of listing on the PBS, the Responsible Person for the First New Brand is expected to agree an AEMP equal to the Effective Price (i.e. no price reduction required). The responsible person for the First New Brand will be notified of the price expected by the Commonwealth prior to acceptance of a price offer.

[18] The detailed statement will address the matters set out in footnote 17 above, as updated under this Agreement.

Responsible Person for the Existing Brand to enter into a new price agreement under section 85AD of the Act. Listed Brands that have the same drug and manner of administration as the New Brand, but are a different Pharmaceutical Item to the New Brand, will also have their Approved Ex-Manufacturer Price reduced by the same percentage reduction that applied to the Existing Brand upon the listing of the New Brand.

9.5.3 Amendments will be sought to the Act so that where a single ingredient Listed Drug that forms part of one or more Combination Items takes a price reduction under the Act, the Approved Ex-Manufacturer Price for the Combination Items containing that Listed Drug will be adjusted by legislated mechanism without the need for the Minister and Responsible Person for that Combination Item to enter into a new price agreement under section 85AD of the Act. This will be given effect through the formula at Appendix 2.

9.6 Ministerial discretion

9.6.1 During the Term, the Minister will continue to have the existing discretions to reduce or not apply Statutory Price Reductions under Division 3A of Part VII of the Act, and the Act will be amended to provide for Ministerial discretion for the new Statutory Price Reductions described in this clause 9, such that Ministerial discretion will be available for all Statutory Price Reductions in Division 3A of Part VII of the Act during the Term. For clarity, this includes the flow on price reductions referred to in clause 9.5. The procedure for flow on price reductions will ensure that the Responsible Person for a Listed Brand has an opportunity to apply for the exercise of Ministerial discretion before any reduction to the trigger item takes effect.

9.6.2 The Minister will continue to exercise the discretions to reduce or not apply Statutory Price Reductions having regard to the Ministerial Discretion Guidance Material (as updated from time to time in consultation with relevant stakeholders, including Medicines Australia).

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9.7 Clarification in respect of arrangements

9.7.1 Nothing in this Agreement is intended to limit:

(a) the ability of the Commonwealth or the Minister to accept or implement, and flow through, Reference Pricing Policy based price reductions or price reductions as a result of a price offer by Responsible Persons; or

(b) the operation of Departmental processes that enable Responsible Persons to seek increases or decreases in the price of medicines.

9.7.2 Where a Drug is on F1 and has been subject to one or more amendments to its listing (for example, listing of new indications) after becoming a Listed Drug, any anniversary Statutory Price Reductions for Listed Brands that have that Listed Drug will continue to be calculated from the date on which the Listed Drug was first listed on the PBS, although the exercise of Ministerial discretion may be sought in respect of any such Statutory Price Reduction.

APPENDIX 4: Excerpts from the *National Health (Pharmaceutical Benefits) Amendment (2021 Measures No. 1) Regulations 2021* (Cth)

65A Price reductions for single brands of combination items

(1) This section sets out, for the purposes of subsection 99ACC(2) of the Act, the method for calculating the reduced approved ex-manufacturer price of a single brand of a combination item on the reduction day mentioned in that subsection.

(2) The reduced approved ex-manufacturer price of the brand of the combination item is the amount worked out by the following formula:

$$\text{reduction day component AEMPs} \times \frac{\text{day before combination item AEMP}}{\text{day before component AEMPs}}$$

where:

day before combination item AEMP means the approved ex-manufacturer price of the brand of the combination item on the day before the reduction day.

day before component AEMPs means the sum of:

(a) the approved ex-manufacturer prices, on the day before the reduction day, of any one brand of each of the listed component items, adjusted in accordance with subsection (3); and

(b) if the combination item includes one or more component drugs that are not listed component drugs—the non-listed component price.

listed component item, for each listed component drug contained in the combination item, means the pharmaceutical item that has:

(a) the listed component drug; and

(b) the same manner of administration as the combination item as referred to in subsection 99ACC(7) of the Act; and

(c) subject to subsection (4) of this section, the smallest difference in the total quantity or amount of the listed component drug contained in the quantity or number of units in the pricing quantity of any one brand of the pharmaceutical item compared to the total quantity or amount of the listed component drug in the pricing quantity of the brand of the combination item.

non-listed component price means the day before combination item AEMP reduced (but not below zero) by the day before component AEMPs.

reduction day component AEMPs means the sum of:

(a) the approved ex-manufacturer prices, on the reduction day, of any one brand of each of the listed component items, adjusted in accordance with subsection (3); and

(b) if the combination item includes one or more component drugs that are not listed component drugs—the non-listed component price multiplied by the differential reduction percentage.

differential reduction percentage means the difference between 100% and the percentage (or average percentage) by which the approved ex-manufacturer price of any one brand of each listed component item in the combination item has been reduced under a provision mentioned in subsection 99ACC(6) of the Act on the reduction day.

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(3) For the purposes of the definition of ***day before component AEMPs*** in subsection (2), adjust the approved ex-manufacturer price of a brand of a listed component item so that the value attributed to the listed component drug in the combination item reflects:

(a) any difference in quantity or amount; and

(b) any difference in pricing quantity;

of the listed component drug in the listed component item.

(4) For the purposes of paragraph (c) of the definition of ***listed component item*** in subsection (2), if there is more than one pharmaceutical item that has the smallest difference as referred to in that paragraph, the pharmaceutical item that results in the largest reduction under this section to the approved ex-manufacturer price of the brand of the combination item is taken to be the listed component item for the purposes of this section.

85A Flow on price reductions for brands of combination items

(1) This section sets out, for the purposes of subsection 99ADHB(2) of the Act, the method for calculating the reduced approved ex-manufacturer price of an existing brand of a combination item on the reduction day mentioned in that subsection.

(2) The reduced approved ex-manufacturer price of the brand of the combination item is the amount worked out by the following formula:

$$\text{reduction day component AEMPs} \times \frac{\text{day before combination item AEMP}}{\text{day before component AEMPs}}$$

where:

component drug, in relation to a drug in a combination item, means a drug or medicinal preparation that is contained in that drug.

day before combination item AEMP means the approved ex-manufacturer price of the brand of the combination item on the day before the reduction day.

day before component AEMPs means the sum of:

(a) the approved ex-manufacturer prices, on the day before the reduction day, of any one brand of each of the listed component items, adjusted in accordance with subsection (3); and

(b) if the combination item includes one or more component drugs that are not listed component drugs—the non-listed component price.

listed component drug means a component drug in relation to which a declaration under subsection 85(2) is in force.

listed component item, for each listed component drug that is in the combination item and in a non-combination item as mentioned in paragraph 99ADHB(1)(d) of the Act, means the pharmaceutical item that has:

(a) the same listed component drug as the non-combination item; and

(b) the same manner of administration as the combination item as referred to in subsection 99ADHB(7) of the Act; and

(c) subject to subsection (4) of this section, the smallest difference in the total quantity or amount of the listed component drug contained in the quantity or number of units in the pricing quantity of any one brand of the pharmaceutical item compared

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to the total quantity or amount of the listed component drug in the pricing quantity of the brand of the combination item.

non-listed component price means the day before combination item AEMP reduced (but not below zero) by the day before component AEMPs.

reduction day component AEMPs means the sum of:

(a) the approved ex-manufacturer prices, on the reduction day, of any one brand of each of the listed component items, adjusted in accordance with subsection (3); and

(b) if the combination item includes one or more component drugs that are not listed component drugs—the non-listed component price multiplied by the differential reduction percentage.

differential reduction percentage means the difference between 100% and the percentage (or average percentage) by which the approved ex-manufacturer price of any one brand of each listed component item in the combination item has been reduced under a provision in Division 3A of Part VII of the Act on the reduction day.

(3) For the purposes of the definition of ***day before component AEMPs*** in subsection (2), adjust the approved ex-manufacturer price of a brand of a listed component item so that the value attributed to the listed component drug in the combination item reflects:

(a) any difference in quantity or amount; and

(b) any difference in pricing quantity;

of the listed component drug in the listed component item.

(4) For the purposes of paragraph (c) of the definition of ***listed component item*** in subsection (2), if there is more than one pharmaceutical item that has the smallest difference as referred to in that paragraph, the pharmaceutical item that results in the largest reduction under this section to the approved ex-manufacturer price of any one brand of the combination item is taken to be the listed component item for the purposes of this section.

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PHARMACEUTICAL BENEFITS

PRICING AUTHORITY

POLICIES, PROCEDURES AND METHODS

USED IN THE RECOMMENDATIONS FOR PRICING OF PHARMACEUTICAL PRODUCTS

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April 2009

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PHARMACEUTICAL BENEFITS PRICING AUTHORITY

POLICIES, PROCEDURES AND METHODS

1. ABOUT THE PHARMACEUTICAL BENEFITS PRICING AUTHORITY

The Pharmaceutical Benefits Pricing Authority (PBPA) is an independent non-statutory body established by the Minister for Health and Ageing. It makes recommendations to the Minister on prices for new brands of pharmaceutical items that have been recommended for listing on the Pharmaceutical Benefits Scheme (PBS), and for new vaccines recommended for inclusion on the National Immunisation Program, by the Pharmaceutical Benefits Advisory Committee (PBAC). The PBPA may also recommend revised prices where uses of drugs are extended or changed.

In addition, the PBPA reviews prices of all brands of pharmaceutical items listed on the PBS at least once each year. Items are divided into groups by ATC classification with drugs that are used for the same purpose being reviewed at the same time. Prices are reviewed at the price to pharmacist level (except for Section 100 items which are at ex-manufacturer level and WAMTC reviews which are at dispensed price level).

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The PBPA's objective is to secure a reliable supply of pharmaceutical benefits at the most reasonable cost to Australian taxpayers and consumers, consistent with maintaining a sustainable, viable and responsible pharmaceutical industry in Australia.

For pricing reviews, the PBPA currently meets three times per year, in line with the three meetings per year of the PBAC. PBAC meetings are held in March, July and November, while PBPA meetings are held in April, August and December with the interval between PBAC and PBPA meetings being about 5-6 weeks.

The PBPA is serviced by a secretariat which is part of the Pricing Section of the Pharmaceutical Evaluation Branch of the Department of Health and Ageing (DoHA).

See Attachment A for timings of the PBPA processes and Attachment D for a flow diagram of the PBS listing process.

2. ABOUT THIS DOCUMENT

The purpose of the document is to enhance the transparency of the processes employed by the PBPA in setting price recommendations for brands of pharmaceuticals items listed on the PBS under the provisions in Part VII of the *National Health Act 1953*. The initial impetus for the document came from the Tambling Review of PBS Listing Arrangements (2000) and more recently from a 'Review of Post PBAC Processes' once a positive recommendation is made by the PBAC (2004), and from general comments from pharmaceutical industry representatives.

Consideration by the PBPA is a stage in the PBS listing process following recommendations by the PBAC. The PBAC's 'Guidelines for the Pharmaceutical Industry on Preparation of Submissions to the Pharmaceutical Benefits Advisory Committee' and the PBPA's Annual Report provide further information about the PBS listing process and PBS pricing arrangements.

This document has been updated to include information about new pricing processes, which were introduced in August 2007, as a result of the PBS Reform amendments to Part VII of the Act. New information in this 2009 version of the PBPA Policies, Procedures and Methods Manual includes:

- Updated glossary to reflect new terminology, e.g. Commonwealth price and claimed price;
- Attachments B, C and E have been updated. Attachment B shows important dates for 2009 and Attachment E has the new dispensing fee and pharmacy mark-up amounts in effect from 1 August 2008;
- Attachment F outlines the drug formularies (F1, F2A and F2T) and the statutory price reductions; and
- Attachment G provides examples of the application of the statutory price reductions given different scenarios.

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3. GLOSSARY OF COMMONLY USED TERMS AND ABBREVIATIONS

This glossary is intended to provide a plain English version of the definition of the particular term. If there is any discrepancy between the meaning of the term as defined in the Act or the supporting Regulations, and the explanation provided in this glossary, the meaning in the Act will prevail.

Act	*National Health Act 1953* (the Act)
Agreed price	This is the maximum price for sales of the brand of the pharmaceutical item to approved pharmacists that the Minister has agreed with the responsible person by reference to a quantity or number of units of the pharmaceutical item.
Approved price to pharmacist	The agreed or determined price. This forms the basis of the dispensed price for the listed maximum quantity.
ATC	Anatomical Therapeutic Chemical. An international therapeutic classification for drugs used in the Schedule of Pharmaceutical Benefits.
Authority required	A pharmaceutical benefit, or proposed prescription in relation to a pharmaceutical benefit, that requires the prior approval from Medicare Australia (or the Department of Veterans' Affairs) before prescribing. In some cases the application must be made in writing.
Authority required (streamlined)	An authority required listing whereby prior approval is no longer required by the prescriber. However the prescriber needs to include a four-digit code in the authority prescription form (introduced July 2007).
Benchmark product	The brand of pharmaceutical item at the lowest dispensed price for a pharmaceutical item or for a therapeutic group, which is the base price for other brands/drugs referenced to it.
Bioequivalent brands	Brands of a pharmaceutical item which have been demonstrated to provide similar blood levels to the satisfaction of the TGA.
Brand	The proprietary or trade name under which a responsible person supplies a pharmaceutical item. If there is no trade name, the name of the responsible person.
Brand premium (BP)	Premium charged by a responsible person above the benchmark subsidised price of the bioequivalent brands of pharmaceutical items. A brand premium will be applicable where the approved price is a determined price rather than an agreed price, and is reflected in a special patient contribution payable by the patient.

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BP nominated amount	This is the difference between the claimed price and the determined price, where that difference is in relation to a brand premium.
Brand substitution	Substitution of a bioequivalent brand of the same or a different pharmaceutical item by the pharmacist without reference back to the prescriber where the patient agrees (when not disallowed by the prescriber).
Claimed price	The price claimed by a responsible person, by reference to a quantity or number of units, to be the price for sales of a brand of a pharmaceutical item to approved pharmacists. This comprises the determined price plus the additional amount that the responsible person requires to list the pharmaceutical benefit.
Co-marketed brands	This describes the circumstance where two brands are introduced into the market and PBS listed at the same time (need to be TGA registered within four months of each other, PBS listed at the same time, no other brands of that item and no bioequivalent brands of any other pharmaceutical item). The two brands are treated as a single brand and listed under F1.
Combination drug list	An administrative list which sets out the single-brand combination drugs that are not on formularies.
Commonwealth price	This is the price paid to approved pharmacists by the Commonwealth for the supply of a pharmaceutical benefit which has an agreed price. It is based on the approved price to pharmacist plus additional fees which are paid to pharmacists as determined by the Pharmaceutical Benefits Remuneration Tribunal. These fees include the pharmacy mark-up and the dispensing fees. This term is also defined in the Community Pharmacy Agreement). The Commonwealth price is equal to the Dispensed Price for Maximum Quantity (DPMQ) for brands of pharmaceutical items that have an agreed price. In essence, it is the Benchmark DPMQ.
Community Pharmacy Agreement	An agreement made between the Pharmacy Guild of Australia and the Commonwealth.
Co-payment	This is an amount paid by the patient for supply of a pharmaceutical benefit. There are two levels of co-payments. Concession patients make a smaller contribution to the cost of a pharmaceutical benefit. General patients (those who do not fit the concessional beneficiary criteria set out in the Act) make a greater contribution. Current co-payment amounts can be found in the current version of the Schedule of Pharmaceutical Benefits (www.pbs.gov.au). The level of co-payment made by a patient can also be reduced as a result of reaching the PBS safety net threshold for a particular calendar year.

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Cost-effective	A drug proposed for listing on the PBS is considered acceptably cost-effective by the PBAC if the Committee considers that, for a specified main indication, the incremental benefits of therapy involving the proposed drug over therapy involving its main comparator(s) justify its incremental costs and harms.
Cost minimisation	A type of cost-effectiveness analysis where the PBAC considers that the drug and its main comparator produce similar health benefits, at similar cost. Where appropriate, the PBPA seeks to recommend the lowest price for drugs with similar health benefits.
Determined price	The maximum price for sales of the brand of the pharmaceutical item to approved pharmacists that the Minister has determined (when agreement between the Minister and responsible person could not be reached) for a quantity or number of units of the item as an appropriate basis for subsidy of that brand on the PBS.
Dispensing fee	The fees payable by the Commonwealth to pharmacists for dispensing pharmaceutical benefits. These fees are set by the Pharmaceutical Benefits Remuneration Tribunal and apply to both the Pharmaceutical Benefits Scheme (PBS) and the Repatriation Pharmaceutical Benefits Scheme (RPBS).
Dispensed price	Price of a medicine including wholesaler and pharmacist mark-ups and pharmacist dispensing fees.
Dispensed price for Maximum Quantity (DPMQ)	This is the Commonwealth price or responsible person's Commonwealth Price, depending on whether the brand has an agreed or a determined price respectively.
DoFD	Department of Finance and Deregulation
DoHA	Department of Health and Ageing
DUSC	Drug Utilisation Subcommittee of the PBAC
Effectiveness	The extent to which a therapy produces a benefit in a defined population in uncontrolled or routine circumstances.
ESC	Economic Subcommittee of the PBAC
Ex-manufacturer price	Price direct from the manufacturer to the wholesaler or pharmacist i.e. with no wholesaler's mark-up.
Ex-Manufacturer Price (approved)	This is a calculated price derived by subtracting the wholesale mark-up amount from the approved price to pharmacist.
Flagging	Refers to the '[a]' or '[b]' superscript applied to brands of a pharmaceutical item, and sometimes brands of other related items, to indicate that these brands are bioequivalent and may be interchanged without expected differences in clinical effect.

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Formularies	The two main divisions of drugs listed on the PBS. Formularies were introduced as a result of the PBS Reform amendments to Part VII of the Act which commenced on 1 August 2007. Essentially, drugs in F1 are drugs in pharmaceutical items which have only single brands, and drugs in F2 are drugs which have multiple brands or are in a therapeutic group with drugs that have multiple brands.
F1	Formulary 1 – contains drugs that: • Have only one brand of each form and strength listed on the PBS; and • Are not interchangeable at the patient level with a drug that has multiple brands listed on the PBS (i.e. not part of a therapeutic group that has multiple brands).
F2	Formulary 2 – contains all drugs (excluding single brand combination drugs) that do not meet the criteria for F1 i.e.: • Multi-branded pharmaceutical items; and • Drugs which are in therapeutic groups because that are interchangeable with other drugs that have multiple brands. • For a transitional period, from 1 August 2007 until 31 December 2010, F2 will be divided into two parts: F2T and F2A. On 1 January 2011, F2T and F2A will be merged into a single formulary – F2.
Generic medicine	A non-innovative version of a medicine for which the patent has expired.
Generic name	The accepted pharmaceutical name (not the chemical formula name).
GMiA	Generic Medicines Industry Association, the industry association representing the generics medicines industry.
Guaranteed brand	The brand of a pharmaceutical item which must comply with the Guarantee of Supply requirements under the Act.
Guaranteed period	The period during which the responsible person must comply with the Guarantee of Supply requirements for a particular brand.
HSD	Highly Specialised Drug (for which special supply arrangements are made under section 100 of the *National Health Act 1953*, and where prescribing for supply under the PBS requires hospital involvement).
ICER	Incremental cost-effectiveness ratio. The difference in net cost between the new therapy and its comparator divided by the difference in health benefits between the new therapy and its comparator, commonly expressed as a dollar figure per QALY (quality adjusted life year).
Innovative medicine	A new, usually patented medicine.

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Interchangeable	Refers to brands of a pharmaceutical item with a particular strength (and brands of related pharmaceutical items) where evidence of bioequivalence or therapeutic equivalence (refer to Therapeutic Group) on an individual basis (or justification for not needing such data) has been accepted by the TGA.
Medicare Australia	Medicare Australia (administers, as part of its functions, Medicare and the Pharmaceutical Benefits Scheme).
MA	Medicines Australia, the industry association representing research-based pharmaceutical companies.
NIP	National Immunisation Program, for which vaccines are designated under section 9B of the Act. This program is administered by the Population Health Division, DoHA.
Nominated amount	This is the difference between the claimed price and the determined price. The nominated amount is used in reference to special patient contributions (SPC), and includes amounts for brand premiums, therapeutic group premium and other special patient contributions.
Orphan drug	Medicines for rare diseases, which are registered under special arrangements by the TGA.
PB11	The application form to accompany an application for the listing of a drug as a pharmaceutical benefit.
PB11a	A price alteration acceptance form. This form constitutes written agreement for the purpose of an agreed price.
PB11b	A confidential cost information form.
PBAC	The Pharmaceutical Benefits Advisory Committee.
PBPA	The Pharmaceutical Benefits Pricing Authority.
PBS	The Pharmaceutical Benefits Scheme which is provided under Part VII of the Act.
PBS Listed	Drugs contained in brands of pharmaceutical items are listed on the PBS by declaration made under section 85 of the *National Health Act 1953* (the Act).

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Pharmaceutical benefit	Where there is a brand determination, the pharmaceutical benefit will be the brand of a pharmaceutical item. Pharmaceutical benefit can also mean: • the listed drug (where there is listed drug, but no form, manner of administration or brand determination). • the listed drug in the form determined under the Act (where there is a listed drug and form determination, but no manner of administration or brand determination); the listed drug in the form and with the manner of administration determined under the Act (where there is a listed drug and form and manner of administration determinations, but no brand determination).
Pharmaceutical item	A pharmaceutical item is a particular PBS-listed drug in a particular form with a particular manner of administration. It is covered by a unique PBS code.
Pharmacy mark-up	The pharmacy mark-up is paid to pharmacists for the handling and storage of medicines at the pharmacy. The mark-ups that apply are determined by the Pharmaceutical Benefits Remuneration Tribunal.
PHD	Population Health Division, DoHA.
PILLS	The Publishing, Industry Liaison and Listing Section of the Pharmaceutical Evaluation Branch, Department of Health and Ageing.
Premium	Additional price above that of the benchmark price.
Price disclosure	The responsible person is required to provide sales information to the Department of Health and Ageing on certain products listed on the PBS. Price disclosure may be undertaken under mandatory or voluntary provisions set out in Part VII of the Act. A detailed explanation of price disclosure can be found in the price disclosure "Procedural and Operational Guidelines" as published from time to time.
Price to pharmacist	The price of a medicine supplied to the pharmacist consisting of the price paid to the responsible person and the wholesaler mark-up, but no pharmacist mark-ups or dispensing fees.
Reference pricing groups	Sub-groups of therapeutically related drugs listed on a cost minimisation basis which are considered equivalent for pricing purposes
Regulations	*National Health (Pharmaceutical Benefits) Regulations 1960.*
Relativity	The relationship of one medicine to another such as dosage and effectiveness.

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Responsible person	The person determined by the Minister to be the responsible person for a brand of pharmaceutical item. This is the person who has notified the Minister they are, or will be, the supplier of a particular brand of pharmaceutical item to wholesalers, or in cases where no wholesalers are involved, to approved pharmacists directly. The same person must be the responsible person for all pharmaceutical items that have that brand. The responsible person can be a company.
Responsible person's Commonwealth price	This is the price paid to approved pharmacists for the supply of a brand of a pharmaceutical item which has a claimed price. It is based on the claimed price plus additional fees which are paid to pharmacists as determined by the Pharmaceutical Benefits Remuneration Tribunal. In certain instances, the Government will pay the responsible person's Commonwealth price eg. authority approved exemption from Therapeutic Group Premium or other Special Patient Contribution. The Responsible person's Commonwealth price is equal to the Dispensed Price for Maximum Quantity (DPMQ) for brands of items that have a claimed price.
Restricted benefit	A PBS listing of a medicine that can only be prescribed for specific therapeutic uses as noted in the Schedule of Pharmaceutical Benefits.
Review of post PBAC processes	A collaborative effort between the Department of Health and Ageing and Medicines Australia to explore innovative options to reduce the time taken to list approved drugs on the Pharmaceutical Benefits Scheme so that they are more quickly available to the Australian community.
Section 100 items	Drugs provided under special arrangements where normal supply via community medical practitioners and community pharmacy is considered less than optimum. Pricing is negotiated at ex-manufacturer level.
Special patient contribution (SPC)	The difference in price for a medicine where the responsible person and the Government are unable to agree on price. It is the difference between the Responsible person's Commonwealth (dispensed) price and the Commonwealth (dispensed) price (based on the approved price to pharmacist).
Special Supply Arrangements	An arrangement for the supply of medicines (usually under Section 100) where the usual PBS supply arrangements are unsuitable.
Other SPC premium	This is the portion of the difference between the Dispensed Price for Max Qty and the Benchmark Dispensed Price for Max Qty that relates to the Other SPC nominated amount.

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Other SPC nominated amount	This is the difference between the claimed price and the determined price, where that difference is in relation to a premium other than a brand premium or Therapeutic Group premium.
TGA	Therapeutic Goods Administration
Therapeutic Group	Therapeutic Groups contain drugs that the Pharmaceutical Benefits Advisory Committee has advised are interchangeable with another drug or medicinal preparation at the individual patient level. Therapeutic Groups were previously known as TGP groups.
Therapeutic Group premium (TGP)	Premium charged by a responsible person above the benchmark price of a medicine in one of the six therapeutic groups under the Therapeutic Group Premium policy and is paid by the patient.
Therapeutic Group premium nominated amount	This is the difference between the claimed price and the determined price, where that difference is in relation to a Therapeutic Group premium.
Therapeutic Relativity Sheets	Advice produced by the PBPA detailing the relativities between different medicines.
The Schedule	The Schedule of Pharmaceutical Benefits (http://www.pbs.gov.au)
Tier 1	Applications for the listing of new drugs where the claim is one of cost minimisation (or 'at least no worse than' according to the PBAC guidelines), where pricing is based on a nominated dosage relativity, and where the prices to pharmacist proposed are in accord with the PBPA methods of price calculations.
Tier 2	Submissions for new drug listing where the claim is one of acceptable incremental cost effectiveness (or new drug listings where the claim is one of cost minimisation but where pricing is not in accord with the PBPA criteria) and applications for changes to listings, both cost minimisation and cost effectiveness, and where the estimated net cost to the PBS is less than $10 million per annum in any of the first four years of listing.
Tier 3	Any submission where the estimated net cost to the PBS is estimated to be $10 million or more in any of the first four years of listing.
Unrestricted benefit	Medicines listed on the PBS which have no restrictions on their therapeutic uses or prescribing.
WAMTC	Weighted Average Monthly Treatment Cost. A reference pricing method whereby the pricing of a group of drugs, which have been accepted by the PBAC as being therapeutically equivalent, are adjusted so that their cost per patient per month's treatment is the same.

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Wholesale mark-up	The percentage or flat amount added to the ex-manufacturer price that the wholesaler applies to the ex-manufacturer price of a brand of an item as the fee for supplying pharmaceutical benefits to pharmacists. Like the pharmacy mark-up, the wholesale mark-up is calculated based on the maximum quantity determined for a pharmaceutical item or pharmaceutical benefit, not the pack size. Details on the mark-ups are detailed in the Fourth Community Pharmacy Agreement.
Yellow Book	Previous colloquial name of the *Schedule of Pharmaceutical Benefits*.

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4. FACTORS CONSIDERED BY PBPA

In considering the price of items recommended for listing and in reviewing the price of items already listed on the PBS, the PBPA takes account of the following factors:

(a) PBAC advice on clinical and cost-effectiveness;

(b) prices of alternative brands;

(c) comparative prices of items containing drugs in the same Anatomical Therapeutic Chemical groups (ATC);

(d) cost information, when provided by the responsible person or estimated by the PBPA;

(e) prescription volumes, economies of scale, special storage requirements, product stability, special arrangements;

(f) level of activity being undertaken by the company in Australia, including new investment, production, research and development;*

(g) prices of items containing the drug in reasonably comparable overseas countries;

(h) other factors the applicant may wish the PBPA to consider;

(i) any directions of the Minister;

* Factor (f) is presently not taken into consideration when recommending prices.

5. PRICING METHODS USED

The PBPA uses a number of methods to arrive at recommendations for, and/or review, the price of products listed on the PBS. The more common pricing methods used include Cost Plus method, Reference Pricing and Weighted Average Monthly Treatment Cost (WAMTC).

5.1 Cost Plus Method

Prior to the introduction of the PBS reforms in August 2007, the cost plus method was normally used in the case of stand-alone products, those recommended on the basis of acceptable cost-effectiveness and where no specific relativity exists, or when recommending a benchmark price for a therapeutic group.

In these cases a gross margin may be granted based on the cost of manufacture. This margin can vary and is determined on a case by case basis. A margin on costs of around 30% is usually considered reasonable, but higher margins may be recommended for low volume products (particularly those with a cost to the PBS of $50,000 per annum or less) and lower ones may be recommended for high volume products.

The cost plus method relies on responsible persons' cost data (usually presented on PB11b forms) which provides for a detailed breakdown of the manufacturing costs including landed cost, packaging, drug content, quality assurance, plant and equipment, manufacturing overheads and Therapeutic Goods Administration (TGA) fees. In one case, the cost of setting up a patient registry was accepted by the PBPA as a legitimate cost. Perhexiline maleate tablet, tranexamic acid tablet, and terbutaline injection are examples of products for which the cost plus method is used.

With the introduction of revised PBS Reform pricing arrangements in August 2007, the cost plus method became applicable to a larger range of drugs, as the reference pricing method (see below) now applies to F1 drugs and those in Therapeutic Groups, but not to drugs in F2.

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5.2 Reference Pricing

Prior to August 2007, this was the most common pricing method used by the PBPA. Under this system, where drugs are considered to be of similar safety and efficacy for pricing purposes they are linked and recommended by the PBAC as cost-minimised. The lowest priced brand or drug sets a benchmark price for either the other brands of that drug or the other drugs within the same sub-group of therapeutically related drugs. Pricing within these sub-groups is based on the therapeutic relativities between drugs as noted on the Therapeutic Relativity Sheets (see section 6.1 for an explanation of Therapeutic Relativity Sheets). The protease inhibitors, aromatase inhibitors and the corticosteroids for oral inhalation are examples of such groups.

When making cost minimisation recommendations the PBAC gives advice about the equi-effective doses of the new drug or a new indication for an existing drug and its comparator. The PBPA uses the dose relativity advice to determine the price of the new drug. The dose relativity advice is indicated in the PBPA Therapeutic Relativity Sheets.

An example of a cost minimisation recommendation is:

> *"bicalutamide 50mg daily was accepted on a cost minimisation basis compared to flutamide 250mg three times daily."*

In the above example, a Reference Pricing Group is formed by flutamide, bicalutamide and any other drugs already cost minimised to flutamide.

If a responsible person demonstrates to the PBAC a clinical advantage for a particular drug over its cost-minimised comparator then the drug may be granted a higher subsidised price over the alternatives.

Under the reforms introduced in August 2007, reference pricing applies to drugs in formulary F1 and the Therapeutic Groups, but not to other drugs in formulary F2. Single brand combination products which were listed on the basis of some relativity between the combination and the component drugs may also be subject to pricing being reviewed based on their therapeutic relativity.

As a result, the PBPA's 'Reference Pricing Group' document, which groups drugs which are linked for pricing purposes, has been amended to contain only drugs in F1 and drugs on the Combination Drugs List (where the combination is not in F2).

It is important to note that for new drugs being considered by the PBAC for listing on the PBS that comparators for pricing purposes may be in either formulary.

<u>Cost-minimised but with different listed dispensed prices</u>

Often drugs that are cost-minimised to one another do have the same dispensed price in the PBS schedule. However, there are a number of scenarios which will result in the dollar value of two equi-effective drugs being different. Such scenarios include the six listed below:

- the dosage relativity recommended by PBAC does not reflect the tablet strengths;
- two or more reference priced drugs are available in different pack sizes;
- two or more reference priced drugs are available in different number of strengths;
- price differences resulting from rounding;
- ratio of prices between strengths is different; and
- one drug may be worth different amounts for different indications, this is what is referred to as a "weighted price".

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5.3 Weighted Average Monthly Treatment Cost (WAMTC)

The WAMTC methodology is a particular type of reference pricing. The aim is to adjust the prices of drugs that have been accepted by the PBAC as providing similar health outcomes so that their cost per month's treatment is not statistically significantly different.

The methodology has recently been reviewed and the new methodology was introduced for consideration by the PBPA at its first meeting in 2004. The WAMTC Users' manual is available on the Department of Health website. A brief description of the process follows below. The drug groups subject to the WAMTC methodology are:

- Angiotensin converting enzyme (ACE) inhibitors.
- Angiotensin II receptor antagonists (ATRAs).
- Calcium channel blockers (CCBs)
- H_2-receptor antagonists (H2RAs).
- The HMG Coenzyme A reductase inhibitors, pravastatin and simvastatin (statins).
- Proton pump inhibitors (PPIs).

These are all Therapeutic Groups. WAMTC methodology is automatically applied to drugs that form Therapeutic Groups whether or not they are in F1. However if drugs are in F2, reference pricing, including WAMTC methodology, no longer applies, unless they form a Therapeutic Group.

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5.4 Pricing arrangements introduced 1 August 2007

The arrangements introduced under the PBS Reform since 1 August 2007 involve:

- Statutory price reductions for drugs listed in Formulary F2 – 2% on 1 August of 2008, 2009, and 2010 for brands on F2A and 25% on 1 August 2008 for all brands on F2T.
- A statutory price reduction of 12.5% for the first new brand of an item which is bioequivalent to the existing brand (provided the 12.5% reduction has not previously been applied).
- Price disclosure arrangements for drugs in the F2 formulary.
- Guarantee of Supply arrangements for certain brands.

See Attachment F for more detail on PBS Reform topics, also see PBS Reform fact sheet at:

http://www.health.gov.au/internet/main/publishing.nsf/Content/24693658DD49E286CA2572750081DB74/$File/PBS%20Reform%202Feb07.pdf

5.5 Other pricing methods

Pricing of new brands of existing items

Since 1 August 2005, the Commonwealth Government introduced a policy whereby responsible persons seeking to list the first new brand of a medicine already included on the PBS, needed to offer a minimum 12.5% price reduction in the approved price to pharmacist for the drug. Since 1 August 2007, the requirement for a 12.5% price reduction became mandatory rather than policy.

The minimum 12.5% mandatory price reduction applies to any new bioequivalent brand of any PBS listed pharmaceutical item that has not previously been subjected to a 12.5% reduction, either administratively or mandatory. The price reduction will flow on to other brands of items of that drug which share the same manner of administration as the new brand. If the new brand contains a drug in a Therapeutic Group, the reduction also flows on to the items containing other drugs in that Group that have the same manner of administration.

See Attachment F, section 3 for more detail on Statutory Price Reductions.

Applications for the listing of new brands of current PBS items do not need to be presented to the PBAC. However, before a new brand can be listed in the Schedule certain information is required from responsible persons by the Listing Unit within PILLS, of the Pharmaceutical Evaluation Branch.

Applications from companies wishing to list a new brand at a price lower than the current benchmark price are no longer presented to the PBPA for consideration. This is a process undertaken by the PBPA Secretariat to expedite the listing of these items. Where such brands become the sole benchmark product, assurance needs to be given that the responsible person can supply at least 20% of the market in all States and Territories.

For such applications, pricing details should be submitted by the 1st of the month after the PBPA meeting, whereas applications to list new brands at the current price may be submitted later than these dates and the listing may become effective in any of the monthly PBS Schedule up-dates. In relation to the three Schedules where changes to pricing can be made the cut-off dates are thus:

PBS Schedule effective date	Cut off for new brands resulting in pricing changes	Cut off for new brands not involving pricing changes
1 April	1 December	8 January
1 August	1 May	15 May
1 December	1 September	15 September

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See Section 8.2 for more details on the documents required for listing.

If the existing item on the PBS forms part of a Therapeutic Group subject to pricing review using the WAMTC methodology, then an application for a new brand which will lower the price of a drug listed at the benchmark (no premium), will commence a responsible person-initiated or 'ad-hoc' WAMTC review of that therapeutic group. For such ad-hoc WAMTC reviews, the source of the dosage data is the same as for the most recent annual review and matters other than pricing (e.g. exemptions, content of the group etc.) will not be considered. The time frame is shorter than for an annual WAMTC review where dosage data sources may be considered. An ad-hoc WAMTC review process should start 10 weeks prior to a PBPA meeting.

If an offer of a price reduction is received after the 10 week cut off, the brands of the same active moiety will be subject to a price reduction or a Brand Premium can apply, while an ad hoc review for the other drugs in the WAMTC group will take place in time for the next available PBPA meeting, if the global test shows this is necessary. (See the *WAMTC Users' Manual* for more details).

Pricing of new strengths of existing items

For new strengths of already listed drugs, as a general rule, the pricing of half strength formulations is at two-thirds to 70% of the full strength. For example, a new 10 mg tablet would be priced at about two-thirds of the existing 20 mg tablet.

Likewise, a double strength is usually one and two-thirds of the single strength. There are no general guidelines for other ratios.

These guidelines do not apply in all cases, for example if there is 'flat' pricing or for expensive drugs where history indicates pricing of the different strengths is based on the same price per unit (or mg or gram).

Pricing of combination products

A combination product is a product that is made up of more than one active moiety. The pricing of combination products where both or all components are PBS listed is usually, but not always, based on the sum of the individual components at the time of listing, at price to pharmacist level (in accordance with PBAC guidelines). Advice from the PBAC in relation to relativity is also taken into account. For example, the combination tablet containing enalapril maleate 20 mg plus hydrochlorothiazide 6 mg was recommended on a cost minimisation basis compared with enalapril maleate 20 mg and hydrochlorothiazide 12.5 mg as individual items.

Where a new combination product contains a formulation where one component is not represented by an actual strength (eg 100 mg-2.5 mg but where the listed items are 100 mg and 5 mg), the guidelines applying to new strengths of listed drugs may be invoked (eg for the 100 mg-2.5 mg formulation the sum of the price to pharmacist for the 100 mg and two-thirds of the 5 mg listing).

Under the PBS reforms introduced in August 2007, single brand combination items where at least one drug in the combination is PBS listed, are not included in F1 or F2, but are set out in an administrative list, the Combination Drug List.

See Attachment F, section 5 for more detail on Single Brand Combinations.

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6. PBAC – PBPA RELATIONSHIP

The PBAC is an independent statutory body, which meets three times per year (March, July and November), and is responsible for recommending to the Minister for Health and Ageing the drugs and medicinal preparations for subsidy under the PBS and the vaccines for listing under the National Immunisation Program. In doing this, PBAC is required to consider the clinical and cost effectiveness of the proposed drugs and medicinal preparations. Following due process, PBAC regularly reviews the list of PBS items, including restrictions, maximum quantities and number of repeats. It also provides advice about any other matters relating to the PBS that are referred to it by the Minister.

There are important distinctions between the roles of PBAC and the PBPA. The PBAC is the expert clinical body and responsible persons who disagree with PBAC advice, either on clinical or economic evaluation grounds, should raise the matter with the PBAC rather than ask the PBPA to address such issues.

The following sub-sections relate to areas of responsibility held by the PBAC, unless otherwise indicated.

6.1 PBAC recommendations of therapeutic relativities and cost-effectiveness

One of the main mechanisms to determine the initial listing of new products is the advice of the PBAC arising from the cost-effectiveness information supplied by the responsible person and evaluated by the Pharmaceutical Evaluation Section, and DUSC and/or ESC of the PBAC.

Since 1993, submissions requesting Commonwealth Government subsidy under the PBS have been required to include an economic analysis. The fundamental aim is to evaluate the costs associated with the new drug, or new indication, against the health benefits gained from its use, and compare the resultant cost-effectiveness ratio to the ratio from existing therapy. New drugs are most commonly recommended by the PBAC on the basis of either cost minimisation or an acceptable incremental cost-effectiveness ratio (ICER).

Cost minimisation is applied to those new therapies where the health outcomes are no worse than an existing therapy. In this situation the price for the new drug, or extension to listing of current drug, will be the same as for the comparator accepted by the PBAC, usually based on the dosage relativities between the new drug and the comparator i.e. the therapeutic relativity. The considerations of cost minimisation analyses usually consider drug costs only, but, if indicated by the PBAC, other cost offsets may be incorporated. For example, cost minimisation is not necessarily restricted to a comparison of oral versus oral but may be orally administered therapy versus IV infusion.

With the introduction of classifying PBAC applications according to their 'Tier' status (as recommended by the 'post-PBAC review'), straight forward cost minimisation applications where pricing is in accordance with the PBPA's usual pricing methodologies, will be classed as Tier 1. Tier classification is undertaken by the PBPA Secretariat prior to the PBAC deliberation of the submission. Advice is then given to the responsible person about the status and details the dates for providing documentation for listing and PB11(b) and PB11(a), these are usually due prior to the PBAC meeting. It is important for responsible persons to note that if all of the submission's claims are accepted by the PBAC and there are no significant changes resulting from this recommendation then an expedited listing may proceed without formal price consideration by the PBPA. A current description of Tier categories is listed below:

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Tier Category	Description
Tier 1	Applications for the listing of new drugs where the claim is one of cost minimisation (or 'at least no worse than' according to the PBAC guidelines), where pricing is based on a nominated dosage relativity, and where the prices to pharmacist proposed are in accord with the PBPA methods of price calculations.
Tier 2	Submissions for new drug listing where the claim is one of acceptable incremental cost effectiveness (or new drug listings where the claim is one of cost minimisation but where pricing is not in accord with the PBPA criteria) and applications for changes to listings, both cost minimisation and cost effectiveness, and where the estimated net cost to the PBS is less than $10 million per annum in any of the first four years of listing.
Tier 3	Any submission where the estimated net cost to the PBS is estimated to be $10 million or more in any of the first four years of listing.

Cost-effectiveness applies where treatment outcomes vary between the new drug and its comparator. Occasionally the advice that accompanies a listing recommendation is that the

clinical effectiveness is acceptable but the incremental cost-effectiveness ratios are 'high'. This is a signal that the PBAC has noted that the incremental cost-effectiveness ratio is higher than normal but that in this particular case it is 'acceptable'. The PBPA has sometimes sought to achieve prices lower than proposed to the PBAC in these circumstances.

Therapeutic Relativity Sheets

The Therapeutic Relativity Sheets mainly show specific dosage relativities between drugs within groups of therapeutically related drugs recommended by the PBAC. As the PBAC provides advice on dose relativity irrespective of its PBS Reforms formulary allocation the Therapeutic Relativity Sheets may include drugs from the F2 formulary. The insertion of these relativities maintains the importance of the Therapeutic Relativity Sheets in providing a historical context for PBAC decisions. The introduction of the PBS reform arrangements since 1 August 2007 form the basis of pricing decisions by the PBPA in relation to drugs in formulary F1 and Therapeutic Groups. The relativities are commonly based on PBAC advice but may also be historically based. An example of PBAC therapeutic advice is when aripiprazole was recommended for listing:

'Aripiprazole was recommended for listing on a cost minimisation basis versus olanzapine with 23.1 mg aripiprazole = 16.3 mg olanzapine'.

An example of an historically-based relativity is: 'The listed antacids, both tablets and liquids, have historically been listed at the same price'. These items have been listed before the legislative requirement for the PBAC to consider comparative costs.

Occasionally, a relativity statement will refer to some action in relation to pricing that has been instigated by the PBPA itself e.g. 'In relation to the bisphosphonates used for Paget disease, from the relativities initially advised by PBAC, the PBPA initially accepted that a 60 mg infusion of pamidronate = six months' of alendronate = three months' of tiludronate = two months' of risedronate. Following further advice, partly based on usage data, the PBPA has now accepted that a 60 mg infusion of pamidronate = three months' of alendronate = 1.5 months of tiludronate = 1.5 months' of risedronate. For pricing purposes, the PBPA has decided to compare the three oral drugs in accordance with this ratio and to review the pricing of pamidronate separately'.

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Responsible persons may request a change to the stated relativities by providing appropriate submissions to the PBAC if the original advice came from the PBAC, or to the PBPA if not based on PBAC advice (if consideration of clinical issues or clinical data are required, then the matter should be sent to the PBAC for review). Any changes to the relativity sheets are ratified by the PBPA at its regular meetings and updated by the PBPA Secretariat.

The Therapeutic Relativity Sheets are available electronically on the DoHA website or in hard copy from the PBPA Secretariat.

As indicated above, with the introduction of the PBS reforms since August 2007, reference pricing applies to drugs in F1 and drugs in the Therapeutic Groups and to some single brand combination products, but no longer applies to F2 drugs (other than those in Therapeutic Groups). Items in formulary F2 are affected by statutory prices reductions. The Therapeutic Relativity Sheets and relativities between drugs have become less influential in the annual pricing reviews. Thus, in relation to the serotonin antagonists, the relativity between dolasetron, granisetron and tropisetron (in F1) will continue to apply, whereas, ondansetron (in F2) will no longer have pricing based on the relativity statements.

6.2 Risk sharing arrangements

There are occasions where the listings of new drugs need to be accompanied by risk sharing arrangements. The most common type of arrangements are rebate agreements where the responsible person offers a rebate (of varying size) for the cost of increased expenditure over set annual subsidisation caps/thresholds. Such arrangements may be suggested or requested by the PBAC, the PBPA, the responsible person or be required should the drug require Cabinet consideration.

Rebate agreements can be used to address a variety of risks in a range of ways:

- Rebating a percentage of the price of each unit sold that is in excess of agreed annual set caps.

Example: The responsible person agrees to rebate x % of the cost of each unit sold for any sales in excess of $20 million in a year.

- Estimating the potential use outside the PBS restriction and rebating a proportion of this use.

Example: The responsible person and the Department agree that up to y % of a particular drug's sales may be for uses that are not subsidised by the PBS. The responsible person would thereby rebate y% of that drug's total sales to the Commonwealth.

- Agreeing to a common annual sales cap for all the drugs used to treat a particular condition and rebating any excess according to each responsible person's market share.

Example: Four drugs are used to treat a particular condition and the agreed cap for their combined sales is $80 million per year. In a particular year, sales are $100 million, with the four responsible persons having sold: $10 million, $20 million, $30 million and $40 million respectively. Responsible persons rebate a total of $20 million to the Commonwealth, paying: $2 million, $4 million, $6 million and $8 million, respectively, based on their market share.

- Absolute rebate based on the price of an alternative drug (where use of drug A above a certain level may be inconsistent with the cost-effectiveness recommendation of the PBAC).

Example: The responsible person agrees to supply drug A at the drug's agreed price (say $100) for sales up to $15 million per year, but then supply the drug at the price of the cheaper alternative drug B (say $60) for any sales in excess of $15 million, rebating the difference in the prices to the Commonwealth.

A combination of the various rebate arrangements may be required depending on the drug, the types of risks being addressed and the nature of the market for the drug.

Where a new drug is approved for an indication where a risk sharing arrangement is in place for an existing product, the responsible person may be asked to include its product within the existing arrangement or accept a similar arrangement. Wherever it is feasible, responsible persons will be given advance notice of the request.

For more information on Risk Sharing Arrangements, see:
http://www.health.gov.au/internet/main/publishing.nsf/Content/pbs-pbpa-policies-contents~pbs-pbpa-policies-ch3

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6.3 Section 100 and special pricing arrangements

Section 100 of the *National Health Act 1953* provides for an alternative means of providing a pharmaceutical benefit in circumstances where the usual PBS supply arrangements are unsuitable. There are several programs funded under this provision, including the Human Growth Hormone Program, the IVF/GIFT program and the Highly Specialised Drugs (HSD) program.

For a drug to be approved under the HSD program and be included in the PBS, it must receive a positive PBAC recommendation and comply with specific criteria agreed between the Australian Commonwealth and the State/Territory Governments (via the Highly Specialised Drugs Working Party).

6.4 Cost Implications

Submissions to the PBAC are required to estimate the cost implication for the PBS for the first five years of PBS subsidy. The predicted net cost to the PBS is one aspect taken into account by the Commonwealth Government when considering listing. Those submissions to be presented to Cabinet are required to provide estimates for the first four years of subsidy. Following each PBAC meeting, DoHA provides a list of all proposed new listings and amendments to listed indications (with estimated costs) to the Department of Finance and Deregulation (DoFD).

DoHA needs to obtain DoFD's agreement to the estimated costs where the expected net PBS expenditure is more than $5 million in one year or where there is significant potential for prescribing outside of the agreed restrictions that would result in net cost increases of more than $5 million in any one year.

It is Government policy that Cabinet must consider all proposed listings with a predicted net cost to the PBS in excess of $10 million per annum in any of the first four years of listing. This means that, where DoHA in consultation with DoFD has estimated the cost of a proposed new listing as being above this threshold, Cabinet consideration will be required before the listing can be finalised.

Experience has shown that the Cabinet process for new listings (and extensions) can lead to uncertainty about timing. Furthermore, Cabinet will request details on the risk that cost estimates may be higher than predicted and what is proposed to reduce these risks. It is therefore mandatory that listings being considered by the Cabinet include some type of risk-share arrangement (see Section 6.2). It is also important for responsible persons and the Pharmaceutical Evaluation Branch to come to an agreed position on the estimated costs to the PBS. It is thus in a responsible person's best interest to commence negotiations on pricing arrangements and usage estimates soon after the PBAC has made a positive recommendation (or even earlier in the listing process if a company foresees that the arrangements or estimates may have particular problems or difficulties).

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7. PBAC RECOMMENDATIONS AND SUBMISSIONS TO PBPA

Once the recommendations of the PBAC for listing new items or extension to listing of existing items are made, the PBPA considers the pricing implications. The following section outlines the information that the PBPA Secretariat utilises when compiling PBPA submissions for new listings and extension to listing.

7.1 New product and extension to listing

Following PBAC meetings, the PBPA Secretariat is provided with a summary of new products that have been recommended for listing on the PBS and of items where extensions to the indications or other changes for a currently subsidised drug have been recommended. Responsible persons are contacted by the PBPA Secretariat and asked to provide cost information as detailed on PB11b forms and invited to supply any other data that the responsible person considers relevant for consideration at the next PBPA meeting. The matters addressed should relate only to any factors that are relevant to the PBPA's consideration of pricing.

The cost information data together with a PBPA Secretariat overview and the advice from the PBAC are evaluated by the PBPA. The Secretariat overview includes information such as:

- the trade name and responsible person;
- proposed price and overseas prices (commonly UK and New Zealand);
- alternatives listed on the PBS and their prices;
- estimated PBS/NIP expenditure;
- cost of goods and margin;
- price calculations; and
- PBAC advice.

The evaluation summaries presented to PBAC, the advice from the PBAC, ESC and DUSC and responsible persons' 'pre-PBAC' responses are available at the meeting if needed. The PBPA makes its recommendations for prices of new listings and extensions and changes to listings based on this information.

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For extensions to listing (eg new indications or relaxed restrictions) if the estimated increased cost to the PBS is substantial, the PBPA often recommends unit price reductions. The level of any reduction usually depends on several factors such as the present cost to the PBS, the estimated increase in cost, pricing history and current cost of goods.

Excluding Section 100 and WAMTC items, the PBPA's consideration of prices are almost exclusively undertaken at price-to-pharmacist level. The PBPA's view is that pharmacist mark-ups and dispensing fees should not be included as this may confound the true drug-cost to drug-cost comparison.

Section 100 items are usually provided direct from the responsible person to the pharmacy. As such, consideration of these is usually at the level of the price ex-manufacturer. WAMTC calculations are undertaken at dispensed price level.

PBPA CONSIDERATION	PRICE POINT	RATIONALE
Listing under Section 85	Price to pharmacy	Mark-ups and dispensing fees may confound drug-cost comparison
Listing under Section 100	Ex-manufacturer	Supplied direct from the responsible person to pharmacy
WAMTC Review	Dispensed Price Maximum Quantity	Calculator methodology to reflect monthly treatment cost.

Price Negotiations

Price negotiations with the responsible person are undertaken by the PBPA Secretariat on behalf of the Minister and are based on PBPA recommendations. In line with recommendations from the post-PBAC review, these negotiations with responsible persons may commence at any time prior to, or immediately after the relevant PBPA meeting.

Initial price offers are made in writing, usually by email, and may proceed in writing or verbally according to the responsible persons' wishes. Furthermore, price negotiations *are not finalised* until cost information data (PB11b) are received by the PBPA Secretariat. Under normal circumstances, a PB11b form is required prior to consideration at the PBPA meeting. Therefore, it is in the interest of responsible persons to provide the information at their earliest convenience. The PBPA Secretariat may approach responsible persons prior to or after a PBAC meeting to discuss issues such as:

- relativities to already listed items that may impact on price;
- requested margin being outside the policy set by PBPA; and
- the need to consider a risk sharing arrangement, for example to address leakage.

When a price is agreed the responsible person is requested to send in a price alteration/acceptance form (PB11a) or a letter with the confirmed price for the product and date the listing is to take effect. Any agreement however, is subject to Ministerial (or his/her delegate) approval.

No Price Agreement

If a price is not agreed between the PBPA Secretariat and the responsible person before the PBPA, the PBPA will provide the Secretariat with guidance on how to proceed. Further negotiations may proceed after the PBPA meeting.

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7.2 Reviewing listed products

Each year, the PBPA reviews the prices of every brand of pharmaceutical item listed on the PBS, thus providing responsible persons the opportunity to submit price change requests. This includes all brands within each drug form and strength. With three PBPA meetings each year, a third of PBS listed items (approximately 1000 products) are reviewed at each meeting. A letter is sent out to responsible persons listing the ATC groups and the dates of the PBPA meetings at which the groups will be reviewed. Included in the letter are the closing dates for submissions (usually six weeks prior to the meeting date) for responsible persons who may wish to submit information relating to the review of their products. A link to the Therapeutic Relativity Sheets is also included as this may provide information on the comparator drug and relativity for pricing purposes. Please see Attachment A – Time Line for a typical PBPA meeting.

If a responsible person wants the PBPA to consider a price increase for a PBS subsidised product within a relevant ATC group, it needs to send in a PB11b (cost information) form and include any supporting documentation it wants to be taken into consideration.

When assessing price increase requests from a responsible person who has the majority market share, the PBPA uses a 20% guideline as the minimum market share for the minor suppliers at the benchmark price. The PBPA would also take into account the number of suppliers of the drug, the number of drugs in the related ATC group and the sales volumes.

Possible reasons for price changes

A drug may receive a price increase if:

- the drug that sets the benchmark price requests an increase and there are no other F1 or Therapeutic Group drugs in that therapeutic group or sub-group, or identified in the relativity sheet, that offers a lower price;
- all F1 or drugs within a Therapeutic Group or whose prices are linked through the relativity sheets seek a price increase at the same time;
- the drug has no comparators i.e. F2 or is an "orphan" F1 drug and the company requires an increased price to continue to make it available on the Australian market;
- the gross margin is in a range considered acceptable by the PBPA (see Section 5.1 Cost Plus Method).

Note that more than one of the above factors may need to be met, e.g. the drug is the lowest priced in a group and the margin is acceptable.

Other reasons for price changes might include:

- the benchmark brand or product changes price, either up or down;
- there is a change in cost of goods that may justify a price increase or decrease;
- a change in PBAC advice, for example regarding relativities for F1 drugs;
- a change in listing restrictions;
- the responsible person requests a change in premium;
- the outcome of a WAMTC review;
- pricing arrangements, such as price volume agreements (see Section 6.2 Risk Sharing Arrangements).

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Additional indications for currently listed drugs

Where an additional use has been recommended by the PBAC for a drug that is currently PBS listed, the PBPA may recommend that some compensatory price alteration be negotiated. Whether there is a need for any price alteration (and the degree if so recommended) depends on the current PBS expenditure, the predicted cost due to the new use and the pricing and margin history. Where current expenditure is large and the additional cost to the Commonwealth is predicted to be considerable and the past and present margins are close to the 30% level, it is usual for some reduction in unit cost to be recommended.

Ad-Hoc Reviews

Products may be reviewed on an ad-hoc basis at either the regular PBPA meetings, or if subject to a premium policy, through a process undertaken by the PBPA Secretariat to expedite any changes to these items to coincide with the release of the Schedule.

The main reason for seeking an ad-hoc price review at regular PBPA meetings is because of unexpected cost increases. However, responsible persons should be aware that price increases are unlikely to result from ad-hoc reviews if the drugs concerned have relativities with other drugs where price increases have not been sought i.e. they are in the F1 formulary.

The closing date for ad-hoc submissions is usually the same as for items on the PBPA regular review schedule, i.e. approximately six weeks. Please check with the PBPA Secretariat for actual dates.

Reviews of Brand or Therapeutic Group Premiums or Special Patient Contributions
The responsible persons of items that are subject to the brand premium (see section 9.1) or therapeutic group premium arrangements (section 9.2) have the opportunity to make price changes three times a year on 1 April, 1 August and 1 December. As mentioned previously, this is a process undertaken by the PBPA Secretariat to expedite the listing of these items.

See Attachment B for details/timelines.

For any benchmark price decreases resulting from a PBPA meeting, the responsible persons of the alternative brands will be notified of the new benchmark price and given the opportunity to review the prices/premiums for their brands.

If a responsible person requests a change to its premium price, this can be done without any need to go to the responsible persons of the alternative brands. Suppliers are then notified by the same means as if their products were considered in a normal review as stated above.

Requests for increase in the benchmark price need to be referred to the next PBPA meeting.

See Attachment C for some common examples of the calculations performed in the pricing of pharmaceuticals.

8. OUTCOMES OF PBPA

All responsible persons who made submission to the PBPA are formally notified in writing of the Ministerial approved recommendations as soon as possible.

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8.1 Notification

New item and Extension to listing
Following this notification, responsible persons must submit a PB11 (a) form to confirm that they agree with the price recommended by the PBPA. This PB11 (a) is required for new items listing and extension to listing. This form must be received by the Secretariat before listing can take place.

If no agreement is reached between the PBPA Secretariat and the responsible person following the PBPA meeting, the responsible person may refer their submission, with additional information, back to the PBAC or back to the PBPA for further discussion and recommendation.

Review of existing items
Following the PBPA meeting, a letter is sent to responsible persons of drugs for which a premium (either brand or therapeutic) may be introduced or changed. Responsible persons are asked to either match the benchmark price or to advise the level of premium to apply to their particular brand (see Section 9 on Brand and Therapeutic Group arrangements for more details). No advice is sent where the responsible person has not sought an adjustment and the benchmark price has not changed. If a response is not received within one week it is assumed that responsible persons wish to maintain the current price.

After responses to premium price letters have been received, Ministerial approval is sought for the recommended price changes from the PBPA meeting.

Once Ministerial approval has been granted, responsible persons are contacted by phone and advised of the price changes for their products. They are requested to send in PB11a (price alteration/acceptance) forms, which confirm any price change and the date of effect for the new

price. After the PBPA Secretariat receives the price confirmations, companies are sent out a meeting result letter that confirms the new prices. In addition, this letter provides reasons why the responsible person's other products did not receive requested price changes.

8.2 Listing

New items

The current cut-off dates for Tier 2 applications by which all matters relating to listing of a product can be found at:
http://www.health.gov.au/internet/main/publishing.nsf/Content/57513D599AA9FC38CA257244007C3DBA/$File/Summary%20of%20Deadlines%20for%20the%20PBS%20Monthly%20Listing%20Process%2009.pdf

Effective date of listing on the Schedule of Pharmaceutical Benefits	**Deadline for finalisation of all details related to listing**
1 April	8 January
1 August	15 May
1 December	15 September

For applications needing Cabinet consideration, the listing dates cannot be predicted. Responsible persons should endeavour to provide all information to the Department at the earliest opportunity.

The deadline for listing of new brands that have no price change implications is the 15th of the month, three months before the listing date, i.e. for 1 June listing date the deadline is 15 March. The listing of brands that do have price change implications, i.e. new brands or ad hoc price reviews, occurs at three points – 1 April, 1 August and 1 December. The deadline for listing new brands with price change implications is four months before the respective listing date. The deadline for ad hoc price reviews of existing brands is five months before the listing date.

For Tier 1 applications where the expedited listing process is requested by the responsible person, listing is possible from two-months after the PBAC, provided the final documentation has been submitted to the Listing Unit, within the Publishing, Industry Liaison and Listing (PILLS) Section, by the 15th of the month prior to the PBAC meeting.

Before a product can be listed in the Schedule the following information is required from the responsible person by the Listing Unit, within PILLS:

- A copy of the TGA marketing approval letter including 'Manufacturing and Product Details'
- A completed *Application to list a Drug or Medicinal Preparation as a Pharmaceutical Benefit* 'PB11'.
- A copy of the current Certificate of Registration or Certificate of Listing for the product issued by the TGA.
- A copy of the current approved Product Information for the product.
- Copies of the primary labelling of the product.
- A signed original responsible person declaration form.
- Advice about the proposed listing date and written assurance that stock of the product will be available on the proposed date of listing in the Schedule.
- A completed *Cost Information* 'PB11b' form is also required by the PBPA Secretariat.

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New brands of existing items

Before a new brand can be listed in the Schedule certain information is required from responsible persons by the Listing Unit within PILLS, of the Pharmaceutical Evaluation Branch.

The information includes:

- A letter of application, which includes details of the timing of listing being sought, and any other relevant information.
- A completed *Application to list a Drug or Medicinal Preparation as a Pharmaceutical Benefit* "PB11".
- A completed *Cost Information* 'PB11(b)'. Responsible persons can also check the Reference Pricing Groups document to determine whether the 12.5% price reduction policy may affect the drug for which the application is being made. (see 12.5% Price Reductions).
- A copy of the letter from the Therapeutic Goods Administration (TGA) approving the entry of the product in the Australian Register of Therapeutic Goods (ARTG), including manufacturing and product details.
- A copy of the current Certificate of Registration or Certificate of Listing for the product issued by the TGA.
- A copy of the current approved Product Information for the product, where applicable.
- Copies of the primary product labelling and packaging of the product.
- New brands must be listed with an equivalence indicator. In order for a brand equivalence indicator to be included in the entry for the new brand, it is the responsible person's responsibility to request a statement from the TGA indicating that it is appropriate for an equivalence indicator to be shown in the PBS Schedule, and against which other brands. The TGA will provide this advice directly to the Listing Unit, PILLS.
- Written assurance that stock of the product will be available on the proposed date of listing in the Schedule.
- A signed original responsible person declaration form.
- If other than the current base price is being requested, contact should be made with the PBPA Secretariat.

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9. SPECIAL PATIENT CONTRIBUTIONS

Special patient contributions may apply to some drugs when the responsible person and the Commonwealth Government do not agree on a price for subsidy purposes. Should the Minister determine that the drug should continue to be listed and subsidised on the PBS, the patient must pay an additional amount on top of the normal patient co-payment.

Under PBS reforms, the *National Health Amendment (Pharmaceutical Benefits Scheme) Act 2007* contains definitions of the different prices to pharmacist that can arise:

- Agreed price to pharmacist (or ex-manufacturer for section 100 items) – a price to pharmacist where the Minister and the responsible person have been able to agree on price;

- Determined price to pharmacist – the price to pharmacist to be used in calculating the subsidised price where the Minister and the responsible person have been unable to agree on price;

- Claimed price to pharmacist – the price to pharmacist used to calculate the dispensed price required by the responsible person when the Minister and the responsible person are unable to agree on price

Note that the difference in the calculated dispensed prices based on the determined and claimed prices to pharmacist, becomes the special patient contribution.

9.1 Brand Premium Arrangements

The benchmark price of a drug (the lowest priced brand for that form of drug or drugs) is determined by the PBPA based on pricing methodologies mentioned above. Responsible persons of alternative brands may charge a premium provided their brand is proven to be bioequivalent and/or interchangeable with the benchmark brand. Brands that are interchangeable are indicated in the Schedule by having like superscripts next to the brand name for a particular drug form and strength, eg [a] Poly-Tears; [a] Tears Naturale. The level of the premium is a matter for the responsible person of that brand, however, the Minister may not agree to list a brand at a price requested. The amount of the premium is payable by the patient in addition to the patient co-payment. Pharmacists are able to substitute brands provided the patient agrees, and such action is not vetoed by the doctor.

The rationale for this approach to brand premiums is that consumers should always have access to at least one brand at the benchmark price.

Under PBS reforms introduced on 1 August 2007, the benchmark price to pharmacist is referred to as the 'agreed' or 'deemed' price, whereas brands with a premium have a 'claimed' price.

9.2 Therapeutic Group Arrangements

The Therapeutic Group arrangements were originally introduced as the Therapeutic Group Premium policy. The arrangements are now covered by legislation and currently relates to six particular groups of drugs, namely the H_2-receptor antagonists (H_2RAs), proton pump inhibitors (PPIs), calcium channel blockers (CCBs) (dihydropyridines), angiotensin converting enzyme (ACE) inhibitors, angiotensin II receptor antagonists (ATRAs) and the HMG CoA reductase inhibitors (statins) pravastatin and simvastatin. The construction of these groups is based on advice from the PBAC, which is based on the principle of therapeutic interchangeability on an individual basis.

The products in these groups have their prices reviewed on a regular basis by WAMTC methodology and at least one drug from the group will set the therapeutic benchmark price. While the subsidy price for the alternate drugs in the group will be at the same level as the benchmark price, responsible persons of the alternate drugs may charge a premium. The amount of the premium is payable by the patient in addition to the patient co-payment. However, as for brand premiums, the rationale for this approach is that patients should always have access to one product in each of these six groups at the benchmark price.

There are provisions for exemption that prescribers may seek from Medicare Australia, through Authority prescription provisions, for patients having to pay the premium if:

- adverse effects occur with all of the base-priced drugs;

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- drug interactions occur with all of the base-priced drugs;
- drug interactions are expected to occur with all of the base-priced drugs; or
- the transfer to a base-priced drug would cause patient confusion resulting in problems with compliance.

Pharmacists are not able to substitute between different chemical entities.

9.3 Other Special Patient Contribution Arrangements (or Special Pharmaceutical Benefits)

Other special patient contribution arrangements (listed in the Schedule as Special Pharmaceutical Benefits) can also apply where brand or Therapeutic Group premiums are not applicable.

Some medicines in reference pricing groups may not be interchangeable for patients. Unlike products with brand or therapeutic group premiums, patients may not be able to avoid paying this extra cost through the use of another drug.

Prior to the 12.5% pricing policy, these arrangements had rarely been used. There are now five drugs that are listed under these arrangements (for example levetiracetam, naratriptan and escitalopram). For these recently listed drugs, there are provisions for exemption for patients having to pay the special patient contribution, where the prescribing doctor believes that there is no clinically appropriate alternative, prescribers may seek an exemption from Medicare Australia through Authority prescription provisions. For example:

- adverse events have occurred with other suitable PBS-listed medicines; or
- medicine interactions have occurred with other suitable PBS-listed medicines; or
- medicine interactions are expected to occur with other suitable PBS-listed medicines; or
- transfer to another suitable PBS-listed medicine would cause patient confusion resulting in problems with compliance; or
- transfer to another suitable PBS-listed medicine is likely to result in adverse clinical consequences.

For details of the drugs currently listed as Special Pharmaceutical Benefits look at the PBS schedule on line at www.pbs.gov.au.

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10. USEFUL LINKS

The PBAC Guidelines:
http://www.health.gov.au/internet/main/publishing.nsf/Content/pbacguidelines-index

General information about the PBS:
http://www.pbs.gov.au/html/home
http://www.medicareaustralia.gov.au.

The Pharmaceutical Benefits Pricing Authority Annual Report:
http://www.health.gov.au/internet/main/publishing.nsf/Content/health-pbs-general-pricing-pbparpt.htm

Useful documents in preparing pricing submissions:
http://www.health.gov.au/internet/main/publishing.nsf/Content/PBS+Pricing-2

National Health Act 1953
http://www.austlii.edu.au/au/legis/cth/consol_act/nha1953147/

PBS Reform Fact Sheet
http://www.health.gov.au/internet/main/publishing.nsf/Content/pbs_reform_02feb07.htm

WAMTC User's Manual and Calculator
http://www.health.gov.au/internet/main/publishing.nsf/Content/health-pbs-general-pricing-wamtc

11. USEFUL CONTACTS

Secretary
Pharmaceutical Benefits Pricing Authority
MDP 83
Department of Health & Ageing
PO Box 9848
CANBERRA ACT 2601
Phone: 02 6289 6968
Fax: 02 6289 8633
Email: pbspricing@health.gov.au

Pricing Adviser
Pricing Section
Pharmaceutical Evaluation Branch
MDP 83
Department of Health & Ageing
PO Box 9848
CANBERRA ACT 2601
Email: pbspricing@health.gov.au

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ATTACHMENT A

TIMELINE

EXAMPLE OF A TYPICAL PBPA MEETING TIMELINE

The August meeting of the PBPA sets the dates and agenda for meetings over the next 12 months. An example of the timing for information needed for PBPA meetings is indicated in the following table. This is a guide only.

DATE	INFORMATION
10 weeks prior to PBPA	▪ Responsible persons are sent a 'product listing' (list of responsible person's products which are being reviewed at the meeting) together with the relevant therapeutic relativity sheets for the groups. Responsible persons are allowed 1 month to supply submissions to the PBPA Secretariat.
6 weeks prior to PBPA	▪ Cut off date for ad-hoc submissions for August meeting.
	▪ When responsible persons are contacted by the PBAC Secretariat with a positive recommendation for listing on the PBS, they should contact the PBPA Secretariat and confirm what cost information data (PB11b form) and any other relevant data required by the PBPA.
6 weeks prior to PBPA	▪ Cut off date for regular submissions.
5 weeks prior to PBPA	▪ Preferred cut off date for receipt of cost information data for new listings.
PBPA meeting	▪ PBPA meeting held to review prices of existing products and recommend prices of new listings. ▪ After the meeting responsible persons of items that may have premium prices adjusted are given the opportunity to introduce or amend premium levels or reduce to benchmark. They are given 1 week to respond.
2 weeks after PBPA	▪ Minister asked to consider pricing agreements or determinations in relation to the PBPA recommended price changes.
Within 4 weeks after PBPA	▪ After consideration by the Minister, responsible persons are advised of any price changes and asked to send in PB11a form to agree or confirm price and date of effect. ▪ Letters are sent out confirming prices and date of effect and also details of reasons for rejections. ▪ PB11a forms are received showing agreement to or confirmation of prices and date of effect.
Approx. 5 weeks after PBPA	▪ Confirmation letters sent out to responsible persons for the benchmark priced brands and those with SPC. Guarantee of Supply arrangements are also confirmed.
1st of the month (May, September or December)	▪ Cut off for changes for next Schedule of Pharmaceutical Benefits when price changes can be effected.
1st of the month (April, August or December)	▪ Schedule of Pharmaceutical Benefits with price changes released. Prices are shown in the Schedule as dispensed prices.

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ATTACHMENT B

DATES FOR 2008-2009 PBS SCHEDULES

Type of price change	Industry deadline for submission	PBPA meeting	Effective date for price change
New brand with price reductions (includes 12.5%)	1 May 1 Sep 1 Dec	- - -	1 Aug 1 Dec 1 Apr
Ad hoc premium adjustments and price reductions	1 May 1 Sep 1 Dec	- - -	1 Aug 1 Dec 1Apr
Scheduled and ad hoc reviews of ATC Groups* Group 1 Group 2 Group 3 Vaccines on NIP	 1 Mar 1 Jul 1 Nov 1 Nov	 Apr Aug Dec Dec	 1 Aug 1 Dec 1 Apr PHD to advise
WAMTC review CCBs & H2RAs ACEIs & Statins PPIs & ATRAs	 1 May 1 Jan 1 Sep	 Apr Aug Dec	 1 Aug 1 Dec 1 Apr

Changes to Schedule with no pricing implications: **eg, new brands without price changes, change of details and deletions**	**Deadlines for industry submission**	**Effective date for listing on Schedule**
	22 Sept 08	1 Dec 08
	22 Oct 08	1 Jan 09
	15 Nov 08	1 Feb 09
	1 Dec 08	1 Mar 09
	8 Jan 09	1 April 09
	15 Feb 09	1 May 09
	15 Mar 09	1 June 09
	15 Apr 09	1 July 09
	15 May 09	1 Aug 09
	15 June 09	1 Sept 09
	15 Jul 09	1 Oct 09
	15 Aug 09	1 Nov 09
	15 Sept 09	1 Dec 09
	15 Oct 09	1 Jan 10
	15 Nov 09	1 Feb 10

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*ATC Groups Scheduled Reviews

April PBPA (GROUP 1)	August PBPA (GROUP 2)	December PBPA (GROUP 3)
Blood & blood forming organs	Dermatologicals	Alimentary tract & metabolism
Cardiovascular system	Musculoskeletal system	Sensory organs
Antineoplastics & immunomodulating agents	Nervous system	Various
Respiratory system	Antiparasitic products	Systemic hormonal preparations, excluding sex hormones
Genito urinary system & sex hormones	Section 100 items	General antiinfectives for systemic use

ATTACHMENT C

EXAMPLES OF COMMONLY USED CALCULATIONS[1]

Many responsible persons have difficulty understanding how calculations are performed and there have been numerous requests for examples of commonly used calculations to be added to the PBPA Policies, Procedures and Methods manual. Although not every calculation performed is mentioned, the examples listed below are from the most frequent requests.

The examples below reflect the fees and mark-ups from the Fourth Community Pharmacy Agreement. These examples reflect the fees and mark-ups that are effective until 31 July 2009 (refer to Attachment E for information on the increase in fees and restructure of mark-ups). The formulas below will remain the same, but the values of the fees and mark-ups will change.

There are different mark-ups on prices to pharmacist depending on the overall cost of the drug. From 1 August 2008 drugs up to and including $30.00 (at price to pharmacist) the mark-up is 15%. For drugs between $30.01 and $45.00 the mark-up is $4.50. For drugs between $45.01 and $180 the mark-up is 10%. For drugs between $180.01 and $450 the mark-up is a flat fee of $18. For drugs between $450.01 and $1750.00 the mark-up is 4%. For drugs over $1750.00 the flat fee is $70.00. The dispensed price includes the pharmacist mark-up as well as dispensing fees[2].

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Dispensed Price calculations

Price to pharmacist + mark-up + dispensing fee = dispensed price

1. **To calculate dispensed prices for items with a price to pharmacist of $30.00 or less for the listed maximum quantity (15% mark-up):**

   Price to pharmacist + 15% mark-up + dispensing fee = dispensed price

   E.g. $25.00 + $3.75 + $5.99 = $34.74

   or $25.00 x 1.15 + $5.99 = $34.74

   To calculate the price to pharmacist from the dispensed price for the above:

   (Dispensed price – dispensing fee) – mark-up = price to pharmacist

   ($34.74 – $5.99) ÷ 1.15 = $25.00

2. **To calculate dispensed prices for items with a price to pharmacist between $30.01 and $45.00 for the listed maximum quantity ($4.50 mark-up):**

   Price to pharmacist + $4.50 mark-up + dispensing fee = dispensed price

[1] Prices are rounded to two decimal points following completion of each step of the calculation.
[2] Dispensing fees are adjusted each year: from 1 July 2007 $5.32, from 1 August 2007 $5.44. From 1 August 2008 the dispensing fee is $5.99.

E.g. $40.00 + $4.50 + $5.99 = $50.49

To calculate the price to pharmacist from the dispensed price for the above:

(Dispensed price – dispensing fee) – $4.50 = price to pharmacist

($50.49 - $5.99) - $4.50 = $40.00

3. **To calculate dispensed prices for items with a price to pharmacist between $45.01 and $180.00 for the listed maximum quantity (10% mark-up):**

Price to pharmacist + 10% mark-up + dispensing fee = dispensed price

E.g. $100.00 + $10.00 + $5.99 = $115.99

or $100.00 x 1.1 + $5.99 = $115.99

To calculate the price to pharmacist from the dispensed price for the above:

(Dispensed price - dispensing fee) ÷ 1.1 = price to pharmacist

($115.99 - $5.99) ÷ 1.1 = $100.00

4. **To calculate the dispensed price for items with a price to pharmacist ranging from $180.01 to $450.00 ($18.00 flat fee):**

Price to pharmacist + $18.00 flat fee + dispensing fee = dispensed price

E.g. $200.00 + $18.00 + $5.99 = $223.99

To calculate the price to pharmacist from the dispensed price for the above:

Dispensed price - dispensing fee - $18.00 = price to pharmacist

$223.99 - $5.99 - $18.00 = $200.00

5. **To calculate the dispensed price for items with a price to pharmacist ranging from $450.01 and $1750.00 (4% mark-up):**

Price to pharmacist + 4% mark-up + dispensing fee = dispensed price

E.g. $500.00 + $20.00 + $5.99 = $525.99

or $500.00 x 1.04 + $5.99 = $525.99

To calculate the price to pharmacist from the dispensed price for the above:

(Dispensed price - dispensing fee) ÷ 1.04 = price to pharmacist
($525.99 - $5.99) ÷ 1.04 = $500.00

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6. To calculate the dispensed price for items with a price to pharmacist over $1750.00 ($70.00 flat fee):

Price to pharmacist + $70.00 flat fee + dispensing fee = dispensed price

E.g. $1800.00 + $70.00 + $5.99 = $1875.99

To calculate the price to pharmacist from the dispensed price for the above:

Dispensed price - dispensing fee - $70.00 = price to pharmacist

$1875.99 - $5.99 - $70.00 = $1800.00

Pharmacy Pack Size calculations **(smaller than the maximum quantity permitted under the PBS)**

1. To calculate the dispensed price for items with a price to pharmacist of $30.00 or less for the listed maximum quantity (15% mark-up)

Price to pharmacist	$12.50
+ 15% mark-up	$1.88
Sub total	$14.38
x Max qty price	$28.76 (multiply by 2 i.e. if pack is 1 but max qty is 2)
+ Disp fee	$5.99
Dispense Price	$34.75

To calculate the price to pharmacist from the dispensed price for the above:

(Disp price - disp fee) ÷ max qty = sub total - mark-up = price to pharmacist

($34.75 - $5.99) ÷ 2 = $14.38 - $1.88 = $12.50
or
($34.75 - $5.99) ÷ 2 = $14.38 ÷ 1.15 = $12.50

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2. To calculate the dispensed price for items with a price to pharmacist between $30.01 and $45.00 for the listed maximum quantity ($4.50 mark-up):

Price to pharmacist	$13.33
+ $4.50 mark-up	$1.50
Sub total	$14.83
x Max qty price	$44.49 (multiple by 3 i.e. if pack size is 1 but max qty is 3)
+ Disp fee	$5.99
Dispense price	$50.48

To calculate the price to pharmacist from the dispensed price for the above:

(Disp price - disp fee) ÷ max qty = sub total -flat fee = price to pharmacist

($50.48 – $5.99) ÷ 3 = $14.83 - $1.50 = $13.33

3. To calculate the dispensed price for items with a price to pharmacist between $45.01 and $180.00 for the listed maximum quantity (10% mark-up):

Price to pharmacist	$50.00
+ 10% mark-up	$5.00
Sub total	$55.00
x Max qty price	$110.00 (multiply by 2 i.e. if pack size is 1 but max qty is 2)
+ Disp fee	$5.99
Dispense price	$115.99

To calculate the price to pharmacist from the dispensed price for the above:

(Disp price - disp fee) ÷ max qty = sub total - mark-up = price to pharmacist

($115.99 - $5.99) ÷ 2 = $55.00 - $5.00 = $50.00
or
($115.99 - $5.99) ÷ 2 = $55.00 ÷ 1.1 = $50.00

4. To calculate the dispensed price for items with a price to pharmacist ranging from $180.01 to $450.00 for the listed maximum quantity ($18.00 flat fee):

Price to pharmacist + flat fee (if maximum quantity of 2 i.e. $18.00 ÷ 2 = $9.00)

Price to pharmacist	$92.00
+ Flat fee	$9.00
Sub total	$101.00
x Max qty price	$202.00 (multiply by 2 i.e. if pack size is 1 but max qty is 2)
+ Disp fee	$5.99
Dispense Price	$207.99

To calculate the price to pharmacist from the dispensed price for the above:

(Disp price - disp fee) ÷ max qty = sub total -flat fee = price to pharmacist

($207.99 - $5.99) ÷ 2 = $101.00 - $9.00 = $92.00

5. To calculate the dispensed price for items with a price to pharmacist ranging from $450.01 to $1750.00 for the listed maximum quantity (4% mark-up):

Price to pharmacist	$390.00
+ 4% mark-up	$15.60
Sub total	$405.60
x Max qty price	$811.20 (multiply by 2 i.e. if pack size is 1 but max qty is 2)
+ Disp fee	$5.99
Dispense price	$817.19

To calculate the price to pharmacist from the dispensed price for the above:

(Disp price - disp fee) ÷ max qty = sub total - mark-up = price to pharmacist

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($817.19 - $5.99) ÷ 2 = $405.60 - $15.60 = $390.00
or
($817.19 - $5.99) ÷ 2 = $405.60 ÷ 1.04 = $390.00

6. **To calculate the dispensed price for items with a price to pharmacist over $1750.00 for the listed maximum quantity ($70.00 flat fee):**

Price to pharmacist + flat fee (if maximum quantity of 4 i.e. $70.00 ÷ 4 = $17.50)

Price to pharmacist	$390.00
+ flat fee	$17.50
Sub total	$407.50
x Max qty price	$1630.00 (multiply by 4 i.e. if pack size is 1 but max qty is 4)
+ Disp fee	$5.99
Dispense price	$1635.99

To calculate the price to pharmacist from the dispensed price for the above:

(Disp price - disp fee) ÷ max qty = sub total - mark-up = price to pharmacist

($1635.99 - $5.99) ÷ 4 = $407.50 - $17.50 = $390.00

7. **To calculate brand premiums using price to pharmacist (dispensed price includes 15% mark-up. i.e. price to pharmacist for maximum quantity of $30.00 or less):**

Drug A's responsible person's claimed price is $12.56, whilst the benchmark (agreed) price to pharmacist is $11.10.

Benchmark:	$11.10 + $1.67 = $12.77
Drug A:	$12.56 + $1.88 = $14.44
	difference = $1.67 = premium

If the product was packaged and priced as a pack of 30, but listed with a maximum quantity of 90 (3x30), then the premium of $1.67 would be multiplied by 3, which would equal a $5.01 premium.

The price to pharmacist is always based on the actual pack size. The maximum quantity that is shown in the Schedule has to be included in the calculations for working out dispensed prices if it differs from the pack size.

Dangerous drug fees:

Note that a dangerous drug fee of $2.71 needs to be added to the dispensing fee when calculating the dispensed price for drugs listed in section 8 of the Uniform Poisons Schedule (or deleted if calculating price to pharmacist from PBS dispensed price). As with the dispensing fee, the dangerous drug fee is adjusted from 1 July each year.

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Extemporaneously prepared drugs fees:

Note that an extemporaneously prepared drug fee of $2.04 needs to be added to the dispensing fee when calculating the dispensed price for extemporaneously prepared drugs. As with the dispensing fee, the extemporaneously preparation fee is adjusted from 1 July each year.

Section 100:

The pricing of Section 100 items are undertaken at price to Government or price ex-manufacturer level - i.e. they do not attract a wholesaler's margin. They are mostly dispensed through a hospital pharmacy and when provided from public hospitals do not attract any pharmacy dispensing fee or mark-up.

When completing a PB11a form:

The list price is the price to pharmacist for the listed pack size not the maximum quantity that is dispensed. The price to wholesaler is the list price ÷ 1.0752 because the wholesalers mark-up, up to and including $930.06 is 7.52%. For amounts over $930.06, a flat fee of $69.94 is applied.

Example:

Price to pharmacist ÷ 1.0752 = price to wholesaler (ex-manufacturer)

$20.00 ÷ 1.0752 = $18.60

Price to wholesaler x 1.0752 = price to pharmacist

$18.60 x 1.0752 = $20.00

Example:

Price to pharmacist - $69.94 = price to wholesaler (ex-manufacturer)

$1500.00 - $69.94 = $1430.06

Price to wholesaler + $69.94 = price to pharmacist

$1430.06 + $69.94 = $1500.00

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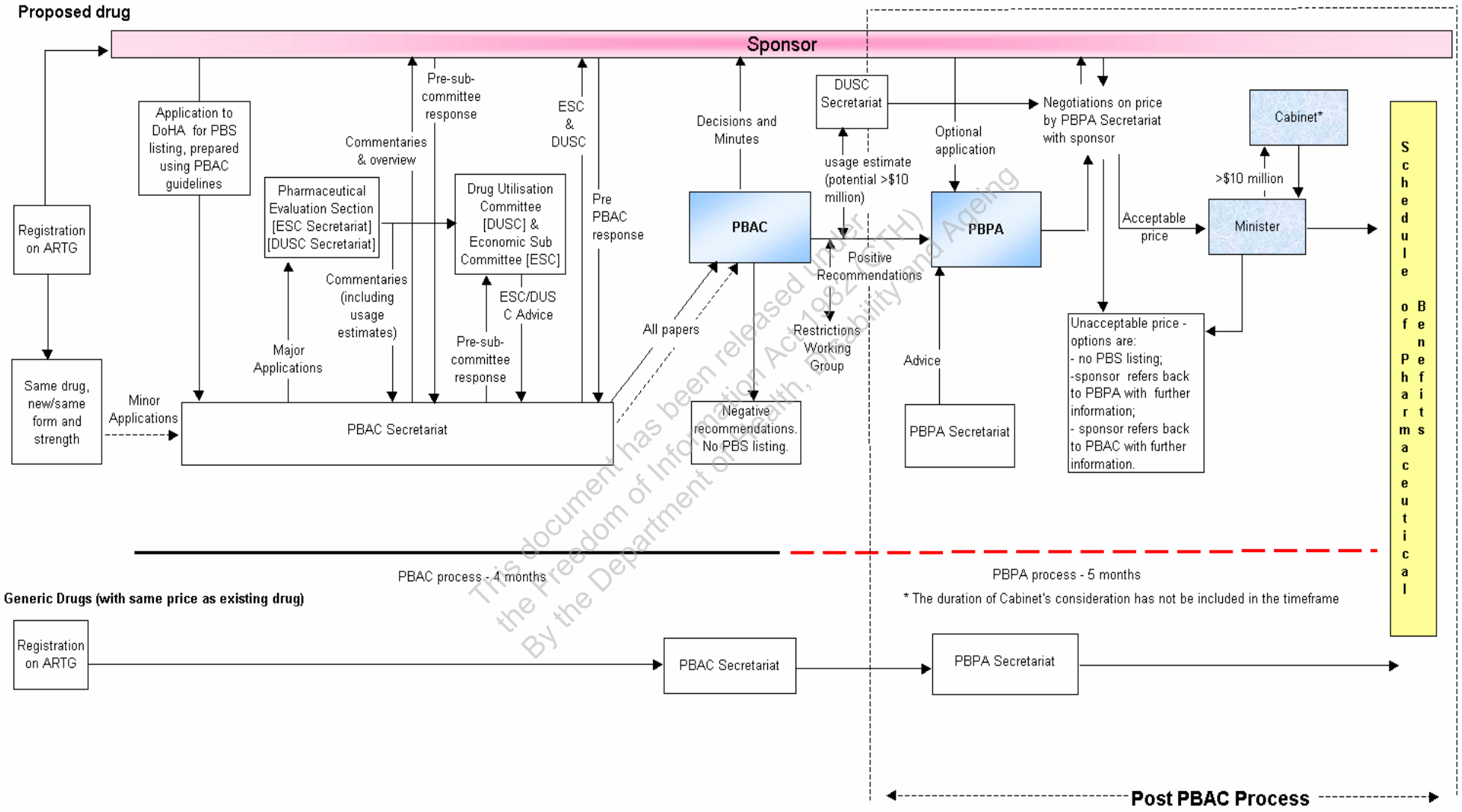
ATTACHMENT D

Process to gain PBS listing for registered drugs



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ATTACHMENT E

Fourth Community Pharmacy Agreement[3]
New dispensing fees, mark-ups and handling fees

From 1 July 2007 – 31 July 2008 the following pharmacist mark-ups and dispensing fees and wholesaler mark-ups apply.

Type of Payment	Basis of Payment	Date of Effect	Value
Wholesale mark-up[4]	(mark- up on ex-manufacturer's price)		
	Up to and including $930.06	1 July 2006	$7.52%
	Over $930.06		$69.94
Pharmacy Mark-up	(mark-up on Approved Price to Pharmacist)[5]		
	Up to and including $180.00	1 July 2006	10.0%
	Between $180.01and $450.00		$18.00
	Between $450.01and $1000.00		4.0%
	Over $1000 00		$40.00
Dispensing Fee (Ready Prepared)		1 July 2007	$5.32
Dispensing Fee (Ready Prepared)		1 August 2007	$5.44
Special Handling Fees[6]	Dangerous drug	1 July 2006	$2.71
	Extemporaneously prepared		$2.04

From 1 August 2008 the following pharmacist mark-ups and dispensing fees will apply.

Type of Payment	Basis of Payment	Date of Effect	Value
Pharmacy Mark-up	(mark-up on Approved Price to Pharmacist)		
	Up to and including $30.00	1 August 2008	15%
	Between $30.01 and $45.00		$4.50
	Between $45.01 and $180.00		10%
	Between $180.01 and $450.00		$18.00
	Between $450.01 and $1750.00		4%
	Over $1750.00		$70.00
Dispensing Fee (Ready Prepared)		1 August 2008	$5.99

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[3] The Fourth Community Pharmacy Agreement includes other payments and incentives not included in this table. For further information refer to http://www.health.gov.au/internet/main/publishing.nsf/Content/pharmacy-4cpa2

[4] Wholesale mark-up are fixed for the life of the Fourth Community Pharmacy Agreement, until 30 June 2010.

[5] Pharmacy mark-up was restructured effective 1 August 2008.

[6] Special Handling Fees remain the same for the life of the Fourth Community Pharmacy Agreement, until 30 June 2010.

ATTACHMENT F

FURTHER INFORMATION IN RELATION TO PBS REFORM

1. Formularies

Since 1 August 2007, drugs on the PBS, except those in single brand combination items, are included in separate formularies:

a) Formulary 1 (F1) which comprises drugs with only a single brand;
b) Formulary 2 (F2) comprising drugs with multiple brands and single brand drugs that are in a Therapeutic Group with a drug that has multiple brands.

For a transitional period, from 1 August 2007 until 31 December 2010, F2 will be divided into two parts: F2T and F2A. On 1 January 2011, F2T and F2A will be merged into a single formulary – F2.

The separation of drugs into F1 and F2 allows the Commonwealth Government to pay competitive prices for multiple brand drugs without affecting the viability of single-brand drugs that do not operate in a competitive market. This is achieved through de-linking the prices of drugs in F1 from the prices of drugs in F2 and then applying statutory price reductions to drugs in F2. In addition, drugs in F2 may be subject to price disclosure. http://www.health.gov.au/internet/main/publishing.nsf/Content/pharmaceutical-benefits-scheme-price-disclosure

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Since 1 August 2007, price links exist between:

a) drugs in F1 where the drugs are in the same Reference Pricing Group or Therapeutic Group;
b) drugs in F2 that are members of a Therapeutic Group;
c) drugs listed on the Combination Drugs List and the individually listed component drugs (which may be in F1 or F2).

Formularies will affect the ongoing pricing arrangements for drugs once they are listed. However, the formularies are not intended to alter the current price setting practices for the listing of new drugs/items or extensions to listings. Consequently, comparators for an F1 drug may be in F2 and vice versa.

In order to meet the requirements of the above policies, the Reference Pricing Group document which groups drugs whose prices are linked has been amended to contain only drugs in F1 or drugs on the Combination Drugs List.

Drugs, not items, are listed on a formulary. A drug can only be allocated to one formulary at any one time and therefore, all brands of all items containing the drug must be on the same formulary. If a drug moves from F1 to F2, it means that all brands of items containing that drug are considered to be in F2 and will be affected by the relevant statutory price reductions unless they are specifically exempted.

Exceptions to the allocation of single or multi-branded drugs to their respective formularies as mentioned above may apply for:

a) co-marketed brands (which are included in F1 while the brands meet the co-marketing criteria specified in the legislation)

b) single-brand combination drugs (which are included in the Combination Drugs List rather than in a formulary (F1 or F2), while they remain single-branded)

c) Therapeutic Group drugs (single-brand drugs in a Therapeutic Group are allocated to F2 if the group contains one or more drugs with multiple brands.

The listing of a new brand that is bioequivalent to an existing brand of an F1 drug will trigger a move of that drug from F1 to F2 (F2A prior to 1 Jan 2011, or if the drug is in a therapeutic group with a drug already on F2T it will go into F2T). There are no exceptions.

When a drug that is a member of an existing Therapeutic Group moves from F1 to F2, all other drugs in that Therapeutic Group also move to F2.

Drugs in F2 cannot move back to F1, even if circumstances change and the drug now satisfies the criteria for F1. The only exception is where a guaranteed brand has been delisted as a result of failure to supply during the guarantee period, its original listing triggered a move of that drug from F1 to F2, and the drug otherwise meets the F1 criteria. In this circumstance, the Minister may move a drug from F2 to F1. If the drug is in a Therapeutic Group, all other drugs in the Group may also be moved into F1.

In addition, a drug cannot move from F2T into F2A or F2A into F2T.

The Department will publish the names of drugs on the formularies on its website and update the list monthly to reflect those drugs listed on the latest version of the Schedule of Pharmaceutical Benefits.

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2. Co-marketed brands

The legislation allows brands that are determined to be co-marketed to be treated as one brand and therefore, the drug contained in the co-marketed brands will be allocated to F1 rather than F2.

This provision was included in the legislation to ensure that two or more responsible persons who made a global business decision to jointly develop and market a drug are not disadvantaged when they market their drug in Australia. Such arrangements are relatively rare.

The Minister may determine that two or more brands are co-marketed if they meet criteria outlined in section 84AE of the Act (see http://www.health.gov.au/internet/main/publishing.nsf/Content/pharmaceutical-benefits-scheme-price-disclosure).

Co-marketed brands in existence at 1 August 2007 were grandfathered by being prescribed in the Regulations based on information provided during the PBS Reform negotiation process.

3. Statutory price reductions

Overview

Legislation mandates that, other than exempt items, price reductions of the following percentages apply to brands of items containing drugs in F2:

- 12.5%
- 2%
- 25 %

The key differences between the 12.5% reductions and the 2% and 25% reductions are:

- A 12.5% reduction is triggered by the listing of a bioequivalent brand of a pharmaceutical item containing the drug, whereas the 2% reduction and 25% reduction occurs as a result of the formulary allocation of a drug on a certain date;

- A 12.5% reduction does not necessarily apply to all items of a drug, whereas the 2% and 25% reductions apply to all items, unless determined by the Minister to meet exempt item criteria;

- A 12.5% reduction is applied once only but will be a relevant consideration on an on-going basis.

Common requirements for the three statutory price reductions applying to existing brands of pharmaceutical items are:

- they are deemed to occur on a certain date unless a reduction that is greater than the percentage required by the legislation is accepted by the Minister or unless the drug is a combination drug;
- deemed reductions are applied to the approved price to pharmacist and the claimed price (if there is one) that is in place the day prior to the reduction day;
- they do not apply to items that are determined to be exempt;
- they do not apply if a reduction arising from price disclosure is due to occur on the same day, providing the reduction arising from disclosure is greater than that required for the statutory price reduction;
- a brand that offers a price reduction that is greater than the statutory percentage and whose offer forms the basis of the new agreed price for the item must agree a price i.e. they cannot have a determined price.

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A deemed statutory price reduction occurs where the approved price to pharmacist and the claimed price (if any) reduces by the legislated percentage. Therefore, agreed prices or determined and claimed prices prior to the reduction day will become ‘deemed agreed’ or ‘deemed determined’ and ‘deemed claimed’ following the reduction.

The exception to this, where a price reduction may be negotiated, rather than deemed, is when a reduction that is greater than the legislated percentage is accepted by the Minister. For example, reducing the price of an item that has an approved price to pharmacist of $3.00 by 2% or 2.1% results in the same approved price i.e. $2.94. Therefore, reducing the price by 2.1% is not sufficient to enable the reductions to be negotiated.

If prices are negotiated, brands may move from a determined and claimed price to an agreed price or from an agreed price to a determined and claimed price. In the latter case, there is no legislative limit on the size of the claimed price (which forms the basis of the Responsible person’s Commonwealth price for that brand and thus the special patient contribution). However, one of the considerations that may be taken into account by the Minister when deciding whether to determine a price and a claimed price in this situation is the

commitments given to Parliament that the Reforms will not increase the special patient contributions that will be paid by patients.

12.5% statutory price reduction

Between 1 August 2005 and 1 August 2007, 12.5% reductions were applied administratively by forming one of the considerations for the price the Minister would agree or determine in relation to a brand of a pharmaceutical item. Therefore, there may be drugs in F2 that have not yet been affected by a 12.5% reduction and there may be F1 drugs that have been affected by a 12.5% reduction because of the way that the 12.5% policy operated prior to 1 August 2007.

Since 1 August 2007, most 12.5% reductions are statutory. The legislation requires that:

- a new brand that is bioequivalent to, and has the same manner of administration as, an already listed brand must list at a price that is 12.5% lower than the agreed price for the existing brand unless a 12.5% reduction has already occurred in certain circumstances;
- the 12.5% reduction is then flowed on to other brands of items containing that drug which have the same manner of administration as the new brand;
- if the drug in the new brand is in a Therapeutic Group, the reduction also flows on to items containing other drugs in the Group that have the same manner of administration as the new brand.

A 12.5% reduction will not be triggered by the new brand if:

- a 12.5% reduction has previously applied to another brand of the existing item; or
- a 12.5% reduction has previously applied to another item that has the same drug and manner of administration as the new brand; or
- the drug in the new brand is in a Therapeutic Group and a 12.5% reduction has previously applied to another item containing another drug in the Therapeutic Group with the same manner of administration as the new brand.

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A drug listed after 1 August 2007 on a cost-minimisation basis against another drug with brands affected by a 12.5% reduction will in effect be listing at a price that is 12.5% lower than it would otherwise have been. However, the legislation does not consider this new drug as having been subject to a 12.5% reduction.

The legislation does not allow a 12.5% reduction to be reversed under any circumstances. The legislation does permit the Minister to make further agreements and determinations in relation to the price of the brand of pharmaceutical item on a day after the reduction day.

The price of a brand may be increased by the Minister as a consequence of the delisting of another brand that failed to meet its Guarantee of Supply commitments. In addition, the Minister may determine that a 12.5% reduction has not applied to the pharmaceutical item. This is so, even if the increase in price does not restore the price of the brand to the pre-12.5% reduction level. This ensures that if a new brand subsequently lists, the 12.5% reduction can be re-triggered.

2% statutory price reduction

2% statutory price reductions apply to all brands of drugs listed in F2A on each of the following dates:

- 1 August 2008;
- 1 August 2009; and
- 1 August 2010.

Drugs listed in F2A on each of the above dates receive a 2% price reduction. Brands of items are exempt from a 2% reduction due that year if:

- a 12.5% reduction has been applied to those items on 1 April of that year;
- a 12.5% reduction will apply to those items on 1 August of that year;
- a reduction arising from price disclosure is due to occur on the same day;
- a reduction arising from price disclosure occurred in the past.

See Attachment F, section 4 (below) for further explanation on exempt items.

The 2% reduction will still be applied in that year to all items that have not had a 12.5% reduction because they have a different manner of administration to the items affected by the 12.5% reduction. Thereafter, any remaining 2% reduction scheduled will be applied to all items containing that drug.

The 2% reduction will still be applied in that year to all items that have not had a reduction arising from price disclosure because they have a different manner of administration to the items affected by the disclosure-based reduction.

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25% statutory price reduction

A 25% reduction applied to all brands of drugs in F2T on 1 August 2008. However, how the reductions were applied depended on whether the drug was multi-branded or single-branded.

A single 25% reduction applied to all multi-brands of drugs listed in F2T on 1 August 2008 only. The reduction occurred to the approved price to pharmacist and the claimed price (if any) in place on 31 July 2008.

For the five single-brand drugs listed on F2T, it was agreed that the 25% reduction would be phased-in over a number of years. For these five drugs, lercanidipine, esomeprazole, lansoprazole, pantoprazole and rabeprazole, the actual amounts to be subtracted from the price to pharmacist is specified through the combined effect of Section 99ACK of the *National Health Act 1953* and the *National Health (Pharmaceutical Benefits) Regulations 1960*.

Unlike the 2% reduction, legislation required that a 25% reduction be applied to brands of drugs scheduled to have a 12.5% reduction on 1 August 2008.

4. Exempt items

The legislation quarantines certain items containing drugs in F2 from the statutory price reductions (and price disclosure requirements) by making them ‘exempt items’.

Exempt items for 1 August 2007 were determined by the Minister following receipt of PBAC advice.

Responsible persons with drugs in F2 may pursue PBAC consideration of items not already on the exemptions list with the PBAC Secretariat.

Once a new bioequivalent brand of the exempt item is listed, the item is removed from the exemptions list and a 12.5% reduction is triggered.

Once the item is removed from the exemptions list, it will be subject to any remaining reductions applying to the F2 drug, in accordance with the rules relevant to the formulary.

A copy of the exempt items list will be published at www.health.gov.au.

5. Single-brand combination drugs

The legislation excludes single-brand combination drugs from being listed in a formulary and therefore, these drugs are grouped together on an administrative list called the Combination Drugs List (CDL).

The CDL was created to support a Commonwealth decision that the price of single-brand combination drugs should remain linked to that of the individual components until the combination becomes multi-branded. Such price links could not be maintained if single-brand combination drugs were included in F1 or F2.

As with the formularies, drugs, not items, are listed on the CDL. When a second bioequivalent brand containing the combination drug is listed, the combination drug moves to F2.

The Department will publish the names of drugs on the CDL on its website and update the list monthly to reflect those drugs listed on the latest version of the Schedule of Pharmaceutical Benefits.

While a drug is listed on the CDL a12.5%, 2%, 25% or price-disclosure reduction applying to any of the component drugs will be taken into account when arriving at an agreed price for the brands of pharmaceutical items containing the combination drug.

A price reduction to the brand of combination item containing the combination drug would apply to the proportion of the approved price to pharmacist represented by the component drug whose price has been reduced (adjusted for any differences in the quantities).

If a 12.5% reduction applies to items containing an individually listed drug, that reduction will be taken into account when the Minister considers flowing on the price reduction to all combination items containing the component drug, irrespective of whether the brand that triggered a 12.5% reduction for the individually listed drug has a different manner of administration to the combination items containing the component drug.

There is scope for the Minister not to flow on the full reduction required to a component drug in a single-brand combination item if he/she receives certain advice from the PBAC. In such instances, the Minister may determine that only a partial price reduction or even no price reduction should flow on to the component drug in the combination item. If the PBAC advises that a combination item does offer benefits over the alternative, the Minister will consider the extent, if any, to which the 12.5% reduction should be applied.

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Alternatively, if there is no PBAC advice, the legislation requires that the Minister must take the price reduction in the component drug into account when agreeing a price for the single brand combination item.

6. Responsible person

The responsible person is the person (which may be a corporation) determined by the Minister that is, or will be, the supplier of a particular brand of a drug to wholesalers, or in cases where no wholesalers are involved, to approved pharmacists directly. The responsible person must be the same for all pharmaceutical benefits supplied under a particular brand.

Since 1 August 2007, legislative provisions place obligations on the responsible person in relation to price disclosure and Guarantee of Supply, and it is the person with whom pricing negotiations occur. Therefore, any changes to responsible person details should be advised to the Department as soon as they are known. This will allow the Department to make the required changes in a timely manner.

7. Therapeutic groups

The 'Therapeutic Groups' described in the legislation are the same as the previous 'TGP' groups. They contain drugs with the same therapeutic action that the PBAC has advised are interchangeable at the individual patient level and are grouped together for pricing purposes because they provide the same health outcome.

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Consequently, in the legislation, the drugs in a Therapeutic Group are grouped together on the same formulary and their prices remain linked (even if they are in F2) until a reduction arising from price disclosure applies to a brand of a drug in the Therapeutic Group. At this point, the drug affected by the reduction is removed from the Therapeutic Group so that the price reduction does not flow on to the drugs remaining in the Therapeutic Group.

The effect of the provisions in the legislation is to treat drugs in a Therapeutic Group as one drug for formulary allocation purposes and movements between formularies. The legislation also ensures that new drugs added to an existing Therapeutic Group are given the same formulary allocation as the other drugs in the Therapeutic Group. Therefore, some single-brand drugs may be included in F2 if another drug in the Therapeutic Group has multiple brands.

The legislation requires the Minister to obtain advice from the PBAC in order to create a new Therapeutic Group which may or may not be comprised of combination drugs. The Minister may also seek advice from the PBAC in order to change the membership of a Therapeutic Group.

8. Guarantee of Supply

Since 1 August 2007, a responsible person for a guaranteed brand must supply that brand for a guaranteed period, even if the listing circumstances of that brand change, such as being subject to a price reduction.

During the guaranteed period, responsible persons will be required to notify the Minister if they form the belief that they will fail to supply or will be unable to supply, or if they actually fail to supply or are unable to supply. There are criminal penalties for failing to comply with

the notification requirements. The guarantee of supply period for the guaranteed brand of the pharmaceutical item will be up to 24 months from the date of listing.

The Guarantee of Supply (GoS) provisions are intended to deter responsible persons from supplying without a viable business model able to support their long-term participation in the market as this causes disruption to patients, prescribers, pharmacists, wholesalers, and other responsible persons.

GoS requirements apply to:

- new brands that are bioequivalent to an existing brand; and
- existing brands of F2 drugs offering agreed price reductions.

Responsible persons will be advised by the Department, at the time of listing a brand, whether the brand is subject to GoS requirements. They will also be advised if the guarantee period ceases before the 24 months have elapsed.

Failure to supply occurs when a responsible person fails to supply the guaranteed brand if they are requested to supply by a wholesaler or pharmacist and they do not do so within a reasonable period after receiving the request.

Inability to supply occurs where a responsible person for a guaranteed brand would be unable to supply any amount of the guaranteed brand within a reasonable period of being requested, on that day, by a wholesaler or pharmacist to supply the guaranteed brand.

Responsible persons must notify the Minister as soon as practicable, if they form the belief that they will fail or will be unable to supply or if they actually have failed or have been unable to supply a guaranteed brand during the guarantee period.

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ATTACHMENT G

CALCULATIONS AND DEFINITIONS IN RELATION TO PBS REFORM

Interaction of 2% reductions and other reductions for F2A drugs

The following tables show if a 2% price reduction applies to F2A drugs in various scenarios.

Table 1: F2A New Brands with a 12.5% price reduction at the time of listing

Listing start date (with 12.5% reduction)	2% price reduction 1 August 2008	2% price reduction 1 August 2009	2% price reduction 1 August 2010	Potential disclosure reduction from the following dates
1 Aug 2007	yes	yes	yes	1 Aug 2009
1 Dec 2007	yes	yes	yes	1 April 2010
1 Apr 2008	no	yes	yes	1 April 2010
1 Aug 2008	no	yes	yes	1 Aug 2010
1 Dec 2008	not applicable	yes	yes	1 April 2011
1 April 2009	not applicable	no	yes	1 April 2011
1 Aug 2009	not applicable	no	yes	1 Aug 2011
1 Dec 2009	not applicable	not applicable	yes	1 April 2012
1 April 2010	not applicable	not applicable	no	1 April 2012
1 Aug 2010	not applicable	not applicable	no	1 Aug 2012
1 Dec 2010	not applicable	not applicable	not applicable	1 April 2013

Table 2: F2A New Brands with a price reduction offer at the time of listing

Listing start date (where a price reduction offer additional to the mandatory reductions has been made)	2% price reduction 1 August 2008	2% reduction price reduction 1 August 2009	2% price reduction 1 August 2010	Potential disclosure reduction from the following dates
1 Aug 2007	yes	yes	yes	1 Aug 2009
1 Dec 2007	yes	yes	yes	1 April 2010
1 Apr 2008	yes	yes	yes	1 April 2010
1 Aug 2008	yes	yes	yes	1 Aug 2010
1 Dec 2008	not applicable	yes	yes	1 April 2011
1 April 2009	not applicable	yes	yes	1 April 2011
1 Aug 2009	not applicable	yes	yes	1 Aug 20011
1 Dec 2009	not applicable	not applicable	yes	1 April 2012
1 April 2010	not applicable	not applicable	yes	1 April 2012
1 Aug 2010	not applicable	not applicable	yes	1 Aug 2012
1 Dec 2010	not applicable	not applicable	not applicable	1 April 2013

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cont

Table 3: All other F2A New Brands with no price change at the time of listing.

Listing start date (with no price reductions)*	2% price reduction 1 August 2008	2% reduction price reduction 1 August 2009	2% price reduction 1 August 2010	Potential disclosure reduction from
Aug 2007	yes	yes	yes	1 Aug 2009
Sept 2007 to Jul 2008	yes	yes	yes	1 April 2010
Aug 2008	yes	yes	yes	1 Aug 2010
Sept 2008 to Mar 2009	not applicable	yes	yes	1 April 2011
Apr 2009 to Jul 2009	not applicable	yes	yes	1 April 2011
Aug 2009	not applicable	yes	yes	1 Aug 2011
Sep 2009 to Nov 2009	not applicable	not applicable	yes	1 Aug 2011
Dec 2009 to Jul 2010	not applicable	not applicable	yes	1 April 2012
Aug 2010	not applicable	not applicable	yes	1 Aug 2012
Sep 2010 to Nov 2010	not applicable	not applicable	not applicable	1 Aug 2012
Dec 2010 to Jul 2010	not applicable	not applicable	not applicable	1 April 2013

*Date ranges are best estimates and may be subject to slight variation

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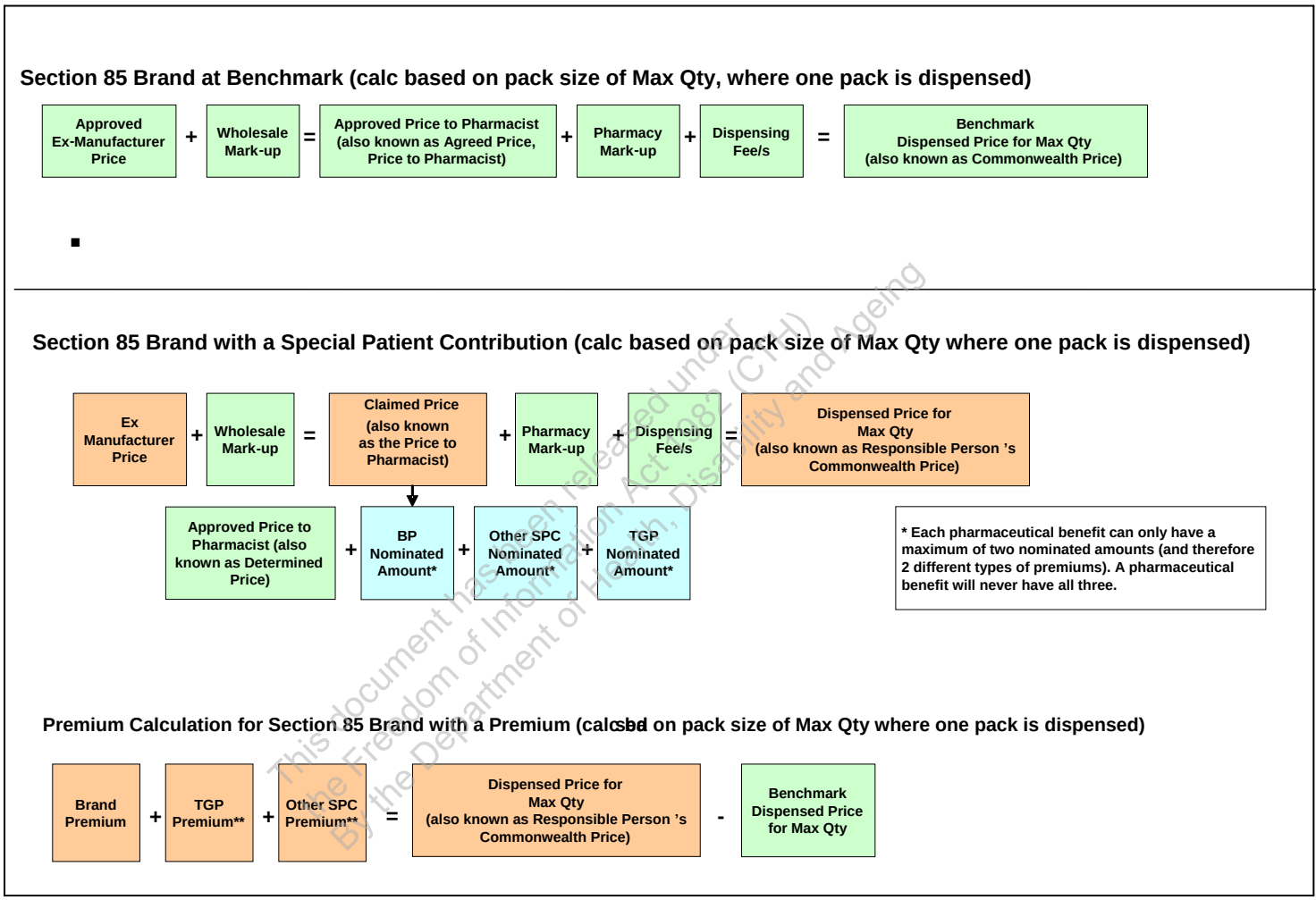
Attachment G part 2

Components of pricing calculations and definitions

The diagram below shows the interaction of the various components of the pricing calculations when the pack size corresponds to the maximum quantity. The definitions of each of the components are provided in the Glossary.



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Attachment G part 3

Application of statutory price reductions (SPR) to single-brand combination drugs

Scenario 1 – 2% SPR to drug A which is a component of Drug C

- Combination Drug C contains Drug A and Drug B.
- The item containing drug A (in the same form and quantity as in the combination) has an approved price to pharmacist (APP) of $30.
- The item containing drug B (in the same form and quantity as in the combination) has an APP of $30.
- The APP of combination item C is $100 (not $60) and is therefore not based on the sum of the APPs of its component drugs (drugs A and B).

Where it is flowed on, the 2% reduction flows on to the portion of the approved price to pharmacist that is attributed to drug A in combination item C. In this case 50% of $100 is attributed to drug A so the 2% reduction applies to $50. The new approved price to pharmacist for a combination item with the 2% reduction flowed on would be calculated as follows: ($50 x 98%) + 50 = $99

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Fact sheet – Setting an approved ex-manufacturer price for new or extended listings

Page la t updated 25 July 2017

Making a price agreement or determination

Price negotiations with the responsible person for new or changed listings are undertaken by the Pricing Section on behalf of the Minister, following a positive PBAC recommendation A Cost Inform (PB11b) form is required to be submitted by the responsible person as part of the initial application to the PBAC

After a price has been negotiated, the responsible person is requested to submit a Request for Approved Ex manufacturer Price (PB11a) form in order to formalise the price offer The responsible pe is then notified by email when the Minister has formally agreed to the negotiated price

Pricing methods used

Cost plus method

The cost plus method is most commonly used in the case of stand alone products, those recommended on the basis of acceptable cost effectiveness and where no specific relativity exists, or when recommending a benchmark price for a therapeutic group

In these cases a gross margin may be granted based on the cost of manufacture This margin can vary and is determined on a case by case basis A margin on costs of around 30% is usually consi reasonable for new drug listings, but higher margins may be recommended for low volume products and lower ones may be recommended for high volume products

The cost plus method relies on responsible persons' cost information (usually presented on a PB11b form) which provides for a detailed breakdown of the manufacturing costs including landed cost, packaging, drug content, quality assurance, plant and equipment, manufacturing overheads and Therapeutic Goods Administration (TGA) fees

Reference pricing

Reference pricing is a Government pricing policy which applies where drugs considered to be of similar safety and efficacy for pricing purposes are linked, and recommended by the PBAC as cost-minimised. The lowest priced brand or drug sets a benchmark price for either the other brands of that drug or the other drugs within the same sub-group of therapeutically related drugs. Pricing withi these sub-groups is based on the therapeutic relativities between drugs. Those relativities may be direct or indirect (for example, in the case of combination products, they may be based on relativitie between drug components).

Reference pricing applies to drugs in F1, single brand combination products on the Combination Drug List and to drugs in Therapeutic Groups regardless of formulary, but not to other drugs in F2.

For new drugs being considered by the PBAC for listing on the PBS comparators for pricing purposes may be in either formulary.

Pricing of new strengths of existing items

For new strengths of already listed drugs, as a general rule, the pricing of half strength formulations is at two-thirds to 70% of the full strength. For example, a new 10 mg tablet would be priced at ab two-thirds of the existing 20 mg tablet. Likewise, a double strength is usually one and two-thirds of the single strength. There are no general guidelines for other ratios.

These guidelines do not apply in all cases, for example if there is 'flat' pricing or for expensive drugs where history indicates pricing of the different strengths is based on the same price per unit (or m gram).

Weighted Pricing

For a small number of drugs with multiple indications, each indication may have an indication-specific price which relates to its cost-effectiveness for the eligible patient population. The indication-spe price is usually different (i.e. higher or lower) from the published price. In this case, it is usual practice to employ a weighted pricing methodology to fulfil the requirements of the *National Health Act 19* have a single published list price per pharmaceutical item. This generally involves applying a weighting to each indication-specific price and then adding these prices together in order to arrive at a s weighted price.

The weightings represent the estimated proportion of drug utilisation for each indication. These weightings are generally based on Medicare Australia (Services or Benefits) data for the particular indication over a dispensing period. For new indications with less than 12 months of Medicare data, it is usual practice to use the projected utilisation estimates accepted by the PBAC.

The published price may be re-calculated prior to PBS listing of each new indication, as appropriate and any indications subject to a Special Pricing Arrangement (SPA) are included in the weighted p calculation at the unrebated indication-specific price.

The indication-specific price continues to exist and is the price used in any future indication-specific reference pricing actions. This price will be shared with any new sponsor upon a positive PBAC recommendation.

For example, consider Drug X listed currently for Indication I at a published price (AEMP) of $100.000. A new indication, Indication II, has been recommended for listing, at an indication-specific price (AEMP) of $75.00. At the time of its listing, the projected annual expenditure for Indication II is $15,000,000, while the average annual expenditure based on Medicare Benefits for Indication I is estim to be $10,000,000. The following steps show how a weighted price may be calculated.

Step 1

Calculate total annual expenditure for Drug X across all indications:

Indication	***Average annual expenditure***
I	*$10,000,000.00*

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Indication	*Average annual expenditure*
*II**	*$15,000,000.00*
Total	*$25,000,000.00*

**projected annual expenditure*

Step 2

Work out the weighting for each indication, based on its percentage proportion of expenditure as follows:

- *Indication I:*
  *(10,000,000/25,000,000)*100 = 40%*
- *Indication II:*
  *(15,000,000/25,000,000)*100 = 60%*

Step 3

Apply the weighting worked out in Step 2 to the indication-specific prices (AEMP) for Drug X as follows:

- *Indication I: $100 x 40% = $40*
- *Indication II: $75 x 60% = $45*

Step 4

Add the resulting prices in Step 3 to arrive at a weighted price across all indications:

- *Indication I: $40*
- *Indication II: $45*
- *Total: $85*

The weighted price of $85 (AEMP) will become the basis for the published price of Drug X on the PBS

In the event of a new product seeking reimbursement for Indication I on a cost-minimisation basis, the price of $100 will be the resultant price for the new product.

In the event of a new product seeking reimbursement for Indication II on a cost-minimisation basis, the price of $75 will be the resultant price for the new product.

Pricing of combination products

A combination product is a product that is made up of more than one active moiety. The approved ex-manufacturer price of combination products where both or all components are PBS listed is usua but not always, based on the sum of the approved ex-manufacturer prices of the individual components at the time of listing (in accordance with PBAC guidelines). Advice from the PBAC in relation t cost-effectiveness and relativity is also taken into account. For example, the combination tablet containing enalapril maleate 20 mg plus hydrochlorothiazide 6 mg was recommended on a cost minimisation basis compared with enalapril maleate 20 mg and hydrochlorothiazide 12.5 mg as individual items, and the combination products containing the drug fluticasone with vilanterol were recommended on a cost-minimisation basis with the combination products containing the drug fluticasone with salmeterol.

Where a new combination product contains a formulation where one component is not represented by an actual listed strength, the guidelines applying to new strengths of listed drugs may be invoke order to work out a theoretical component price. For example, where the new combination product has a 100 mg – 2.5 mg formulation, but the listed component drugs are 100 mg and 5 mg, the pric the new combination product might be the sum of the approved ex man price for the 100 mg component drug and two-thirds of the approved ex-man price for the 5 mg component drug.

Single brand combination products where at least one drug in the combination is PBS listed, are not included in F1 or F2, but are set out in an administrative list, the Combination Drug List (CDL).

Changes to the price of one or more of the component drugs are generally 'flowed on' to the price of the relevant combination drug:

- *for drugs on the CDL* – the flow-on occurs under section 99ACCC of the *National Health Act 1953* (the Act). This applies for the 16% 'first new brand' reduction and other statutory price reductions, including price disclosure. For more information about flow-on of F1 5% Statutory Price Reductions commencing 1 April 2016 please see the Fact Sheet. Drugs on the CDL are als generally subject to administrative reference pricing, but any F1 5% flow on reductions are not being reference priced.
- *for drugs on F2* – the flow-on of price disclosure reductions occurs under section 99ADHB of the Act. For more information about flow-on of price reductions to F2 combination items, please s the 2015 Price Disclosure Changes – Fact Sheet. Drugs on F2 are not subject to administrative reference pricing.

If the combination product has PBAC advice on significant improvement over alternative therapies under s101(4AC) of the Act, there is a discretion not to flow on the statutory price reduction.

Factors considered by the Pricing Section in making a recommendation to the Minister

In considering the price of items recommended for listing and in reviewing the price of items already listed on the PBS, the Pricing Section takes account of the following factors:

(a) PBAC advice on clinical and cost-effectiveness;

(b) prices of alternative brands;

(c) comparative prices of items containing drugs in the same Anatomical Therapeutic Chemical (ATC) groups;

(d) cost information provided by the responsible person;

(e) prescription volumes, economies of scale, special storage requirements, product stability, special arrangements;

(f) prices of items containing the drug in reasonably comparable overseas countries;

(g) other factors the applicant may wish the Pricing Section to consider;

(h) any directions of the Minister.

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