SUPPLEMENTARY INFORMATION FROM MEDICINES AUSTRALIA
FOR THE SENATE COMMUNITY AFFAIRS LEGISLATION COMMITTEE
INQUIRY INTO *THE NATIONAL HEALTH AMENDMENT (PHARMACEUTICAL BENEFITS SCHEME BILL) 2010*

1. Provide a detailed response to the suggestion/claim that additional incentives to dispense generics should be introduced.

Medicines Australia is committed to a competition driven market in F2. There are several existing incentives to dispense generics, some of which were introduced during the PBS Reforms in 2007. These include widespread awareness campaigns, including those run by the National Prescribing Service, and the financial ($1.53) incentive for every time pharmacists dispense a medicine without a patient premium. Medicines Australia contends that additional incentives are not currently necessary because:

- Existing incentives to dispense generics are increasingly effective with the share of generics dispensing continuing to rise (key facts below). This would suggest that there is no need for additional incentives to drive market share to generic brands.
- Additional (sectoral based) incentives would not benefit taxpayers as the government pays the same price regardless of the sectoral source for the medicine
- Other proposed incentives may distort the competitive market which in turn limits savings to Government, and may create sectoral advantages which in turn disadvantage consumers

It is unclear how the taxpayer would benefit by additional incentives to dispense generics. The most powerful existing incentive is the long-standing policy that Government pays any manufacturer the same benchmark price for a medicine regardless of which brand is used. The Government does not pay anymore than the lowest or benchmark priced brand and pays the same price for a medicine regardless of whether it is an originator brand or a generic brand that is dispensed. Increased dispensing of one sector of generic sales will not actually save the Government any money, or be of any benefit to taxpayers.

For this reason, any move to deliberately drive increased dispensing of one sector of the market over another sector is itself, a form of protectionism. This measure is likely to impede competition.

In fact, existing policy means that any effort on the part of any manufacturer to maintain its price can only be achieved by applying a patient premium which in turn results in volume loss and greater shares for generics. Many originators have not sought to apply patient premiums due to this volume loss which in turn means they are indistinguishable from generic brands.

Medicines Australia argues that for consumers, the best policy interventions in this area are those directed at increasing provision of premium-free brands (which may be generic brands or originator brands) while retaining choice for the consumer. This means that

market dynamics prevail and a highly competitive market enables choice. Existing policy measures are consistent with this goal.

Medicines Australia would oppose any measures that discriminate in favour of the manufacturers of generic medicines (compared with the manufacturers of originator medicines) as this creates an unlevel playing field and is essentially a defacto industry support program for generic manufacturers offering the same commodity to consumers.

Furthermore, Medicines Australia would reiterate the views of physicians and pharmacists (including in other jurisdictions) about the importance of ensuring continued consumer decision for the chosen brand with input from their physician and pharmacist. For a minority of patients, there are clinical reasons for maintaining a patient on the same generic or originator brand and financial incentives for others in the supply chain should not be allowed to overtake this facility.

Medicines Australia considers that generics and originator brands are appropriately currently indistinguishable in policy terms and are treated equally in this commodity market. There is no advantage to taxpayers in increasing "generic" brands, as opposed to "premium-free" brands; current policy is directed at increasing the latter and Medicines Australia supports this. MA contends that disrupting the market dynamics through sectorally based incentives is both inappropriate and inconsistent with further driving market competition.

Finally, the current measures strike a reasonable balance. Further measures would require cautious application and much consultation with physicians, patients and consumers to ensure that pecuniary interests do not override sound clinical decision making. Clinical considerations are at least equally important as financial considerations in consumer choice and any policy decisions must ensure that balancing these factors must not override clinical considerations.

Key Facts

- In the decade to 2007-08, the Generics share of the PBS scripts has increased from 24% to 37%.[1]
- Over 50% of the prescriptions for patent expired medicines will have a generic substituted.[2]
- Top generics have an estimated substitution of over 65%.[2]
- The value of the PBS medicines that will lose patent rises from $500 million in 2010 to over $2.5 billion in the time period to 2014. [3]
- An evaluation of the consumer awareness campaigns conducted by the National Prescribing Service from June 2008 to July 2009 concluded that it had been successful in achieving its objective of increasing confidence and understanding about safety and efficacy of prescription generic medicines.[4]
- Several studies in the past have repeatedly pointed to the fact that Australian prices for patent expired medicines are higher than other comparable countries.

Existing generic incentives

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[1] Victoria University, T*he Impact of PBS Reforms on PBS Expenditure and Savings*, Table 6.5, 2009.
[2] Ascent Pharmaceuticals, ASX announcements, Annual General Meeting 2010 - Presentation to shareholders, 31 May 2010.
[3] Sigma Pharmaceuticals Limited, ASX announcements, Results Presentation for the Full Year ending 31 January 2010, 31 March 2010

- The $1.53 premium free dispensing incentive costed taxpayers an estimated $102.4 million in 2008-09.[4]
- Consumer awareness campaign costing $20 million was announced as part of the 2007-08 Budget.
- According to the 2010-11 Federal Budget, the Government will provide a further $10 million over four years to the National Prescribing Service to develop and implement a public awareness campaign about generic medicines

2. The data (sets/sources) used by MA to determine and validate MA members companies' share of the Generics market and other claims evidenced by graphs in our submission.

The Medicines Australia Members' share of the generic market was derived using multiple independent sources. The sources for each component are set out below:

- **Share of expenditure and prescription - GMIA, non-member generics and MA companies** - Pharmaceutical benefits Pricing Authority, Annual Report 2008-09, Department of Health and Ageing, Table 4 and 5 available at http://www.pbs.gov.au/industry/pricing/pbs-items/pbpa-annual-report-2008-09.pdf
- **The estimated expenditure and prescriptions by suppliers was further tested using IMS Health data** which reports sales ex-wholesalers into pharmacies. Data available upon payment from IMS Health (http://pma.au.imshealth.com/)
- **The share of expenditure by formulary (F1 and F2)** was based on the analysis by the Centre for Strategic Economic Studies, Victoria University, available at http://www.medicinesaustralia.com.au/pages/images/MA-FactsBook1.pdf
- **The share of expenditure was further tested using data available from Medicare Australia** supplied to Medicines Australia by the Department of Health and Ageing on monthly basis for Section 85 drugs, the formulary allocation and the Schedule of Pharmaceuticals Benefits available from www.pbs.gov.au .
- **The estimation of the 'Below-the-Co-Payments' market** was based on Pharmacy Guild Drug Utilisation Sub-Committee Survey data for the 12 months to December 2009. Available upon request from the Pharmacy Guild of Australia.
- **The estimates of the 'Below-the-Co-Payments' market** were further tested using the Australian Institute of Health and Welfare analysis *Trends in prescribed medicines* published in Australia's Health 2010, Pg 393-94 available at http://www.aihw.gov.au/publications/aus/ah10/ah10.pdf

3. Provide information on what percentage of PBS scripts are for medicines from F1 and the F2 formulary

   Based on the analysis done by the Centre for Strategic Economic Studies, Victoria University, in 2007-08, PBS scripts were divided as such:

   F1 formulary – 30%
   F2A formulary – 13%
   F2T formulary – 50%
   Combinations drugs list – 7%

[4] Commonwealth of Australia 2010, *The Impact of PBS reform, Report to Parliament on the National Health Amendment (Pharmaceutical Benefits Scheme) Act 2007*.

Source: the Centre for Strategic Economic Studies, Victoria University, available at http://www.medicinesaustralia.com.au/pages/images/MA-FactsBook1.pdf

4. What percentage of PBS medicines MA members sell, are manufactured in Australia? Please provide overall figures as well as those for each of the F1 and F2 formularies specifically?

   Based on MA member's economic survey results and other available information, on an average, just over half (53%) of all the pharmaceuticals produced by MA members in Australia is for the domestic market. However, it should be noted that this varies considerably between companies. Medicines Australia are unable to provide the F1/F2 split of production information in the time available to respond to the Senate. MA are happy to provide more information if required in the future.

5. Media stories on pharmacy discounting referred to in Medicines Australia's testimony

Attachment 1: 'Chemist get rich as we take our medicine', by Sue Dunlevy, *The Daily Telegraph*, Page 36 (Friday, 5 Feb 2010)
Attachment 2: 'Don't be fooled by generic savings', by Sue Dunlevy, *The Daily Telegraph*, Page 36 (Fri 24 Nov 2006)
Attachment 3: 'Drug kickbacks for pharmacists face chop', by Mark Metherell, *Sydney Morning Herald*, Page 3 (Mon 9 Oct 2006)
Attachment 4: 'What price our health?' By Annabel Stafford, *The Age*, Page 13 (Wed 16 Aug 2006)
Attachment 5: 'UK dumps generic substitution', Pharma in Focus, 12 November 2010, www.pharmainfocus.com.au

The statement made in Medicines Australia testimony quoting former health minister Tony Abbott on 2007 PBS reforms.

"The other matter that I should briefly touch on, the Generics Medicine Industry Association is not, as I understand it, especially happy with these changes. It believes that these changes will make it harder for them to maintain market share by removing the scope for them to offer discounts to pharmacists.

I make a couple of points in response. First of all, I point out that 70 per cent of the Australian generics market is occupied by companies which are not members of the Generic Medicines Industry Association, they are in fact members of Medicines Australia. They are the manufacturers and marketers of innovative patented drugs as well as of off patented drugs.

The other point I make is that we are, as part of these changes, ruling out a tendering system and I think that the whole sector including GMIA should be pleased that we are not going down the New Zealand path.

The final point I would make is that by removing the gross discounts from the system, we should ensure that domestic generic manufacturers are less at risk from predatory newcomers such as some of the Indian generic drug manufacturers."

Transcribed verbatim from the Transcript, Minister for Health and Ageing, Leader of the House of Representatives, Tony Abbott, MHR
Press Conference-PBS reform, Commonwealth Parliamentary Offices, Sydney.
Thursday, 16 November 2006
Available at http://www.health.gov.au/internet/ministers/publishing.nsf/Content/health-mediarel-yr2006-ta-abb161106.htm?OpenDocument&yr=2006&mth=11

MEDIA MONITORS

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Attachment 1

Daily Telegraph
05-Feb-2010
Page: 36
General News
Region: Sydney
Circulation: 369781
Type: Capital City Daily
Size: 609.72 sq.cms
MTWTFS-

Chemists get rich as we take our medicine

AS WORKERS knocked off early on Christmas Eve, distracted by preparations for their holidays, the Rudd Government dumped the details of a $15 billion pharmacy agreement that protects pharmacists and duds consumers.

In the media management business, this tactic is known as "putting out the garbage": Governments wanting to make unpopular changes hope to hide from exposure by issuing the press release late Friday evening — after the deadline for the major newspapers.

Releasing something on Christmas Eve is even better as most newspapers don't publish on Christmas Day.

The pharmacy announcement held bad news for chemists, who will lose about $40,000 a year in government payments from July this year — but it also contained bad news for consumers.

The Daily Telegraph revealed last year that taxpayers were losing hundreds of millions of dollars a year because our medicine subsidy system has created a monopoly for chemists and results in taxpayers paying between 50 and 80 per cent too much for drugs.

Health Minister Nicola Roxon is negotiating with pharmacists over the details of the new five-year agreement.

The last five-year pharmacy agreement (expiring on June 30) meant taxpayers paid pharmacists $12 billion to stick labels on their drugs, give advice about how to take them and record the sale for the drug subsidy scheme.

The new agreement will pay them $15 billion over the next five years.

There are about 5000 pharmacies, so that works out at — wait for it — about $600,000 per pharmacy per year.

Nicola Roxon has managed to save taxpayers $200 million a year by axing a 40c payment pharmacists were given to submit their claims for PBS subsidies electronically to Medicare. She also has frozen the indexation of their $6.42 per script dispensing fee for two years.

This will cut payments to pharmacies by an average of $40,000 a year.

It's a big win against a lobby group regarded as one of the most powerful and successful in Canberra.

But it carried some political risk because the cutbacks — angering 5000 small business people — will start in the middle of an election year.

The bad news for consumers in this agreement is that the Government has agreed to preserve the monopoly pharmacists have on dispensing drugs.

The suburban chemist has been turned into a multi-million-dollar business able to charge high prices thanks to these Government rules giving pharmacists a monopoly on prescription sales.

> Anyone can own a medical practice but only a pharmacist can own a pharmacy

Restrictions on pharmacy ownership are part of the reason consumers pay $13 more per script than they need to.

Under our system, while anyone can own a medical practice, only a pharmacist can own a pharmacy.

Attempts to change this have not been successful. A series of federal governments has prevented supermarkets from opening pharmacies.

The worst aspect of this monopoly is that it even works to prevent pharmacists and pharmacy graduates from opening up their own business because of rules that prevent a new pharmacy opening within 1.5km of an existing one.

These rules have meant the licences to operate a pharmacy are now selling for almost $550,000 — that's up $150,000 in the past year. They have also turned many pharmacists into millionaires.

Pharmacies in Sydney have been advertised for sale for $2.4 million on the website Ravens Business Services, which also reveals that some have an annual turnover of more than $3.3 million.

There are about 18,000 pharmacists but only 3000 pharmacy owners, many owning more than one outlet.

This lack of competition means consumers are paying as much as $13 per script more than they need to for about 200 commonly used medicines.

And that practice will continue if this monopoly is preserved.

The other huge problem with our drug subsidy scheme is that its out of date price setting system has not kept pace with the huge price drops for generic drugs and taxpayers are paying up to $30 per script more than they should for drugs like Simvastatin, which lowers blood cholesterol.

Chemists can buy packs of the 80mg version of this drug for as little as $18 but the Government re-imburses them at the rate of $48.18 per pack.

The Daily Telegraph has calculated that on this group of drugs alone taxpayers could save more than $72 million a year if the Government paid the true price for this drug, not the inflated price it pays chemists.

This newspaper has obtained a price list from a major drug wholesale company that shows chemists are able to buy hundreds of subsidised drugs at discounts of up to 63 per cent on the price the taxpayer pays them for the same medicine.

This particular aspect of medicine pricing is not covered by the five year agreement with pharmacists.

Next year, instead of putting out the garbage on Christmas Eve, wouldn't it be nice if the Rudd Government played Santa and delivered even bigger savings to taxpayers and consumers from its drug subsidy scheme?

Attachment 2: Don’t be fooled by generic savings

Author: **SUE DUNLEVY**
Publisher: **News Ltd**
Publication: **The Daily Telegraph, Page 036 (Fri 24 Nov 2006)**
Keywords: **medicine (3),Health (1),Minister (1),Tony (1),Abbott (1),pharmaceutical (2),Government (6),pharmacists (4),medicines (1),Pharmacia (1)**
Edition: **1 - State**
Section: **Features**

IMAGINE you saved 25 per cent on the purchase of a major household item only to discover that if you'd shopped longer you could have saved 50 per cent or even 70 per cent off the price.

Then imagine how you'd feel if most of the money from your 25 per cent saving had to be paid back to the shopkeeper you bought the goods from.

You'd feel ripped off.

Well, according to some pharmacy insiders, that's just what happened to you as a taxpayer and as a **medicine** consumer last week.

Health Minister Tony Abbott signed off on a major set of **pharmaceutical** reforms that will leave you paying much higher prices than you should for medicine.

And most of the savings he did achieve will be paid back to the shopkeeper you buy your medicines from -- the suburban pharmacists.

What's happened here can best be illustrated by looking at the case of one of the most commonly used drugs in Australia -- the cholesterol lowering **medicine** Simvastatin.

The Federal **Government** is paying **pharmacists** $55.93 for a pack of 40mg tablets of this drug under our drug subsidy scheme.

But some generic drug companies are selling the drug to pharmacists for as little as $16.78 a pack.

Pharmacists who take advantage of this generic deal are making a $39.15 profit on every pack of Simvastatin they sell.

The aim of the Government's reforms is to claim back that $39.15 profit for the taxpayer.

But instead of saving taxpayers the full $39.15, the Federal Government's plan will save them just $13.82.

This is because, when the Government's reform plan takes effect in August 2008, it will cut the price it pays for Simvastatin by just 25 per cent instead of 70 per cent.

There are 2.5 million scripts written every year for this basic medicine, so that means more than $63 million of your taxes is being wasted subsidising just one medicine.

It is also bad for you as a consumer -- if you've got a cholesterol problem and you don't get a pensioner discount you're paying $29.50 a pack for a drug that should really only cost you $23.60.

Under the Government's system it will be three years -- not until 2009 -- before the full 70per cent discount is taken into account when calculating what the **Government** will pay under this system.

Now you can see why **pharmacists** and the big drug companies are happy with the **Government**'s reforms.

The **pharmacists** are happy because, although the profits they are making from selling generics will be eroded, they're getting compensated.

The Government estimates it will save $1.7 billion over the next four years from these measures but they will give back $1.1 billion of these savings to pharmacists in increased dispensing fees.

This compensation will be crucial to the survival of up to one in five pharmacists, who industry insiders say only stay above water because of the profits they make from the sale of generic drugs.

And the Pharmacy Guild says it will also help end the perception that pharmacists are getting secret deals from drug companies.

Instead of being forced to rely on drug company discounts to make a profit, **pharmacists** will now be paid a more realistic fee by the **Government** to cover the cost of dispensing subsidised **medicines** to consumers.

This is a positive move.

The big drug companies are happy because their breakthrough new drug treatments will be quarantined from the 25per cent price cuts.

But former managing director of big **pharmaceutical** company **Pharmacia** and generic manufacturer Bellwether Chris Bilkey says the **Government** could have achieved much bigger savings.

Generic drug companies commonly offer discounts of between 50 and 70 per cent on commonly used medicines such as anti-depressants, blood pressure drugs, diabetes drugs and arthritis treatments, he says.

Peter Brown, the former manager of discount pharmacy Pharmacy Direct, confirms he was being offered industry discounts of up to 50 per cent off the price of drugs.

But Pharmacy Guild president Kos Sclavos says the tendering system these two men are proposing to achieve these savings would have meant only drug companies offering the lowest price would get the right to supply medicine to the drug subsidy scheme.

This would have left consumers with no choice about the brand of drug they took, could leave them with second rate drugs, as has happened in New Zealand, and could leave them vulnerable if the only supplier ran out of stock.

One of the main reasons we pay such high drug prices in this country is that 70 per cent of people want to use the more expensive brand name drug rather than cheaper copies, even when it costs them more.

So the higher prices we are paying for drugs are partly our own fault.

It's time both the Federal **Government** and the **medicine** consumer became more savvy shoppers.

Attachment3: Drug kickbacks for pharmacists face chop

Author: **Mark Metherell**
Publisher: **Fairfax**
Publication: **Sydney Morning Herald, Page 3 (Mon 9 Oct 2006)**
Edition: **First**
Section: **News and Features**

PHARMACISTS would forgo secret kickbacks from **drug companies** in return for compensation costing the taxpayer hundreds of millions of dollars, under a scheme the federal Minister for Health, Tony Abbott, is believed to be considering.

Pharmacists have fought to hold on to under-the-counter discounts of up to 70 per cent for dispensing some of the most lucrative **prescription drugs**, quadrupling profit margins approved under the **Pharmaceutical Benefits** Scheme.

For generic versions of widely used **medicines** such as cholesterol-lowering **drugs**, **pharmacists**' profits can dwarf the officially calculated margin of $10.74, yielding $49.89 for one prescription, according to figures provided to the Herald. But under a "give-back" scheme, it is understood Mr Abbott is considering an interim plan to return to **pharmacists** the **PBS** savings from scrapping the discounts.

The aim is to lift the secrecy cloaking the discounts **drug manufacturers** pay **pharmacists**.

This has been proposed as part of a **government** revamp to unlock potential savings to the **PBS** on generic **drugs** that cost significantly less overseas. The **PBS** sets the **price** the **Government** pays for a **prescription drug**, allowing **pharmacists** $10.74 in mark-ups and dispensing fees for a standard **prescription**.

Generic makers of chemically identical medicines can vie for business by offering discounts of 50-70 per cent to persuade chemists to dispense their brand.

For the generic version of a cholesterol-lowering **drug** such as Simvastatin, this can mean a 70 per cent **price** cut, and the **pharmacy** pays just $16.78 for a **drug** listed by the **PBS** at $55.93.

Generic versions of Fluoxetine, originally Prozac, have a **PBS**-approved **price** of $23.72 but can be sold to **pharmacies** for about half that.

Mr Abbott is getting heat from other cabinet ministers, including the Treasurer, Peter Costello, and the **Industry** Minister, Ian Macfarlane - the latter said to be outraged at the kickbacks to **pharmacists**' - to deliver the savings available from the rise of generics. But Mr Abbott is also under intense pressure from the influential **Pharmacy Guild** to protect its revenues.

Under the **PBS** subsidies, concession card holders pay only $4.70 for a prescription while consumers pay up to $29.50. The Government pays the rest if the cost of the **medicine** is higher.

Critics say that while the **PBS** has delivered universal access to modern high-cost **drugs**, it fails to provide real **competition** to keep **pharmacy prices** down.

Chris Bilkey, a former **drug company** chief executive, said there was an overwhelming need to change the **PBS**.

Mr Bilkey was the Australian chief of the former **drug** giant **Pharmacia** and later managing director of the generic company Bellwether **Pharma**.

He said analyses by both companies had shown the Government was paying $500 million a year more than it needed to for **generic medicines**.

Mr Abbott said yesterday that he would take seriously any proposal that a reputable organisation put to the Government to offer a better deal on **generic medicines**.

Attachment 4: What price our health?

Author: **Annabel Stafford**
Publisher: **Fairfax**
Publication: **The Age, Page 13 (Wed 16 Aug 2006)**
Keywords: **pharmaceutical (1),Government (22),medicines (6),PBS (9),medicine (4),Health (2),Minister (2),Tony (2),Abbott (2),Pharmacists (8),Pharmacy (3),pharmacies (3)**
Edition: **First**
Section: **News**

FOCUS - THE COST OF DRUGS

Is the **pharmaceutical** industry blocking **government** attempts to lower the price of **medicines**? Annabel Stafford investigates.

The dumbest smart guy he'd ever met. That was a colleague's description of federal Liberal MP Andrew Laming, adviser to then health minister Kay Patterson in 2002.

Certainly, understanding the pick-up-sticks system of Australia's Pharmaceutical Benefits Scheme (PBS) - shift one stick and hundreds of others move or fall over - let alone come up with a method for reforming it, takes some smarts.

And taking on what is considered one of the most powerful and effective lobbying blocs in Australia is, for a fledgling politician such as Laming, well, kinda dumb.

Laming's first encounter with an unhappy Pharmacy Guild of Australia came in November last year when the guild wrote to its member chemists in Laming's electorate of Bowman on the outskirts of Brisbane. Guild president Kos Sclavos accused the Government of devising "secretive plans ... behind our backs to restructure the PBS", which would "decimate community pharmacy".

He warned "your local member Dr Andrew Laming is one of the key people proposing the structure change according to my sources within the **Government**".

Earlier that year, Laming had called for reform of the **PBS** in an opinion piece for The Age. By November, demands for reform of the $6 billion-plus scheme were coming from several sources in and outside the Government. A secret inter-departmental working group had also been formed to figure out how to cut spending.

There was a common strand running through most reform options put forward - cut the price of generic or copycat medicines, for which Australia pays comparatively high prices - as well as the original drugs whose patents had expired. And boost generic drugs' share of the market.

These reforms would mean a big cut not just to the earnings of the drug manufacturers, but to the chemists who take a cut of the earnings through discounts from manufacturers and wholesalers. It works like this: the **Government** pays chemists for a **PBS**-subsidised **medicine**, which the chemist then buys from a drug company or wholesaler. But often chemists buy the **medicines** for much less than the allowance they get from the **Government** and so make a profit.

In the November letter, Sclavos charged doctors - of which Laming is one - with being the major culprits behind the blow-out in the cost of the PBS, since it was doctors who pushed up the PBS by poor prescribing.

The guild and other members of the pharmaceutical industry also wrote to federal MPs seeking their help to "meet ministers without delay so that the long-term viability of all industry ... are taken into account in the consideration of any new PBS policy options".

But this did not deter Laming and in January he wrote another opinion piece, this time for The Australian, criticising Australia's inflated generic drug prices and made other public comments on the same issue.

The guild responded by drawing the attention of Bowman pharmacists to "derogatory comments from Dr Andrew Laming".

Sclavos again warned chemists "if your pharmacy can't afford to lose $100,000 plus from the bottom line then you need to start doing something about this. Your patients need to be informed that Dr Laming is trying to close community pharmacies."

Many in Canberra see the Pharmacy Guild as the main heavy hitter in an industry noted for its political influence.

Woolworths chief executive Roger Corbett - who came up against the guild when trying to get pharmacies into his supermarkets - says it "has been described by some of the most senior politicians as the most powerful and effective lobbying group in the land".

"It comes from the fact that they play off the vast network of pharmacies throughout Australia and political influence they can be to their customers," he says.

Corbett believes almost everyone agrees with his argument "for the deregulation of the pharmacy market to bring competition, which would bring down the enormous cost the community is paying for pharmacy products. But because of its political clout (the guild) carried the day."

Australian Divisions of General Practice chief executive officer Kate Carnell, who has previously bargained on the guild's side for one of its five-yearly agreements with the **Government** covering how much they are paid to dispense **PBS** drugs, says its power comes from "4500 members".

The guild "have a very efficient backbench and marginal seats approach ... and the majority of Australians see their pharmacist every year. They know the public, they are trusted by the public and they know how to work the system."

Carnell, also a former ACT chief minister, says that while a drug company may have difficulty getting Government backbenchers to go into the Health Minister's office to lobby them on an issue, the guild is a master at it.

Chris Bilkey, former managing director of generic medicines company Bellwether Pharma, says with "5000 windows on the community, (the guild) is a lobbying group from which the Government and just about all the stakeholders take fear".

Its influence is demonstrated, for example, in "the very, very effective job they've done in keeping pharmacies out of supermarkets ... by mounting a scare campaign through their pharmacies (warning) the quality of care would deteriorate."

As one of those publicly calling for more competition and cheaper generic prices - though not disinterestedly, given that reform would help Bellwether break into a generic market currently thought to be commanded by Alphapharm and Sigma Arrow - Bilkey says he has personally experienced the guild's influence.

Early this year he was fired from his job as Bellwether managing director, though he remains on the board and a part-owner of the company.

About that time, Bilkey told this reporter that the Bellwether board had cited performance-related issues and a campaign against the company by the guild as reasons for his dismissal. Internal documents supported this. Bilkey says performance issues had not been previously raised with him and in his opinion were a smokescreen.

But Sclavos vigorously denies having any involvement in Bilkey's dismissal and says neither he nor his colleagues had any contact or relationship with Bellwether or Bilkey before his dismissal. While the guild has campaigned against "a proposal being credited to a certain individual ... I absolutely deny that we campaigned against him or made any contact with Bellwether. It's just garbage." Sclavos says Bilkey is using the excuse of the guild campaigning against him to mask his own underperformance.

In the latest iteration of proposed **PBS** reforms, put forward by **Health Minister Tony Abbott**, the guild's interests have once again been protected.

The reforms include requiring doctors to prescribe a cheap generic **medicine** unless they get **Government** permission to dispense a brand alternative, imposing mandatory 5 per cent price cuts on **PBS** drugs when generic medicines with the same health outcome are added to the **PBS** and forcing manufacturers to disclose at what price they sell PBS drugs to pharmacists. All this could substantially cut pharmacists' incomes.

But Abbott's proposal also includes compensation to **pharmacists** for income they lose as a result of PBS policy changes. A spokeswoman for Abbott said the **Government** was not bowing to pressure from the **pharmacists**, but that it did not want any group unduly affected by the reforms.

Sclavos says **pharmacists** are being reimbursed because the **Government** had committed to certain remuneration for chemists in the **Pharmacy** Agreement signed in November last year and the reforms would have substantially cut that.

In any case, the guild was not simply out for their own financial interests, but for the good of the PBS, he says. If they simply cared about the money, chemists would now be supporting Abbott's reforms. Instead, the guild was opposing the reforms along with the rest of the pharmaceutical industry.

Sclavos argues PBS reform is unnecessary. A new guild-commissioned report shows even without reform the cost of the PBS will be about $5.5 billion lower than predicted over the next five years. "This translates to $1 million for a pharmacy turnover or $200,000 turnover a year (for a chemist) and that's why we've been fighting so hard ... The existing system is (already) delivering savings."

Bilkey however, argues the discounts are not part of the negotiated dispensing and other fees that come under the agreement. But, he says, "the pharmacists are saying they have now built discounts into their revenue and to take them away would mean 10 per cent or more **pharmacies** would be forced to close, which is bulls---."

The **Government** could also save a lot of money by cutting out these unofficial payments. Bilkey reckons **pharmacies** buy **medicines** at up to half the allowance the **Government** provides for them. At Bellwether "we were competing with the other wholesalers (for **pharmacy** business) and we started with a 50 per cent discount (on the **Government** price). Our smallest discount was 50 per cent, the highest was 70 per cent - and we were not the deepest discounter.

"Pharmacists always target their (lobbying) campaign very effectively but this will be true in spades in this instance because of the seriousness of the revenue impact (from these reforms). Generic pharmaceuticals constituted around $800 million worth of sales last year and if you assume the average discount is between 40 and 50 per cent then we're talking about $300 million to $400 million ... going to **pharmacists** that is not part of the fee (agreed through the guild-**Government** agreement)."

Sclavos counters that "if there is so much profit in generics, why is generic substitution so low and ... why is the minister trying to increase generic substitution?"

Sclavos also denies "that those discounts are in the marketplace ... That sounds like he's saying that's the norm. It might be the discount for ... close-to-expired stock but that's certainly not the (average) discount."

Carnell says the guild "are just doing what their members expect them to. You can't blame lobbying groups for lobbying well."

Laming denies the Government has capitulated to the guild by agreeing to reimburse them for lost revenue, saying "there was always the idea that ... if the gains were sufficient they could be used to reimburse those groups affected by the reforms."

Laming says that despite fears among some that the guild could mount a marginal seats campaign before the election if they were unhappy with the reforms, he has "serious doubts about whether the guild would ever actually (do it)". And while there was "certainly ... a sense of alarm about my proposals early on" he has met the pharmacists in his electorate and is "confident their concerns have been allayed".

Sclavos says "from time to time we do naturally have to bring the attention of our membership (to articles such as Laming's). We wouldn't be doing our job if we didn't bring their attention to what was going on ... (but) we didn't say don't vote for him or vote for someone else."

Sclavos adds that when it comes to "PBS reform one issue that had to be considered was the role of doctors. Dr Laming should have at least put forward proposals for doctors to do better prescribing."

Bilkey argues the **Government** should not be reimbursing the **pharmacists** for money that was never rightly theirs. "Leaving aside the issue of whether discounts at that level are appropriate, this is a question of social justice. Is it appropriate that we as taxpayers should subsidise **pharmacies** to the tune of $300 million to $400 million a year simply because the **Government** can't find a way to make generic pricing competitive and is scared of the ability of the guild to wage an effective lobbying campaign against it?"

HOW THE **PBS** WORKS

THE **Government** says it subsidises about 80 per cent of prescriptions through the **PBS**, with patients contributing a small amount - $29.50 for general patients and $4.70 for concession card holders - regardless of how much the drug costs.

The **Government** negotiates with drug companies over how much it will pay for the **medicine** and then adds some money on top of this to cover costs such as distribution and dispensing.

Pharmacists receive this sum from the **Government** for **medicines**, which they then buy from a manufacturer or wholesaler. But many **pharmacists** buy some **medicines** for much less than this **Government** allowance and so make a profit.

THE INDUSTRY

THE **Pharmacy** Guild of Australia says it has about 4500 members and a presentation by ANZ Bank in 2005 estimated the industry earned about $9 billion in revenue in 2003-04.

PBS REFORM

THE reform plan put forward by **Health Minister Tony Abbott** and being negotiated with the industry includes:

- Forcing manufacturers to tell the **Government** the price at which they sell their **medicines** to **pharmacists**, allowing the **Government** to lower the amount it pays in line with that.

- Five per cent cuts to the price of PBS medicines when off-patent medicines with the same health outcome are added to the PBS - which will come on top of existing 12.5 per cent cuts when the first generic is added to that health outcome group.

- Requiring doctors to prescribe a low-cost generic version of a **medicine** unless they get **Government** permission to prescribe a generic alternative.

Caption :TWO PHOTOS: Andrew Laming (pictured) denies the **Government** has capitulated to the guild.

Attachment 5

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8 - 14 Nov 2010

News

***Instant Update*: Fri 12 Nov**

PBS 'blind' says MA boss

Legal changes to the PBS scheme are necessary to reveal the real price of medicines and ensure the Government is not paying inflated costs, Medicines Australia CEO Dr Brendan Shaw has told the Medicare Conference in Sydney.

Dr Shaw said the disclosure of the price at which companies are selling drugs to pharmacists needs to be mandated as currently it is optional and the Government is "paying overblown prices for older, off-patent medicines". He said the PBS was currently "blind to the real price of medicines.

"While in markets like the US and the UK typically the price of a medicine drops substantially after patent expiry and the entry of generics, historically in Australia this did not happen, or did not happen to anywhere near the extent as in other countries.This was an inefficiency in the market that meant that patients and taxpayers were paying too much for generics, while some manufacturers were enjoying the benefits of taxpayers subsidising the rebates they paid to pharmacists. Greater transparency and competition needs to be promoted in the off-patent medicines market," he said.

"The antibiotic Vancomycin for example cost $33.30 prior to price disclosure. Post-price disclosure the price is $12.19. That's a saving of $21.11 that goes back to the patient." The National Health Amendment (PBS) Bill needs to be passed in order for the MoU between the Federal Government and Medicines Australia to take effect. **SS**

Orphan status for Clinuvel drug

Australian-based Clinuvel has received orphan drug designation from the TGA for its photo-protective drug, Scenesse (afamelanotide), for the sun sensitivity condition erythropoietic protoporphyria (EPP).

EPP is a rare inherited disorder characterised by absolute intolerance to the sun. Exposure causes the skin to swell and scar, and the associated pain is described like having hot needles stuck into the skin. Sufferers can require continuous treatment with analgesics to cope with the pain and sun avoidance is recommended.

The drug has been granted Orphan Drug Designation by the EMA, FDA and Swissmedic for EPP and it is fully reimbursed in Italy, under a special approval program for drugs to treat conditions where no alternative therapy exits when the drug is still in clinical development.

Earlier this week the company announced the FDA has provided positive guidance on the data package required for a new drug application.

"It is rewarding to learn that drug safety appears to have been met. We will continue our program in EPP and other diseases to generate more safety and efficacy data in preparation of registration of afamelanotide in the US," Clinuvel's Chief Scientific Officer, Dr Hank Agersborg said. **SDT**

Plugging the PBS data gap

Provisions of the legislation underpinning aspects of the MoU will "address a missing data link" by allowing for improved data collection about PBS prescriptions under the co-payment , the NPS has said.

CEO Lynn Weekes said the NPS was particularly keen to see the realisation of improved data collection, which would provide a more complete picture of how the PBS was working for Australians. "For many years, NPS and other industry stakeholders have sought stronger provisions for collecting data about PBS prescriptions that do not attract a co-payment, in order to have accurate information about Australians' medicines use," she said, adding that the cost to consumers for under co-payment medicines is currently inaccessible.

From a quality use of medicines perspective, access to complete information about prescribing, dispensing and usage of medicines was a key factor in being able to identify areas for improvement, Dr Weekes said.

Statutory price reductions and price disclosure contained in the legislation would support the financial viability of the PBS, she added. "NPS is keen to see commitment from government, the medicines industry and the health sector more broadly in ensuring the sustainability and stability of the PBS." **NM**

Avexa bets on 'Twiggy' Forrest

Local drug developer Avexa is ending a difficult year on a high note by investing in Allied Medical, a device and biotech company whose major shareholder is the billionaire CEO of Fortescue Metals, Andrew 'Twiggy' Forrest.

Avexa will pay Allied Medical $1.5 million in two tranches, giving it a 24% stake. The first $750,000 will be paid immediately giving it a 14% share. It will also appoint a director to the board. The second payment is dependent on Allied Medical's ASX listing.

In July Allied Medical announced it was investing $3 million in Coridon, a vaccines-focused company, which is developing treatments for diseases such as hepatitis C and cancer. Co-creator of the cervical cancer vaccine Professor Ian Fraser is the Chairman and a director of Coridon. The funds from Avexa's investment will be used to pursue the Coridon technology.

Avexa chairman Joe Baini said it was drawn to Allied Medical because of its profitable business, growth potential, quality management led by Mr Forrest and the core science of Coridon. "Coridon's infectious diseases programs are complementary to, and have synergies with, Avexa's programs," he said. In May Avexa controversially halted its lead HIV development program. Calzada then acquired a 17% shareholding, which led to months of dispute over board control and the direction of the company. Last month Calzada sold its shares. **NM**

UK dumps generic substitution

The new UK Government has decided not to go ahead with a system of generic drug substitution proposed under its predecessor because of fears for patient safety.

In its response to a consultation on the issue conducted earlier this year, the government said, "In the light of the strong perception that generic substitution poses a threat to patient safety, the inconclusive position on cost effectiveness and the ability to utilise or explore other mechanisms to support the use of generic medicines, DH [Department of Health] will not be progressing any further the implementation of generic substitution. Instead, the DH will be looking at further ways to support the use of generic medicines in a way that is acceptable to patients, recognising that there are still some savings that can potentially be delivered in this area."

The proposed system - similar to that operating in Australia - gained a strong negative reaction from respondents to the consultation. "There were 225 comments on patient issues, the majority of which related to patient safety and wellbeing, epilepsy drug patient safety concerns and patient confusion, anxiety and non-compliance," the government said.

Unlike Australian doctors, most UK prescribers use generic rather than branded drug names with 83% of scripts written generically. **NL**

Thursday 11 November

Govt books $27m PBS saving

A PBS saving of $27 million will accompany the listing of Novartis' Novicrit (epoetin lambda) on the Highly Specialised Drugs program from December 1, according to the Mid-Year Economic and Fiscal Outlook (MYEFO) report published by Treasury on Tuesday.

The listing of the anaemia treatment will result in a "reduced price to Government for other drugs currently listed on a cost-minimisation basis to each other," the MYEFO said.

It added that $15.3 million would be spent over four years as the result of new listings including Humira (adalimumab) for the treatment of severe active juvenile idiopathic arthritis, Relpax (eletriptan) for the treatment of migraine attacks, Prolia (denosumab) for the treatment of osteoporosis and Seroquel (quetiapine) and Seroquel XR, for the treatment of bipolar disorder. The new listings and price amendments will provide net savings of $11.7 million over four years, the report said.

The MYEFO also says the Government has agreed to a number of minor new listings on the PBS and RPBS at a cost of $51.7 million over four years. This includes funding for Byetta (exenatide) for the treatment of Type 2 diabetes, Isentress (raltegravir) for the treatment of HIV and Remicade (infliximab), for the treatment of fistulising Crohn's disease. **SDT**

Bayer expands on re-branding

Bayer has confirmed its new branding strategy will affect divisions within Australia.

Christian Hartel, Communications and Media Relations Representative from the company's German headquarters, says the new worldwide branding strategy affects not only affect Bayer Schering Pharma but also business segments and product groups of all Bayer subgroups and service companies.

"Altogether, the brands to be dropped comprise about 20-30 third-level trademarks," Mr Hartel said "As part of our thorough brand architecture analysis of the whole Bayer portfolio, a detailed analysis following defined criteria will be done for all brands. Final decision on all brands still has to be done," he said.

He said the strategy will focus on existing brands and will be implemented in steps. "Visible measures will include new signage on buildings and business cards for example. The impact on our product packaging is a question that is currently being clarified internally.

"With regard to our employees, the new brand strategy will make it easier for marketing and sales to place strong product brands with customers. Internally, it should facilitate employees' identification with the company," he said. **SDT**

Cymbalta tries pain indication

Eli Lilly Australia has said it is "working with local regulatory agencies to determine relevant and appropriate paths to consider" in relation to an expanded pain indication for its antidepressant Cymbalta (duloxetine).

Last week the FDA approved the drug for the management of chronic musculoskeletal pain. In Australia it is indicated for the treatment of major depressive disorder, diabetic peripheral neuropathic pain and generalised anxiety disorder.

Cymbalta's exact mechanism of action in reducing musculoskeletal pain is unknown. It is a non-narcotic pain reliever to be taken once-a-day. Global Development Leader for Psychiatry and Pain Disorders at Lilly, Dr Robert Baker, said: "It's important that people with chronic musculoskeletal pain have different treatments available to them because responses to medications can be highly individualised. This is why we are happy to be able to provide doctors and patients with a new option." **NM**

Janssen pulls Yondelis filing

Documents just released by the TGA show that Janssen has withdrawn a marketing application for cancer drug Yondelis (trabectedin) following rejection by the minister's delegate and the Advisory Committee on Prescription

Medicines (ACPM) on the grounds that efficacy had not been established and that the risk-benefit was unfavourable.

The initial requested Indications were for the treatment of patients with relapsed ovarian cancer in combination with pegylated liposomal doxorubicin hydrochloride (PLD) and for the treatment of patients with advanced soft tissue sarcoma, after failure of anthracycline and ifosfamide.

The delegate was critical of the clinical evidence provided to support Janssen's application and found for ovarian cancer that the increase in progression-free survival with trabectedin of 1.5 months (per protocol) was not clinically noteworthy, overall survival or quality of life was not significantly increased and possible efficacy in platinum-sensitive patients needed confirmation in view of contradictory results for PFI 6-12 months and PFI > 12 months.

For soft tissue sarcoma, the delegate found that the treatment population likely to benefit was not defined, optimal trabectedin dosing regimen was not determined and the clinical significance of tumour responses and survival with trabectedin was uncertain when compared with the limited historical data provided and said a larger historical database including data for sarcoma subtypes was required. For both conditions, the delegate noted that the drug was associated with significant toxicity including toxicity-related deaths.

Janssen offered revised indications to be limited to patients with platinum-sensitive disease but these were still rejected.

The ACPM agreed with the delegate's proposal and recommended rejection of the indications but before a decision could be made Janssen withdrew its application. **SS**

Wednesday 10 November

MoU hangs in the balance

The MoU between the Government and Medicines Australia hangs in the balance following heated debate at yesterday's Senate Community Affairs Inquiry, which was dominated by questions about the level of stakeholder consultation by government and who represents the lion's share of the generics market.

Liberal Senator Concetta Fierravanti-Wells asked whether the MoU was not a potentially "protectionist" approach as a trade-off to MA members for savings. "It seems to me, given the way this agreement came into being, that it is a legitimate gripe of the generics industry," she said.

Deputy Secretary of the Department of Health, David Learmonth, conceded that whilst the GMiA was not consulted on the MoU when it was announced key elements of it, such as price disclosure were discussed with them. He said they were extremely clear they did not want existing price disclosure.

Liberal Senator Russell Trood questioned why the Department had not felt obliged to tell anyone it was negotiating an MoU even though it was engaging in a course of action that would be detrimental to the generics industry.

GMiA chairman Martin Cross maintained their members supply 75% of the volume of generic medicines and 68% of the value. He said "the government has an imperfect view of the market". The GMiA also questioned whether the MoU was legal under the Trade Practices Act.

Mr Learmonth said the Department had not sought specific legal advice but nothing had been raised by its lawyers during the drafting of the Bill. He added it was the Department's legal perogative to bring forward policy. He also said everyone had an imperfect view of the market. "We have a perfect view of what we pay for," he said and Medicines Australia represented the majority of the share of the off-patent market.

Medicines Australia said its members represent 60% of the cost of off-patent medicines. CEO Brendan Shaw said MA had calculated the market share several different ways. "Whichever way you cut it, our members account for the majority of the off-patent market," he said.

The committee expressed frustration and confusion at the discrepancies in the figures and sought details of where the GMiA, MA and the Department got them from by the end of the week. The committee is due to report next Tuesday. **NM**

Genzyme 'open' to sanofi

As its bid for Genzyme remains in limbo, sanofi-aventis has received a letter from its target reiterating that the offer price is too low but expressing a willingness to meet if the offer is improved.

Genzyme said the US$69-per-share offer is "not an appropriate starting point for discussions" because it "dramatically undervalues the company."

In particular Genzyme points to the revenue potential of its experimental multiple sclerosis drug alemtuzumab which, it says, sanofi has chosen to ignore while sticking to an "opportunistic and inadequate" offer.

The letter adds, however, that the Genzyme board is open to a transaction that recognises Genzyme's intrinsic value and prospects, and will meet with Sanofi if it makes an offer that the Board of Directors deems appropriate. **SDT**

Bayer to re-brand

The Bayer Group has announced that it will no longer conduct its pharmaceuticals business under the name Bayer Schering Pharma but only under the Bayer HealthCare brand.

The move is part of plans to implement a new branding strategy to strengthen the overall recognition and competitiveness of the umbrella Bayer brand.

Individual units within subgroups and service companies will be gradually discontinued and the brand portfolio will be restructured to raise Bayer's profile and products in the marketplace.

"We have thoroughly analysed our brand portfolio and found that the diversity of brands in the Bayer Group has diluted the umbrella brand," explained Dr. Marijn Dekkers, Chairman of the Board of Management. "Our goal is to significantly increase the value of our brand portfolio by concentrating on the umbrella brand and our product brands." **SS**

Generic perindopril recalled

Apotex is undertaking and urgent recall of certain batches of APO-Perindopril after it was found 2mg cartons may contain 8mg tablets.

The affected batch numbers are listed on the TGA website and, to date, no adverse events have been reported. Patients have been advised to return the affected products to their pharmacy as quickly as possible to arrange for a replacement.

"Perindopril is a medicine used to treat high blood pressure and heart failure," the TGA notification said.

"A patient taking an 8mg tablet instead of a 2mg tablet could suffer serious adverse effects such as low blood pressure, dizziness and fainting," it said.

Apotex declined to comment. **SDT**

Tuesday 9 November

GMiA takes the gloves off

On the eve of today's Senate hearing on the MoU, the GMiA has mounted an unprecedented public attack on the agreement and the policy behind it.

The organisation placed a full page advertisement in

metropolitan newspapers, including Sydney's *Daily Telegraph,* yesterday calling the MoU a "damaging policy" and a "cynical cash grab by Government".

The ad says price cuts will disrupt the supply of life-saving medicines to patients and that local jobs and opportunities will disappear. It calls the MoU a protectionist deal negotiated in secret between the Government and large branded companies that will damage Australia's leading manufactured goods export industry.

The Consumer Health Forum called the campaign "scaremongering".

"Some of the claims made in these ads are misleading and will frighten vulnerable people who are reliant on regular access to prescription medicines," said Executive Director, Carol Bennett. "Under current agreements, wholesalers and pharmacists have an obligation to provide timely access to medicines. If there is any suggestion that this will not happen, the Government can introduce transition arrangements. These measures will make medicines more affordable for those who most need them." **SDT**

Pan case goes to mediation

Pharm-a-Care Laboratories versus the TGA, the leading case in the $120 million class action arising from the 2003 recall of Pan Pharmaceutical products, will begin mediation next week in a last ditch attempt to settle the protracted legal battle.

If mediation is unsuccessful two months of court dates have been scheduled for a final hearing between March 7 and May 6 next year. Mediation is scheduled to begin on Monday, November 15 with a mention in the Federal Court due to take place one week later on November 22.

The action, involving businesses that allege they lost money as a result of the recall, was launched in December 2008. Led by Pharm-a-Care Laboratories, it names a number of former and current TGA officers as respondents as well as the Commonwealth.

Pan Pharmaceuticals collapsed in 2003 after the TGA ordered it to shut down and initiated a recall of more than 200 of its products. In 2008 its founder, the late Jim Selim, won a $50 million settlement plus costs after suing the TGA for misfeasance in public office. He claimed the recall was motivated by a vendetta within the regulator. **NM**

Lipitor rivals line up

A number of generic versions of the world's biggest selling drug, Lipitor (atorvastatin), have been registered on the ARTG ahead of its 2012 patent expiration.

Alphapharm and Apotex have both registered generic versions of the cholesterol lowerer over the last year. PBS outlays on the statin were $597 million in the year to June and it brings in around US$11.4 billion in global sales annually for Pfizer.

The company has defended Lipitor in court challenges by Ranbaxy around the world, including in Australia. A 2008 settlement cleared the way for entry of generic versions of the drug three months earlier than expected in February, 2012. **NM**

MabThera seeking extension

Roche has confirmed it is awaiting a verdict from the TGA on use of MabThera (rituximab) as first line maintenance therapy for follicular lymphoma after filing the new indication in June.

The company recently announced that the European Commission has approved the use of the drug as a maintenance treatment for people suffering from follicular lymphoma who have responded to initial induction therapy. The approval is based on results from the phase III PRIMA study with a site at the Peter MacCallum Cancer Centre in Melbourne, which showed MabThera doubled progression free survival when taken as a maintenance treatment in patients who responded to initial treatment with MabThera plus chemotherapy.

"The European approval of first line MabThera maintenance treatment of follicular lymphoma is excellent news for patients," Dr Hal Barron, Head of Global Development and Chief Medical Officer at Roche said.

"Reducing the number of times the disease relapses and requires subsequent treatments will improve the lives of patients with this specific type of blood cancer," he said.

The drug has been submitted for approval for the same indication in the US, Japan and Canada. **SDT**

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