

20 March 2013

Committee Secretary
Senate Standing Committees on Community Affairs
PO Box 6100
Parliament House
Canberra ACT 2600
Via email to: community.affairs.sen@aph.gov.au

Dear Sir/Madam

I am writing in reference to the Senate Community Affairs References Committee inquiry into the 'Supply of chemotherapy drugs such as Docetaxel'. Medicines Australia's submission to the inquiry is attached.

Medicines Australia is the peak organisation representing the research-based pharmaceutical industry in Australia. Its members comprise over 80% of the prescription medicines market and play an integral role in delivering better health outcomes for Australians through the discovery and bringing to market of new and innovative medicines.

In the attached submission, Medicines Australia reaffirms its commitment to the architecture of PBS reforms, which have delivered significant savings and will continue to provide savings into the future. To achieve a more transparent health care delivery system, Medicines Australia supports an open and collaborative approach with stakeholders to determine the appropriate system to deliver the necessary services associated with complex medicines.

To this end, Medicines Australia reiterates the recommendations as follows:

- Note the architecture of PBS reforms and how the price disclosure mechanism delivers appropriate, efficient prices for medicines;
- Note the structure of PBS subsidy includes multiple components, including the funding for the medicine and funding for supply services;
- Recommend that the Government work with the stakeholders involved in the supply of chemotherapy drugs to ensure Australian patients continue to receive the treatments they need in a timely and affordable manner; and
- Recommend that affected stakeholders utilise the Pharmaceutical Industry Discussion Group (PIDG), a forum convened to consider issues relating to PBS.

Yours sincerely,

Ms Elizabeth de Somer
Director, Health Policy & Research

MEDICINES

Australia

Better Health through Research and Innovation

**Submission to the Senate Community Affairs
References Committee Inquiry into:**

‘Supply of chemotherapy drugs such as Docetaxel’

20 March 2013

Introduction

Medicines Australia is the peak organisation representing the research-based pharmaceutical industry in Australia. Its members comprise over 80% of the prescription medicines market and play an integral role in delivering better health outcomes for Australians through the discovery and bringing to market of new and innovative medicines.

The innovative pharmaceutical industry has been providing treatments for cancer for several decades, and the industry remains committed to research and development of new advances in cancer therapy with as many as 932 cancer medicines currently under development.¹

The introduction of new medicines, including cancer treatments, relies on the sustainable management of the Pharmaceutical Benefits Scheme (PBS). For this reason, Medicines Australia has been a consistent supporter of systematic reforms that deliver a sustainable system. Major reforms include the PBS reforms introduced in 2007 and the further pricing reforms of 2010, which were negotiated with the Commonwealth in the Memorandum of Understanding (MoU) with Medicines Australia.

Together these reforms have hard-wired sustainability into the PBS by subsidising older, off-patent medicines at prices determined by competition in the market while continuing to value new medicines on the basis of delivery of health outcomes and cost effectiveness. Australia's rigorous evaluation processes mean that only new medicines that can demonstrate 'value for money' are added to the PBS.

Equitable access to medicines in Australia is made possible by Government subsidies through the PBS. The subsidy is paid by the Government to the dispenser, (generally through hospital or community pharmacies). The Government subsidises not only the cost of medicines, but also a number of supply chain services between the manufacturer and the supply of the medicine to the patient. Supply chain services include distribution, processing, dispensing, and in the case of some chemotherapy drugs like docetaxel, specialised pharmaceutical compounding services.

Greater transparency of the various components of medicines funding (both product and service related) should enable the Government to ensure that each component is funded appropriately. The subsidy level set on the PBS constitutes distinct components:

- The ex-manufacturer cost of the drug supplied by the manufacturer;
- The costs of the supply chain to deliver the drug from manufacturer to dispenser; and
- Remuneration for the dispensing of the drug by qualified health care professionals. Recently, amendments were included to accommodate the funding of particular chemotherapy drugs, such as docetaxel.

Before PBS reforms, the difference between the price of the medicine purchased by the dispenser and the price subsidised by the Government was used by pharmacy supplement the provision of supply services. However, following the 2007 and 2010 reforms, the Government now bases its subsidy to the dispenser, for off-patent medicines, on the prices at which such medicines are purchased in the market (e.g. by pharmacies and private hospitals). The price disclosure mechanism simply adjusts the price of the drug product, and this should not be conflated with the separate and distinct costs of providing the service. If these changes have challenged the existing supply

¹ Medicines Australia Facts Book, Edition 3 (March 2013), at page 57. Available online: http://medicinesaustralia.com.au/files/2010/11/MAFactsBook3_2013-FINAL.pdf

model then this highlights the need for Government to work with all supply chain stakeholders to discuss how their businesses are affected, consider whether the provision of supply services is jeopardised and determine how this may be remedied.

This is a separate matter to the pricing of the medicines determined through the existing and successful price disclosure mechanisms

Medicines Australia recommends that the Committee:

- Note the architecture of PBS reforms and how the price disclosure mechanism delivers appropriate, efficient prices for medicines;
- Note the structure of PBS subsidy includes multiple components, including the funding for the medicine and funding for supply services;
- Recommend that the Government work with the stakeholders involved in the supply of chemotherapy drugs to ensure Australian patients continue to receive the treatments they need in a timely and affordable manner; and
- Recommend that affected stakeholders utilise the Pharmaceutical Industry Discussion Group (PIDG), a forum convened to consider issues relating to PBS.

Supply of chemotherapy drugs

Subsequent to the structural PBS reforms regarding the pricing of medicines (detailed in sections below) the *Revised Arrangements for the Efficient Funding of Chemotherapy Drugs* regarding relevant supply services commenced on 1 December 2011. These arrangements were designed in consultation with stakeholders to set appropriate remuneration levels for chemotherapy drug supply services and to achieve greater efficiency in the use of injectable and infusible chemotherapy medicines.

The new arrangements require prescribers to write dose specific prescriptions using milligrams and payment is based on the combination of vials that most cost efficiently makes up the required patient dose.

Chemotherapy drugs covered by these Revised Arrangements are now supplied under the section 100 program of the PBS. As shown in Table 1, there are different sets of fees and mark-ups available depending on the classification of medicines on the PBS and the type supplier (community pharmacy, public hospital and private hospital). For the supply of docetaxel in public hospitals the PBS list price (Dispensed Price for Maximum Amount, DPMA) is \$931.47 whereas the supply of docetaxel in private hospitals and private clinics has a DPMA of \$1002.81.

Pharmacies and hospitals have argued that the current fees and mark-ups do not fully reimburse the costs associated with supplying chemotherapy drugs.

	s94 Public	s90 Community	s94 Private
Mark-up on ex-manufacturer price			
Mark ups <i>s90 Mark up (as per 5CPA DPEMA)</i>	\$0.00	Up to and including \$30.00: 15% Between \$30.01 and \$45.00: \$4.50 Between \$45.01 and \$180.00: 10% Between \$180.01 and \$450.00: \$18.00	1.40%
Applicable fees			
Wholesale fee		\$24.38	\$24.38
Diluent fee		\$4.83	\$4.83
Preparation fee	\$40.64	\$40.64	\$40.64
Ready prepared dispensing fee		\$6.52	\$6.52

Stakeholder consultation

The amount the Government reimburses for off-patent drugs such as docetaxel is subject to price disclosure and the true prices the drug is sold for in the market, as explained in more detail in sections below. From 1 December 2012, the Government adjusted its reimbursement for docetaxel in line with the discounted prices manufacturers were providing to pharmacists.

The costs relating to supply chain services are distinct and separate from the prices of the individual medicines and the policy which underpins the pricing regime. They should be treated separately for the purposes of resolving policy concerns in order to maintain transparent and efficient pricing across the products and services required to deliver equitable access to medicines for Australians.

Medicines Australia recommends that the Government agree to work with the affected stakeholders to understand the different components of medicines services in order to overcome any issues affecting the supply of chemotherapy drugs and to establish whether supply services are appropriately funded.

It is inefficient for one part of the health care budget to supplement another without any visibility or accountability. If stakeholders allege this has been occurring, transparent and accurate analysis of the costs of services required to deliver medicines such as docetaxel to patients should be conducted. Different reimbursement rates based on where a medicine is supplied further highlights the need for review, as supply chain fees apply whether the drug is supplied through community pharmacy, public hospital or private hospital.

The Government should work together with the relevant stakeholders and Government departments to determine the appropriate funding model that enables timely and affordable delivery of medicines and services, in line with the commitment to a universal health care system.

Pricing of medicines

The reduction in the reimbursed price for docetaxel from 1 December 2012 is an example of how PBS reforms have successfully introduced greater transparency and sustainability into the pricing of medicines on the PBS.

These reforms, commencing in 2007 under the previous Coalition Government, introduced a series of microeconomic changes to the scheme designed to take advantage of market driven competition in off-patent and generic medicines. This necessitated dividing the PBS into two distinct formularies and markets, F1 and F2:

- **F1 Formulary is for single brand medicines** (i.e. typically patented, originator medicines without competition) where efficient price setting and cost control is achieved through rigorous cost effectiveness evaluation and initial prices are set by reference to different therapies used to treat the same conditions. The price paid by Government for these medicines is that which can be demonstrated by the evidence to be 'value-for-money'.
- **F2 Formulary is for multiple brand medicines or medicines that are deemed interchangeable at the patient level.** Therefore, competition between brands establishes the price paid for by the taxpayer. Before PBS reforms, the Government reimbursed pharmacists for the full listed price of a medicine, regardless of discounting within the supply chain. PBS reforms introduced the first price disclosure policy, the objective of which was to make the prices that companies sell new F2 medicines to pharmacists and wholesalers at more transparent. The reimbursed price is then adjusted to a weighted price that accounts for the average price at which manufacturers sell individual medicines to the market. The elegance of the price disclosure policy is that it uses companies' own decisions to extract savings, thus minimising direct Government intervention in the marketplace.

The further PBS reforms of 2010, negotiated as the MoU between the Commonwealth and Medicines Australia, built upon the principles and architecture of the 2007 reforms by expanding and accelerating the price disclosure policy. These reforms came with a substantial financial impost to industry. In return, Medicines Australia sought a period of stable and predictable business and policy operating environment through agreed provisions of the MoU including a moratorium on the formation of new therapeutic groups and a four-year period of no new pricing policy.

A key aspect of PBS reforms was to deliver savings in order to create headroom for access to innovative new medicines. In the area of new cancer therapies, this promise of access is not being delivered upon. Instead, there is growing evidence that the reimbursement of new cancer therapies is becoming increasingly difficult, with a very high rejection rate by the PBAC and real difficulties in terms of evidence requirements which cannot be met. Medicines Australia believes that access to cancer therapies is as pressing an issue as supply concerns regarding older chemotherapy products

Savings from price disclosure

Price disclosure has been running since 1 July 2007 and evidence demonstrates that the market competition based price disclosure mechanism is working to deliver better value for tax payers in the multiple brands F2 Formulary. Currently there are 302 medicines² in various forms (and by route of administration) included in price disclosure under the current mechanism.

According to the Department of Health and Ageing 2011-12 annual report, the Government saved an estimated \$112.5 million from Price Disclosure; up 165% from \$42.5 million in 2010-11. Similarly, the Government saved over \$189.3 million from 2010 Further PBS Pricing Reforms in 2011-12 compared to \$30 million in the year prior. Together these reforms delivered \$302 million in savings to the tax payers in 2011-12. To put these savings in perspective, in the year to 30 June 2012, the total increase in PBS expenditure was \$282 million.³

In recognition of the savings to be delivered through 2007 PBS reforms the Government implemented “a support package to help pharmacy to adjust to the new arrangements.” According to The *Impact of PBS Reform* report tabled to Parliament in December 2009, the total cost to Government of the structural adjustment package was \$359.3 million to June 2009.⁴

Pharmaceutical Industry Discussion Group

Stakeholders should also raise their chemotherapy supply concerns through the Pharmaceutical Industry Discussion Group (PIDG). The PIDG was convened “to identify and examine any potential unintended consequences of, or relevant issues relating to, the *National Health Amendment (Pharmaceutical Benefits Scheme) 2010*, which gave effect to the 2010-11 Budget Measure ‘Further Pharmaceutical Benefits Scheme (PBS) Pricing Reform’ and commenced on 1 December 2010”⁵.

Representatives on the PIDG comprise industry peak bodies, including Medicines Australia, AusBiotech, the Pharmacy Guild of Australia, the Generic Medicines Industry Association and the Consumers Health Forum, among others. At meetings held to date, the group has noted that:

- reductions of the price Government pays for reimbursed medicines have ranged between 10.45 per cent to 82.71 per cent;
- from the 1 April 2012 cycle alone, the price of medicines to consumers has dropped, with more than 60 drugs falling below the general co-payment and 126 brands with a reduced special patient contribution premium;

² Department of Health and Ageing, *Drugs subject to Expanded and Accelerated Price Disclosure - 1 March 2013*. Available online at <http://www.pbs.gov.au/info/industry/pricing/eapd/eapd-drugs> (accessed on 20 March 2013)

³ Department of Health and Ageing, Annual Report 2010-11 (page 99) and 2011-12 (page 103), Part 2, Outcome 2 Access To Pharmaceutical Services. Available online at <http://www.health.gov.au/internet/main/publishing.nsf/content/annual+reports-3> (accessed on 20 March 2013)

⁴ Department of Health and Ageing, *Impact of PBS Reform* Report to Parliament on the National Health Amendment (Pharmaceutical Benefits Scheme) Act 2007, 2010, at page 9. Available online at [http://www.health.gov.au/internet/main/publishing.nsf/Content/95DCCB478B78DBD9CA2576C500130B0A/\\$File/Impact%20of%20PBS%20Reform%20Report.pdf](http://www.health.gov.au/internet/main/publishing.nsf/Content/95DCCB478B78DBD9CA2576C500130B0A/$File/Impact%20of%20PBS%20Reform%20Report.pdf) (accessed on 20 March 2013)

⁵ Department of Health and Ageing, Pharmaceutical Industry Discussion Group (PIDG) Report, September 2012 at page 4. Available online at: <http://www.health.gov.au/internet/main/publishing.nsf/Content/PIDG-report> (accessed on 15 March 2013)

- the dispute resolution mechanism provides opportunity to resolve issues raised; and
- the total value of EAPD savings will be achieved as anticipated

Conclusion

In conclusion, Medicines Australia reaffirms its commitment to the architecture of PBS reforms, which have delivered significant savings and will continue to provide savings into the future. To achieve a more transparent health care delivery system, Medicines Australia supports an open and collaborative approach with stakeholders to determine the appropriate system to deliver the necessary services associated with complex medicines. To this end, Medicines Australia reiterates the recommendations as follows:

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