A submission to the inquiry by the **Senate Standing Committee on Community Affairs** into the **Supply of chemotherapy drugs such as Docetaxel**

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Submission

The terms of reference of this Senate inquiry correspond directly with the concerns that have been expressed in recent times by a number of groups involved with cancer chemotherapy.

Since the middle of 2012, private and public hospital pharmacists along with oncologists, cancer patient support groups and hospital operators have expressed concern in public and directly to the government, that the drop in the Pharmaceutical Benefits Scheme [PBS] reimbursement level for docetaxel due to be implemented on 1st December 2012 as a result of Weighted Average Price Disclosure [WAPD], would reduce the viability and so capacity of pharmacy services to provide PBS funded chemotherapy.

The supply to patients of PBS listed cytotoxic chemotherapy drugs such as docetaxel involves not only the dispensing of the medicines as prescribed but also the safe and accurate reconstitution of the dispensed products into sterile dose forms able to be administered to patients in a timely manner. This requires substantial investment in training, facilities, equipment and monitoring plus compliance with national practice standards and guidelines established by professional bodies. The costs to pharmacy services of these resources and processes are substantial and have historically been met out of the revenue derived from a small number of chemotherapy drugs, most notably during recent periods, docetaxel.

While the use of a cross subsidy is not an appropriate method to maintain viable supply of medication including supply of cancer chemotherapy, removal of the revenue stream that has been the source of the subsidy without compensatory arrangement will put at risk the functions that the revenue has supported.

The Minister for Health agreed in late November to address the issue in relation to docetaxel however the matter remains outstanding and the ‘savings’ extracted by the government as a result of the reduction in the level of reimbursement for docetaxel will negatively impact not only the supply of docetaxel but also the supply of other cancer chemotherapy drugs.

The reduction in the level of reimbursement for docetaxel will impact not just pharmacy services but will flow through to the users of the services including patients, oncologists and health care facilities. Unless compensatory arrangements are instituted, the reduced revenue related to the supply of docetaxel will have a direct impact on patients’ access to treatment and result in additional costs being passed on to patients or their agents.

One of the principle concerns for all patients suffering cancer, their families, health care regulators and health care funding bodies, must be the capacity of health care clinicians and particularly pharmacists to safely and effectively deliver chemotherapy drugs such as docetaxel in accordance with professional standards resulting in patients receiving safe, timely and effective therapy.

Supporting detail

Cancer chemotherapy entails the use of highly toxic drugs that must be handled with a high degree of caution, require accurate dose calculation, significant manipulation in a controlled environment and coordination between multiple parties to ensure administration in accordance with diagnosis-specific treatment protocols.

- Cancer chemotherapy frequently entails cyclical administration [weekly, monthly etc] of one or a number of cytotoxic drugs in doses tailored to each patient for each occasion of treatment. Consequently the dispensing of chemotherapy drugs such as docetaxel requires calculation and confirmation of individualised doses for each patient on each occasion of supply.

- The reconstitution for parenteral administration of dispensed doses of cytotoxic chemotherapy drugs such as docetaxel is a high-risk and complex process requiring training in aseptic techniques and accurate manipulation, specialised facilities and environmental and quality controls. Such facilities are limited to locations where the volume of reconstitution can justify the resources required.

- The administration of parenteral doses of cytotoxic chemotherapy drugs such as docetaxel benefits from a high level of clinical pharmacy service to ensure patients, nursing and medical staff are able to use the drugs safely and to best effect. This input may be required both prior to and after the dose has been prepared and can entail confirmation of protocols, monitoring of patient pathology results, dose calculation, monitoring for side effects, advice to nursing staff regarding administration of doses and counselling of patients.

- Due to their chemical stability once reconstituted and the aseptic method used in preparation of the doses, many chemotherapy drugs have relatively short shelf lives, in the order of hours or days. The capital investment and training required to be able to safely and viably prepare doses limits the location of reconstitution facilities and along with the short shelf life and the need to protect the dose, personnel and environment during transport, pharmacy services must ensure close coordination so that doses are available when and where required in accordance with the treatment protocol while at the same time minimising waste through expired doses.

The supply of chemotherapy drugs such as docetaxel is consequently a very complex and costly process, requiring training and resources disproportionate to the provision of any other PBS dispensed medication.

For many chemotherapy drugs, particularly the newer more expensive agents which are still patented, the current standard PBS dispensing fee and capped mark-up and recently introduced reconstitution fee fail to adequately cover the dispensing, reconstitution and clinical services costs associated with the supply of the drugs. However as docetaxel is no longer patented, prior to 1st December 2012 discounts available in the market [which form the basis of the governments WAPD policy] resulted in pharmacists deriving a level of revenue from the supply of this drug, which could be used to cross subsidise these non-viable functions.

Reliance on a cross subsidy from the revenue derived from the supply of docetaxel to be able to afford to supply other chemotherapy drugs is not a sustainable business practice for the pharmacy services concerned but removal of the revenue stream that was the source of the subsidy with no compensatory arrangements puts at risk the functions that the revenue was supporting.

Long term sustainable funding model

The resolution of this matter must be a sustainable funding model that is comprehensive, transparent, equitable, adequate, generally applicable and preferably aligned with existing government funding models.

- Comprehensive: The model should account for all components of the dispensing and supply of chemotherapy drugs such as docetaxel. This should include all aspects of dispensing, reconstitution of dose and clinical services in accordance with practice standards and guidelines.

- Transparent: The model should enable all parties to be aware in advance of the costs and funding associated with the supply of chemotherapy drugs such as docetaxel.

- Equitable: The model should provide all patients protection from catastrophic costs associated with PBS listed chemotherapy medicines in an equitable manner.

- Adequate: The model should meet the costs associated with the supply of chemotherapy drugs such as docetaxel and provide an appropriate margin to address commercial risks and return in the private sector.

- Generally applicable: The model should be applicable with minimal modification in all patient care settings.

  The model should be applicable in other areas of PBS supply and pharmacy services where reduction in levels of reimbursement will eventually impact on the capacity to continue to deliver professional services that have historically been cross subsidised from dispensing income [e.g. the provision of PBS medicines in dose administration aids [DAA] in residential aged care facilities if the reduction in PBS subsidy that currently subsidises these DAA services occurs without compensatory arrangements].

- Aligned: To the extent practical the model should align with existing funding models.

  Options for funding the clinical pharmacy service component include the pharmacists being entitled to an MBS payment on referral from an oncologist. Alternately the Home Medication Review model of referral by general practitioner [oncologist] to an accredited pharmacist [accredited oncology pharmacist] for a review of a patients medication [for a cycle of chemotherapy treatment] leading to a report and case conference with the referring doctor could be used as a basis for funding of clinical oncology pharmacy services.

Further contribution to the inquiry

Based upon my involvement over 30 years with pharmacy services providing cancer chemotherapy and particularly my involvement with the use of the PBS in acute care settings including for the supply of chemotherapy drugs, I am willing to provide additional information to he inquiry or to attend the inquiry if necessary.

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Current appointments
President, Western Pacific Pharmaceutical Forum
Director, Australian Pharmacy Council
Board member, Pharmaceutical Society of Australia
Chairman, Advisory Committee on Medicines Scheduling, Dept of Health and Ageing
Member, Health Service Medication Expert Advisory Group, ACSQHC
Member, Advisory Board and Director of Pharmacy Practice, APHS
Member, Human Research & Ethics Committee, The Avenue Hospital, Melbourne
Convener, Drafting Group, Vision for Pharmacists' Practice in Australia