PHARMACEUTICAL BENEFITS

PRICING AUTHORITY

POLICIES, PROCEDURES AND METHODS

USED IN THE RECOMMENDATIONS FOR PRICING OF PHARMACEUTICAL PRODUCTS

April 2009

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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).

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.

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.

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.

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.

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.

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).

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.

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.

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.

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*.

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.

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".

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.

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

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.

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:

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'.

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

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).

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.

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.

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).

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.

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.

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.

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;

- 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.

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

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.

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

*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

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].

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

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

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

($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.

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:

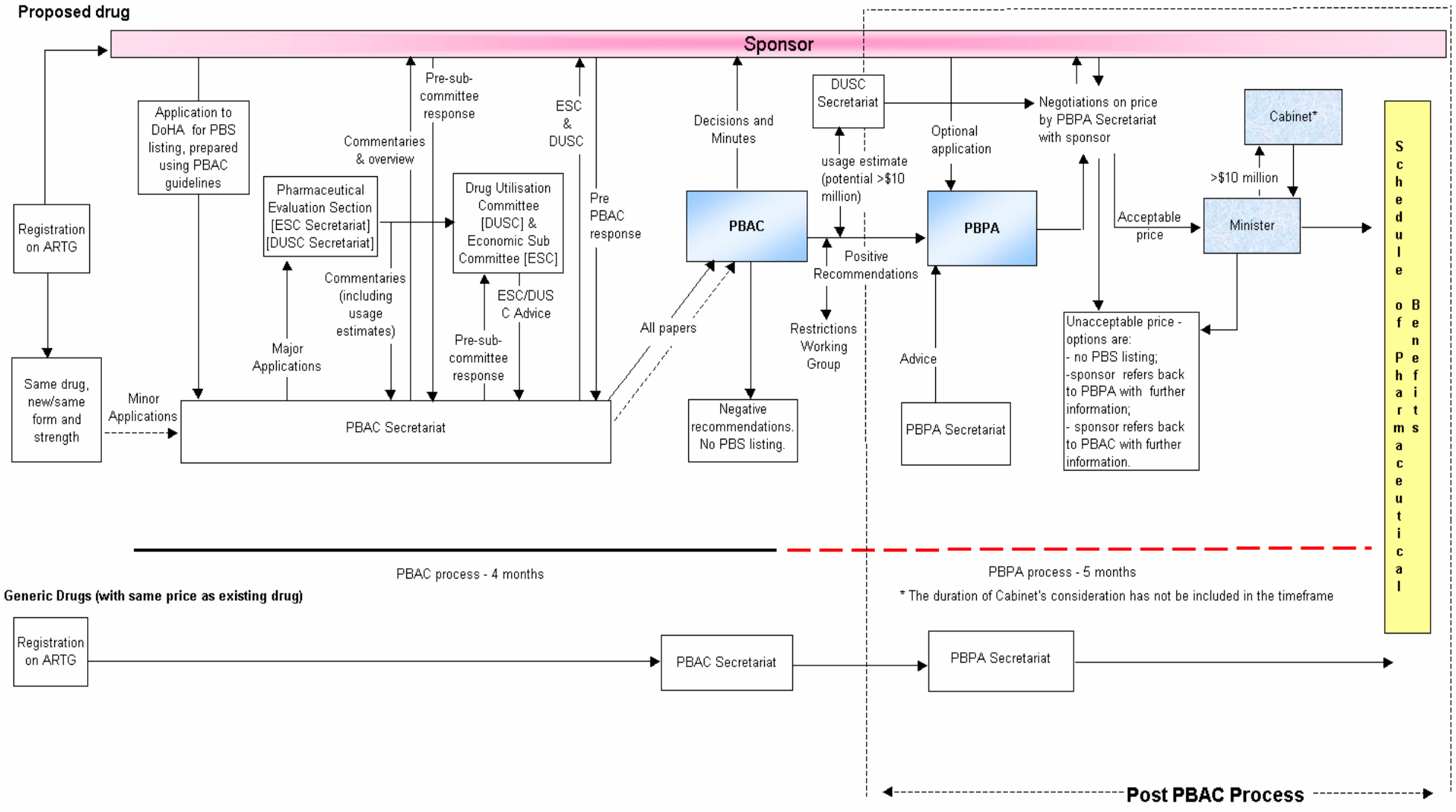
Price to pharmacist - $69.94 = price to wholesaler (ex-manufacturer)

$1500.00 - $69.94 = $1430.06

Price to wholesaler + $69.94 = price to pharmacist

$1430.06 + $69.94 = $1500.00

Process to gain PBS listing for registered drugs



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

[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

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.

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.

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.

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.

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.

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.

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.

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

cont

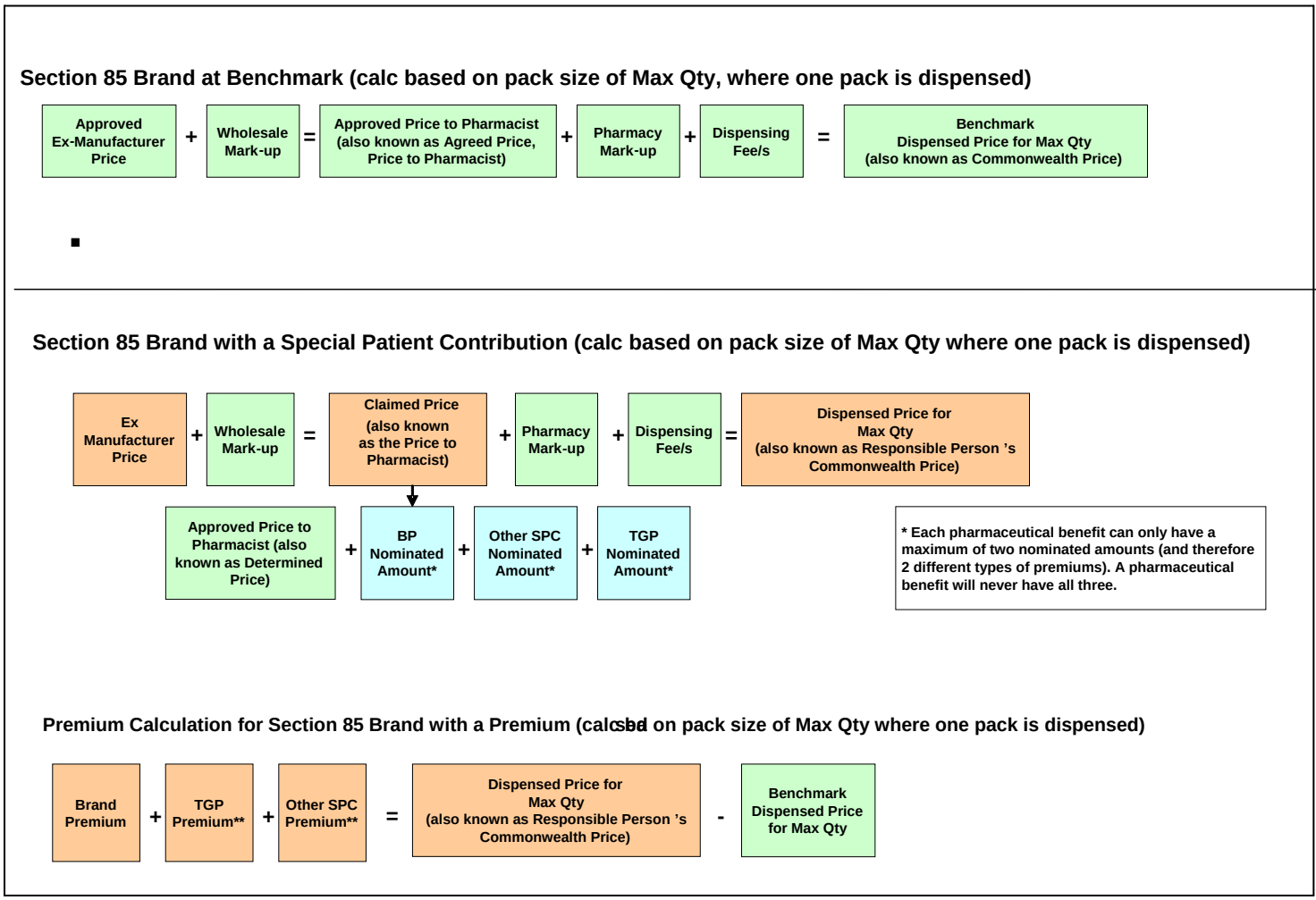
Table 3: All other F2A New Brands with no price change at the time of listing.

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.

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.



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