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14 March 2013

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

By email transmission: community.affairs.sen@aph.gov.au

Dear Committee Secretary,

Senate Committee Inquiry into the Supply of Chemotherapy Drugs Such as Docetaxel

Graham Slade and I are pharmacists and the joint owners and operators of Slade Pharmacy Services, a specialised hospital pharmacy business which provides comprehensive pharmacy services to cancer patients in private hospitals in NSW and Victoria. We also own and operate a separate Therapeutic Goods Administration-licenced (TGA) facility which prepares, under strict sterile conditions, chemotherapy medicines.

We are proud of the business we have built, and of the important role we play in preparing and supplying chemotherapy medication and associated pharmacy services to cancer patients in hospitals and day clinics across Australia.

Cancer medicines are life-saving. As they are injected into patients' blood stream or spinal tissue, their manufacture requires special handling by pharmacists and other trained personnel, along with rigorous quality systems and purpose-built infrastructure to ensure they can be prepared and delivered safely.

We are very concerned about the impact of price disclosure on chemotherapy medicines such as Docetaxel and believe urgent government intervention and funding is required to ensure a viable and safe system of cancer treatment in the private sector.

Cancer medicines – the Role of the Pharmacy Team

The preparation of cancer medicines is complex. Highly toxic, each dose needs to be checked by a pharmacist and customised to ensure it suits each patient's particular disease state and body type. The medications must be prepared under strict sterile conditions in a sterile environment which protects both the medicine from any contamination and the people who handle them. They are then delivered to the nursing staff of an oncology ward, in a ready-to-use form for administration to the patient.

Many people are unaware that a pharmacist is involved in each step of the process, outlined as follows:

- Initial consultation with the patient
- Checking of the dose ordered by the doctor
- Coordination of the sterile preparation and delivery of the medicine
- Liaison with nursing staff who administer the medication to the patient
- Counselling patients how best to take their medication

Due to the many steps and safety precautions in place, the cost associated with the preparation and delivery of cancer medicines is, unavoidably, very high.

Efficient Funding of Chemotherapy and the Impact of PBS Price Disclosure

Whether intended or not, Pharmaceutical Benefits Scheme (PBS) funding of chemotherapy medication has been supported by significant cross-subsidisation across a range of chemotherapy drug types due to the vagaries of Price Disclosure under the PBS. To explain simply, pharmacists have used the margin made from the dispensing of certain PBS cancer medicines to subsidise the cost of preparing and suppling other cancer medicines.

Unfortunately, as a result of price disclosure, whereby the price paid for medicines by government is reduced to reflect the actual price paid by the pharmacist to the supplier (which does not include the additional costs we incur to prepare the product for patient specific administration), the margin used by the pharmacist to cross-subsidise the multi-faceted pharmacy service is gone.

There is now a massive funding shortfall whereby the cost to supply cancer medicine is significantly greater than the price a pharmacist receives from the PBS.

This critical impact was first communicated to the Government in 2008 when it introduced the Efficient Funding of Chemotherapy (EFC) model as a budget measure. At that time, the Government was advised by pharmacists like me who provided this specialised cancer service that, unless some of the Price Disclosure savings were returned back to pharmacy, the supply chain of chemotherapy would become unsustainable.

Despite these warnings, the remuneration in the EFC was set at a level that did not cover costs or provide any return on capital invested on the expensive facilities and equipment required for the safe and efficient preparation of chemotherapy infusions. This model was destined to fail.

The fact that the pharmacy supply chain has been viable to 1 December 2012 was only possible due to the discounts available to pharmacies from suppliers of some off-patent (generic) drugs like Docetaxel. These discounts have now eroded as a result of Price Disclosure.

Facilities for Sterile Preparation of Cancer Medicines

Cancer medicines must be prepared under strict sterile conditions. Many of these drugs are unlike standard “off the shelf” medicines routinely supplied by a community pharmacy. Rather, a range of patient-specific variables such as age, weight, sex, blood type and stage of medication cycle will determine the specific dose, which must then be prepared especially for that patient. This requires the handling of some highly-dangerous cytotoxic (literally ‘cell killing’) products, as well as a high level of skill to ensure that the correct dose is prepared for each patient. Additionally, many of these products have a very short expiry, and can only be prepared in the hour immediately before the patient’s treatment.

All of this means the service of preparing chemotherapy medication is highly complex, expensive and labour-intensive, and demands an environment and investment that does not compromise on quality.

To ensure our business continues to meet these exacting requirements, we have invested millions of dollars designing, building, commissioning and operating a dedicated sterile facility in Mt Waverley, in Melbourne’s east. This site is licensed and audited by the TGA and compliant with all aspects of Good Manufacturing Practice to ensure quality products are supplied on time,

every time. From this site, we prepare customised, life-saving chemotherapy medication for the treatment of hundreds of individual cancer patients in private hospitals and day clinics every month.

The pictures below show the facilities in which chemotherapy infusions are prepared, the personnel and some of the equipment which must be worn, and the air handling and environmental systems which deliver purified and filtered air to the clean rooms in which they are made.

1. **Specialised air handling systems ensure sterile air is passed into the compounding facility**

2. **Specially-trained compounding technicians prepare infusions in cytotoxic drug safety cabinets**

3. **Compounding technicians wear special sterile garments to protect themselves from any spillage and to ensure the sterility of the product**

4. **Each infusion of chemotherapy must be custom-made to suit each individual patient**

5. **The finished infusion needs to go through a series of double-checks (performed by a pharmacist) to ensure product safety**

Ongoing Supply

There is now a massive funding shortfall whereby the cost to supply the cancer medicine is significantly greater than the price a pharmacist receives from the PBS. Without a solution to this shortfall, it will not be viable for Slade to continue to prepare and supply cancer medication where the PBS does not cover costs or provide any return on capital invested. As it stands, Slade is now supplying many critical cancer medicines at a loss due to the impact of the latest rounds of Price Disclosure. We cannot keep doing this.

We have explored passing on costs to our hospital customers, however we understand that their health fund contracts will not permit them to seek health fund recovery or contribution to any such additional costs, nor will they permit the hospital to pass on the costs to the patients. Our hospital customers are simply not in a position where they can agree to absorb such increases due to the already high costs they carry in providing the highest level of care and treatment to patients with cancer.

In our view, there needs to be an appropriate and sustainable funding model in place which ensures cancer patients can continue to receive their therapy in a safe, timely and affordable way. We strongly urge the Government to review this issue again and consider reinvesting some of the price disclosure savings back into the sector to establish a viable supply chain which ensures PBS cancer medicines can be prepared and supplied with no additional costs to

patients, caregivers, families or hospitals. Without this remuneration the current system is likely to collapse.

The Government's own website, http://www.pbs.gov.au/info/about-the-pbs), accessed 13th March 2013, states: "…. the PBS provides timely, reliable and affordable access to necessary medicines for Australians. The PBS is part of the Australian Government's broader National Medicines Policy. The aim of the National Medicines Policy is to meet medication and related service needs, so that both optimal health outcomes and economic objectives are achieved. Under the PBS, the government subsidises the cost of medicine for most medical conditions. Some medicines, like cancer medicines are dangerous to administer and need medical supervision (such as chemotherapy drugs) and are only accessible at specialised medical services, usually hospitals."

It is well and good to have these specialised cancer drugs listed and subsidised by the PBS, however they are of little use to patients, if they can't be safely prepared, delivered and administered due to a lack of PBS funding. As stated in the preceding paragraph, it is the sole responsibility of the PBS to ensure the cost of the drug and the cost of its preparation be included in any PBS reimbursement to pharmacists.

I strongly believe that the most sensible solution in every respect to this challenging issue is to put in place a more transparent and sustainable model of funding that moves away from cross-subsidisation to one that, instead, better recognises the service provided by pharmacy that ensures the safe preparation and delivery of chemotherapy treatments. Specifically, this could be achieved through an increase in the current infusion fee to a level that recognises the professional services provided. I appreciate that this requires ongoing support from the Government, but this would ensure the ongoing viability of the supply of chemotherapy medication to private hospitals providing cancer treatment, without compromising hospital staff, patient safety or treatment outcome.

I invite you to visit our pharmacy and TGA facility so you can fully appreciate the situation we are now facing. A positive outcome must be reached urgently for the benefit of cancer patients and their families, carers, doctors, nurses, pharmacists, hospitals and other health organisations.

I would welcome the opportunity to speak directly with the Senate Committee in more detail on my concerns and thoughts on this important subject.

Yours sincerely,

David Slade
Managing Director
Slade Pharmacy Services