GMiA Generic Medicines Industry Association Pty Ltd

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Generic Medicines Industry Association

Submission to Senate Community Affairs References Committee

Inquiry into consumer access to pharmaceutical benefits

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i. Executive Summary

Governments - Commonwealth, states and territories - healthcare educators, healthcare practitioners, and other healthcare providers and suppliers, the medicines industry, healthcare consumers, and the media recognise the benefits of a National Medicines Policy (NMP) and have resolved to work together as partners to promote the objectives of the policy. Members of the Generic Medicines Industry Association (GMiA) take seriously their responsibility to achieve each of the below objectives of the NMP and consider these central objectives in any relevant initiatives.

i. timely access to the medicines that Australians need, at a cost individuals and the community can afford;
ii. medicines meeting appropriate standards of quality, safety and efficacy;
iii. quality use of medicines; and
iv. maintaining a responsible and viable medicines industry.

The Pharmaceutical Benefits Scheme (PBS) provides Australians an unrivalled world class program delivering access to medicines at an affordable price. Consumer access to essential medicines through the PBS will be compromised if any of the above four objectives are not appropriately balanced and managed.

The Australian Government has traditionally and appropriately stated that the Government pays for the health outcomes delivered by the medicines listed on the PBS. This provides for a fundamental tenet of the PBS that the Government should pay equal cost for equal health outcomes.

Medicines are listed on the PBS after rigorous assessment of cost-effectiveness yielding a schedule of benefits where prices of medicines reflect the health outcomes delivered by the medicines. Government subsidy of medicines at a level where equal health outcomes receive equal subsidy is important as:

- It ensures that funding of a social subsidised scheme such as the PBS is targeted to health outcomes; and
- It ensures that sponsors of medicines are incentivised to develop and commercialise medicines that deliver improved health outcomes.

The recent PBS reforms that separate the PBS formularies results in the Government paying higher prices for F1 medicines that deliver the same health outcomes as F2 medicines, in some instances.

Sponsors should be incentivised to develop and bring to market products that deliver improved patient health outcomes. Products that offer a true advancement in the delivery of health outcomes have the opportunity to secure a price premium over F2 products via the demonstration of cost-effectiveness as evaluated by the Pharmaceutical Benefits Advisory Committee (PBAC). Where products cannot demonstrate an additional health benefit, it is inappropriate that a publicly funded scheme, such as the PBS, should pay a higher price for a new medicine if a less expensive alternative can deliver the same health outcomes.

The elimination of reference pricing outside of therapeutic groups has imposed a significant cost impost on the PBS as there are no demand side limitations concurrently imposed on the more expensive F1 medicine. This provides an additional incentive to the sponsors of F1 medicines to switch patients from F2 products to F1 products through heavy market promotional activities. Not

only do the sponsors of F1 medicines receive the benefit of the monopoly market in F1, under the separated formularies sponsors receive a higher price per health outcome, in some instances.

In the absence of reference pricing across the F1 and F2 formulary, there is a need for the adoption of other policy mechanisms to ensure that more expensive medicines are used appropriately and that the most cost effective use of PBS expenditure is achieved.

GMiA notes that one of the key consequences of PBS reform is the reduction of prices of generic medicines. The generic medicines sector plays a crucial role in delivering affordable medicines to the Australian public after the market exclusivity period of originator medicines has expired. The commercial viability of the generic medicines sector is driven by volume. A Government policy that reduces the PBS list price of generic medicines in the absence of volume drivers significantly risks undermining the viability of the generic medicines sector.

The presence of a generics sector has saved the PBS $1.4 billion (Government contribution) over 4 years (2005/06 – 2008/09) and savings stemming from the presence of the generic medicines sector are growing over time. The savings to the PBS stemming from the presence of the generic medicines sector in 2008/09 was $681.7 million (Government contribution).

The share of PBS receipts to the F2 formulary has declined by 17.7%, in contrast the share of PBS receipts to the F1 formulary has increased by 35.4% (Government contribution) over 4 years (2005/06 – 2008/09).

GMiA requests that Government introduce three important policy initiatives:

Recommendation 1: <u>Provide a clear price signal for consumers to choose a generic medicine</u>

A clear price advantage that provides an incentive for the patient to choose a generic medicine is critical to ensure that Australians continue to receive the important savings that generic medicines offer the community.

GMiA advocates that the Government implement this initiative by placing an additional $5.00 patient brand co-payment (indexed) on the original brand of the medicine immediately upon PBS listing of the second brand that triggers the 12.5% price reduction. That is, the concessionary and general patient pay a total copayment of $10.40 and $38.50, respectively, for every brand prescription where there is an alternative brand available on the PBS. This measure would be introduced when a molecule moves to F2 from 1 January 2011.

Health outcomes are not jeopardised as generic medicines provide patients access to safe, effective, high-quality alternatives and are therefore integral to the quality use of medicines.

Recommendation 2: <u>Provide a floor price for generic medicines</u>

GMiA notes that there a number of products listed on the PBS at very low unit prices, for example diazepam 2 mg tablet is $1.19 price to pharmacy, amoxyxcillin 250 mg capsule is $1.85 price to pharmacy, betamethasone valerate 15 g cream is $1.85 price to pharmacy. Suppliers of generic medicines are concerned that if there are further reductions to the price of generic medicines, the ongoing supply of low cost essential medicines and patients' health may be jeopardised.

GMiA advocates that Government introduce a floor price of $5.00 ex-manufacture below which, when a medicine reaches the floor price through price disclosure or voluntary price drops, no further price cuts will be applicable to the medicine. This will ensure the ongoing supply of low cost essential medicines. This measure would be introduced from 1 January 2011.

Recommendation 3: Amend the PBS listing process to enable entry of new generic medicines on the PBS each month.

Timely access to market of generic medicines has the potential to provide significant savings to health budgets. Currently, sponsors have three opportunities a year to introduce a new generic medicine; notification must be given to Government by 1 December, 1 May or 1 September to effect a PBS listing on 1 April, 1 August or 1 December, respectively. That is, advice must be provided to Government 3 - 4 months before the PBS listing becomes effective.

There will be inherent cost savings in allowing monthly entry onto the PBS to occur at any of the monthly updates, rather than the current three points in every year. The benefit of the cost savings on some products could be realised up to three months earlier than allowed under the current system.

For example, the patent on atorvastatin expires in May 2012. Under current regulation, the first additional brand of atorvastatin will be listed at the earliest on the PBS on 1 August 2012. Total benefits through the PBS for atorvastatin for December 2008 were $45m. The mandatory price cut of 12.5% represents a saving to the Commonwealth of $5.6m per month. Thus, if atorvastatin were to be PBS listed on 1 June 2012, rather than on 1 August 2012 as will occur under current regulation, the Commonwealth will save $11.2m on one item alone. This measure would be introduced from 1 January 2011.

High quality generic medicines provide a “smart” solution for Australian payers and patients. Generic medicines provide patients access to safe, effective, high-quality alternatives and are therefore integral to the quality use of medicines - encouraging the wise selection and management of medicines; choosing suitable medicines (if a medicine is considered necessary) so that the best available option is selected; and using medicines safely and effectively to obtain the best possible results.

It is critical that Commonwealth Government policy not only addresses affordable medicines for the Australian public, it is just as critical that Commonwealth Government policy ensures the long term sustainability and supply of generic medicines that play a crucial role in making medicines affordable.

1. Introduction

This submission, prepared by the Generic Medicines Industry Association (GMiA), addresses the terms of reference of the inquiry into consumer access to pharmaceutical benefits as referred by the Senate to the Community Affairs References Committee on 25 November 2009.

GMiA acknowledges that the pressure on the public health budget will continue given the prospect of a progressively ageing population, the increased prevalence of chronic disease and the understandable desire on the part of health care providers and patients to access new health technologies, including pharmaceuticals, to diagnose and treat disease. In the face of these ongoing pressures, implementation of sound public policy is required to ensure continued access to pharmaceutical benefits through the Pharmaceutical Benefits Scheme (PBS).

Sound medicines policy should be underpinned by an efficient market that supports the cost-effective supply of medicines, minimises the administrative burden within the system and creates a predictable policy environment for all market participants.

2. The generic medicines sector and the PBS

2.1 Why the generic medicines sector is important to the PBS

The guiding principles of the members of the Generic Medicines Industry Association are:

(a) To support the long term sustainability of the PBS by ensuring the timely and cost effective provision of generic medicines to consumers.

(b) To support the quality use of medicines (QUM) in partnership with other stakeholders.

(c) To support the development of policies that facilitate timely access to generic medicines for all Australians.

(d) To support the development of policies that promote the continued viability of a local manufacturing base for generic medicines (for domestic and export markets).

(e) To encourage a high level of awareness and general knowledge of the safety, efficacy and appropriate interchangeability of generic medicines amongst healthcare practitioners, government and consumers.

(f) To support balanced intellectual property rights in the pharmaceutical sector that enable timely, cost effective access to generic medicines.

The members of GMiA supply more than 90% of total prescriptions supplied by generic sponsors in Australia, making the Association highly representative of the sector. The members of GMiA:

- Sold more than 50 million or 33% of all services by volume on PBS over 2008/09 (PBPA annual report);
- Sold 100 million packs in Australia; a large proportion of the generics sector is below the PBS co-payment (GMiA survey 2009);
- Employ 5,000 Australians with almost half these roles being in manufacturing or R&D representing functions that generate strong economic multiplier benefits (GMiA survey 2009;
- Export $470 million worth of products which represents 12% of the current pharmaceutical export market.

In summary, the generic medicines sector is a high value add sector offering the potential to deliver significant benefits to the Australian public by way of affordable medicines and high skilled jobs. The right policy settings are critical to the viability of the generic medicines sector as most aspects of commercial activity by suppliers of generic medicines are impacted by Government legislation and regulation. A cohesive generic medicines policy in Australia would enable the generic medicines sector to make an even greater contribution to Australian healthcare and the economy generally.

Generic medicines can provide a "smart" solution for Australian payers and patients. Generic medicines provide patients access to safe, effective, high-quality alternatives and are therefore integral to the quality use of medicines - encouraging the wise selection and management of medicines; choosing suitable medicines (if a medicine is considered necessary) so that the best available option is selected; and using medicines safely and effectively to obtain the best possible results. In turn, the quality use of medicines is one of the central objectives of Australia's National Medicines Policy.

Sponsors of generic medicines play an important role in introducing competition and reducing prices after the monopoly market period enjoyed by the originator sponsor has expired. The benefits of competition from generic medicines should accrue to payers and patients but this may not always occur due to the regulated nature of the PBS**.** Timely market access for generic medicines will also contribute to the sustainability of the PBS.

The presence of competition from generic medicines provides many additional important balances in the market including:

- Prior to PBS reform, a role in ensuring that products referenced to the generic molecule also reduced in price, a fundamental tenet of equal public cost for equal health outcomes.
- A role in ensuring that new technology continues to offer true improvements by delivering better health outcomes.
- A role in discouraging patients from being switched to new and more expensive medicines if they do not deliver an improved health outcome.
- A stimulant to further drug discovery and innovation more generally. Extended or permanent monopolies on pharmaceutical products remove the incentive to discover new medicines and the benefit of patents to the producer of the intellectual property must be carefully weighed against the cost to the public of patents. (Gruen 2009)
- Keeping in check potential activity by sponsors of originator medicines that may inappropriately apply patents on undeserving technology or extend the patent life of their products.

In the face of muted price signals under the provisions of the PBS, a viable generic medicines sector needs to be actively promoted by a robust generic medicines policy. This is evidenced by international experience where markets that have fostered a supportive generic medicines policy have promoted a viable generic medicines sector and vice versa. (Simoens 2006 p9)

The ability of the generic medicines sector to exert downward price pressures can only be achieved and sustained with high volume turnover. A low price/low volume environment threatens the economic viability of the generic medicines sector. Policies should ensure that prescribers, pharmacists and patients have reasons to choose generic medicines and that there is market confidence in the safety, quality and efficacy of generic medicines. (Simoens 2006 p76)

In summary, sound medicines policy should be underpinned by an efficient market that supports the cost effective supply of medicines, minimises the administrative burden within the system and creates a predictable policy environment for all market participants.

The generic medicines sector plays a crucial role in delivering affordable medicines to the Australian public after the market exclusivity period of originator medicines has expired. The commercial viability of the generic medicines sector is driven by volume. A Government policy that reduces the PBS list price of generic medicines in the absence of volume drivers significantly risks undermining the viability of the generic medicines sector.

2.2 Retrospective analysis of PBS expenditure

GMiA has analysed PBS expenditure from April 2005 to April 2009. GMiA used the PBS dataset compiled by Medicare Australia that is available to the general public. The dataset was copied into a database and the analysis was performed using MS Excel and MS Access.

The savings to Government stemming from the presence of a generics sector has been calculated by year and by specific policy and is presented in Table 2.3.1. At a minimum, **the presence of a generics sector has saved the PBS $1.4 billion (Government contribution) over this 4 year time period.**

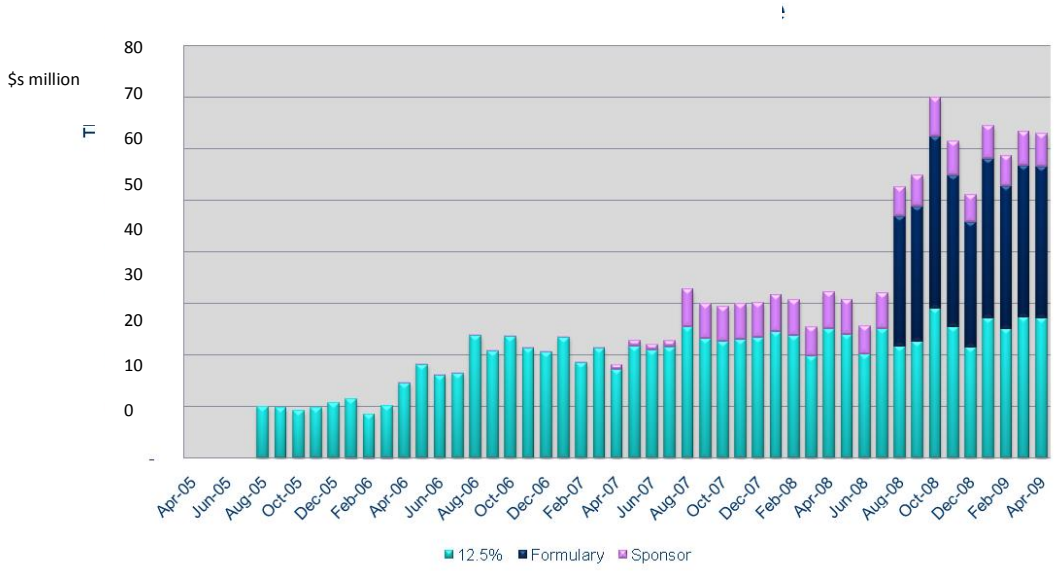
Savings to the PBS stemming from the automatic price reductions of 12.5% upon PBS listing of the second brand have netted $952 million (Government contribution) over four years. Savings to the PBS stemming from the price reductions applicable to the F2A formulary have netted almost $10 million (Government contribution) over four years. Savings to the PBS stemming from the price reductions applicable to the F2T formulary have saved $299 million (Government contribution) over four years. Savings stemming from voluntary price reductions initiated by the sponsor have saved the PBS $154 million (Government contribution) over four years.

These savings are also presented by bar chart by month in Table 2.3.2. **Savings stemming from the presence of the generic medicines sector are growing over time.**

Table 2.2.1: Savings to Government stemming from the presence of the generic medicine sector (Government contribution) ($ million)

	12.5%	F2A	F2T	Sponsor	Total
F2006	127.8	-	-	0.3	128.1
F2007	249.1	-	-	4.4	253.5
F2008	276.0	-	-	75.3	351.4
F2009	299.3	9.6	298.7	74.0	681.7
Total	952.4	9.6	298.7	154.1	1,414.8

Table 2.2.2: Savings to Government stemming from the presence of the generic medicine sector presented by bar chart by month (Government contribution) ($ million)



The proportion of PBS expenditure flowing to the F1 versus the F2 formulary over time was analysed by both services and benefits as presented in Tables 2.3.3 and 2.3.4. **The share of PBS receipts to the F2 formulary has declined by 17.7%, in contrast the share of PBS receipts to the F1 formulary has increased by 35.4% (Government contribution).**

The number of services in the F2 formulary has been relatively stable, declining marginally on average 1.2% per annum from 122 million services to 116 million services and the cost to the PBS of the F2 formulary has declined on average 4.5% per annum from $2.8 billion to $2.32 billion (Government contribution) from April 2005 to April 2009 (MAT).

In contrast, the number of F1 PBS services has grown on average 5.8% per annum from 47 million services to 58 million services from April 2005 to April 2009 (MAT), however the growth of the total cost of PBS benefits on the F1 formulary has been considerable, increasing on average 13.8% per annum from $2.68 billion to $4.15 billion (Government contribution) over this same period.

Table 2.2.3: PBS expenditure by formulary (Government contribution) (million)

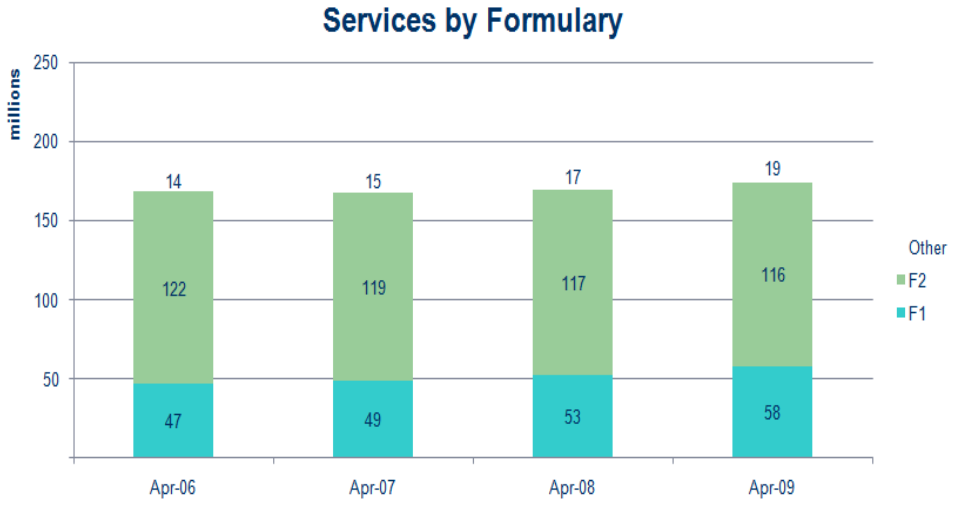
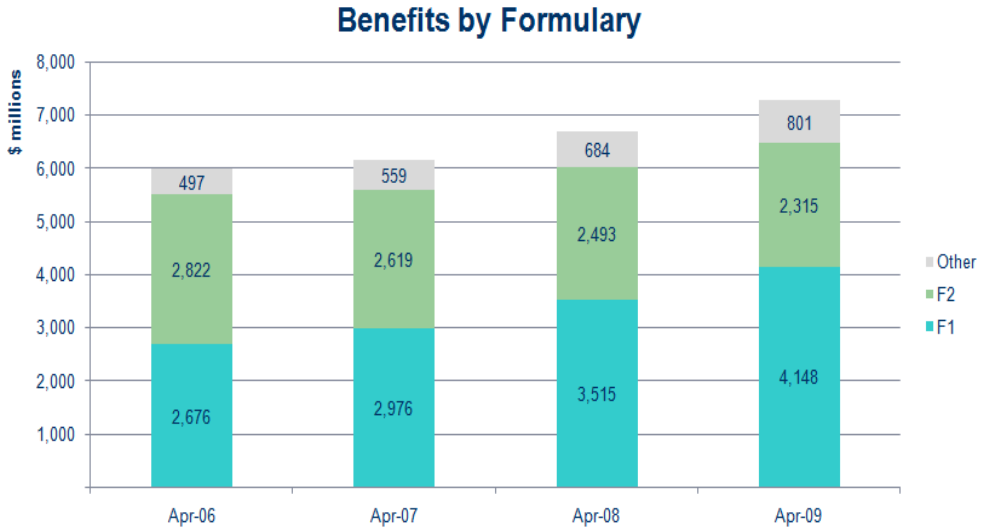


Table 2.2.4: PBS expenditure by formulary (Government contribution) ($ million)



GMiA analysis found that the proportion of PBS expenditure distributed amongst the supply chain has changed from 1 April 2005 to 1 April 2009 as presented in Tables 2.3.5 and 2.3.6. The Community Service Obligation additional funding of $69 million over three years to compensate distributors is not included in the GMiA analysis.

PBS receipts to the pharmacist and the F1 manufacturer have increased from 1 April 2005 to 1 April 2009. In contrast, PBS receipts to the F2 manufacturer and the distributor have declined over the same period.

- The pharmacist has received an increase in PBS receipts from $1.24 billion to $1.56 billion (pharmacy mark up plus dispensing fee); or from 20% to 22% of the total PBS spend.

- The F1 manufacturer has received an increase in PBS receipts from $2.13 billion to $3.39 billion (price to wholesaler); or from 35% to 48% of the total PBS spend.
- The F2 manufacturer has experienced a decrease in PBS receipts of $2.25 billion to $1.74 billion (price to wholesaler); or from 37% to 25% of the total PBS spend.
- The distributor has experienced a decrease in PBS receipts from $0.49 billion to $0.39 billion (wholesaler mark up); or from 8% to 6% of the total PBS spend.

Table 2.2.5: Proportion of PBS expenditure by supply chain (dispensed price) ($ million)

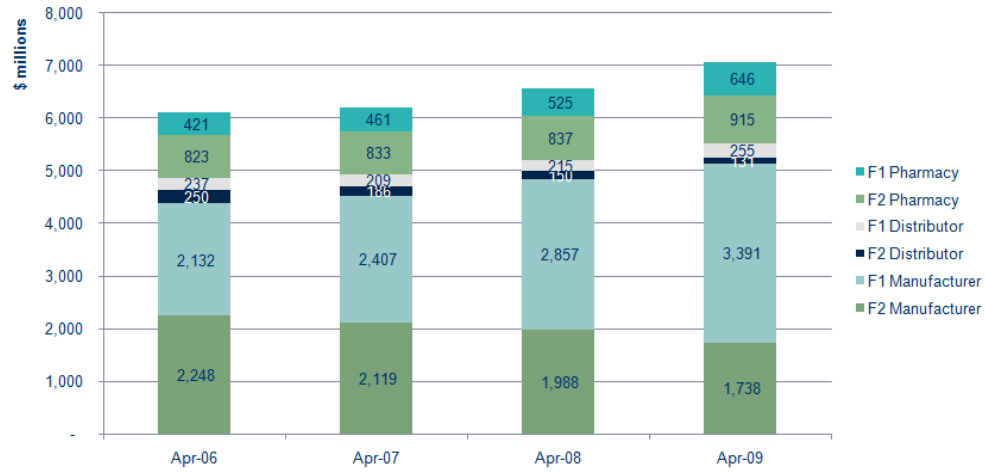
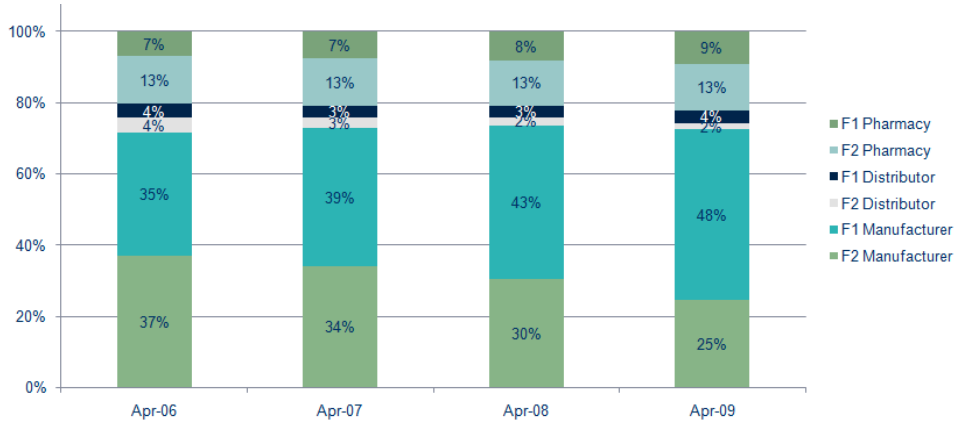


Table 2.2.6: Proportion of PBS expenditure by supply chain (dispensed price) (%)



3. Senate Inquiry: Terms of Reference

(a) The impact of new therapeutic groups on consumer access to existing PBS drugs, vaccines and future drugs, particularly high cost drugs

The creation of therapeutic groups provides Government with a policy tool to ensure that medicines on the PBS delivering the same health outcomes receive the same level of Government subsidy. Government subsidy of medicines at a level where equal health outcomes receive equal subsidy is important as:

- It ensures that funding of a social subsidised scheme such as the PBS is targeted to health outcomes; and
- It ensures that sponsors of medicines are incentivised to develop and commercialise medicines that deliver improved health outcomes.

The impact of therapeutic groups to consumer access should be negligible, as the principle of therapeutic groups is that there is always at least one medicine within each therapeutic group available without a patient premium. Further, if there is a medical reason for a patient to take a specific medicine with a premium rather than the alternative product, the prescribing doctor can request an exemption from the premium from Medicare Australia.

(b) The criteria and clinical evidence used to qualify drugs as interchangeable at a patient level

Substitution of a different brand of the same medicine by the pharmacist, with consent by the patient, was introduced in Australia on 1 December 1994. This policy has provided significant benefits to the Australian public by making medicines more affordable.

(c) The effect of new therapeutic groups on the number and size of patient contributions

Varying the size of the patient contributions can be important, contributing strongly to good medicine policy. Consumers should be rewarded financially, encouraged and empowered to make fully informed and wise medicine choices. Variable patient contributions provide a market mechanism to financially reward consumers who make wise medicines choices.

GMiA recommends that patients who choose a generic medicine should be rewarded financially. The sponsor of an originator product has a lengthy market monopoly period to establish brand loyalty and consequently the sponsor of a generic product does not face a level playing field upon market entry. If the generic medicine sector is to continue to deliver important savings the PBS, it is essential that there exist a clear market signal to encourage patients to choose a generic medicine. Patients who choose to support the generic medicine sector and the important savings delivered from this sector should also benefit directly and personally from these savings.

(d) Consultation undertaken in the development of new therapeutic groups

The development of new therapeutic groups should be made in the context of appropriate expert advice. The GMiA supports the concept of therapeutic groups.

(e) The impact of new therapeutic groups on the classification of medicines in F1 and F2 formularies

The Australian Government has traditionally and appropriately stated that the Government pays for the health outcomes delivered by the medicines listed on the PBS. This provides for a fundamental tenet of the PBS that the Government should pay equal cost for equal health outcomes.

Medicines are listed on the PBS after rigorous assessment of cost-effectiveness yielding a schedule of benefits where prices of medicines reflect the health outcomes delivered by the medicines. Government subsidy of medicines at a level where equal health outcomes receive equal subsidy is important as:

- It ensures that funding of a social subsidised scheme such as the PBS is targeted to health outcomes; and
- It ensures that sponsors of medicines are incentivised to develop and commercialise medicines that deliver improved health outcomes.

The recent PBS reforms that separate the PBS formularies results in the Government paying higher prices for F1 medicines that deliver the same health outcomes as F2 medicines, in some instances.

In the absence of reference pricing across the F1 and F2 formulary, there is a need for the adoption of other policy mechanisms to ensure that more expensive medicines are used appropriately and that the most cost effective use of PBS expenditure is achieved.

Sponsors should be incentivised to develop and bring to market products that deliver improved patient health outcomes. Products that offer a true advancement in the delivery of health outcomes have the opportunity to secure a price premium over F2 products via the demonstration of cost-effectiveness as evaluated by the PBAC. Where products cannot demonstrate an additional health benefit, it is inappropriate that a publicly funded scheme, such as the PBS, should pay a higher price for a new medicine if a less expensive alternative can deliver the same health outcomes.

GMiA notes that one of the key consequences of PBS reform is the reduction of prices of generic medicines. Under a system of cost effectiveness analysis such as the Australian PBAC system, the price of a new medicine is referenced to an older medicine via the comparator. GMiA recommends that the PBAC actively take into account the reduced price of comparators as a result of PBS reform and consider adjusting upwards its acceptable level of cost per health outcome post PBS reforms as compared to pre PBS reforms.

(f) The delay to price reductions associated with the price disclosure provisions due to take effect on 1 August 2009 and the reasons for the delay

The policy of price disclosure is incompatible with the principle of equal Government subsidy for equal health outcome. A clear incentive for sponsors to invest in new medicines that deliver improved health outcomes is provided when medicines are subsidised at a level reflecting the health outcome delivered. Government subsidy of medicines should reflect the health outcome delivered, not the cost of developing the medicine.

Under a cost-effectiveness system, the generic medicine may form the reference price for new a medicine. It is therefore appropriate that the price of generic medicines also reflects the health outcome. The application of unpredictable price reductions to products via the price disclosure policy yields a set of PBS prices unrelated to the health outcome delivered by the product. This obstructs a simple and straightforward regime where the price of a new medicine is directly comparable to the price of the existing medicine.

Therapeutic groups will not provide the Government a means of ensuring that medicines delivering the same health outcomes are priced at the same level once an item is subject to competition from generic brands. Paragraph 99 of the Department of Health and Ageing document, "Pharmaceutical Benefits Scheme Price Disclosure Arrangements: Procedural and Operational Guidelines", July 2007 states, "There will be no price flow-ons (that result from disclosure) to other drugs within a Therapeutic Group. The drug that has been subject to price reductions as a result of price disclosure will be removed from the Therapeutic Group."
http://www.health.gov.au/internet/main/publishing.nsf/Content/DF28ED589369BDEECA257341000792B8/$File/Procedural%20and%20Operational%20Guidelines.pdf

Once a product is subject to a price reduction due to price disclosure, by means of the above regulation, it will be removed from the therapeutic group and the other products in the therapeutic group will not be subject to the price reduction or any future price reductions. Thus, therapeutic groups will not support the principle of equal Government subsidy for equal health outcome where products are subject to price disclosure.

The introduction of price disclosure has created unnecessary and avoidable administrative burden on both Government and industry. Cost and time resources associated with the collection and analysis of data to support the price disclosure policy are significant and probably higher than originally envisaged. It is inappropriate to burden industry with such a high level of administration. Price disclosure creates significant uncertainty for the Government and industry as future cost savings to the PBS cannot be easily predicted.

Since the introduction of the price disclosure policy on 1 August 2007 sponsors of new medicines listed on F2A are required to provide information to the Department of Health and Ageing about the price at which they sell their brands in the market. Sponsors of other brands of the same medicines may voluntarily provide this information. Based on this information, the Department of Health and Ageing calculates a 'weights average disclosed price' (WADP) for each PBS item in that price disclosure group. If the WADP is at least 10% below the PBS price, the price of that item is reduced to the WADP.

Weighted average price disclosure calculations are complex and, due to the commercial-in-confidence nature of the input data, calculations are necessarily non-transparent creating significant risk of errors.

There have been significant administrative issues and legal challenges with the application of the policy. While the first price reductions should have taken effect 1 August 2009, to date there have been no application of any price changes.

Table 3.1 sets out the items subject to the price disclosure policy and the resultant price reduction after the first year of the regime. In total, of the nineteen items subject to price disclosure, seven items (or 37%) have been required to take a price reduction as a result of the price disclosure policy. The annual savings to the PBS stemming from the first year of price disclosure are estimated to be only **approximately $30 million** (Government contribution), based on the level of services as at April 2009.

The extent of price reductions varies considerably - from 0% to 71.8%. The large variation in the extent of the price reductions across items is not well understood.

The Department of Health and Ageing cites the significant administrative issues and legal challenges as the cause of the delays to the implementation of the price reductions. The price reductions that should have been applied to doxorubicin, mitozantrone and ondansetron were implemented by a voluntary price reduction agreed to by a sponsor and applied 1 December 2009. There is currently no scheduled date for the price reduction applicable to meloxicam. Price adjustments to the remaining products will take effect on 1 April 2010.

Table 3.1: Items subject to price disclosure policy and resultant price reduction after 1st year of review

Round 1		Round 2		Round 3	
Doxorubicin IV infusions	63.54%	Fluconazole oral	55.26%	Carvedilol	27.29%
Mitozantrone injections	34.42%	Vancomycin	71.80%	Sumatriptan	0%
Ondansetron injections	15.37%	Alendronic acid	0%	Enalapril	0%
Meloxicam tablets/capsules	0%	Ceftriaxone	0%	Irinotecan	0%
Amisulpride	0%	Naltrexone	0%		
Fosinopril	0%	Octreotide	0%		
Oxybutiynin	0%				
Perindopril	0%				
Valproic acid	0%				

In summary,

- Price disclosure is **incompatible with the principle of equal Government subsidy for equal health outcome**.
- The process places considerable **administrative burden** on both sponsors and Government. Cost and time resources associated with the collection and analysis of data to support the price disclosure policy are significant.
- The regime is both **administratively and conceptually complex**. The risk of inadvertent error by both sponsor and Government is high and there is limited capacity in the system to identify these errors. Further, the WADP calculations are complex and, due to the

commercial-in-confidence nature of the input data, WADP calculations are necessarily **non-transparent**.

- The process creates **uncertainty for the sponsor** over future price levels. Results to date emphasise the **unpredictability and variability of price reductions** resulting from implementation of the price disclosure regime. An efficient regulatory environment provides the sponsor with certainty and predictability.

(g) The process and timing of consideration by Cabinet of high cost drugs and vaccines

GMiA supports timely market access of new medicines on the PBS. Consideration by Cabinet of high cost drugs and vaccines should not cause delays to PBS listing of these medicines

Similarly, there should be no delays of new generic medicines listing on the PBS. Currently new generic medicines precipitating a price change can only PBS list three times per year on specifically defined dates. GMiA recommends monthly PBS listing of new generic medicines that will provide important public savings to the PBS.

GMiA understands that the current practice of limiting PBS listing of new generic medicines precipitating a price change to four monthly stems from paragraph 36 of the Fourth Community Pharmacy Agreement between the Commonwealth of Australia and the Pharmacy Guild of Australia that is currently being re-negotiated.

Members of GMiA recommend reviewing the current processes between the time that the sponsor of the generic medicine advises the Government of its intention to list a new generic medicine (3-4 months prior to the effective PBS list date) and the time the market is made aware of the PBS listing of a new generic medicine and the resultant price reduction. Through improved efficiencies it should be possible to increase the notification period by Government to the pharmacist, while not changing the already lengthy notification period by the sponsor of the generic medicine.

A relevant example of significant savings that should be delivered to the PBS by adopting this important policy reform is atorvastatin. The patent on atorvastatin expires in May 2012. Under current regulation, the second brand of atorvastatin will be listed at the earliest on the PBS on 1 August 2012. Total benefits through the PBS for atorvastatin for December 2008 were $45m. The mandatory price cut of 12.5% represents a saving to the Commonwealth of $5.6m per month. Thus, if atorvastatin were to be PBS listed on 1 June 2012, rather than on 1 August 2012 as will occur under current regulation, **the PBS would save $11.2m on one item alone**.

Delays to PBS listing and consequential delays to savings to the PBS also stem from the inherent complexity in pricing of medicines on the PBS. This complexity creates significant uncertainty and administrative burden for sponsors of medicines.

The PBS listing of the second brand of pantoprazole was recently delayed from 1 February 2010 to 1 April 2010. This delay of two months represents **an unnecessary additional cost to the PBS of $4.2**

million, inappropriately extends the patent life of pantoprazole and creates uncertainty and unpredictability for sponsors of generic medicines.

The Department of Health and Ageing cited the following explanation for the delay to PBS listing of pantoprazole. A 25% reduction to F2T products was applied on 1 August 2008. While pantoprazole is an F2T product, the application of this 25% reduction was staggered for a small number of products including pantoprazole. This fact was not known by sponsors of generic pantoprazole who were commercially ready to launch new brands effective 1 February 2010. It was not until sponsors had made their submissions to PBS list 1 February 2010, were they advised that PBS entry is to be delayed until 1 April 2010 as the full 25% price reduction on pantoprazole had not yet been triggered. Thus, the entry of the second brand of pantoprazole will trigger a 21% price change and PBS listing of generic brands must be delayed until 1 April 2010.

(h) Any other related matters

GMiA notes that there a number of products listed on the PBS at very low unit prices, for example diazepam 2 mg tablet is $1.19 price to pharmacy, amoxyxcillin 250 mg capsule is $1.85 price to pharmacy, betamethasone valerate 15 g cream is $1.85 price to pharmacy. Suppliers of generic medicines are concerned that if there are further reductions to the price of generic medicines, the ongoing supply of low cost essential medicines and patients' health may be jeopardised.

GMiA advocates that Government introduce a floor price of $5.00 ex-manufacture below which, when a medicine reaches the floor price through price disclosure or voluntary price drops, no further price cuts will be applicable to the medicine. This will ensure the ongoing supply of low cost essential medicines. This measure would be introduced from 1 January 2011.