Submission to Senate Committee

Supply of chemotherapy drugs such as Docetaxel

Summary of key points:

Key points - Patient Access

- *Cuts to PBS prices for chemotherapy medicines may result in loss of compounding pharmacies, resulting in decreased access to niche products OR chemotherapy medicines used less commonly*
  - *Large multinational manufacturers unlikely to fill the gap (commercially unviable)*
- *Rural patients may be affected:*
  - *Access to short-expiry medicines (i.e. less than 24 hours) may occur due to high distribution costs associated with short expiry drugs*
- *Patient waiting times may increase as:*
  - *Compounding pharmacies may have to reduce number of deliveries due to high costs*
  - *Withdrawal of clinical and administrative services will increase errors relating to scheduling of orders and planning access to treatment*
- *'No prescription, no service'. Withdrawal of pharmacy administrative support means:*
  - *Less PBS prescriptions will be provided on time & patients may be refused supply*
  - *Nursing activities will shift from patient care to administrative duties*
  - *Increased number of treatment cancellations when products are already prepared (which costs the PBS and taxpayer money) and deferrals*
- *Without changes to the current system, patient access to oncology clinical pharmacy services will decrease. This is a medication safety issue*

Key points – Cost to pharmacists and suppliers

- *Costs and risks are significant in the following key areas:*
  - *Drug preparation (facility maintenance, specialised workforce, high-cost insurance)*
  - *Distribution & inventory handling*
  - *Administration*
  - *Treatment cancellations*
  - *Clinical pharmacy support*
  - *Research and validation of drug stability*
- *Based on internal calculations, the real cost of compounding a sterile product is between $150 and $230*
  - *The current compounding fee is inadequate for compounding pharmacies*
- *Cross-subsidisation of these costs has occurred in the past as the current PBS compounding fee is inadequate. The high return on PBS items such as Docetaxel has been used to offset supply of:*
  - *other aseptically-prepared medicines with an overall negative return on investment, due to high preparation cost and low margins; and*
  - *clinical pharmacy services*
- *Without changes to the current funding model, clinical pharmacy services are likely to be lost, resulting in:*
  - *Increased wastage of chemotherapy medicines prepared ahead of time (costs to PBS)*
  - *Administrative burden shifted to nursing staff*
  - *Patient safety potentially compromised*
- *Without changes to the current compounding fee, compounding pharmacies will become unviable and close*
  - *This will result in outsourcing to multinational manufacturers (monopoly), leading to decreased competition and potential supply issues long-term (as uncommon or unviable products will not be manufactured).*

Key points – Cost to private and public hospitals

- *Private hospitals provide oncology administration as a service, not as a driver of income*
  - *They supply day oncology units with cross-subsidisation from other services provided in the hospital*
  - *Therefore, private hospitals are unable or unwilling to invest in clinical pharmacy services. Without changes to the current pharmacy funding model, clinical and administrative pharmacy services will reduce, resulting in administrative burden passed onto nursing staff*
- *Without appropriate compensation of compounding costs, there is pressure on nursing staff to prepare products such as monoclonal antibodies (i.e. Herceptin and Mabthera) "on the bench" instead of ordering aseptically-prepared products*
  - *This is poor practice, potentially placing the nurse at risk of occupational exposure and the patient at risk of harm from a contaminated product or drug/dose error.*

Key points – Long term sustainable funding models

- *Current funding model is inadequate for preparation (compounding) and distribution costs*
- *Clinical services for oncology patients in the private setting requires subsidy*
- *We advocate for a model outside the PBS payment system which encourages*
    - *Incentives for reducing wastage of PBS-funded chemotherapy*
    - *Increased remuneration for compounding pharmacies directly*
        - *MBS item code*
    - *Direct reimbursement of clinical services*
        - *Payment model similar to the current HMR/MedsCheck models*
- *An alternative model could provides payment for the entire service (inclusive of compounding, distribution, consumables and associated devices) similar to the current DVA funding model for compounding and supply of antibiotic infusers*

Key points – Related matters

- *Improved reimbursement models for drug preparation and clinical services will support hospital avoidance and early discharge strategies such as Hospital in the Home (HITH)*
- *Pharmacy is well placed to support new models of healthcare delivery but require stakeholder engagements and consideration for appropriate reimbursement of services.*
- *These issues are not exclusive to chemotherapy but include all aseptically compounded products, such as*
    - *Antibiotic infusers*
    - *Palliative care infusions*
    - *Rheumatology infusions*
    - *Osteoporosis infusions*
    - *Chronic pain infusions*

- *Some medicines are stable for as little as EIGHT hours after compounding. We support introduction of a system at the point of PBS listing (i.e. at the level of the Pharmaceutical Benefits Advisory Council review (PBAC)) whereby drug manufacturers are required to provide assurance of a minimum period of extended stability in the product information (PI) to minimise wastage and costs incurred to the PBS/taxpayers due to short-dated medicines (i.e. at least 7 days).*
- *We suggest a national administration chart for chemotherapy medicines, which can double as a PBS prescription (similar to the systems used in residential aged care and private hospital inpatients) to reduce administrative burden on pharmacists*

Introduction

About us

Our pharmacy is a compounding facility providing aseptic compounding pharmacy services targeted at Day oncology suites (such as chemotherapy), with our customer base in both private and public hospitals. We also provide clinical pharmacy services to a private hospital. With the growing market of 'Hospital in the Home' (HITH) infusion services, our organisation also focuses on supporting HITH nursing organisations and associated prescribers (specialists and GP's); providing pharmacy and aseptic compounding services in this specialised area. In order to support an integrated home infusion pharmacy service (such as HITH), we provide pharmacy services and products such as intravenous infusions of antibiotic, chemotherapy and palliative care drugs.

In order to deliver best practice care to patients, we have spent many years innovating and developing our pharmacy services and systems to meet the needs of healthcare teams and their patients, with particular focus on clinical services; information technology systems; and innovative infusion devices, to improve safety and cost effectiveness of services.

What is aseptic compounding?

Compounding, also known as extemporaneous dispensing, refers to 'the preparation and supply of a single unit of a product intended for immediate use by a specific patient'. Preparation refers to mixing, assembling, altering, packaging, and labelling of a drug, drug-delivery device, or device in accordance with a licensed practitioner's prescription, medication order, in the course of professional practice.

At present, chemotherapy medicines (such as Docetaxel) are supplied by manufacturers in vials, at standard doses. These medicines require preparation (compounding) into a syringe or infusion bag, so the prescribed dose of the medicine can be administered intravenously to the patient. Medicines administered by injection (e.g. intravenous, subcutaneous, or intramuscular) need to be sterile, as product integrity is paramount to ensure patient safety. Aseptic compounding, also referred to as sterile compounding, refers to a specific compounding process whereby injections and other products are prepared in a tightly controlled environment free of contamination by particles and microorganisms (e.g. bacteria) that can compromise the product integrity. Products such as chemotherapeutic agents (i.e. Docetaxel) are prepared aseptically by trained operators, where the risks associated with product contamination, occupational health and safety, and medication errors are greatly reduced to those prepared on the ward at the patient bedside.

Many of the aseptic products prepared in Australia primarily come from large manufacturing facilities, rather than from aseptic compounding pharmacies like our organisation and those found in public hospitals. These large manufacturers are one-step removed from the patient, and are not able to (nor are required) to dispense medicines or deliver clinical care as a pharmacy does. Consequently, when sterile products are purchased from a manufacturing facility, a pharmacist must still be involved in the dispensing process and clinical services.

Why are the cuts to PBS prices for chemotherapy medicines an issue?

Public hospitals are funded to provide clinical pharmacy services in accordance with the APAC (Australian Pharmaceutical Advisory Council) guidelines for continuity of care. The requirements of a clinical pharmacy service are outlined within the Society of Hospital Pharmacists of Australia (SHPA) guidelines and Pharmaceutical Society of Australia (PSA) National Competency standards. However, private hospitals (and pharmacists providing clinical services to private hospitals) are unable to claim money for clinical pharmacy services, and to ensure equitable access to healthcare, these cost of delivering these services must be sought through other means.

Our pharmacy prepares and supplies chemotherapy to a private hospital. However, the clinical pharmacy services and administrative services that accompany this supply are significant. We employ a 0.75 FTE pharmacist at our own cost, to work solely in the hospital providing clinical pharmacy services (such as liaising with medical and nursing staff, providing education, reviewing treatment orders, checking chemotherapy doses and counselling patients) and administrative services (chasing PBS prescriptions, clarifying orders, obtaining the 'go ahead' from the oncology ward (as high-cost, short-dated items are not prepared until the patient is confirmed to receive treatment that day)).

There are also significant costs in maintaining aseptic compounding facilities according to the standards set by the Therapeutic Goods Administration (TGA), and costs in preparing and distributing sterile medicinal products.

For years, higher margins for some items dispensed through the PBS (such as Docetaxel) have

- offset (cross subsidised) the cost of compounding the majority of chemotherapy medicines where the financial cost of supply far exceeds the return via the PBS.
- offset (cross subsidised) the delivery of clinical services and administration related to the PBS.

For years, this is the business model our organisation, and others, have used to provide clinical, administrative and compounding services, primarily due to the inadequate funding required to deliver high quality, best practice healthcare.

To ensure equitable access to suitable medicines that are safe and effective (National Medicines Policy) and avoiding a 'user pays' system developing, it is a requirement of governments to ensure that healthcare providers can deliver these outcomes cost effectively. However, without appropriate and transparent reimbursement, these objectives are not achievable.

As pharmacists, we are in support of cuts to the price of PBS medicines. We agree taxpayers should not be paying unnecessary high prices for generic medicines, especially as more high-cost drugs come off patent. **Current funding for supply of chemotherapy AND associated clinical services is inadequate. We would like to see a funding model that compensates compounding pharmacies for the true costs of compounding these products and providing clinical pharmacy services to these patients.**

Addressing the terms of reference:

a) Supply of chemotherapy drugs such as Docetaxel, in relation to:

(i) Patient access to treatment

Key points - Patient Access

- *Cuts to PBS prices for chemotherapy medicines may result in loss of compounding pharmacies, resulting in decreased access to niche products OR chemotherapy medicines used less commonly*
    - *Large multinational manufacturers unlikely to fill the gap (commercially unviable)*
- *Rural patients may be affected:*
    - *Access to short-expiry medicines (i.e. less than 24 hours) may occur due to high distribution costs associated with short expiry drugs*
- *Patient waiting times may increase as:*
    - *Compounding pharmacies may have to reduce number of deliveries due to high costs*
    - *Withdrawal of clinical and administrative services will increase errors relating to scheduling of orders and planning access to treatment*
- *'No prescription, no service'. Withdrawal of pharmacy administrative support means:*
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    - *Increased number of treatment cancellations when products are already prepared (which costs the PBS and taxpayer money) and deferrals*
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(ii) Cost to pharmacists and suppliers

We have identified number financial imposts to pharmacies and suppliers for the provision of compounded chemotherapy drugs and through our daily work. The primary focal point is the cost of compounding.

The cost of compounding incorporates a number of associated costs in order to achieve the required health outcomes. These costs can be summarised as drug preparation (labour and consumables), facility, inventory, distribution, clinical pharmacy services, and administrative costs.

Key points – Cost to pharmacists and suppliers

- *Costs and risks are significant in the following key areas:*
  - *Drug preparation (facility maintenance, specialised workforce, high-cost insurance)*
  - *Distribution & inventory handling*
  - *Administration*
  - *Treatment cancellations*
  - *Clinical pharmacy support*
  - *Research and validation of drug stability*
- *Based on internal calculations, the real cost of compounding a sterile product is between $150 and $230*
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- *Without changes to the current compounding fee, compounding pharmacies will become unviable and close*
  - *This will result in outsourcing to multinational manufacturers (monopoly), leading to decreased competition and potential supply issues long-term (as uncommon or unviable products will not be manufactured).*

Costs associated with drug preparation (compounding)

Expensive and complex infrastructure and monitoring systems are required to prepare parenteral products ready for administration to patients. Minimising the risks of contamination by microorganisms and particles is one of the primary objectives of aseptic drug preparation. There are a number of other key objectives that result in costly facility and operations expenses, such as: protecting staff from occupational exposure, prevention of drug cross contamination, and accuracy of drug doses prepared.

In order to achieve this all facilities must adhere to strict codes of good manufacturing practices (cGMP) which are costly to adhere to from a facility design point of view; but also ongoing monitoring, management, staff training, and maintenance of such a facility. For example, the cost of continual environmental monitoring (to monitor bacterial counts) requires not only specialised equipment but also specialised staff (i.e. a quality assurance pharmacist). It also requires significant contingency plans (alternative sites) and equipment (large generators) in place in the unlikely event the facility does not operate within specifications, all of which are expensive but unseen costs. **From our estimates, the cost of compounding each item can vary from $150 to $230** depending on the complexity of product preparation (i.e. nab-paclitaxel (Abraxane®) takes 30 minutes to prepare), the container compounded (i.e. syringe versus infusion bag), and the ability to advance prepare the product (depends on expiry date). **We only receive $45.47 reimbursement back from the PBS for each item compounded** (a $40.64 preparation fee + $4.83 diluent fee). This is inadequate.

The management of these facilities and adherence to regulation are far more complex and laborious than the regulatory requirements of operating and adhering to general pharmacy regulations. As we are a registered pharmacy and a compounding facility, we are exposed to all levels of regulation, including those that relate to OH&S, the Pharmacy board, Pharmacist competency standards, National Health Act, Controlled Substances Act, Cold chain and Hazardous goods transport, and cGMP. This is without consideration of the organisational risk mitigation and management strategies in place for compounded intravenous products that can potentially result in significant and immediate harm to a patient related to the route of administration (i.e. intravenous).

Specialised staff and relevant operator training is another component essential to drug preparation that results in significant cost burden. This came to light recently in South Australia, when a number of incidents occurred with the incorrect dosage preparation of chemotherapeutic medicines etoposide and etoposide phosphate (Government of South Australia, 19th December 2008). This resulted in a number of working groups and reviews into South Australian cancer services all of which highlighted the deficiencies in staff training and resourcing in the public sector, which are limited by available funds (Communio, 3 April 2009).

More recently, there have been a number of reviews into the state of compounding in Australia, such as the review into manufacturing in South Australian public hospitals, Pharmacy Board of Australia manufacturing working party, and the National Coordinating Committee on Therapeutic Goods (NCCTG). These reviews set out the future standards that are required of compounding pharmacies. This does not include tightening regulation (nationally and internationally) relating to issues such as occupational exposure of hazardous drugs, all of which require investment in changing practices across all healthcare facilities and institutions (National Institute for Occupational Safety and Health, September 2004).

As pharmacists we are in support of these measures to ensure patients receive safe and efficacious chemotherapy products. However, the above costs highlight that without adequate funding or reimbursement models, many compounding pharmacies may no longer be sustainable in this area of pharmacy practice as they will no longer be in a financial position to meet these requirements, leaving manufacturers that can achieve economies of scale (i.e. multinational manufacturers) to provide cost effective supply.

Distribution

Traditional models of care provided by pharmacies are that of a centralised distribution model, whereby a patient will come into the pharmacy, have a medicine dispensed directly to them and receive appropriate professional advice. However, in the model of care for compounded products (not limited to chemotherapy), sterile products are compounded offsite then distributed to a centralised administration site (day oncology centres) or to patient homes (as for Hospital in the Home). The model of care for compounded products has the opportunity to result in greater patient outcomes, but it is a far more costly method of distribution from the pharmacy perspective. In addition to greater transport costs with this model, there is also greater reliance on

communication systems between healthcare providers to ensure appropriateness of supply. Current transport fees are not adequate to cover these costs (current PBS reimbursement for distribution is $24.38).

There are a number of other factors that affect the efficiency of the distribution system, these include: administrative burden of the PBS, inefficient patient scheduling and ordering systems, and short expiry drugs. These key factors result in significant inefficient and costly distribution systems, in many cases resulting in multiple last minute preparation and delivery of compounded products and delays in patient treatments. For example, in order to minimise the risk of failure to adhere to regulation underpinning the PBS, drugs cannot be prepared until the PBS prescription is authorised, received, confirmed, and dispensed. A pharmacist or technician usually liaises with the prescriber to obtain the prescription before the medicine can be supplied, meaning the patient waits to receive treatment.

Inventory handling

The cost of purchasing inventory is not generally considered by payers. As the number of newer, expensive chemotherapy medicines increases so has the purchase cost of these items. The cost to purchase and hold inventory for a small organisation such as ours is significant, especially when some of these items are used rarely, but as part of the service we are required to stock them for when an order is placed. Given that issues with scheduling patients has been an ongoing issue in both the public and private system, procuring the product 'last minute' is not feasible. As many pharmacies of our size are running a significant overdraft, the cost of financing with such a small return on investment as projected margins from the PBS is untenable. Hence, cross subsidisation has been critical up until recently to providing a complete service.

The costs to procure medicine vials for items such as Trastuzumab, Cabazitaxel and Rituximab are significant ($2000-$7000 depending on the drug and vial strength). After taking into account the internal handling requirements of hazardous drugs and adherence to cGMP requirements, insurance, and the financing of these products (i.e. overdraft), a distribution fee of $24.38 clearly shows this is not a worthwhile investment. This does not include the time invested by professional staff to deliver clinical services and follow up on the administration associated with the PBS reimbursement (as highlighted in the following section).

It should also be pointed out that it is far more difficult for smaller organisations such as ours to decrease the cost of goods (COGS) compared to large multinationals, who not only own the drug supply chain but can also cross subsidise with other hospital lines provided (such as infusion bags, infusion lines, electronic pumps etc).

Administrative burden

Medicare Australia's National Compliance Program addresses fraud and noncompliance in the delivery of social, health and welfare payments through the PBS. Compliance measures are a necessary activity. However, PBS compliance is a major administrative task for compounding pharmacies and measures taken by the compliance programs illustrate the disconnect between the regulators and the practice of healthcare delivery.

The following is an extract from Medicare Australia's National Compliance Program 2009-2010 report, whereby a pharmacy supplied a PBS medicine to a hospital(s) but did not comply with the strict requirements of the National Health Act which underpin PBS medicine supply (Medicare Australia, 2010).

Chemotherapy

In previous years we have identified concerns in relation to supply of chemotherapy drugs after the death of the patient. In 2009–2010, we will continue to actively pursue those cases where drugs are being supplied after the patient has passed away.

Case study—medicine supply after date of death

We identified a community pharmacy as having claimed payment for a pharmaceutical benefit where data indicated supply had occurred after the patient had passed away. A further review of claims submitted by the pharmacy identified numerous similar instances, all of which involved chemotherapeutic agents supplied to patients at local hospitals—both public and private.

As a result we undertook a comprehensive assessment of all information, including hospital records. In consultation with the pharmacist and their staff we identified, those benefits claimed where data and the prescription record indicated supply had occurred after the date of death. The total recoverable amount for these supplies was determined at almost $650 000.

(Medicare Australia, 2010)

The above case is not an unusual situation to be in for many pharmacies that are involved in the supply of chemotherapy to private hospitals, as highlighted in the SHPA senate submission. The normal process of supply and reimbursement under the PBS (i.e. community pharmacy) requires a PBS prescription to be duly prepared by the prescriber prior to supply (authorised by Medicare, written and signed, sent to pharmacy) then processed in the pharmacy dispensing system and supplied to the patient. However, in addition to this process, the hospital setting requires the prescriber provide a hospital administration chart. The clinical pharmacist is required to check both the PBS prescription AND the hospital administration chart for validity and appropriateness prior to sending the order to the compounding pharmacy.

The need for these two concurrent processes (the hospital chart AND the PBS prescription) means there are potential medication safety issues (what if the script and the chart don't match?) and also results in significant frustration. Due to this administrative burden, it is not uncommon that prescribers do not provide the PBS prescription in as requested in a timely manner; their feedback suggests that providing a PBS prescription in addition to the medicine chart is "unnecessary administrative burden" and "detracts from patient care". Consequently, in the interest of the patient, ensuring treatment is not delayed; pharmacists may compound and supply the product based on the hospital administration chart in accordance with the Controlled Substances Act (relating to supply of scheduled medicines). The PBS prescription is then followed up retrospectively and completed at a more convenient time for the prescriber (referred to as "owing prescription"), which is in clear contravention of the law (National Health Act). If the time to follow up the PBS prescription is delayed and the patient passes away, there is a significant risk to the pharmacy, as they have been caught between "duty of care to patients" and "legislative bureaucracy".

There are also significant difficulties in achieving compliance for supply of PBS medicines, especially authority items (many of which are chemotherapeutic agents).

Although these requirements have been altered for public hospitals, this is not the case for private hospitals. Hence supply of PBS medicines under the legislative requirements of the National Health Act are out-dated and in many cases unworkable as they do not integrate with standard practices of care in the hospital setting.

Patient access programs

There are a number of programs that provide free of charge to the patient that is not part of the PBS provided by government and pharmaceutical industry. These include Herceptin® for late stage metastatic breast cancer through the Medicare Specialised Drug program and Avastin® patient access scheme provided through Roche. Despite the noble gesture to provide these medicines free to patients, all other healthcare providers are paid for the delivery of such a service. However, **compounding pharmacies such as ours are required to prepare and distribute products under patient access schemes (such as Herceptin free) without being paid a compounding and distribution fee**. In many cases, especially for those access schemes provided by the pharmaceutical industry, we are morally forced to prepare and distribute these products at no cost (or minimal cost, far below actual cost) to the patient "in the spirit" of the access program.

Despite there being significant amounts of pharmacy administration related to the delivery of these programs there are no avenues for appropriate reimbursement except through direct billing of the patient or hospital. The suggestion of such an approach has been met with significant resistance and anger from patients, carers, treating hospital and their prescribers who feel this unreasonable and is not "in the spirit" of the access program; understood as "no cost to the patient". However, what is not made clear to these groups are that the hospital is reimbursed through private health funds as are the prescribers through Medicare (MBS item). Unfortunately pharmacy is left to deliver services for these programs at significant loss and once again rely on the cross subsidisation of other high margin PBS drugs to make up to shortfall.

Patient cancellations/deferrals

Patients make an appointment to be administered their chemotherapy. Chemotherapy items are pre-ordered from compounding pharmacies/manufacturers ahead of time so the patient can receive the medicine at the appointment without having to wait for the medicine to be prepared and delivered. However, there is no guarantee that the patient will receive treatment on the day of the appointment. This can be due to a number of factors including: low blood counts, patient illness, changes in treatment plans, and patients failing to present for treatment. If the medicine has already been supplied, either the pharmacy or the PBS wears the cost.

Costs due to chemotherapy wastage can be significant. In one Australian tertiary hospital, an audit over a four week period found 33 chemotherapy treatment deferrals for a total of 24 patients (Thomas, Chin, & Ambados, 2009). In another study overseas, there were a total of 143 wasted doses in one hospital over a four week period, specifically related to five high cost items (bevacizumab, docetaxel, gemcitabine, oxaliplatin, and rituximab) which resulted in an annualised wastage of more than $500,000 (Gressett & Tran, 2010). The consequence of cancellations and deferrals of treatments is that chemotherapeutic items prepared may be discarded due to expiry of the preparation. Some items that have extended expiry may be reused at a later date (i.e. patient is rescheduled) if treatment not cancelled indefinitely. This wastage is particularly relevant to drugs compounded that have a short expiry, as many of the newer agents (e.g. cetuximab, cabazitaxel, trastuzumab, rituximab, nab-paclitaxel).

The cost of wastage to the healthcare system can be significant. Cancellations and deferrals can translate into direct costs incurred by the pharmacy (drug cost, labour and consumables) where the effect of the high administrative burden of managing drugs dispensed on the PBS results in an item not able to be reimbursed by Medicare and the cost of wastage will be incurred by the pharmacy (refer to section on 'Administrative burden'). The PBS will also incur the cost of the wastage in many circumstances (where the items are PBS items). As a result, **our pharmacy has spent significant resources to develop compounding systems that supports the reduction in wastage through 'on-demand' or 'last minute preparation' and patient scheduling systems despite no PBS incentives to do so. We are saving the PBS hundreds of thousands of dollars annually and bearing high-cost transport associated with on-the-day deliveries.**

Short Expiry Drugs

As mentioned, there are a number of drugs that have limited expiry after compounding which precludes their use where the product is required to be transported overnight to, for example, a regional hospital or interstate location. Furthermore, there are circumstances where the expiry of the compounded product requires preparation immediately (as per current product information and/or published stability studies) prior to drug administration, resulting in costly inefficiencies. Significant investment and resources are therefore required into managing the scheduling of treatments and into research to extend the drug stability of these drugs. The cost to research the stability of a single drug is in excess of $50,000, this is on the proviso that relatively simple validation and measures to extend stability. There is unfortunately significant duplication with substantial spending and resources on performing identical stability studies, due in part to the lack of co-ordination nationally and the commercial imperative to protect intellectual property. This was pointed out in recent commentary at the 2012 European Society of Oncology Pharmacists (ESOP) conference (Vigneron, 2012).

There is a temptation by many to reuse these products however there are a number of safety risks associated with keeping these already prepared intravenous preparations, they relate to drug stability (degradation of the active drug and production of toxic degradation products), and microbial growth. There are a number of standards that relate to the duration compounded products should be kept after preparation (refer to USP 797).

As more agents are brought onto the market many of them have a recommended expiry of less than 24 hours after compounding. This requires many pharmacies to either manage these scheduling of such products, putting high demands on workload and costs. Alternatively, investment in undertaking costly drug stability studies to verify extended stability utilising innovative methods to extend stability (e.g. reformulation). The burden of costs associated with wastage are not limited to inadequate stability data of the final product that will be administered to the patient but also that of the vials reconstituted to prepare those doses. In cases where the entire vial cannot be utilised, extended stability can assist pharmacies manage costs by potentially utilising the remaining dose for subsequent doses in the future. There are obvious safety risks with this practice as mentioned already, and many organisations do not have the financial resources to ensure these practices are appropriate, therefore potentially compromising patients.

(iii) Cost to private and public hospital systems

Key points – Cost to private and public hospitals

- *In some instances Private hospitals may provide oncology administration as a service, not as a driver of income*
    - *Therefore, private hospitals are unable or unwilling to invest in clinical pharmacy services. Without changes to the current pharmacy funding model, clinical and administrative pharmacy services will reduce, resulting in administrative burden passed onto nursing staff*
- *Without appropriate compensation of compounding costs, there is pressure on nursing staff to prepare products such as monoclonal antibodies (i.e. Herceptin and Mabthera) "on the bench" instead of ordering aseptically-prepared products*
    - *This is poor practice, potentially placing the nurse at risk of occupational exposure and the patient at risk of harm from a contaminated product or drug/dose error.*

b) Long-term sustainable funding models for the supply of chemotherapy drugs, including Docetaxel

Key points – Long term sustainability

- *Current funding model is inadequate for preparation (compounding) and distribution costs*
- *Clinical services for oncology patients in the private setting requires subsidy*
- *We advocate for a model outside the PBS payment system which encourages*
    - *Incentives for reducing wastage of PBS-funded chemotherapy*
    - *Increased remuneration for compounding pharmacies directly*
        - *MBS item code*
    - *Direct reimbursement of clinical services*
        - *Payment model similar to the current HMR/MedsCheck models*
- *An alternative model could provides payment for the entire service (inclusive of compounding, distribution, consumables and associated devices) similar to the current DVA funding model for compounding and supply of antibiotic infusers*

From our perspective there are two key areas that need to be addressed. They are increased remuneration for product preparation (compounding and distribution) & remuneration for professional (cognitive) services.

Reimbursement of compounding (drug preparation)

As highlighted throughout this document, the remuneration is not sufficient to ensure medicine safety, quality use of medicines and equitable access to medicines. As previously stated, compounding costs vary between $150-230 per item, but we believe remuneration for compounding should be increased to a minimum of $150, but it be done in conjunction with a number of strategies to ensure that the money invested by the Australian government is used appropriately. These strategies include:

1. Reimbursement paid directly to the compounding pharmacy
    a. Consider an MBS item code (similar payment method to prescribers) - sustainable model for pharmacies to continue compounding
    b. Payment for entire service (includes compounding, distribution, consumables and devices)
        i. Similar to Department of Veteran Affairs (DVA) who pays for the entire product including specialised containers/devices
2. Incentives for minimising wastage of PBS medicines
    a. Payment to support patient scheduling (which reduces cancellations due to supply issues)
    b. Support to cover administrative burden associated with PBS (could be a direct pharmacy payment or based on an individual prescription).

Reimbursement of professional services

We recommend development of reimbursement system for clinical pharmacy support (similar to current HMR or MedsCheck program), paid on a per patient basis to increase transparency and ensure equitable access. Using the business model for HMR's would allow independent pharmacist practitioners to receive a payment for clinical services OR the pharmacy itself. A separate clinical pharmacy reimbursement model would separate payments for clinical services and supply, creating a model with greater transparency of the true cost of the system, and reduce cross subsidisation in the future.

c) Related matters

Key points – Related matters

- *Improved reimbursement models for drug preparation and clinical services will support hospital avoidance and early discharge strategies such as Hospital in the Home (HITH)*
- *Pharmacy is well placed to support new models of healthcare delivery but require stakeholder engagements and consideration for appropriate reimbursement of services.*
- *These issues are not exclusive to chemotherapy but include all aseptically compounded products, such as*
    - *Antibiotic infusers*
    - *Palliative care infusions*
    - *Rheumatology infusions*
    - *Osteoporosis infusions*
    - *Chronic pain infusions*

- *Some medicines are stable for as little as EIGHT hours after compounding. We support introduction of a system at the point of PBS listing (i.e. at the level of the Pharmaceutical Benefits Advisory Council review (PBAC)) whereby drug manufacturers are required to provide assurance of a minimum period of extended stability in the product information (PI) to minimise wastage and costs incurred to the PBS/taxpayers due to short-dated medicines (i.e. at least 7 days).*
- *We suggest a national administration chart for chemotherapy medicines, which can double as a PBS prescription (similar to the systems used in residential aged care and private hospital inpatients) to reduce administrative burden on pharmacists*

Other compounded preparations

Although the issues highlighted throughout this submission relate to that of chemotherapy, they apply to all parenteral drugs compounded aseptically. They include, but not limited to, the following drug infusions: antibiotics, palliative care, rheumatology, osteoporosis, parenteral nutrition, and chronic pain. These products are best prepared aseptically but no funding is offered for aseptic preparation, despite proven patient and pharmaco-economic benefits.

Hospital in the Home: chemotherapy in the home and antibiotic infusions

Demand for inpatient care has been growing in Australia in the context of a limited public hospital bed supply. There was a 37% increase in hospital admissions over the last decade with public hospitals accounting for 60% of all admissions. At the same time, the number of public acute hospital beds has fallen by 30% (Deloitte Access Economics, 2011).

The administration of medications to patients in the home setting, termed 'Hospital in the Home' (HITH), has been internationally recognised for some time as an alternative method of care to that of the acute care in the hospital. This system of care provides direct benefits to health outcomes, and supports the ever-strained health care system through early hospital discharge, hospital avoidance and minimising hospital readmissions (BUPA Home Healthcare, 2011).

In addition to hospital avoidance, providing a clinically safe alternative to hospital care treatments such as chemotherapy at home can increase capacity through easing pressure on busy wards and outpatient units allowing them to focus on those most in need of in-hospital care (Bazian Ltd, September 2010; Bazian Ltd, September 2010). Despite these benefits there are a number of barriers and considerations that need to be addressed to ensure cost effective implementation. These include:

- current issues with lack prescriber reimbursement for those patients appropriate to enter the program and be treated in the home (prescribers aren't paid)
- Increased pharmacy costs for decentralised distribution (directly to patient homes)
- Acknowledgement at governmental level of savings to the overall system (i.e. decreased infection, hospital avoidance, better patient outcomes).
- No available incentives to pharmacy to support this model of care despite the advantages to the healthcare system.
- Consideration to comparable issues observed with chemotherapy reimbursement, such as: administrative burden and need clinical pharmacy supports

Chemotherapy at home is not the only home based treatment that would benefit from increased support and reimbursement of associated pharmacy services (e.g. pharmacy compounding and clinical pharmacy services). There is real benefit to be derived from increased treatment of infections in the home setting using aseptically prepared antibiotic infusion devices. For example, switching 10% and 100% of cellulitis patients from hospital care to home (HITH) care would result in a $1.1 million and $60 million saving to the government, respectively. (Deloitte Access Economics, 2011)**. Therefore, we recommend reimbursement models for compounding pharmacies should not be limited to chemotherapy medicines alone.**

Short-dated expiry of newer chemotherapy medicines should be addressed

Newer chemotherapy medicines approved for listing on the PBS often have very short expiry dates once they are aseptically prepared (i.e. as little as 8 hours expiry). This means on-the-day preparation of medicines is required and if treatment is cancelled, the doses cannot be re-used. However, stability studies performed years after PBS listing often show these medicines are in fact relatively stable. For instance, manufacturers of drugs such as Mabthera® and Herceptin® stated these medicines were only stable for 24-48 hour when aseptically prepared when they were approved for use in Australia, however now there is evidence these medicines have up to three months expiry when aseptically prepared.. **We would support introduction of a system at the point of PBS listing (i.e. at the level of the Pharmaceutical Benefits Advisory Council review (PBAC)) whereby drug manufacturers are required to provide assurance of a minimum period of extended stability in the product information (PI) to minimise wastage and costs incurred to the PBS/taxpayers.**

Methods to reduce administrative burden with PBS prescription management: Creation of a national chemotherapy drug chart

We suggest a national administration chart for chemotherapy medicines, which can double as a PBS prescription, similar to the systems used in residential aged care and private hospital inpatients. This would reduce administrative burden on pharmacists. It would also reduce duplication of orders (i.e. PBS prescription and a chemotherapy administration chart), which runs the risk for dosing and ordering errors.

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