

Joint Submission to the Senate Inquiry

## **Supply of Chemotherapy Drugs such as Docetaxel**

**Clinical Oncological Society of Australia  
and Cancer Pharmacists Group**

**March 2013**

The **Clinical Oncological Society of Australia (COSA)** is Australia’s peak multidisciplinary society for health professionals working in cancer research, treatment, rehabilitation and palliative care with over 1600 members. COSA is an advocacy organisation whose views are valued in all aspects of cancer care.

The **Cancer Pharmacists Group (CPG)** is a group of COSA comprised of pharmacists practising in a variety of settings including medical oncology, haematology, palliative care and cytotoxic preparation services. The CPG provides the only national multidisciplinary forum for pharmacists working in cancer services.

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## Key Recommendations

- **The federal government must ensure that, whatever the resolution, there is no disadvantage to any cancer patient in Australia in respect to cost, accessibility or safety.**
- Patients must not be disadvantaged by having to pay more for chemotherapy as a consequence of any funding changes.
- It is vital to ensure ongoing provision of regional and rural cancer services so that no cancer patient has to travel further to access chemotherapy.
- The needs of cancer patients in regional and rural locations (who already have poorer outcomes) and older patients (who are disproportionately affected by cancer) must be at the forefront of any resolution.
- Patient safety must not be compromised as an unintended consequence of any changes to the reimbursement of docetaxel or any other chemotherapy medicine in Australia.
- Every dose of cancer medicine for every cancer patient in Australia should be checked by a chemotherapy competent pharmacist to ensure that it is safe and clinically appropriate to proceed with treatment.
- These highly toxic medicines must continue to be prepared and delivered safely to patients without any additional costs to pharmacists, cancer clinics or hospitals.
- Any proposed funding model should remove the need for payment cross subsidisation (which currently underpins the system) and provide sustainable access for patients to chemotherapy services regardless of the setting.
- The funding model must acknowledge the complexity of providing treatment with chemotherapy and include reimbursement for the pharmacy clinical service component.

## 1 Introduction

The Clinical Oncological Society of Australia (COSA) and Cancer Pharmacists Group (CPG) welcome the opportunity to provide comment on the factors affecting the supply of chemotherapy drugs such as docetaxel.

Docetaxel, a chemotherapy drug used to treat breast, lung, prostate and ovarian cancer had a PBS price reduction of 76.2% applied on 1<sup>st</sup> December 2012. Many pharmacies that provide chemotherapy, particularly in the private sector, have relied on the docetaxel PBS margin to cross-subsidise the costs of providing a clinical pharmacy service to cancer patients. In the short-term, while negotiations with the Government continue, these costs are being absorbed but this is not viable in the longer term, particularly with another round of price reductions due on 1<sup>st</sup> April 2013.

If there is no longer an income stream to maintain the clinical pharmacy services associated with the supply of chemotherapy, this is likely to affect the **cost of care** and **patient access**. Centres will close or pass on the additional costs to patients in order to remain viable. Either outcome could result in increased costs to patients, the need to travel further to access chemotherapy and/or being forced onto potentially long waiting lists in the public health system. Any disruption and increased costs to patients and their families, particularly in regional and rural areas, is considered unacceptable.

There are also considerations related to **patient safety** with the use of these highly toxic medicines. Complex cancer treatment protocols with multiple chemotherapy medicines have the potential to result in serious patient harm when medication errors occur. Every dose of every cancer medicine for every individual patient should be checked by a chemotherapy competent pharmacist to ensure that it is safe and clinically appropriate to proceed with treatment.

Clinical pharmacy services are vital for the safe delivery of chemotherapy to cancer patients. A more appropriate and transparent funding mechanism which includes the clinical service component is needed.

## 2 Terms of Reference

### 2.1 The supply of chemotherapy drugs such as docetaxel, particularly in relation to:

#### 2.1.1 Patient access to treatment

##### Cancer treatment by sector and expenditure item

More than 50% of all cancer care in Australia is provided in the private sector.<sup>1,2</sup>

In 2000-01 (the most recent national data), expenditure for private medical services in hospitals was \$1,822 million out of a total of \$2 billion for overall cancer-related hospital services.<sup>3</sup>

The average Australian cancer patient will be admitted to hospital 11 times and use 33 community-based prescriptions for cancer drugs, in addition to drugs that are administered while in hospital.<sup>4</sup>

Medicare Australia PBS data shows that more than 13,000 life-saving infusions are prepared and dispensed by community and private hospital pharmacies for cancer patients each week.

According to the most recent national data on overall cancer care expenditure (2005), the total annual cost of non-hospital cancer pharmaceuticals was \$183 million. This represented around 6.5% of the total cost of cancer care in Australia.<sup>5</sup> This figure does not include prescription medicines provided in the private and public hospital settings. These are quantified as part of overall hospital expenditure; hospital services overall are the most expensive item in cancer care.<sup>6</sup>

No national analysis has been published since 2005, however the PBS listing of a number of high-cost cancer pharmaceuticals since that time<sup>7</sup> would suggest that both the aggregate and percentage of Australia's cancer budget allocated to chemotherapy has increased.

The proportion of expenditure on pharmaceuticals varies between different cancers. For example, the most expensive cancer for males is prostate cancer (\$201 million). Of this expenditure, 48% was for non-hospital pharmaceuticals (\$97 million), in addition to pharmaceuticals administered in the hospital setting, which are quantified as hospital costs.<sup>8</sup>

Just over 3 million prescriptions for community pharmaceuticals were cancer-related in 2000–01. Breast cancer (258,000), prostate cancer (241,000) and lung cancer (113,000) were the conditions for which pharmaceuticals were most frequently prescribed in a community setting.<sup>9</sup> Substantial increases in the incidence of these cancers combined over this period<sup>10</sup> would indicate that the current volume would be significantly higher.

**Whilst the reimbursement price of many chemotherapy drugs has decreased, the cost of providing vital clinical pharmacy services to an increasing number of patients has not. If the current system for the preparation and supply of chemotherapy drugs through private hospitals and private clinics collapses, cancer patients are likely to be forced into the already over stretched public hospital system. The public hospital system does not have the capacity to deal with closures of cancer clinics in the private system.**

## Cancer treatment and outcomes by location

Evidence shows that the further a cancer patient lives from a metropolitan centre, the more likely they are to die within five years of diagnosis.<sup>11,12,13</sup> For some cancers, remote patients are up to 300% more likely to die within five years of diagnosis.<sup>14</sup> Cancer care is less accessible as geographical isolation increases, with survival rates correlating directly to quality and availability of services.<sup>15</sup> Geographic isolation, shortage of healthcare providers and a higher proportion of disadvantaged groups are contributing factors.<sup>3</sup>

Capital funding for the establishment of 20 regional cancer centres across the country under the Rural Cancer Centres Initiative has the potential to reduce geographic inequity in cancer care outcomes. However, the current federal investment is capital funding only; there is no coordinated intergovernmental plan to underpin the sustainability of these and other regional cancer centres.

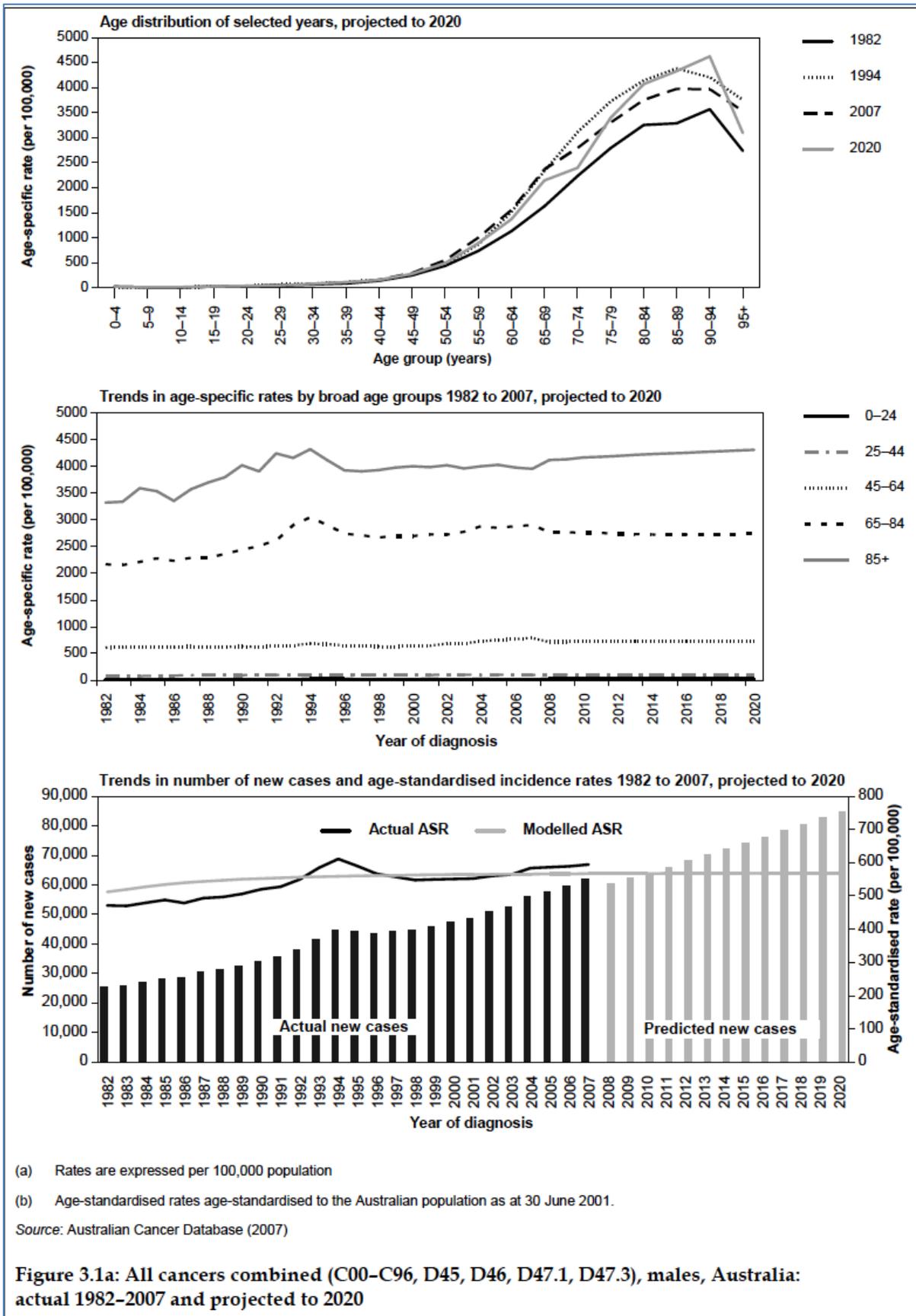
A national analysis published by the Clinical Oncological Society of Australia in 2006 showed that the further an individual cancer patient is located from a metropolitan or larger regional hospital, the poorer their access to chemotherapy services. The availability and sustainability of cancer pharmacy services in small regional hospitals in particular is limited, by comparison with larger centres.<sup>16</sup>

**If centres in regional and rural locations were forced to close, patients would have to travel substantially further to access chemotherapy or have delayed access to treatment. Any threat to the viability of oncology pharmacy services in remote locations poses a significant threat to patient access to appropriately administered chemotherapy. Compromising access to chemotherapy would risk a further widening in the geographic gap in cancer treatment outcomes.**

## Cancer treatment for older patients

The incidence of cancer increases with age. In 2012, it is estimated that 75% of new cancer cases will be diagnosed in males aged 60 and over, and 65% in females aged 60 and over. In 2012, it is also estimated that 1 in 3 males and 1 in 4 females will be diagnosed with cancer by the age of 75. By the age of 85, the risk is estimated to increase to 1 in 2 for males and 1 in 3 for females. These estimates for 2012 are based on 2000-2009 incidence data from the Australian Institute of Health and Welfare.<sup>17</sup>

The number of cases of cancer diagnosed in Australia is projected to rise over the next decade for both males and females and is expected to reach about 150,000 in 2020 - an increase of almost 40% from 2007.<sup>18</sup> Increases in the number of cases diagnosed are due primarily to the ageing and increasing population and are expected to be **most evident in older populations**. This is best portrayed graphically, as shown in Figure 1.



**Figure 1. Projections to 2020**

Whilst many older people may be medically fit until their cancer diagnosis, others will have chronic medical conditions such as high blood pressure, heart failure, diabetes, arthritis etc. for which they may already be taking medicines prescribed by their GP or other specialists.<sup>19</sup> They may also take “over-the-counter” medicines and herbals or supplements that they may not mention to their doctor.

Starting cancer chemotherapy and new supportive medicines for side effects can lead to patients taking multiple medications (called “polypharmacy”).<sup>19</sup> A study of 200 older cancer patients (aged 70 years and over) at Royal Adelaide Hospital found patients were taking a mean of 5 medicines (range none to 18) BEFORE they started chemotherapy.<sup>20</sup> The likelihood of adverse reactions and drug interactions increases exponentially with the number of medications taken.

**Access to clinical pharmacy services is vital for the safe delivery of chemotherapy, particularly given the disease context in which these medicines are being used. Cancer is a disease of the older person and the societal burden will increase with the ageing Australian population.<sup>17,18</sup> These complex older patients, who constitute the majority of the workload, need specialist cancer pharmacy services.**

### **2.1.2 Cost to pharmacists and suppliers**

On 1<sup>st</sup> December 2012, a 76.2% decrease in the reimbursement price for docetaxel came into effect. This price more accurately reflects the cost price of docetaxel to pharmacies. However, for many years pharmacies have been using the reimbursement price of medicines such as docetaxel to fund other loss-making chemotherapy medicines and the provision of vital clinical pharmacy services to ensure the safety of cancer patients. Whilst the reimbursement price of many chemotherapy drugs has decreased, the cost of providing these essential services has not. It could be argued that the cross subsidisation of services that occurred was inappropriate, however there is no definite income stream to maintain the clinical pharmacy services associated with the safe supply of chemotherapy to patients with cancer. Every cancer patient, regardless of treatment setting should have access to these services. The decrease in the reimbursement price of docetaxel has highlighted the need for the essential safety function provided by cancer pharmacists to be funded in its own right.

### **2.1.3 Cost to the private and public hospital systems**

The viability of chemotherapy services provided by the private sector, including those at centrally funded rural chemotherapy treatment centres, is at risk following the reduction in the reimbursement price of docetaxel. During the ongoing confidential negotiations between the Government and the Pharmacy Guild of Australia, chemotherapy services have been maintained by private providers in a gesture of goodwill. This is only a short-term strategy and if no resolution is forthcoming, it is inevitable that closures will occur, reducing access to chemotherapy services and forcing patients to travel further. On 1<sup>st</sup> April 2013 a reduction in the reimbursement price of a number of medicines, including the widely used chemotherapy medicine, paclitaxel, will exacerbate the issue.

Any reduction in the chemotherapy services provided by the private sector has the potential to severely impact upon the public sector. Already stretched public hospitals do not have the capacity to absorb a large increase in their workload. The essential services provided by clinical pharmacists to keep cancer patients safe (as described below) are at risk. It is vital that chemotherapy provision in the private sector is maintained and that the essential role that pharmacists play in keeping chemotherapy patients safe across all sectors is recognised and appropriately funded.

### **The value of the pharmacist's role**

The basis for the role of the pharmacist in the treatment of cancer in both the public and private setting is centred on the **safe, accurate** and **appropriate** provision of chemotherapy. It is necessary to look at the clinical pharmacy services required to treat cancer patients to appreciate the real value of the pharmacist's time.

Medication safety has been identified as a National Safety and Quality Health Service Standard (ACSQHC).<sup>21</sup> One of the priorities is for medication reconciliation (or medication history) to be completed for all hospital patients at admission, intra-hospital transfer and at discharge. This is also required under APAC Guidelines.<sup>22</sup> This is absolutely vital in cancer patients, as chemotherapy has a high potential for harm due to the narrow therapeutic index of the agents and the disease context in which it is being used.

The COSA Guidelines for the Safe Prescribing, Dispensing and Administration of Cancer Chemotherapy<sup>23</sup> clearly state that a medication history should be taken by the pharmacist at the patient's initial and subsequent cycles. This should include prescribed medication, over the counter and herbal medication and must take into account any changes in medication during treatment. The pharmacist must investigate and advise the treating oncologist of any potential drug or disease interactions that could affect the patient's cancer and supportive care medicines.

The components of the chemotherapy order verification process are shown in Table 1.<sup>23</sup> Due to the patient-specific approach of cancer treatment, the varying response and tolerance of each different patient and frequent changes to both doses and drugs, this process must be followed for each and every order to minimise the risk of serious medication errors.

<p><b>Patient Body Surface Area (BSA)</b></p> <p>The patients BSA must be recorded on the chemotherapy order and an independent check carried out.</p>
<p><b>The medications</b></p> <p>Ensure that all medications have been prescribed according to protocol and that there are no omissions with respect to the requirements of the protocols including chemotherapy, targeted therapy, pre medication and supportive therapy.</p> <p>Check that additional medication has been prescribed. e.g. anti emetics, mesna. Verify they are appropriate for the protocol and the length of the course.</p> <p>Verify that the administration route for each medication is correct and is specified.</p> <p>Verify that the duration of infusion and diluent requirements are specified where needed.</p> <p>Verify that the frequency and sequencing (i.e. day 1, day 2 etc.) is correct.</p> <p>Ensure that the patient has no documented allergies/hypersensitivity reactions to any of the medication prescribed.</p>
<p><b>The doses</b></p> <p>Verify that all doses are correct according to protocol, patient weight, BSA, creatinine clearance.</p> <p>Verify maximum and cumulative doses are not exceeded for the dose or the course.</p> <p>Verify dose reductions are correct according to the protocol, patient parameters.</p>
<p><b>Scheduling</b></p> <p>Verify that the length of course and time interval between each cycle is appropriate for the protocol and tumour type.</p> <p>Verify that the appropriate time period has passed between last cycle and current cycle.</p> <p>It is important to maintain an up to date treatment history relating to all chemotherapy medications, doses and treatment dates.</p>
<p><b>The patient blood counts and other results</b></p> <p>Verify that the absolute neutrophil count is appropriate for administration of the chemotherapy.</p> <p>Verify that the renal and liver function is appropriate for the dose of the medication to be administered.</p> <p>Where appropriate obtain results of other tests specific to certain drug toxicities, e.g. lung function prior to bleomycin, methotrexate levels, urine pH level for methotrexate, and ejection fraction for anthracyclines.</p>
<p><b>Protocol variations</b></p> <p>Verify that variations from the original protocol are valid for the patient and protocol. Ensure they are authorised by the prescriber and documented.</p>
<p><b>Drug-drug, drug-disease interactions</b></p> <p>A medication history should be taken by the pharmacist at the initial and subsequent cycles to include prescribed medication, over the counter and herbal medication and must take into account any changes in medication during treatment. The pharmacist must investigate and advise on any potential medication or disease interactions.</p>
<p><b>Adverse drug reactions</b></p> <p>Details of previous and current adverse drug reactions should be verified with the patient and documented. Adverse drug reactions may occur with chemotherapy agents, targeted therapies and supportive therapy during treatment and appropriate recording and reporting must be ensured. Documentation of rechallenges and subsequent reactions is also essential.</p>

**Table 1. Chemotherapy order details to be verified by the pharmacist**

The full steps required for chemotherapy medicines to be administered to each patient are shown in Figure 2. This flowchart clearly demonstrates the value of the pharmacist's role in the safe, accurate and appropriate supply of chemotherapy.<sup>19,23</sup>

### 1. Pre-treatment medication interview with patient

The pharmacist is responsible for medication reconciliation, identification of potential medication issues (e.g. due to co-morbidities and previous adverse drug reactions), and counselling about pre and post treatment medicines.



### 2. Pre-treatment clinical review of intended treatment plan

Working with medical and nursing staff, the pharmacist confirms doses based on weight and body surface area (BSA), manages anticipated medication issues (e.g. due to co-morbidities and previous adverse drug reactions), renal, cardiac and liver function.

*The time required for the pre-treatment medication interview and review is 30 minutes.<sup>24,25</sup>*



### 3. Clinical review of patient prior to each cycle

The pharmacist verifies the dose of every medicine in the cycle of therapy, according to the protocol, patient treatment plan and patient parameters. Prior to each cycle of chemotherapy the patient's weight, BSA, renal function, FBEs, LFTs and U&Es are reviewed and if required, changes to the doses of chemotherapy and support medicines are made. The pharmacist clarifies and resolves any identified discrepancies with the prescriber.

Clinical verification for each cycle of chemotherapy required on average 13 mins per patient per cycle (range 4-22 mins). 37% of orders required further communication to progress the order to the supply stage and took on average 4.6 mins per patient.

*The total time required per cycle for clinical validation is 17.6 minutes.<sup>24,25</sup>*



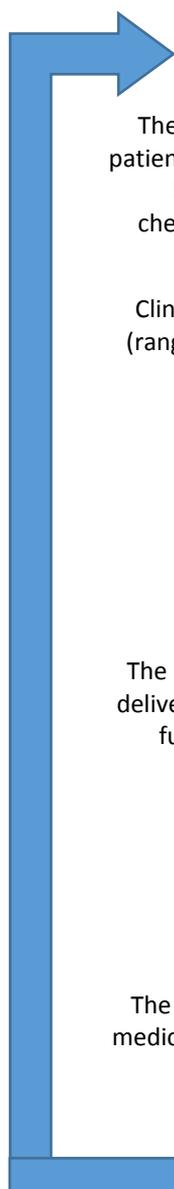
### 4. Manufacture, release and administration of each dose

The pharmacist is responsible for accurately preparing each chemotherapy medicine, in an appropriate delivery device, under controlled conditions to ensure that each dose is ready for administration without further manipulation. Following a final check, all chemotherapy, fluids and support therapies are dispensed and made ready for the patient in a timely and safe manner.



### 5. Discharge medicine provision and advice

The patient receives discharge medicines including medicines to control nausea and vomiting and pre-medications to be taken prior to the next cycle of chemotherapy. The pharmacist counsels the patient on the use of all these medicines.

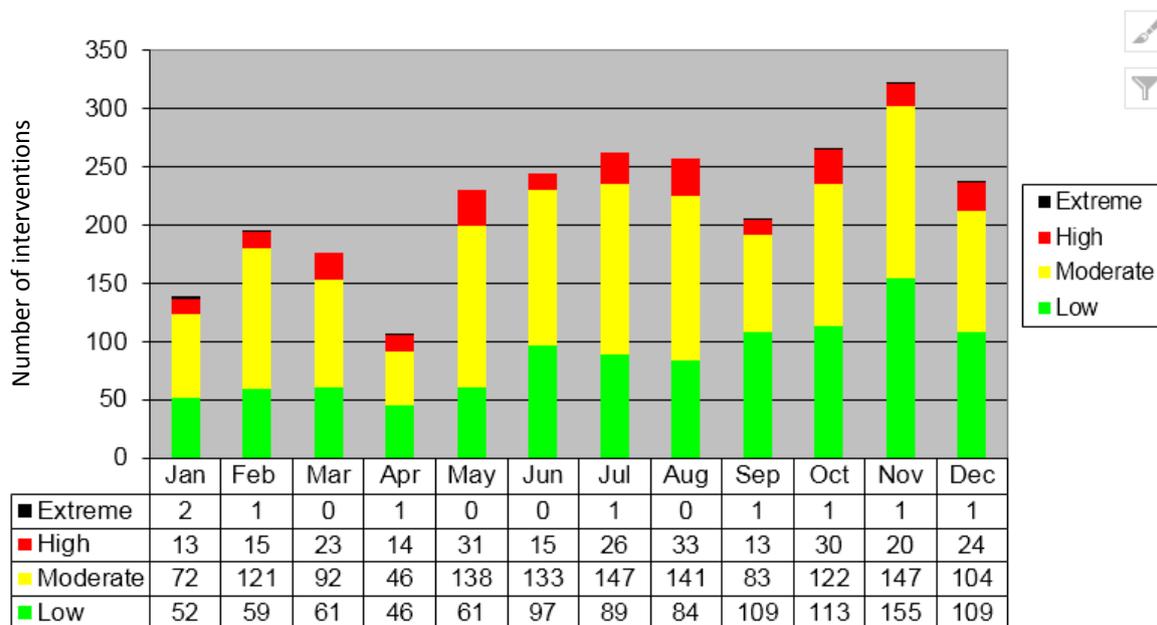


**Figure 2. Clinical pharmacy services required for every cycle of chemotherapy**

## Pharmacist interventions to ensure patient safety

In patients with cancer, overdosage can result in death while underdosing can have significant implications for the management of the disease and patient outcome.<sup>23</sup>

The data in Figure 3 shows the absolute number of interventions made by clinical pharmacists at the Peter MacCallum Cancer Centre during 2012. Details of medication changes brought about by clinical pharmacists (defined as ‘interventions’) were recorded, categorised and graded according to the likelihood and potential consequence of an adverse event (i.e. the level of risk avoided) using a nationally recognised grading tool for pharmacist interventions.<sup>26</sup> All of these interventions were made in patients being treated for cancer, and each one represents a separate case where a pharmacist has ensured patient safety.



**Figure 3. Pharmacy Interventions in 2012**

The following examples demonstrate real situations where pharmacists have intervened to prevent potential patient harm.

- A patient was prescribed ten times the correct dose of a chemotherapy medicine. Had the pharmacist not identified this error prior to the dose of chemotherapy being dispensed, it could have resulted in potentially fatal consequences for the patient.
- A patient was prescribed a similar but incorrect chemotherapy protocol. The pharmacist identified this error and ensured that the patient received the correct chemotherapy medicines. It is possible that the clinical outcome of this patient could have been compromised had the pharmacist not made this intervention.
- A patient with a cancer-related thrombosis was admitted to hospital and not prescribed a treatment dose of anticoagulant. The clinical pharmacist noticed the omission and requested that the correct medicines be prescribed immediately. If the pharmacist had not made this intervention the patient could have suffered a fatal pulmonary embolism.

These examples clearly illustrate the value of a clinical pharmacy service in a health service providing cancer care, regardless of sector.

## 2.2 Any long-term sustainable funding models for the supply of chemotherapy drugs, including docetaxel

Any proposed funding model needs to acknowledge the complexity of providing treatment with chemotherapy, in particular:

- The wide range of protocols used (with considerable variation in the number of cycles of chemotherapy) and the number of days of treatment/number of chemotherapy medicines administered in each cycle.
- The clinical review process that occurs prior to a course of chemotherapy being prescribed and the clinical review process that is required prior to and during each cycle of chemotherapy in the prescribed course.

The cancer pharmacist's clinical review is at least equivalent to the reviews conducted by community pharmacists and funded under the 5<sup>th</sup> Community Pharmacy Agreement (the MedsCheck and Diabetes MedsCheck). These clinical reviews of patients' medications occur within a community pharmacy and are intended to sit between the very limited clinical services (patient counselling) associated with prescription drug dispensing and the more intensive review associated with a Home Medicines Review. The elements undertaken in a MedsCheck or Diabetes MedsCheck are shown in Table 2.<sup>27</sup>

<p><b>Elements</b></p> <p><b>Gather relevant information from the consumer or consumer's carer:</b></p> <ul style="list-style-type: none"><li>a) Verify and complete the list of the consumer's prescription, non-prescription and complementary medicines (medicines list).</li><li>b) Verify any allergies.</li><li>c) Identify any chronic conditions.</li></ul> <p><b>Review and discuss the use of all medicines and medication/monitoring devices, including:</b></p> <ul style="list-style-type: none"><li>a) Assess medication adherence.</li><li>b) Assess education needs including the provision of written information to support improved understanding and use of medicines.</li><li>c) Provide education and guidance on correct use of medication/monitoring devices.</li><li>d) Discuss management of chronic condition(s) including lifestyle factors related to medicine use and self-management.</li><li>e) Attempt to resolve any medication-related issues that have been identified from the information available.</li></ul> <p><b>Develop a written action plan</b> including agreed consumer goals and actions and any agreed follow-up with the consumer's GP and/or other healthcare provider(s).</p> <p><b>Provide consumer with a copy of the consumer report</b> which includes the medicines list and action plan.</p> <p><b>Arrange agreed follow-up actions, which may include:</b></p> <ul style="list-style-type: none"><li>a) contacting the consumer's GP or other healthcare provider(s)</li><li>b) providing a copy of the medicines list and/or action plan to the consumer's GP or other healthcare provider(s).</li></ul>
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**Table 2. Elements in a MedsCheck or Diabetes MedsCheck**

The very real difference between these funded services and those provided by cancer pharmacists in chemotherapy day-infusion centres is that these activities occur once at the start of a new course of chemotherapy and then at the beginning of each new cycle (whereas patients are only eligible for a MedsCheck or Diabetes MedsCheck once a year). In addition, the clinical cancer pharmacist has access both to the patient's medical record (to review relevant pathology reports and other tests) and to the rest of the healthcare team with whom they can discuss the best treatment options for the patient and resolve medication related problems before the chemotherapy goes ahead.

**In summary, the funding model should remove the need for payment cross subsidisation (which currently underpins the system) and address the shortfall in several of the current remuneration categories which are based on the assumption that the service is only the purchase of a product. Furthermore, any proposed funding model must provide sustainable access for patients to chemotherapy services that is equally applicable across all hospitals and types of pharmacy services.**

### **2.3 Any related matters**

No further comments.

## **3 Acknowledgements**

COSA and the CPG thank the review panel for the opportunity to make this submission to the Senate Standing Committees on Community Affairs.

We would like to thank the members of the COSA Cancer Pharmacists Group for contributing their time and expertise to the development of this submission.

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