MEDICAL ONCOLOGY GROUP OF AUSTRALIA INCORPORATED
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PRIVATE CANCER PHYSICIANS OF AUSTRALIA

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The Committee Secretary
Senate Standing Committees on Community Affairs
PO Box 6100
Parliament House
Canberra ACT 2600
Australia

A Joint Submission to the Senate Standing Committees on Community Affairs

On the

SUPPLY OF CHEMOTHERAPY DRUGS SUCH AS DOCETAXEL

Submitted by:

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Introduction

This submission is being made by the Medical Oncology Group of Australia (MOGA) and the Private Cancer Physicians of Australia (PCPA) on behalf of our patients. These groups are the professional organisations representing Medical Oncologists within the Royal Australian College of Physicians and Medical Oncologists and Clinical Haematologists who practice privately in Australia. As the lead groups of clinicians who use chemotherapy and associated techniques to treat people with cancer, we believe the current lack of adequate funding for the safe delivery of chemotherapy within the existing Efficient Funding of Chemotherapy Drugs initiative will seriously impact on our patients' rights to timely, safe, state-of-the-art drug therapy.

Private hospitals and day procedure centres collectively deliver 60% of chemotherapy admissions for cancer patients in Australia - more than 200,000 same-day episodes of treatment per year and some 13,000 infusions per week. A loss of just some of these services has potentially drastic flow-on effects for patients and the public health system.

A flood of patients moving from the private to public health system would cause a severe increase in demand for infrastructure, personnel and funding resources that the public health system would be unable to accommodate.

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Equally, inadequate Pharmaceutical Benefits Schedule (PBS) funding for chemotherapy will also reduce funds for service delivery in many State public chemotherapy units, exacerbating the impact of private patient transfers.

For cancer patients, these changes could cause substantial increases in direct and indirect costs of their care, the need to travel further to receive treatment, delays in life-saving treatment if they are moved to the already strained public health system and increased risks from lack of continuity of care.

This is not, as sometimes portrayed, a simple matter of removing an excessive subsidy for the drug Docetaxel but rather a failure to complete a government initiated reform to chemotherapy funding agreed to by all stakeholders in 2009. Transparent sustainable funding is not achieved by demonstrably inadequate funding. This paper will discuss the history of the present reforms and the effects of failure to complete the 2009 reforms.

Background

In response to a 2008 Budget announcement on chemotherapy funding discussions began regarding "The Efficient Funding of Chemotherapy" in 2008 between the Department of Health and Aging (DOHA) and a group consisting of the following medical professional associations: Private Cancer Physicians of Australia, Medical Oncology Group of Australia, Haematology Society of Australia and New Zealand, Clinical Oncological Society of Australia, pharmacy groups including The Pharmacy Guild, The Community Pharmacy Chemotherapy Supply Group and The Society of Hospital Pharmacists of Australia as well as consumer groups. The combined group view was that the initial proposal for funding based on dose delivered regardless of vial size announced in the 2008 Federal Budget was essentially unworkable with significant practical, financial and clinical difficulties. An alternative proposal based on the concept of nearest vial dosing was proposed with detailed modelling prepared by the combined professional groups.

In June 2009, at a meeting with the Honourable Nicola Roxon, Minister for Health there was recognition of the benefits of a suite of reforms to chemotherapy delivery developed in consultation between the Government, DOHA and the relevant professional and consumer groups.

There was at this stage agreement on a number of issues:

1. Economically rational funding of chemotherapy agents was necessary to maximise access to present and emerging drugs.
2. There was a clear need to rationalise the administrative processes around authority prescribing and reimbursement which were a considerable and costly workload issue.
3. Implementation of new proposals in a reasonable time frame to avoid patient service disruption.
4. Funding in Community Pharmacy and public hospital pharmacies was dependent, at that time, on cross-subsidies from certain high margin chemotherapy agents. There would need to be rationalisation of funding to ensure both transparency and viability going forward. It was recognised that this *would be separate* to the then emerging Fifth Pharmacy Agreement.

The ultimate formal reply from DOHA addressed the following:

1. Confirmed the plan to ''streamline'' chemotherapy agent prescribing, to reduce the excessive paperwork load and the significant carry over costs of administration.
2. Confirmed modification of patient co-payments under any new proposals would not place undue burdens upon patients or hospitals.

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3. The introduction of the concept of the nearest vial proposal which was the core proposal in the chemotherapy reform measures.
4. The development of a viable chemotherapy pharmacy funding model going forward to ensure that the impact of price disclosure would not damage the maintenance of a viable and safe pharmacy model. At this point, resolutions of the issues around funding changes for Docetaxel and Oxaliplatin in 2012 were recognised as essential in developing a viable funding model after bedding down the first parts of the reform.
5. The development of e-prescribing across public and private sectors to further streamline the process of chemotherapy pharmacy.

These proposals were agreed and led to the introduction of "The Efficient Funding of Chemotherapy" (EFC) program as a major reform in the area of chemotherapy delivery in early 2011. We are now faced with the situation where the first three parts of this reform are successfully in place and combined with price disclosure are making savings of greater than $230M/year. MOGA and PCPA have been pleased to be leaders in the fashioning of this reform. However, subsequent progress has been disappointing in view of the agreed outcomes in 2009. There is only slow and seemingly reluctant movement towards part 5.

However, it is part 4 which is now being contested as it threatens the quality and viability of chemotherapy services going forward. In essence while we are prepared to spend $1.45B/yr (2011 PBS figures) on antineoplastic and immune-modulatory agents, we cannot now reinvest $64M of the $230M/yr savings as initially envisaged to ensure safety and reliability of supply of these agents to cancer sufferers.

Preparation and Administration of Chemotherapeutic Agents

There are a number of steps involved in the preparation and delivery of chemotherapy:

1. The oncologist creates the chemotherapy order. This includes the names of the drugs, the doses, the dates of treatment, the method of administration, the type of fluid to contain the drugs and the duration of the treatment.
2. The orders are transmitted to the pharmacy, where the designated oncology pharmacist will review the orders for accuracy and completeness.
3. The oncology pharmacist will prepare the drugs for infusion. Because of potential side-effects from chemotherapy, including myelosuppression, teratogenesis, carcinogenesis and sterility, concern has been raised regarding potential hazards to personnel handling chemotherapy. Studies indicate that observing certain precautions while handling chemotherapy reduces personnel exposure and presumably risk. This preparation is carried out by highly trained staff wearing protective clothing using a specialised biosafety cabinet.
4. The oncology pharmacist will check and label all drugs prepared, as well as providing supportive care medication and deliver it to the infusion centre.
5. The infusion nurse will then check every labeled infusion against the orders generated by the oncologist prior to administration of the drugs.
6. The oncology pharmacist will interview the cancer patient prior to infusion of chemotherapy to determine if any current medication the patient is taking could potentially adversely react with the chemotherapeutic agents. If this is the case, the oncologist will be alerted.
7. The oncology pharmacist will then explain to the patient the supportive care medication they need to take in the days post-chemotherapy. This can involve up to eight medications including anti-emetics, prophylactic antibiotics and colony-stimulating factors.

It is widely acknowledged that specialised oncology pharmacists are vital to the safe and timely administration of chemotherapy and potentially save the health system millions of dollars, through reduction in wastage and

elimination of severe unnecessary drug toxicities through mistakes, drug interactions or patient misunderstanding. National standards have been introduced to codify these necessary practices to ensure patient and carer safety.

Despite this vital and clearly accepted role, DOHA have repeatedly ignored the cost implications of safe chemotherapy delivery according to accepted national standards. It would appear that DOHA regards the PBS preparation and delivery of chemotherapy as equal in complexity and cost as the dispensing of oral penicillin in a community pharmacy. At the very least they have sought to separate those costs in the case of cancer therapy from the PBS responsibility.

Better Funding

We acknowledge the pricing disclosure system must be supported as a means of providing savings that will help pay for other new medicines. It also delivers transparency that allows accurate comparison of costs of new medications. Our previous discussions with the Minister were based on those principles. We support the efficient pricing of all medicines but must stress the current remuneration model for chemotherapy does not reflect how contemporary cancer services are delivered. Furthermore, all parties had agreed to support the pricing disclosure after the department's agreement in 2009 that its impact would not damage the maintenance of a viable and safe pharmacy model. So far, the department has not held up its end of the bargain.

Price disclosure has meant the funding model has now become unviable for community pharmacies or private hospital pharmacy departments. The reality is that pharmacies along with the health system more broadly have been reliant on the trading terms on medicines like Docetaxel to cross-subsidise other medicines and other services, such as clinical pharmacy review and patient education, for many years. The 76.2% price reduction on Docetaxel (which is used to treat breast, prostate and lung cancer) combined with large price reductions on Oxaliplatin (72%) last August and Pacliataxel (87%) planned for 1 April 2013, means that the pharmacy loses an additional $100 per infusion made. Maintaining this loss is not sustainable.

The refusal by the Department to fund these losses is difficult to comprehend when the introduction of Price Disclosure has already delivered substantial savings from chemotherapy drugs (estimated at $200M/year) in addition to the $30-40M/year saving from December 2011 after the introduction of the agreed 2009 changes. Unless the EFC pricing schedule can be adjusted and an alternative source of funding found, the current business models that exist in those pharmacies providing chemotherapy in the private sector will be severely weakened. On the figures provided to our Associations by hospitals and pharmacies, the business case of providing cancer care is now being weakened to the point where Boards and providers of finance do not regard this as a sustainable area of practice. While immediate closures have not taken place (a reflection of the professional commitment of all those involved) there will be a gradual withdrawal of existing providers and a failure to develop new services to meet emerging needs. All this in a sector with a proven capacity to deliver cancer services efficiently, safely and at least equal or lesser cost to the public sector (Productivity Commission Report 2010 and other published data).

These uncompensated changes will mean costs being passed on to patients, closure of rural and regional chemotherapy day centres necessitating greater travel time and delays, increased risk of error and drug interaction causing potentially life-threatening toxicities, and more patients being transferred to the already stressed public sector. The tragic consequences of financial stress in this area have been well demonstrated recently in the UK, US and locally in South Australia.

The solution is to increase the current Infusion Fee to a level that provides adequate funding for the safe preparation and delivery of chemotherapy treatments. This would require sufficient reinvestment by the

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Government to offset the funding shortfall created due to price reductions over the last 12 months, and should be achievable in view of the cost savings already accrued and those that will continue to flow through the system under ongoing PBS Reforms.

Rural Centres

Regional Cancer Centres are a key achievement of the government over the past 5 years. Many of these centres now provide therapies to populations of 200,000 or more who would otherwise have had to travel to unfamiliar large city centres. This initiative was in response to numerous published reports of inferior outcomes in rural patients with cancer. These centres are now particularly under threat because of issues specific to rural oncology:

1. Distance from large compounding centres increases costs of therapy with lower margins before any price reductions.
2. Regional and rural hospitals are more vulnerable to problems in this program due to their smaller patient base and inability to cover costs from other profitable areas. Larger metropolitan centres are noticing the same costs but will have greater ability to absorb them while these negotiations continue.
3. In rural areas both public and private patients are treated by cytotoxics prepared by private community pharmacies. There is no State public hospital alternative other than those provided at considerable distance and inconvenience. In the case of Albury Wodonga, it means a more than 300km trip to Melbourne hospitals that have clearly indicated they do not have the capacity to take on the extra workload.

To quote a large rural service pharmacist, "We are fast approaching the point where private pharmacy oncology services will become unviable. I suspect the first impact will be that pharmacists will be forced to "cherry pick" and only provide profitable treatments. If we take my earlier example, it could mean inability to dispense loss making treatments, in my case 222 treatments in Dec 2012 and 100 treatments in Feb 2013. In our region, how would these patients would be able to continue treatment?"

It is the belief of our Associations that rural services will be the first to feel the adverse impacts of the inadequate reimbursement of chemotherapy services. This is particularly disturbing given that this was previously identified as an area of need with inferior survival and quality of life outcomes.

Conclusion

We all support a sustainable, transparent and fair funding model for the provision of chemotherapy medicines that:

1. Provides equity of access across the country and is equally applicable across all hospitals/types of pharmacy services and, whether or not an external compounder is used;
2. Covers in full the cost of the medicine/s;
3. Provides reimbursement for the range of costs associated with the reconstitution and preparation of the medicine/s in a ready-to-use form; and
4. Recognises and allows for payment of the clinical pharmacy services that support the safe use of these toxic medicines.

All professional and consumer stakeholder groups have demonstrated their commitment and good faith to the principles of transparent, sustainable and efficient funding of chemotherapy. We believe the Parliament confirmed their commitment on behalf of Australian patients by their support for the changes to the legislation in this area. We respectfully ask that Senators consider the history and facts of this commitment to ensure the sustainable and proper completion of these reforms.

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Australian cancer patients and their families need to know that they can continue to have equitable and safe access to chemotherapy regardless of where they live or what their socioeconomic background is. We call upon Government to complete the full suite of chemotherapy reforms negotiated in 2009.

The PCPA and MOGA trust this submission will be of value and would be pleased to provide ongoing advice should this be required.

Kind regards,

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