Generic Medicines Industry Association Pty Ltd

ABN 19 096 009 540

PO Box 222
Pymble BC
NSW 2073

Generic Medicines Industry Association

Submission to Finance and Public Affairs Senate Inquiry on the Government's administration of the Pharmaceutical Benefits Scheme (PBS)

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For further details
Please contact
Kate Lynch, CEO
kate.lynch@gmia.com.au

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Committee's Terms of Reference

On 23 June 2011 the Senate referred the following matter to the Finance and Public Administration References Committee for inquiry and report by 18 August 2011:

The Government's administration of the Pharmaceutical Benefits Scheme (PBS), with particular reference to:

(a) the deferral of listing medicines on the PBS that have been recommended by the Pharmaceutical Benefits Advisory Committee;

(b) any consequences for patients of such deferrals;

(c) any consequences for the pharmaceutical sector of such deferrals;

(d) any impacts on the future availability of medicines in the Australian market due to such deferrals;

(e) the criteria and advice used to determine medicines to be deferred;

(f) the financial impact on the Commonwealth Budget of deferring the listing of medicines;

(g) the consultation process prior to a deferral;

(h) compliance with the intent of the Memorandum of Understanding signed with Medicines Australia in May 2010; and

(i) any other related matter.

Submission

Members of the Generic Medicines Industry Association (GMiA) are concerned about the Federal Government's decision on 25 February 2011 to delay indefinitely PBS listings of several new medicines and vaccines on the Pharmaceutical Benefits Scheme (PBS) and to defer indefinitely the implementation of eight price increases recommended by the Pharmaceutical Benefits Pricing Authority (PBPA).

Deferral of PBS listing of new medicines that have been found to be highly cost-effective is denying the public access to important health benefits. Deferral of implementation of PBPA recommended price increases jeopardises the ongoing supply of essential medicines to patients.

Since 1993, every new product listed on the PBS has undergone rigorous, independent health economic assessment to ensure it is cost-effective to the nation. This means the price paid for each product reflects the health outcome it produces. Only medicines that are demonstrated to be highly cost-effective are recommended for listing on the PBS by the Government-appointed expert, independent Committee, the Pharmaceutical Benefits Advisory Committee (PBAC). The PBS is the most cost-effective element of the health care system in Australia.

The PBS subsidises essential medicines to ensure access to these medicines for all Australians and contributes greatly to the health and well-being of the nation. The economy can afford new medicines and Australians should not be denied access to medicines that have been demonstrated to be cost-effective. Of 24 reporting OECD nations, Australia has the third lowest spend on pharmaceuticals as a percentage of GDP.

The recent reforms to the PBS were designed to achieve greater value for money paid by the Commonwealth for medicines subject to competition, to create 'headroom' for PBS listing of new medicines. These reforms are contributing important savings to the Federal Budget, however the Government is not fully leveraging the savings opportunity stemming from the reforms.

GMiA urges the Government to realise fully the savings potential created by PBS reform. This will ensure that the PBS is sustainable and that the Government can fund new medicines that have demonstrated high cost-effectiveness. The need for Government to impose indefinite deferrals to new PBS listings and PBPA recommended price increases will be eradicated.

GMiA recommends that the Government address the following important areas **to ensure that Australians continue to have access to essential medicines through the PBS**:

1. Counter market strategies deployed by holders of intellectual property for PBS listed medicines that inappropriately impede the market entry of follow-on generic medicines;
2. Ensure sponsors have the opportunity to successfully obtain price increases for specific medicines granted under the rigorous PBPA review mechanism;
3. Direct new policies at doctors, pharmacists and consumers to ensure that further savings accrue to the Government from increased usage of follow-on generic medicines.

1. Market strategies that inappropriately impede market entry of follow-on generic medicines must be countered

Innovations that are novel, inventive and useful should be appropriately rewarded and the patent system is designed to do this. A patent is a set of exclusive rights granted to an inventor or their assignee for a limited period of time in exchange for the public disclosure of an invention.

A patent can be seen as social contract whereby a patentee discloses an invention to the public and in return receives a monopoly for a specified term to commercially exploit their invention. The patent system thus strives to achieve a balance between the competing requirements of having new technology disclosed to, and used by, the public, and the reward of term specific exclusive rights to patentees to solely benefit from their invention.

In Australia the Patents Act (Cwlth) 1990 provides the holder of a patent a period of market exclusivity for twenty (20) years. In certain circumstances, pharmaceutical patents can be extended for a period of up to five (5) years under the pharmaceutical patent extension provisions.

The holder of the pharmaceutical patent has 20 to 25 years of market exclusivity to recoup the investment made in discovering and commercialising the invention during which time the public misses out on the benefits that flow from market competition. After patent expiry, it is important the public realises the benefits stemming from competition - of more affordable pharmaceuticals - by ensuring the prompt and unimpeded market access of follow-on generic medicines.

Market strategies that inappropriately impede market entry of follow-on generic medicines result in the loss of substantial savings to the Government, the PBS, consumers, taxpayers and the generics industry, by preventing the commoditisation of medicines once the granted period of market exclusivity has expired.

Timely availability of follow-on generic medicines in Australia is threatened by a plethora of strategies used by the holder of pharmaceutical patents to extend the period of market exclusivity, which block and/or delay the triggering of important savings to the PBS. This has been exacerbated by the PBS reforms, which provide an even greater incentive to the patent holder to retain market exclusivity by blocking and/or delaying entry of follow-on generic medicines to the market.

There are several, current examples of these practices, which have resulted in the Government forgoing significant savings, that could be prevented by the judicious application of stated, and/or changes to, Government policy.

Recently the Government has intervened in the market to ensure that the legislative framework stays in step with market dynamics by addressing a loophole that was being exploited. The Therapeutic Goods Legislation Amendment (Copyright) Bill 2011, which was given Royal Assent on 27 May 2011, ensures initial brand sponsors can no longer use copyright on product information to block and/or delay follow-on generic medicines entering the market.

There is still more work for Government to do in addressing cases of inappropriate use of intellectual property rights in medicines. The Government must ensure that it is not possible for initial brand sponsors to engage in practices that inappropriately render the market inaccessible or commercially unviable to sponsors of follow-on generic medicines. Barriers to medicines entering the market through the inappropriate use of any intellectual property right impose a significant and unnecessary cost to the community.

The Australian legal infrastructure should:

i. appropriately balance protection of truly innovative medicines and simultaneously support challenge of potentially weak and invalid patents and other intellectual property;

ii. provide protection against unjustified attempts by a patent holder to use court proceedings to delay the entry to market of follow-on generic medicines;

iii. ensure the amendment to section 99ACB of the National Health Act that governs the statutory price reduction of 16% (previously 12.5%) does not have the 'unintended consequence' of impeding the ability of the sponsor of a follow-on generic medicine to list on the PBS while the court considers the validity of a patent; and

iv. ensure that the application of the five year patent term extension for pharmaceutical patents is appropriately applied to patents for pharmaceutical substances *per se* as required under section 70 of the Patents Act (Cwlth) 1990.

2. To ensure the ongoing supply of essential medicines through the PBS, sponsors must have the opportunity to successfully obtain price increases recommended after rigorous PBPA review

The Federal Government's decision to defer indefinitely price increases recommended by the PBPA on the basis of demonstrated commercial grounds, for PBS listed medicines with a demonstrated cost-effective, medical need and no alternative substitute medicine, significantly jeopardises the ongoing supply of these essential medicines to patients.

Price increases are generally only recommended by the PBPA where the sponsor can demonstrate a clear commercial need AND where there is no alternative medicine available at a more competitive price. It is a condition of application for a price increase to a PBS listed medicine that the sponsor discloses to the PBPA the cost of goods of the product. This allows the PBPA to fully review the commercial viability of the product before recommending a price increase. Further, the PBPA will not recommend a request for a price increase if there is an alternative medicine available at more competitive price. As a consequence, some medicines are currently supplied to the PBS at a price below cost of goods.

It should be emphasised that the PBPA review is a comprehensive review. Price increases are only recommended by PBPA in instances where the sponsor is able to demonstrate highly compelling reasons to support the request for the price increase. For example, requests based on changes to

business costs such as exchange rate fluctuations, inflation / price indexes or unspecified increases of product costs are typically denied by the PBPA. If there is any doubt about the validity of the reasons presented by the sponsor to support the request for a price increase, the PBPA will typically deny the request.

The ability of sponsors to obtain price increases on commodity medicines is critical to the effective application of Government policies, such as price disclosure and statutory price reductions, which reduce the price of commodity medicines over time. These Government policies are broad brushed policies that reduce the price of medicines without full consideration of the clinical need or commercial viability of the individual medicine.

To ensure the ongoing supply of essential medicines to Australians, sponsors must be confident that price increases for medicines will be granted when recommended by the PBPA, after its rigorous review mechanism.

Restrictive medicines pricing policy can lead to increased prices over time

Restrictive prescription medicine pricing policy can result in the exit of major generic players, reduced competition in the market place and eventual increased prices of generic medicines over time.

Appendix 1 provides a highly relevant case study that tracks the prices of generic medicines over time in Ontario province, Canada. Restrictive prescription medicine pricing policy imposed by the Ontario government in 1993 triggered a cascade of events that resulted in the market exit of a major generics player, reduced competition in the marketplace and ultimately increased prices of generic medicines by 2001.

In the face of inflation and a weakening dollar, one major generics player was forced to exit the market, denying patients access to a range of prescription medicines manufactured by this company.

Unable to endure the reality of selling goods at below cost, the remaining player was able to re-establish business viability only by increasing prices by an average of 537% across the portfolio – a move that placed further pressure on the government subsidy for many prescription medicines.

The Ontario case study provides clear evidence of the paradoxical effects that emerge from restrictive pricing policy in the prescription medicine market – that is, increased pharmaceutical prices across a reduced portfolio of medicines.

Companies unable to compete on price are paralysed by fluctuating market forces such as inflation and exchange rates. As business becomes unviable, major players are forced to exit, further weakening competition in the marketplace.

Those companies that manage to outlast their fallen rivals are left with one option – to considerably increase prices. In the absence of competition, these price increases are no longer susceptible to the economic paradigm of supply and demand, and are potentially allowed to grow without limitation.

3. New policies directed at doctors, pharmacists and consumers would ensure that further savings accrue to the Government from increased usage of follow-on generic medicines

Every time a follow-on generic medicine is dispensed in Australia, in place of the initial brand, savings are delivered to the national economy. However, the Government is missing out on making significant savings because the opportunity to use a follow-on generic medicine occurs only about half as often as it does in, say, the US. Further, on more than one in every four of those occasions, a follow-on generic medicine - the only kind that drives savings to the national economy - is not dispensed. These savings are lost because of an absence of policies – commonly applied in comparable economies overseas – that promote the timely availability, dispensing and usage of follow-on generic medicines.

The price disclosure policy results in the continual lowering of the price of generic medicines listed on the PBS, generating important savings to the nation, taxpayers and consumers. It is the follow-on generic medicine that drives these important savings, not the patent expired initial brands.

At patent expiry these initial brands have 100 per cent of the market therefore the sponsors of these initial brands do not need to engage in the discounting practices that drive government savings through the price disclosure policy. The greater the volume of follow-on generic medicines dispensed, the greater the price disclosure generated savings to Government.

In the US, there is a generic medicine available for 84 per cent of all prescriptions presented to a pharmacy and on 93 per cent of those occasions a follow-on generic medicine is dispensed. By contrast, in Australia there is a generic medicine available for only 49 per cent of all prescriptions presented to a pharmacy and on only 73 per cent of those occasions is a follow-on generic medicine dispensed.

New policies directed at doctors, pharmacists and consumers could ensure that further savings accrue to the Government from increased usage of follow-on generic medicines. Australian doctors prescribe more patented products than do US doctors and are not incentivised to consider generic medicines.

Patients have little incentive to choose a follow-on generic medicine because often there is no difference in cost between the initial brand and the follow-on generic medicine.

Pharmacists receive a Government incentive to dispense any generic medicine priced at the benchmark, but there is no Government incentive for them to dispense a follow-on generic medicine instead of a patent expired initial brand PBS listed at the benchmark price. The pharmacy incentive should be restricted to the dispensing of generic medicines that drive the savings to the national economy, that is, the follow-on generic medicine.

Appendix 1: Case study - Restrictive medicines pricing policy in the Canadian pharmaceutical market

A.3.1 Background

Canada does not have a national drug scheme, however public coverage is provided to about half of the population through provincial drug schemes.

The focus of this case study is Ontario, the largest province in Canada, where changes to drug prices were seen as a result of products falling below manufacturer's cost on the Ontario Drug Benefit (ODB) Formulary.

A.3.1.1 Ontario Drug Benefit (ODB) Program

Through the Ontario Drug Benefit (ODB) Program, the Ministry of Health and Long-Term Care, covers most of the cost of prescription drug products listed in the Ontario Drug Benefit (ODB) Formulary, as well as some exceptional cases.

Source: http://www.health.gov.on.ca/english/public/pub/drugs/odb.html

A.3.1.2 Canadian Generic Drug Manufacturers 2000-2001

There has been a highly competitive drug industry in Canada for over thirty five years. Ten years ago there were at least eight generic companies operating in Canada.

- Apotex
- Novopharm (now Teva)
- Pharmascience
- Genpharm (now Mylan)
- Ratiopharm
- Nupharm
- Altimed
- Linson

A.3.2 Ontario Market – 30th March 2001

The Ontario government implemented a reimbursement price freeze on all drugs in 1993. Since that time, inflation ran at 2 ½ to 3% per year for a total of over 20% by 2001.

In addition, during that same time period, the Canadian dollar fell about 20% relative to the US dollar, the currency used by Apotex to purchase some of its raw materials. The end result was that many of the drugs listed on the Ontario Drug Benefit (ODB) Formulary fell below manufacturing or product cost.

This in turn resulted in Novopharm (now Teva) taking the decision to discontinue manufacture and supply on many low price products (delisting a number of their brands from the ODB Formulary and exiting from the market), leaving Apotex as the sole generic supplier for public coverage across a range of products – complete list in Appendix 1. At that time, no other generic companies were marketing these products.

A.3.3 Ontario Market – 30th June 2001

Following several years of failed negotiation attempts with the Ontario Drug Benefit Program to increase the cost of many molecules to above manufacturer cost, Apotex unilaterally increased its prices anywhere between 30% to over 1400%, with a 537% average increase. It was no longer viable for Apotex to continue to sell these products at below cost being the only player left to supply the market.

The price increase, instigated by Apotex, occurred on 1st July 2001 – see Appendix 2.

A.3.3.1 "Cost to Operator" approach

Although the reimbursement amount listed in the ODB Formulary did not increase, the "Cost to Operator" approach available in Ontario provided pharmacists with the ability to claim reimbursement from the Government for the cost of a product over and above the price listed in the ODB Formulary.

A.3.4 Ontario Market – 30th January 2002

Apotex further increased their prices in 2002 by an average of 38%

A.3.4.1 Ontario Drug Price Examples

Example 1 – Amitriptyline

		Apotex Pricing				
PRODUCT	Increase Jan 02 to current	Increase Jun 01 to Jan 02	Jan 2002 Price Increase	Jul 2001 Price Increase	Jun 2001 Prices	1998 Prices
			Price/Tab	Price/Tab	Price/Tab	
Only Other Generic Discontinued March 30, 2001						
APO-AMITRIPTYLINE 10 MG	53%	637%	$ 0.0435	$ 0.0150	$ 0.0059	$ 0.0059
APO-AMITRIPTYLINE 25 MG	46%	949%	$ 0.0829	$ 0.0250	$ 0.0079	$ 0.0079
APO-AMITRIPTYLINE 50 MG	52%	811%	$ 0.1540	$ 0.0450	$ 0.0169	$ 0.0169

Price Increases

Price increase in July 2001

- 637% to 949% across the three strengths
- Average price increase of 799%

Price increase in January 2002

- 46% to 53% across the three strengths
- Average price increase of 50%

Example 2 – Trifluoperazine

		Apotex Pricing				
PRODUCT	Increase Jan 02 to current	Increase Jun 01 to Jan 02	Jan 2002 Price Increase	Jul 2001 Price Increase	Jun 2001 Prices	1998 Prices
			Price/Tab	Price/Tab	Price/Tab	
Only Other Generic Discontinued March 30, 2001						
APO-TRIFLUOPERAZINE 1 MG	58%	399%	$ 0.0846	$ 0.0275	$ 0.0170	$ 0.0065
APO-TRIFLUOPERAZINE 2 MG	58%	1442%	$ 0.1110	$ 0.0575	$ 0.0072	$ 0.0072
APO-TRIFLUOPERAZINE 5 MG	58%	1334%	$ 0.1470	$ 0.0875	$ 0.0103	$ 0.0103
APO-TRIFLUOPERAZINE 10 MG	58%	930%	$ 0.1762	$ 0.0375	$ 0.0171	$ 0.0171

Price Increases

Price increase in July 2001

- 399% to 1442% across the three strengths
- Average price increase of 1026%

Price increase in January 2002

- 58% across the three strengths

Example 3 – Diazepam

		Apotex Pricing				
PRODUCT	Increase Jan 02 to current	Increase Jun 01 to Jan 02	Jan 2002 Price Increase	Jul 2001 Price Increase	Jun 2001 Prices	1998 Prices
			Price/Tab	Price/Tab	Price/Tab	
Only Other Generic Discontinued March 30, 2001						
APO-DIAZEPAM 2 MG	0%	824%	$ 0.0508	$ 0.0175	$ 0.0055	$ 0.0055
APO-DIAZEPAM 5 MG	0%	1130%	$ 0.0750	$ 0.0275	$ 0.0061	$ 0.0061
APO-DIAZEPAM 10 MG	0%	1157%	$ 0.0867	$ 0.0375	$ 0.0069	$ 0.0069

Price Increases

Price increase in July 2001

- 824% to 1157% across the three strengths
- Average price increase of 1037%

**further examples available on request from Apotex*

A.3.5 Novopharm Discontinued Product List, effective 30th March 2001

Novopharm Discontinued Product List

Effective March 30, 2001

Discontinued Products	Apotex Equivalent
Novo-Ampicillin (susp. Only) 125/5 mg/mL, 250/5 mg/mL	Apo-Ampi
Novo-Baclofen 10, 20 mg	Apo-Baclofen
Novo-Butamide 500mg	Apo-Tolbutamide
Novo-Butazone 100mg	Apo-Phenylbutazone
Novo-Cromolyn Nebulizer 1%	Apo-Cromolyn nasal solution
Novo-Dipam 2, 5, 10 mg	Apo-Diazepam
Novo-Doparil 15, 25 mg	Apo-Methazide
Novo-Ferrosulfate FCT 300mg	Apo-Ferrous Sulfate
Novo-Flunisolide 0.25%	Apo-Flunisolide
Novo-Flupam 15mg	Apo-Flurazepam
Novo-Folacid 5mg	Apo-Folic
Novo-Furan 50, 100mg susp 25/5 mg/mL	Apo-Nitrofurantoin
Novo-Hexidyl 2, 5 mg	Apo-Trihex
Novo-Medopa 125, 250, 500mg	Apo-Methyldopa
Novo-Mepro 400mg	Apo-Meprobamate
Novoxapam 10, 15, 30 mg	Apo-Oxazepam
Novo-Poxide 5, 10, 25 mg	Apo-Chlordiazepoxide
Novo-Pramine 10, 25, 50 mg	Apo-Imipramine
Novo-Profen SC 300, 400mg	Apo-Ibuprofen
Novo-Pyrazone 100, 200 mg	Apo-Sulfinpyrazone
Novo-Quinidin 200mg	Apo-Quinidine
Novo-Ridazine 10, 25, 50, 100, 200mg, susp. 2mg/mL	Apo-Thioridazine
Novo-Rythro Encap 250mg	Apo-Erythro-EC
Novo-Terfenadine 60mg	Apo-Terfinadine
Novo-Tetra 250mg	Apo-Tetra
Novo-Thalidone 50, 100mg	Apo-Chlorthalidone
Novo-Triedapin 10, 25, 50, 75, 100mg	Apo-Doxepin
Novo-Trifluzine 2, 5, 10 mg	Apo-Trifluoperazine
Novo-Triphyl 200mg	Apo-Oxytriphylline
Novo-Triptyn 10, 25, 50mg	Apo-Amitrityline
Novo-Zolamide 250mg	Apo-Acetazolamide

A.3.6 Apotex Price Increase Letter, 13th June 2001

June 13, 2001

Dear Valued Customer:

Re: Price Increases

As you know, the Ontario government implemented a price freeze in 1993 – seven years ago.

In the past seven years, inflation has been running at 2 ½ to 3% per year for a total of over 20%. Also, the Canadian dollar has fallen about 20% relative to the U.S. dollar, in which raw materials are purchased.

We have been negotiating with the Ontario Drug Benefit Program over the past three years in an effort to obtain price increases for older products which we are currently selling below cost. The Program has been unresponsive.

We thus have no alternative but to proceed with price increases unilaterally.

Commencing July 1st, 2001, price increases will be in effect for the attached products.

We realize that this may create additional paper work for you; however, we believe that long term this is in our mutual best interest, as we cannot continue to sell at below cost. As you are aware there are several hundred drugs listed in the Ontario Drug Benefit that cannot be purchased at the Best Available Price (BAP).

Our understanding is that the current Pharmacy Computer Systems have a program to manage ODB cost to operator claims with minimal extra work.

For third party prescriptions, we have been advised by BCE Emergis and ESI that the new prices will be reimbursed on the effective date. Greenshield is reviewing their policies and expect to have procedures in place by July 1st .

Your continued support is greatly appreciated.

Please do not hesitate contacting me directly at [redacted] if you require any further clarification.

Yours very truly,

APOTEX INC.

Jack M. Kay
President and C.O.O.

JMK/jm

Attachment