The Pharmacy Guild of Australia

Submission to Senate Community Affairs Committee Inquiry:

Supply of chemotherapy drugs such as docetaxel

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ABOUT THE PHARMACY GUILD OF AUSTRALIA

The Pharmacy Guild of Australia ('the Guild') is an employers' organisation servicing the needs of independent community pharmacies. It strives to promote, maintain and support community pharmacies as the most accessible primary providers of health care to the community through optimum therapeutic use of medicines, medicines management and related services.

CHEMOTHERAPY AND COMMUNITY PHARMACY

Chemotherapy is the treatment of disease, especially cancer, by the use of chemical substances. These chemical substances are usually administered in an infusion that is injected into a patient in an oncology facility in a hospital or specialised clinic. In this submission "chemotherapy" is used to refer to the treatment of cancer with chemical substances that required reconstitution into a form that can be infused into the patient, and to those drugs that are subsidised for patients under the Efficient Funding of Chemotherapy (EFC) arrangements established under Section 100 of the *National Health Act 1953*.

Chemotherapy is a vital part of the Australian healthcare system. Due to its complex nature, chemotherapy drugs are dispensed by less than 150 of Australia's 5,240 community pharmacies. These community pharmacies dispense chemotherapy drug infusions safely and efficiently so that they can be administered at a time and place (a private hospital or clinic) that is suitable for the cancer patient. Official data shows that more than 13,000 life-saving infusions are dispensed by community pharmacies for Australian cancer patients every week.

Chemotherapy drugs are highly potent and cytotoxic (toxic to human cells). The preparation of chemotherapy infusions, a process commonly referred to as *reconstitution*, or by the more general term *compounding,* is complex and requires specialised skills and advanced, high cost facilities. It is an extension to the manufacturing process for these drugs and without this process the drugs cannot be used. Reconstitution must occur just prior to the final use of the drug, as the prepared dose has a very limited time to expiry.

Due to the significant capital required to establish a facility that meets the high standards required for reconstitution, less than 5% of the 150 pharmacies that dispense chemotherapy drugs have the in-house facilities to prepare infusions. The remaining pharmacies outsource this specialised function to third parties. Two private, third party reconstitution providers operate in Australia – Baxter Healthcare and Fresenius Kabi Australia.

BACKGROUND

The current funding model for chemotherapy operates through the Efficient Funding of Chemotherapy Drugs initiative (EFC), which came into effect on 1 December 2011. The genesis of these arrangements was through a 2008 Budget measure. The measure, as originally announced in that budget, was unworkable and was based on a fundamental misunderstanding of the sector, risking patient safety as well as access. Cancer patient groups, oncologists, private hospitals, pharmacists, wholesalers and manufacturers all fought the proposed model and, eventually, their views were acknowledged and the measure was delayed.

As the government was determined to proceed with a savings measure an alternative proposal was put forward by the Guild (and others) to allow savings to be generated without jeopardising patient safety or the short term viability of the sector. However, in this proposal and in subsequent discussions the Guild, and other individuals and organisations, warned that unless some price disclosure savings were returned to the sector the model was only a short term solution. It was made viable only by trading terms available to pharmacies from suppliers of some off-patent drugs, and these would be eroded by price disclosure, which is a mechanism to reduce prices of off-patent drugs. These trading terms cross-subsidised the supply of other drugs which were dispensed by pharmacies at a loss.

Despite these warnings, the remuneration in the EFC was set at a level that did not cover costs that are unavoidable in the safe and efficient preparation and dispensing of chemotherapy infusions and the EFC did not include a mechanism, as was recommended in the proposal, to return price disclosure savings to the sector over time. As a result of this, at some point the trading terms that allowed the system to operate viably would inevitably decline to a level that did not allow for provision of chemotherapy drugs and essential related services to cancer patients.

The EFC remuneration is inadequate, however the supplier trading terms available to pharmacies on a small number of off-patent drugs has supplemented remuneration. The surplus on these drugs, such as docetaxel and paclitaxel, has been cross-subsidising the dispensing of other, loss-making drugs. Price reductions on 1 December 2012 (a 76.20 per cent reduction to docetaxel) and 1 April 2013 (an 86.94 per cent price reduction to paclitaxel) mean that this source of cross-subsidy is no longer available. The price reductions remove the trading terms. There are no further trading terms or other sources of income to replace this loss.

It is important to understand that although the Terms of Reference for this Inquiry refer specifically to docetaxel, the problems with the EFC arrangements have consequences for <u>all</u> chemotherapy drugs, not just docetaxel, paclitaxel or others that have been, or will be, subject to price reductions. Ongoing care for <u>all</u> Australian cancer patients, regardless of their type of cancer, is being put at risk by the current arrangements.

The EFC arrangements were implemented without recognition of the impact that price disclosure would have on chemotherapy drugs. This resulted in an unsustainable funding model that was only viable while significant trading terms were available on off-patent chemotherapy drugs. Price disclosure has removed these trading terms.

The Guild estimates that the cumulative impact of price disclosure on chemotherapy drugs is now at the point where the price reductions will be saving the government $210 million in the 2013-14 financial year. As described in Section 6 of this submission this has far exceeded all expectations, by the government and the sector, of the impact of price disclosure over this timeframe. It is now time for some of those savings to be reinvested into the healthcare system that they were taken from, in order to ensure that system's viability and ensure that patient access to these life-saving medicines can continue in all parts of Australia.

ISSUES SUMMARY

The problems are not restricted to the effect of price reductions. Other problems exist with the current funding arrangements and are described in detail throughout this submission. The table below provides a summary of issues and the corresponding sections of the submission.

Issue	Section/Page
The preparation fee does not cover the cost of preparation, regardless of whether the preparation is performed in-house by the pharmacy or is outsourced to a third party compounder.	Section 3, pages 13-14
The dispensing fee of $6.52 per infusion does not adequately account for the range of complex and chemotherapy-specific functions performed by the community pharmacy that ensure safe and optimised cancer treatment for the patient.	Section 3, page 14
The price reductions due to price disclosure on chemotherapy drugs will reach $210 million in the 2013-14 financial year, and have far exceeded the projections made by government in 2010 and the expected impact on the sector.	Section 6, pages 20-21
The price disclosure mechanism does not include, monitor or adjust for the fees and mark-ups charged to pharmacies by third party compounders, and these charges are not limited by any form of regulation or legislation.	Section 6, page 22
Public hospital purchasing – unrepresentative of the private market and intended to be excluded from price disclosure - has distorted, and continues to distort, price disclosure outcomes.	Section 6, page 23
The minimum cost to pharmacies of some patented drugs – particularly some that have been newly listed in 2011 or 2012 – is now significantly higher than the official PBS price.	Section 6, pages 27-29
The minimum cost to pharmacies for some prepared infusions of off-patent drugs is now higher than the amount received.	Section 6, page 22
Unanticipated losses of mark-up have been incurred due to the payment algorithm being illogical and not implemented as the sector had expected.	Section 6, pages 24-27
The remuneration arrangements fail to adequately recognise the costs associated with meeting the increasingly stringent standards required for preparation of chemotherapy.	Section 6, pages 29-31 and Appendix 1, pages 34-39
The costs of containers and devices, which can be over $100 for a single infusion, are not reflected in the remuneration model.	Section 6, page 31
Specific concerns that relate to non-metropolitan areas.	Section 6, pages 31-33

SECTION 1:
THE ROLE OF A PHARMACIST IN DISPENSING A PATIENT'S CANCER MEDICATION - *A COMPARISON WITH DISPENSING OF NON-CHEMOTHERAPY MEDICINES IN A COMMUNITY PHARMACY*

A patient's journey with cancer is a long and complex one. From screening and diagnosis through to treatment and supportive care, a patient will see many different medical professionals.

In order to make this process easier, patients are provided with a dedicated specialist pharmacist (usually referred to as an oncology pharmacist) who will guide them through the course of their treatment. The dispensing process followed by this oncology pharmacist involves similar steps as those in dispensing a prescription in a community pharmacy setting, but is invariably a much more involved process due to the nature of the disease, the treatment regimen and the complexity of chemotherapy drugs. The oncology pharmacist is a vital part of the multidisciplinary team that establishes therapeutic goals in collaboration with patient.

Table 1 (spanning the two pages that follow) provides a snapshot of the role of an oncology pharmacy service compared with a non-chemotherapy community pharmacy dispensing service.

Please note that the "Private Hospital Clinical Service" steps in Table 1 have no corresponding activity in non-chemotherapy community pharmacy dispensing. These form part of clinical service arrangements which are outside the scope of professional dispensing standards adhered to in the dispensing process.

Also, the preparation of the infusion (the orange box in Table 1) has no corresponding activity in standard, non-chemotherapy dispensing. While this fact is recognised by the remuneration structure through the application of the Preparation Fee, that $40.64 fee does not cover the costs of this activity. This will be explained in the following section of this submission.

Notionally, the chemotherapy dispensing activities in Table 1 (first column) that have a corresponding community pharmacy dispensing activity are all intended to be covered by the $6.52 dispensing fee.

Both fees are inadequate and the activities in this diagram have only remained viable, for <u>all</u> chemotherapy drugs, due to the availability of trading terms on a <u>few</u> chemotherapy drugs (such as docetaxel and paclitaxel). Patient access to the full range of activities presented in Table 1, all of which ensure patient health outcomes are optimised from these complex and sometimes expensive medicines, is at risk.

TABLE 1 – ONCOLOGY PHARMACY DISPENSING ACTIVITIES COMPARED TO COMMUNITY PHARMACY

Oncology Pharmacy Dispensing Activity	Corresponding Activity in non-Chemotherapy Community Pharmacy Dispensing	Private Hospital Clinical Service
Referral form received by the Oncology Clinic (first contact Oncology Clinical Nurse Consultant, then referral given to pharmacist).	Prescription presented at pharmacy by patient.	
Pharmacist assesses whether additional pathology tests are required prior to the patient commencing treatment.		Yes
Collect and assess current and past patient clinical, drug and family history necessary to design a pharmacotherapeutic plan.	Establish history of patient at the counter prior to dispensing.	
Pre-treatment chart revision. Pharmacist checks the body surface area, dosages, pre-treatment and take home medications.	Confirm history/dosage checks on dispensing system.	
Pharmacist attends chemotherapy drug/chart write up to consult with treating specialists to discuss treatment.		Yes
Pharmacist participates in a multidisciplinary team meeting to establish therapeutic goals in collaboration with patient.	Contact doctor if confirmation, dose checks or changes required to prescription.	
Pharmacist orders drugs as per the checked chart. This includes all drugs including take home drugs.	Dispensing continues with drug selection and labelling.	

TABLE IS CONTINUED ON FOLLOWING PAGE

Oncology Pharmacy Dispensing Activity	Corresponding Activity in non-Chemotherapy Community Pharmacy Dispensing	Private Hospital Clinical Service
Required dose of IV chemotherapy drugs prepared aseptically by a pharmacy using in-house facilities or sourced from a TGA Licensed third party compounder.	No corresponding non-chemotherapy activity exists. This is the preparation (reconstitution/compounding) stage. It is a very specialised task that requires advanced equipment and specifically trained staff. It must be performed in a controlled, sterile environment. Please see photographs and description of this process at Appendix 1.	
Assessment of the financial impact of the selected treatment on the hospital as well as for the patient.	Once price/co-payment is confirmed any financial issues will be discussed with the patient.	
Compounded chemotherapy products are checked upon arrival for dose, container, compatibility and safety. Labels printed.	Pharmacist checks dispensing – labelling, drug selection, etc.	
<u>For all Patients</u> Individualised patient medication kits are packed. These kits include treatment, pre-med and supportive care medications.	Any supportive material provided (for example, Consumer Medicines Information).	
<u>New Patients</u> During first visit to clinic: provide a Patient Care Kit, Cancer Council Kit and information from EVIQ (an online cancer treatment information resource).	First time use counselling provided by pharmacist.	
<u>For all Patients</u> Assessment of physical signs of drug related effects.	Part of the next visit for the repeat prescription.	
<u>For all Patients</u> Pharmacist, in collaboration with the chemotherapy nurse, conduct a holistic assessment of patients' wellbeing and any non-drug related side effects that may require further referral.		Yes
TABLE IS CONTINUED ON FOLLOWING PAGE		

Oncology Pharmacy Dispensing Activity	Corresponding Activity in non-Chemotherapy Community Pharmacy Dispensing	Private Hospital Clinical Service
For all Patients Monitor compliance with medications, diet, sleeping, nausea, constipation, effect of treatment on lifestyle, medication interactions. Liaise with family members.	Compliance and side effect checks as part of the next visit for the repeat prescription.	
For all Patients Respond to drug information requests; liaise with nursing staff about drug issues.	Follow up patient understanding and further queries as part of the next visit for the repeat prescription.	
For all Patients Liaison with doctors to recommend newly available drugs, extra therapeutic drug monitoring or suggested management techniques to improve patient outcomes.	If follow up with the patient indicates changes to the prescription then consult the doctor by phone.	
PATIENT OUTCOMES ARE OPTIMISED		

SECTION 2: CURRENT REMUNERATION ARRANGEMENTS

Table 2 provides a summary of the remuneration arrangements under the EFC and the issues with each component. These issues are described in greater detail later in this submission.

Importantly, the Guild rejects the notion put by the government that pharmacies are "now paid $76.37 for dispensing chemotherapy drugs."[1] As can be seen from Table 2, **pharmacies only receive $6.52 for the dispensing function**. A further $40.64 is paid for what is essentially an addition to the manufacturing process – that is, turning a vial of the chemotherapy drug (unusable in vial form) into a safe, infusible product that can be administered to the cancer patient. Both fees are inadequate, as shown in the following section of this submission.

The remaining $29.21 of the $76.37 in the Minister's statement in November specifically relates to wholesaler distribution ($24.38 for the pre-pharmacy stage of the supply chain) and the direct cost of diluent used in the infusion (a fee of $4.83 per infusion).

[1] Minister for Health and Ageing statement, 28 Nov 2012: *Peter Dutton Misleads Patients on PBS Listings* http://www.health.gov.au/internet/ministers/publishing.nsf/Content/mr-yr12-tp-tp104.htm

TABLE 2: SUMMARY OF CURRENT REMUNERATION

Remuneration Component	Amount	Description	Comments/Issues
Distribution Fee	$24.38 per infusion	This replaced the wholesale mark-up and is intended to cover the cost (charged to the pharmacy) of the logistics and transport of the vials to the community pharmacy or third party compounder. *NOTE: Although this fee is paid to the pharmacy, it is not part of the pharmacy's remuneration for preparing or supplying the item.*	It is important to note that although the pharmacy is purchasing the product in vials, this fee is paid per infusion to the pharmacy. Many infusions require, for example, 3 infusions so the fee equates to only $8.13 per vial. Vials commonly cost more than $1,000 so this margin is often less than 1%, which is less than the margin changed to the pharmacy by the wholesaler. There is also no legislation limiting what price pharmacies are charged by wholesalers or other suppliers for the drug.
Preparation Fee	$40.64 per infusion	This is intended to cover the cost of taking the medicine from the vial and preparing the infusion (a process that is also referred to as reconstitution or compounding) so that the drug can then be dispensed and administered to the patient in the hospital or clinic. The preparation of a chemotherapy infusion is a manufacturing process that must be performed by highly trained staff with advanced, high cost equipment in a sterile facility. Only a few community pharmacies have in-house facilities. Other community pharmacies outsource this function.	This fee does not cover the cost of reconstitution. This is the case for community pharmacies that have in-house facilities and others that outsource to a third party. Third parties charge a base fee and a considerable, variable mark-up on the cost of the drug. There is no legislated limit on what third party compounded can charge through fees and mark-up. Third party compounders have also had their margins reduced through cuts to their generic trading terms following price disclosure. They have increased the fees and mark-ups charged to community pharmacies in order to make up for this shortfall.
Diluent Fee	$4.83 per infusion	This is intended to cover the cost of the diluting agent used in the reconstitution process.	On average this fee adequately covers the cost of diluent.

Dispensing Fee	$6.52 per infusion	This is the same fee paid for dispensing of non-chemotherapy items by community pharmacies.	Chemotherapy drug regimens are highly complex and in order to safely and efficiently dispense these medicines the pharmacy must carry out tasks and detailed inter-professional collaboration activities which are more time-consuming than for most other medicines. This dispensing fee does not cover the cost of the dispensing activities associated with chemotherapy drugs.
Pharmacy Mark-up	Generally 4% or lower. Average value approx. $15 per infusion.	Is intended to cover the cost of storing and handling the drugs.	The Department of Human Services (DHS) algorithm that calculates the mark-up for each dose is illogical, unreasonable and not as expected by the sector and is inconsistent with PBS pricing documentation. For many drugs there is a significant shortfall in the mark-up compared with what was expected and compared with what was effective under the previous arrangements.

SECTION 3: COSTS OF CHEMOTHERAPY DRUG PREPARATION AND DISPENSING

The Guild has provided the Department of Health and Ageing with detailed costs from 10 community pharmacies providing chemotherapy. The data provided to the Department of Health and Ageing has been provided as individualised and fully identified data. In aggregate this is a very large dataset - more than $2.7 million of costs and almost 16,500 infusions are covered by the sample. Table 3 provides a summary of the cost data. Separate columns are provided for:

a) pharmacies that mainly use a third party (Baxter Healthcare and/or Fresenius Kabi Australia) to provide the reconstitution (preparation) service;
b) pharmacies that have invested in in-house reconstitution facilities.

The costs in Table 3 do not include any clinical services activities provided in or for the private hospital or clinic where the patient's treatment occurs, nor do they include the cost of dispensing activities. Table 3 relates solely to the orange box in Table 1, for which the Preparation Fee ($40.64) is intended to cover the full cost.

TABLE 3: AVERAGE COSTS OF CHEMOTHERAPY PREPARATION

Cost Centre	Average cost per infusion for Pharmacy Using Third Party for Reconstitution	Average cost per infusion for Pharmacy with In-house Reconstitution Facility
Labour (including on-costs such as superannuation)	$12.72	$45.15
Containers/consumables	$1.83	$16.45
Direct Compounding Costs (diluent, microbiology monitoring/testing, aseptic garments, heating/ventilation/air conditioning, maintenance)	$1.05	$21.93
Cleaning & Waste Disposal	$0.22	$4.15
Printing, Stationery, Insurance, IT & Bank Charges	$9.82	$0.19
Third party compounder fees and markup	$108.61	$0.00
Rent (apportioned only for area required for chemotherapy)	$3.07	$10.81
Chemotherapy manufacturing training and validation	$0.50	$2.27
Compliance costs (eg. Therapeutic Goods Administration)	$0.00	$1.17
Total cost per infusion	**$137.82**	**$102.12**
Number of pharmacies/sites in sample	7	3
Number of infusions in sample	16,479	3,632

Note: *Table 3 does not include cost of capital, which is considerable for pharmacies with in-house reconstitution facilities. Table 3 also does not allow for any profit margin for the pharmacy.*

The average cost of preparing an infusion in-house is $102.12. This excludes the cost of capital, such as the capital invested to build the facility and purchase equipment.

The average cost for a pharmacy that mainly uses third party compounders is $137.82, with $108.61 of this being the direct cost of fees and drug cost mark-ups paid to the third party.

The differences in cost between the in-house pharmacies and those that outsource are likely to relate to profit margin of the third party compounder and the third party compounder's need to recoup its own capital cost. Neither of these is accounted for in the calculations relating to pharmacies with in-house reconstitution facilities.

The current $40.64 preparation fee is intended to cover the cost of preparation. Based on Table 3 the shortfall in this fee, conservatively, is between $68 and $97.

This is in addition to a shortfall in the dispensing fee ($6.52) which does not adequately account for the range of complex and chemotherapy-specific functions performed by the community pharmacy in order to ensure safe and optimised cancer treatment for the patient (see Table 1).

It is worth noting that with approximately 800,000 infusions dispensed annually by the private sector, the total savings so far generated by price disclosure (which will amount to an estimated $210 million in 2013-14) represent more than $260 per infusion. Only a fraction of this $260 needs to be reinvested in the EFC remuneration arrangements to allow private sector chemotherapy to be sustainable.

SECTION 4: WHAT WILL HAPPEN IF NOTHING IS DONE?

Since the price reduction to docetaxel on 1 December 2012 the Guild has had a number of reports that pharmacies are choosing not to supply certain chemotherapy drugs (those that result in the largest loss for the pharmacy). These pharmacies are advising the patient's doctor that they will need to seek treatment through the public hospital system. This is a regrettable situation and one which reduces patient choice and weighs on the already overburdened public hospital system. However, in order to maintain services for other chemotherapy drugs until the remuneration arrangements are amended this step has been necessary.

This withdrawal of services is likely to broaden over time and there is significant risk that, if a solution to the current funding shortfall is not found very soon, community pharmacies that currently dispense chemotherapy drugs will be unable to continue to do so (for any drug). This withdrawal may occur first in non-metropolitan areas where community pharmacies are providing these vital services to local, relatively small private hospitals and also, in many cases, to the regional public hospital. Patients may then have no choice but to travel much further from their homes to access cancer treatment.

The Guild is also aware that some community pharmacies have been seeking legal advice on their ability to charge patients for some of the costs the pharmacy is currently incurring in relation to their treatment. The introduction of an additional cost burden to patients is not an outcome the Guild wishes to see as it may reduce access to these medicines and/or push more cancer patients to the public hospital system.

While the Guild does not represent the hospital sector it is important to note that public hospitals will have been affected by price disclosure in a similar manner to the private sector. They have also been able to cross-subsidise their provision of chemotherapy through the availability of trading terms on some off-patent drugs. The public hospital system is therefore at a similar risk of non-viability, although this will not be as visible due to the nature of their budgets and financing arrangements.

SECTION 5: CHEMOTHERAPY ARRANGEMENTS ARE NOT PART OF THE FIFTH COMMUNITY PHARMACY AGREEMENT

The funding arrangements for chemotherapy (the EFC) were implemented as a budget measure, separate to and without reference to the Fifth Community Pharmacy Agreement (5th Agreement). The 2008 Budget measure was announced in the third year of the five-year Fourth Community Pharmacy Agreement (4th Agreement) with an implementation date at the start of the final year of that agreement. The measure was not discussed with the Guild prior to the 2008 Budget and the budget announcement made no reference to the 4th Agreement.

The 2008 Budget measure was regarded as unrelated to the 4th Agreement by both the Guild and government. Although the Guild opposed the 2008 Budget measure, in no communications with government did the Guild contend that the announcement or introduction of the measure was a breach of the 4th Agreement because the Guild understood that chemotherapy arrangements and remuneration were outside the scope of that agreement.

It is clear that the government shared this understanding. Firstly, the government did not seek to negotiate the arrangements with the Guild before the announcement in the 2008 Budget. Secondly, the government did not seek to amend the 4th Agreement to reflect the new chemotherapy funding arrangements and fees after they were announced. Thirdly, the government did not refer to the 4th Agreement in any communications materials or fact sheets that were published about the 2008 Budget measure or the subsequent 2010 Budget measure.

After significant protests from impacted pharmacies, oncologists and patient groups the Government entered into discussions with stakeholders and announced a delay in implementation. Discussions with these stakeholders occurred right up to mid-2009. Although the Minister for Health and Ageing eventually referred the budget measure to be discussed in the context of the 5th Agreement, these discussions were separate from the 5th Agreement negotiations in which the government demanded $1 billion in savings from community pharmacy. The chemotherapy arrangements were not included in the 5th Agreement funding envelope, remained outside of the 5th Agreement, remained a budget measure and were implemented as such.

The savings from the chemotherapy measure were not included in the $1 billion of savings provided by other cuts to community pharmacy remuneration in the 5th Agreement. The savings total of $1 billion, and the make-up of that amount, were included in government media statements.

Unlike 5th Agreement savings measures, the Guild was not privy to calculations of the final quantum of savings provided by the new chemotherapy arrangements, which were announced only in the 2010 Budget.

The 5th Agreement[2], as signed in May 2010, includes no reference whatsoever to the chemotherapy funding arrangements or the fees associated with those arrangements. The 5th Agreement has not been modified to include any reference to the chemotherapy funding arrangements or fees. When community pharmacy fees that are within the scope of the Community Pharmacy Agreement are

[2] http://www.health.gov.au/internet/main/publishing.nsf/Content/fifth-community-pharmacy-agreement-copy

introduced, the agreement is amended. This is what occurred in 2007 when remuneration was restructured to include new fees (relating to premium-free dispensing and the use of PBS Online claiming). This was implemented through an amendment to the 4th Agreement. No such amendments occurred with the implementation of the chemotherapy arrangements on 1 December 2011. Neither the Guild nor the government suggested that such an amendment should occur – because the arrangements are outside of the 5th Agreement.

The 5th Agreement information document[3] released by the Department of Health and Ageing following the signing of the agreement contains no reference to the chemotherapy arrangements or fees.

The Consumers Health Forum (CHF) received funding from the government to analyse the 5th Agreement from a consumer's perspective. Their report[4] contained no reference to the chemotherapy arrangements.

The Legislative Instrument that implements the EFC arrangements, *National Health (Efficient Funding of Chemotherapy) Special Arrangement 2011 (No. PB 79 of 2011)*[5], contains no reference to the 5th Agreement. The Explanatory Memorandum to that instrument[6] also contains no reference to the 5th Agreement.

The current information regarding the new arrangements on the www.pbs.gov.au website[7] includes no reference to the 5th Agreement.

The Explanatory Memorandum[8] to the National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2010, which supported the introduction of the new chemotherapy arrangements contained no reference to the 5th Agreement and referred to the arrangements as a budget initiative.

The Guild was not involved with reviewing documentation on the chemotherapy initiative or the payment and remuneration algorithm that was developed during 2010 and 2011. This is in contrast to 5th Agreement programs and initiatives which are jointly developed by the Guild and the Department and closely monitored by the Guild. For example, in the development of the Continued Dispensing initiative under the 5th Agreement the Guild met with the Department of Human Services (DHS) and the Department of Health and Ageing to discuss and review detailed documentation on the implementation of the arrangements within DHS systems. No such engagement occurred in relation to the chemotherapy arrangements as they were not part of the 5th Agreement.

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[3] *Overview of the Fifth Community Pharmacy Agreement*

[4] *Consumers Health Forum Analysis of the Fifth Community Pharmacy Agreement, May 2010*

[5] http://www.comlaw.gov.au/Details/F2011L02491

[6] http://www.comlaw.gov.au/Details/F2011L02491/Explanatory%20Statement/Text

[7] http://www.pbs.gov.au/info/browse/section-100/chemotherapy and http://www.pbs.gov.au/info/publication/factsheets/shared/revised-arrangements-for-chemotherapy

[8] http://www.austlii.edu.au/au/legis/cth/bill_em/nhabsb2010473/memo_0.html

Any notion that adjustments to chemotherapy supply remuneration must be offset by changes to the 5th Agreement funding pool will be strongly disputed by the Guild. Clause 33 in the 5th Agreement states clearly that the Agreement document signed on 3 May 2010 by the Minister for Health and Ageing and the National President of the Guild "constitutes the entire agreement".

SECTION 6: WHY WAS THE BUDGET MEASURE SUPPORTED IN 2010 AND IT IS NOT SUPPORTED NOW?

The Guild supported the 2010 chemotherapy budget measure as an arrangement that was viable for community pharmacies dispensing chemotherapy drugs at that time (before the impact of price disclosure). It was made clear in the July 2009 proposal document and in discussions with government in 2009 and 2010 that the arrangements would not be viable in the longer term as price disclosure took effect on prices.

This section outlines the major problems and developments that have arisen since the May 2010 budget and how they have affected the viability and sustainability of the safe and efficient system of chemotherapy drug supply through community pharmacy.

The reasons include:

1. The massive impact of price disclosure which has far exceeded government expectations for savings and has been unpredictable due to the nature of the sector and the lack of consideration within the price disclosure mechanism for the differences that exist with the supply of chemotherapy drugs.
2. The absence of any significant off-patent chemotherapy drugs that have not been subject to price reductions due to price disclosure.
3. The unexpected and illogical implementation of the pharmacy mark-up remuneration component.
4. A growing number of chemotherapy drugs, particularly recent listings, unable to be purchased by pharmacies at the PBS agreed price.
5. The introduction of more stringent standards and regulatory requirements for the operation of compounding facilities, which have driven up the cost of preparing chemotherapy infusions.
6. Increasing use of more advanced (and therefore more expensive) containers and drug delivery devices, with the cost not being reimbursed by government.
7. Specific concerns for community pharmacies dispensing chemotherapy in non-metropolitan areas.

These reasons are described in detail in the following pages.

REASON 1 – PRICE DISCLOSURE

In the proposal put forward by the sector in July 2009, and in subsequent discussions, it was made clear to government that any funding model that did not adequately take into account the future impact of price disclosure on chemotherapy drugs would not be sustainable.

The table below shows the price reductions that have applied to chemotherapy drugs as a result of price disclosure and PBS Reforms since December 2009[9], and the approximate government savings that have been generated as a result. Before these price reductions, trading terms available to pharmacies were at levels which provided adequate compensation for the shortfall in the fee structure. However, price disclosure has now reduced these trading terms to levels which no longer offset the difference between remuneration and the cost of safe and effective compounding and dispensing of chemotherapy drugs. Price disclosure is applied to each drug on an ongoing cycle so what minimal trading terms that do remain will be further reduced over the next 12 months and beyond.

TABLE 4 – PRICE DISCLOSURE PRICE REDUCTIONS AND GOVERNMENT SAVINGS

Drug	Dec-09	Apr-10	Aug-10	Feb-11~	Apr-11	Aug-11	Apr-12	Aug-12	Dec-12	Apr-13	*Total Reduction on original price*	Approximate total annual reduction in government cost
DOCETAXEL									-76.20%		**-76.20%**	$ 41,531,627
OXALIPLATIN				-2.00%		-72.54%		-51.76%			**-87.02%**	$ 38,928,432
PACLITAXEL				-2.00%	-52.58%					-86.94%	**-93.93%**	$ 35,870,062
IRINOTECAN				-2.00%	-61.40%		-64.63%				**-86.62%**	$ 24,111,421
GEMCITABINE				-2.00%	-37.00%		-53.65%				**-71.38%**	$ 23,212,439
DOXORUBICIN	-63.54%		-34.62%	-2.00%				-32.97%			**-84.34%**	$ 20,505,664
CARBOPLATIN*				-2.00%			-66.41%				**-67.08%**	$ 9,962,596
EPIRUBICIN*				-2.00%			-78.05%				**-78.49%**	$ 9,003,485
CISPLATIN				-2.00%	-39.02%		-30.37%				**-58.39%**	$ 2,890,044
VINORELBINE				-2.00%			-63.87%			-21.52%	**-72.21%**	$ 2,687,950
METHOTREXATE*				-2.00%			-20.20%			-21.14%	**-38.33%**	$ 442,467
ONDANSETRON^	-15.37%		-17.61%	-2.00%		-22.51%		-77.25%			**-87.95%**	$ 436,964
MITOZANTRONE	-34.42%		-13.33%	-2.00%		-10.61%		-18.25%			**-59.30%**	$ 368,723
Total												**$ 209,951,874**

All of these price reductions have occurred after the alternative proposal was put to government in 2009. For the 12 months starting 1 July 2013 the Guild estimates (based on official data) that the government saving from the impact of price disclosure on chemotherapy drugs will be $210 million. This is based only on the applied and announced price disclosure reductions in the table above and only on the private sector (that is, it excludes the additional savings derived from public hospital chemotherapy that is paid for out of the PBS). This is a massive impact on a small but vitally important part of the community pharmacy sector.

To emphasise the size of this impact, and the degree to which it has exceeded government expectations for savings, consider the modelling of price disclosure savings presented in the

[9] All price reduction information is publicly available at http://www.pbs.gov.au/info/industry/pricing. Calculations have been based on official PBS data from http://www.medicareaustralia.gov.au/provider/pbs/stats.jsp and exclude public hospital item codes.

Department of Health and Ageing report *The Impacts of Pharmaceutical Benefits Scheme Reform*[10] published in February 2010 (just three months before the chemotherapy arrangements were announced in the chemotherapy budget). This report provided projections, year by year, of government savings from price disclosure on the entire PBS. For the 2013-14 financial year, this report estimated that price disclosure savings on all PBS drugs would be between $157m and $296m.

This February 2010 Department of Health and Ageing report examined only the impact of the original price disclosure arrangements. However, the top six drugs in the table above were captured by those arrangements so were within scope of the modeling. The savings from these six drugs alone are now estimated to be $184 million in 2013-14. **This exceeds the Department of Health and Ageing's baseline estimate of price disclosure savings from the entire PBS for the 2013-14 financial year.**

This major piece of Department of Health and Ageing commissioned work, published just three months before the 2010 Budget and informing that budget, profoundly underestimated the impact of price disclosure on the chemotherapy sector. This meant that the government did not have the correct information on which to evaluate the sector's contention (in the July 2009 proposal and in subsequent discussions) that price disclosure would render the sector unviable unless some of the savings generated from price disclosure were reinvested into the remuneration arrangements.

The size of price reductions has been unpredictable for the sector. One of the reasons for this has been that the way that the price disclosure mechanism works is largely incompatible with the structure of the supply chain for chemotherapy drugs.

Price disclosure is a "one size fits all" mechanism. However, there are significant differences in the supply chain for chemotherapy drugs compared with most PBS-listed drugs. These differences have resulted in some consequences which were not, in the Guild's view, within the originally agreed intentions of price disclosure.

As background, the following is an extract from an email from the Department of Health and Ageing to the Guild on 21 May 2012 (the statement is not disputed by the Guild):

"Under price disclosure, manufacturers are required to provide sales revenue, incentive and volume data for each brand and strength of pharmaceutical items on F2 (including different strengths and vial sizes for chemotherapy drugs listed on the Efficient Funding of Chemotherapy program). As this data is collected directly from manufacturers, ***all sales*** *to wholesalers, direct to pharmacies,* ***to third party infusion providers (such as Baxter)****, and to any other suppliers will be included.*" (emphasis added)

The majority of sales that are reported by manufacturers as part of the price disclosure process are to third party compounders (eg. Baxter Healthcare and Fresenius Kabi Australia). The manufacturers' selling prices from these sales are included, unadjusted, as part of the Weighted Average Price Disclosure (WADP) calculations. This gives rise to two problems, described below.

[10] http://www.health.gov.au/internet/main/publishing.nsf/Content/pbs-reform-report

A) Fees and Mark-ups Charged by Third Party Compounders not monitored or included in price disclosure calculations

The first issue is that the third party compounders are free to charge to pharmacies any margin they wish on top of the price that the third party compounder pays the manufacturer for the drug. This is not the case with pharmaceutical wholesalers when they sell non-chemotherapy items to pharmacies. Under the requirements of the government-regulated Community Service Obligation wholesalers must charge only up to a maximum price for those drugs. However, third party compounders of chemotherapy drugs are under no such restriction.

When considering this issue it is important to remember that the government is paying pharmacies to dispense a prepared dose of chemotherapy that can be administered to the patient. The price disclosure process, however, does not collect monitor the cost of a prepared dose. It collects and accounts for only the price of the unprepared drug.

As the margin charged by third party compounders to community pharmacies is not captured there is no way that the Commonwealth can determine that the price disclosure calculation of the Weighted Average Disclosed Price (WADP) bears any relationship to the true market price of the final product that it is paying pharmacists to purchase and dispense for the cancer patient - an infusible dose of chemotherapy. This is a clear point of difference between chemotherapy drugs and other drugs and creates a major discrepancy between the price derived from price disclosure and the reality of the market in which community pharmacies operate.

Third party compounders have been heavily affected by the price reductions that have occurred due to price disclosure. As the margins that they have derived from trading terms on generics have decreased these compounders have increased fees and mark-ups to ensure that their profitability is maintained. This inflation in fees and mark-ups charged to pharmacies has been, and continues to be, invisible to the price disclosure mechanism.

Some Guild members have recently reported losses on off-patent chemotherapy drugs purchased through third party compounders. For example, one pharmacy in regional New South Wales dispensed 38 doses of fluorouracil over a 14 day period of February 2013. Losses were incurred on all 38 doses. The average amount charged by the third party compounder to the pharmacy for these doses was $122.22. The average amount received by the government and the patient, including all fees and mark-up, was $104.28. This resulted in a direct loss of about $18 per dose even before the costs of dispensing are accounted for. Based on current pricing, over a period of 12 months this would be a loss of about $17,700 on just one drug for this pharmacy that services two local hospitals. **Despite the fact that pharmacies like this one cannot buy a prepared dose at a price less than the amount that they are reimbursed, fluorouracil will be subject to a price reduction of 21.52% on 1 April 2013 due to price disclosure.** This will further worsen the losses incurred on this drug. As price disclosure continues these sorts of losses will become more and more common for a range of off-patent chemotherapy drugs.

Combined with the problem outlined under Reason 4 in this section of the submission, which deals with on-patent drugs that are unable to be purchased by pharmacies at the official PBS ex-manufacturers price, it is evident that the current arrangements have several points of failure in the area of drug pricing.

B) Distortion created by public hospital purchasing

The second area where the price disclosure mechanism fails to take into account the unique nature of the supply chain for chemotherapy drugs is in the area of public hospital purchases. As the state governments outsource much of their chemotherapy drug preparation, much of what is purchased by third party compounders is destined for use in the public hospital system. Price disclosure rules specify that manufacturers exclude public hospital purchases from the arrangements[11]. This is because they are run as large-scale tenders and are not reflective of what occurs in the private market. The price disclosure data for chemotherapy drugs includes sales which, while not being sold directly to public hospitals, are heavily influenced by this state government purchasing. The effect of this market was intended to be excluded from price disclosure, however that is not occurring in the chemotherapy sector. The failure of this to occur has resulted in much larger price reductions than the private sector has expected.

In combination, the two problems outlined above have resulted in price disclosure calculations that have been, and continue to be, both unpredictable and unrepresentative of the market in which community pharmacies operate.

REASON 2 – SOURCES OF CROSS-SUBSIDISATION FOR LOSS-MAKING DRUGS HAVE BEEN EXHAUSTED

Of the chemotherapy drugs that are off-patent, docetaxel (price reduced by 76.20 per cent on 1 December 2012) and paclitaxel (price to be reduced by 86.94 per cent on 1 April 2013) have been the final source of significant cross-subsidisation that have enabled the cost of preparing and supplying other chemotherapy drugs that are supplied at a loss (in some cases this is a loss before any dispensing costs or other operational expenses are considered – see Reason 1 above and Reason 4 below – while others are supplied at a loss due to the inadequate remuneration for preparation and dispensing).

The chemotherapy drugs that remain under patent are mainly biologicals (i.e. substances made from a living cell). These are a new type of drug. The drug proteins can be modified in many different ways and it is very difficult to show that generic versions of biologicals are actually identical in terms of their safety and efficacy profiles. When patents for biologicals expire the generics may not be interchangeable with the original brand of the drug, so the market for these drugs will not provide the type of cross-subsidisation that has been available from older drugs. The funding model needs to be fixed now, as there are no new sources of income coming in future. The sources of cross-subsidisation for loss-making drugs have been exhausted.

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[11] Regulation 37G(2), *NATIONAL HEALTH (PHARMACEUTICAL BENEFITS) REGULATIONS 1960*: "Add up the sales revenue for the brand, excluding sales to public hospitals (as disclosed under the price disclosure requirements) for the data collection period for the brand in the disclosure cycle.", http://www.austlii.edu.au/au/legis/cth/consol_reg/nhbr1960445/s37g.html

REASON 3 – IMPLEMENTATION OF REMUNERATION ARRANGEMENTS IS NOT AS EXPECTED

The EFC arrangements introduced on 1 December 2011 significantly changed the way in which the amount paid to pharmacies for these medicines is calculated. Prescriptions are now written as a milligram dose of the drug, whereas previously they were written as a number of vials. A new algorithm was introduced to ensure that the government pays for the lowest cost combination of vials that makes up the required dose.

Part of this algorithm calculates the pharmacy mark-up that applies to the prescription. This has not been implemented in the manner that was expected and this has resulted in a significant shortfall in remuneration.

A Department of Health and Ageing information release in April 2009[12] stated that remuneration arrangements would include a "pharmacy mark-up based on the ex-manufacturer price of the active ingredient contained in each item prepared." The sector understood that this principle would flow through to the new algorithm. It did not. As a result, the mark-up component paid on some drugs is a fraction of what was expected. For some chemotherapy drugs the funding algorithm means that the maximum expected mark-up (which is $70 whenever the price exceeds $1,750) is never allocated for any dose, no matter how many vials of the drug need to be used or how much those vials cost the pharmacy to purchase (which may exceed $10,000 in some cases).

It is important to note that (as this was not a 5th Agreement initiative) the Guild was not consulted during the development of the detailed payment and mark-up algorithm or the related rules and logic. Further, the Guild and its members had no access to software with which to test or analyse the algorithm prior to the implementation of the new arrangements on 1 December 2011.

This issue was only able to be identified through analysis by Guild members of their payments from the Department of Human Services after implementation. Following approaches from these members this issue was the subject of a letter from the Guild's Executive Director to the First Assistant Secretary of the Pharmaceutical Benefits Division of the Department of Health and Ageing on 30 April 2012. The Department's response to this letter, dated 8 June 2012, stated that:

"the algorithm and claims system used by the Department of Human Services in its administration of the Revised Arrangements [for the Efficient Funding of Chemotherapy Drugs]…**operates consistently with PBS pricing policy**."

The Guild disputes this assertion. PBS pricing documentation states that:

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[12] *The Intravenous Chemotherapy Supply Program (ICSP), More efficient arrangements for funding cancer chemotherapy under the Pharmaceutical Benefits Scheme (PBS)*

"The level of pharmacy mark-up is determined by the cost of the medicine to the pharmacist for the listed maximum quantity."[13]

For the purposes of items in the General Pharmaceutical Benefits section of the Schedule of Pharmaceutical Benefits (that is, items that are not in the chemotherapy arrangements), a maximum quantity is normally specified as a number of tablets, capsules, packs or injections. This is the maximum amount that can be prescribed and dispensed on each occasion as a pharmaceutical benefit (unless the prescriber seeks formal authority to prescribe more). Under this general part of the Schedule of Pharmaceutical Benefits the pharmacy mark-up when the maximum quantity is prescribed and dispensed is straightforward. For an expensive drug that has a PBS price of more than $1,750 the mark-up will always be $70 per prescription (which is the maximum mark-up).

Now contrast this with the following examples (Table 5) in the chemotherapy arrangements (note: these are examples only and all chemotherapy drugs that have more than one listed vial size may be affected by this problem).

TABLE 5 – EXAMPLES OF MARK-UP SHORTFALL FOR MAXIMUM AMOUNTS

Drug	Maximum Amount	Ex-manufacturer price of maximum amount	Mark-up for maximum amount, as currently paid through chemotherapy algorithm	Expected mark-up under normal PBS policy	Shortfall
Bevacizumab (Avastin™)	900mg	$3,870.00	**$54.44**	$70.00	**$15.56 per infusion**
Cetuximab (Erbitux™)	880mg	$3,069.00	**$66.11**	$70.00	**$3.89 per infusion**
Pemetrexed (Alimta™)	1100mg	$3,431.69	**$53.02**	$70.00	**$16.98 per infusion**
Rituximab (Mabthera™)	1100mg	$4,979.86	**$53.02**	$70.00	**$16.98 per infusion**

The shortfall in expected mark-up in the examples in Table 5 is up to $16.98 per infusion. The table above is based on dispensing and prescribing at the maximum quantity (which is referred to as the "maximum amount" in the context of chemotherapy). This clearly goes against the PBS pricing documentation's statement that "the level of pharmacy mark-up is determined by the cost of the medicine to the pharmacist for the listed maximum quantity."[14] Based on this statement, in all examples in Table 5 the mark-up should be $70 (which is the level of mark-up applying to the price of the maximum quantity of these medicines). However in all of these examples the mark-up

[13] Explanation of PBS Pricing, Department of Human Services (Medicare), April 2012: http://www.medicareaustralia.gov.au/provider/pbs/pharmacists/pricing.jsp#N102A1

[14] http://www.medicareaustralia.gov.au/provider/pbs/pharmacists/pricing.jsp#N102A1

currently being paid is less than $70, so the Department of Health and Ageing's written assertion that the chemotherapy mark-up algorithm "operates consistently with PBS pricing policy" is incorrect.

The shortfall is even larger for these and other drugs when the prescribed dose is less than the maximum amount (which is often the case with chemotherapy drugs, unlike general PBS items where the maximum quantity is often one pack and that is what is usually prescribed).

For example, a common continuing dose of cetuximab is 550mg (compared with the maximum quantity, as per the table above, of 880mg). The ex-manufacturer price of 550mg of cetuximab is $2,046.00. However the applicable mark-up, based on the current algorithm, is $46.67. This is a **shortfall of $23.33** on the expected mark-up of $70.00, which is the mark-up that applies when the ex-manufacturer price exceeds $1,750.00. Again, this fails to meet the expectations that remuneration arrangements would include a "pharmacy mark-up based on the ex-manufacturer price of the active ingredient contained in each item prepared."[15]

The algorithm currently in use is illogical, unreasonable and does not follow PBS policy. It provides a significantly lower level of mark-up than what the sector expected to receive under the new arrangements.

The EFC mark-up algorithm must be amended to ensure consistency with PBS documentation and the expectation of the sector. Recognising the unique nature of chemotherapy drugs, where the quantity prescribed is a milligram dose that can be made up from a combination of vial sizes, mark-up must be assessed based on the aggregate ex-manufacturer cost of all vials that are used to make up the prescribed dose.

It is important to note that before 1 December 2011 pharmacies received a mark-up per prescription that exceeded $70 for very high cost drugs so the reductions in mark-ups in many cases have been much larger than just the shortfall highlighted earlier in this section. Under those previous arrangements most chemotherapy drugs had a PBS maximum quantity of one vial. However, in order to prescribe the required number of vials for the dose prescribers sought authority to prescribe more than this maximum quantity. For drugs where the price per vial exceeded $1,750 the mark-up was effectively $70 per vial. As an example of the reductions in mark-up between the old and new arrangements, the mark-up for an 1100mg dose of rituximab (Mabthera™) in November 2011 was at least $199.20. It is now only $53.02 (see Table 5), **a reduction of $146.18 per infusion**.

Savings from mark-up reductions were not part of the proposal put forward in July 2009. The Maximum Amounts that currently apply in the EFC were not determined until after the 2010 Budget and this was a process through the Pharmaceutical Benefits Advisory Committee[16]. As a result it was not possible before the 2010 Budget for the Guild or community pharmacies to determine the

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[15] *The Intravenous Chemotherapy Supply Program (ICSP), More efficient arrangements for funding cancer chemotherapy under the Pharmaceutical Benefits Scheme (PBS)*

[16] Official Department of Health and Ageing meeting notes from Stakeholder Engagement Meeting (4 & 6 August 2010): "PBAC have reviewed maximum quantities through stakeholder consultation with internal oncologists and PBAC advisers…representatives of the peak prescriber groups were advised to bring to PBAC's attention any maximum quantities they consider inadequate."

impact that the introduction of the EFC arrangements would have on the mark-up component of remuneration (through examples such as the rituximab one above). The Guild is also unaware of how the government could have modelled and estimated the savings derived from mark-up reductions prior to the 2010 Budget when the Maximum Amounts had not been determined at that time. It is probable that the mark-up effect was not included in the savings over the forward estimates announced as part of this measure in the 2010 Budget measure and therefore that the savings – and the impact on remuneration – were underestimated in 2010.

REASON 4 – DRUGS ARE NOT AVAILABLE FOR PURCHASE BY PHARMACIES AT THE OFFICIAL PBS EX-MANUFACTURER PRICE

A number of chemotherapy drugs have been identified which cannot be purchased at the agreed Commonwealth ex-manufacturer price per vial that is the basis for the reimbursement price paid to pharmacies. In the interest of providing a complete service pharmacies have continued to supply these drugs at a loss, which has only been possible due to trading terms on generic drugs.

There is no legislative impediment to a manufacturer charging in excess of the price they have agreed with the Commonwealth. There is therefore no protection for pharmacies from this practice which, in effect, erodes the remuneration base.

Drugs that have been identified as by Guild members as being unavailable for purchase by pharmacies at the official PBS ex-manufacturer include, but may not be limited to, the following:

- Cabazitaxel (Jevtana™)
- Nanoparticle Albumin Bound Paclitaxel (Abraxane™)
- Cyclophosphamide (Endoxan™)
- Etoposide Phosphate (Etopophos ™)
- Fotemustine (Muphoran™)
- Ifosphamide (Holoxan™)
- Pegylated Liposomal Doxorubicin (Caelyx™)
- Pemetrexed (Alimta™)
- Arsenic Trioxide (Phenasen™)
- Cladribine (Litak™)
- Topotecan (Hycatim™)
- Cetuximab (Erbitux™)

The table below provides some examples of market pricing compared with PBS list prices. The “Price from wholesaler” and “Price from third party compounder” are averages from a sample of Guild members.

TABLE 7 – EXAMPLES OF DRUGS THAT CAN ONLY BE PURCHASED AT A PRICE HIGHER THAN THE OFFICIAL PBS EX-MANUFACTURER PRICE

Brand	Vial Size	PBS Listed Manufacturer's Price per Vial	Price from manufacturer	Price from wholesaler*	Price from third party compounder
Jevtana	60mg	$ **5,814.74**	Cannot be purchased	$ 5,930.60	$ 6,069.35
Abraxane	100mg	$ **401.48**	$ 431.67	Cannot be purchased	$ 453.25
Alimta	500mg	$ **1,559.86**	Cannot be purchased	$ 1,591.68	$ 1,695.00
Erbitux	500mg	$ **1,705.00**	Cannot be purchased	$ 1,773.20	$ 1,987.50
Muphoran	208mg	$ **1,084.33**	Cannot be purchased	$ 1,132.50	$ 1,185.00

* A distribution fee of $24 per infusion is paid to pharmacies. This is in addition to the Manufacturer's Price however most infusions require multiple vials. For example, one infusion for Abraxane often requires four vials so this fee is only $6 per vial in this case.

It can also be noted from the table above that the difference between the price from a wholesaler (which is for a vial that requires preparation/reconstitution before use) and the price from a third party compounder (which is for a reconstituted dose) is considerably more than the $40.64 preparation fee that is intended to cover the reconstitution. The differences above include:

- $215.30 for Erbitux
- $138.75 for Jevtana
- $103.33 for Alimta
- $52.50 for Muphoran

It is important to note that the two drugs above with the highest third party compounder add-on cost have been listed within the last two years – Erbitux on 1 September 2011 and Jevtana on 1 August 2012. This is evidence of a trend toward higher fees and mark-ups being charged to pharmacies for compounding in recent times.

As discussed under Reason 1 in this section, losses are now also being reported on some off-patent drugs due to the failure of price disclosure to take account of the fees and mark-ups applied by third party compounders.

Legislation should be introduced as soon as possible to ensure that:

(a) manufacturers of all PBS-listed drugs (including chemotherapy drugs) cannot sell their product at higher than the ex-manufacturer price they have agreed with the Commonwealth;

(b) wholesalers cannot sell PBS products (including those listed under Section 100 arrangements such as chemotherapy, which fall outside of the Community Service Obligation that applies to wholesalers) at a price higher than the relevant PBS list price;

(c) third party compounders of chemotherapy drugs cannot charge more than the ex-manufacturer price agreed between the Commonwealth and the manufacturer plus an amount equal to the Preparation Fee applicable under the EFC arrangements.

This legislation would ensure that the integrity of the supply chain is not distorted and that the pricing and fees agreed to by the Commonwealth are not exceeded by the market.

REASON 5 – MORE STRINGENT REGULATORY REQUIREMENTS FOR CHEMOTHERAPY RECONSTITUTION

In a similar way to which it inspects drug manufacturing facilities, to ensure patient safety the Therapeutic Goods Administration (TGA) regulates, inspects and accredits facilities that perform chemotherapy reconstitution services, including third party compounders and some of the limited number of pharmacies that have invested in in-house facilities. The standards and codes that are the basis for TGA licensing have become more stringent since 2010. The standards and codes that TGA licensed facilities now have to comply to are:

- Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PICS):
  - Annex 1 - Manufacture of sterile medicinal products
  - Annex 15 - Qualification and validation
  - Annex 20 - Quality risk management
- ISO 14644 - Cleanrooms and associated controlled environments – Operations
- ISO 14698 - Cleanrooms and associated controlled environments - Biocontamination control
- TGA Stability and Sterility Guidelines

This section provides some examples of the recent requirements. It may assist understanding of this section to also refer to photographs of an example TGA-licensed reconstitution facility presented at Appendix 1.

- Facilities must demonstrate an independence between the Environmental Monitoring System (EMS) and the Building Monitoring System (BMS). A BMS monitors and electronically controls Heating, Ventilation and Air Conditioning (HVAC), supply air fans, air speed , room temperature, humidity, extraction fans, room pressures. A BMS does this in response to sensors located inside ducts and, fans and rooms that feed information back into the control panel. However, these sensors cannot be used as the sole source of information on how the facility is performing to code standards. You must use a completely independent EMS with its own sensors for temperature, pressure, humidity and particle counts. This is to ensure that should the BMS fail, falter or malfunction, you have an independent

system informing you of the conditions within the facility and whether or not they are optimal or within the code standards to compound a product. A system such as this costs well in excess of $100,000 to install and more than $20,000 per year to maintain.

- Another major difference with the standards is that whilst manufacturing is occurring it is a requirement that continuous non-viable particle counts must be running both in the cabinets in which the reconstitution is performed by staff (A grade air) and the background environment (Grade B air). This particle monitoring system exists within the EMS, to meet the requirements most facilities have installed a vacuum pump system to run this non-viable monitoring whilst in production. The TGA is enforcing this new requirement on pre-existing facilities.

- Microbiological testing requirements are now extremely stringent. Even an average-sized reconstitution facility must send away between 45 and 50 plates and samples to an external laboratory every day. The requirement is now to take active air samples of every cabinet, every session for every operator. The active air sampler equipment is expensive, and the labour costs of this environment monitoring have created a major financial burden.

- The gowning requirements for staff, and restrictions on their operations in various grades of air, have been made more stringent. TGA has mandated three separate stages of gowning that are required before staff can enter the sterile suite. The first stage involves scrubs, the second facility “blues” (low linting garments) and the final stage is sterile ultrashield coveralls. The garment costs are significantly higher as a result.

- Facilities that meet the code are required to demonstrate a superior quality of air, relating to particle counts, number of air changes for hour, room recovery and smoke testing for airflow and pressure differentials. The standards are referenced by ISO-14644, as opposed to the Australian Standards, which are quite different. Licensed facilities also have an extremely high level of rigour in relation to equipment and facility maintenance and calibration.

- There have also been new requirements for testing staff who work within a facility both prior to employment and yearly during their employment. Under the previous requirements this required only a simple blood test, however now facilities are required to fund a full medical examination in which key areas of testing are identified on risk based principles. This is not a Medicare-funded examination.

- In a licensed facility pass-through hatches are required to be HEPA filtered and not allowed to be used as a separate grading of air to transition products. Facilities can

only classify these hatches as the same grade as their background air which means an extra room is needed to achieve four defined grades of air in cascade within a facility (D through to A). Again, TGA are enforcing this new requirement on pre-existing facilities, creating significant new costs including major refurbishments.

TGA requirements also cover many other areas, including validation, cleaning, training, waste disposal, auditing, stability and sterility testing requirements and others. All of these requirements relate only to the costs and activities intended to be covered by the current, inadequate $40.64 preparation fee under the EFC.

Photographs of an example TGA licensed reconstitution facility can be found at Appendix 1.

REASON 6 – CONTAINER AND DEVICE COSTS INCREASING AND ARE NOT REIMBURSED

Costs of containers and devices used in the preparation and supply of chemotherapy drugs range from about 60 cents through to about $165. There is a rapid trend towards an increasing variety and complexity of dose delivery devices which are requested on the grounds of patient or nurse safety. Some high-priced items include the AH006 Dosifuser and the CADD Medication Cassette Reservoir.

As an example, the Guild understands that Baxter Healthcare (one of the two third party reconstitution providers) currently charges approximately $100 for a 5-fluorouracil (5-FU) infusor. This device allows the dose to be administered to the patient over a period of 48 hours to one week. Use of such devices is increasing and provides a range of benefits to the cancer patient. Currently, the community pharmacy bears the full cost of these devices.

Unless the cost of these dose delivery devices is addressed through fee arrangements there will continue to be cross-subsidisation between the supply of different chemotherapy drugs depending on the containers and devices required. A new arrangement that recognises these costs would minimise the cross-subsidisation that occurs due to different container and device requirements.

REASON 7 – PARTICULAR CONCERNS RAISED IN RELATION TO NON-METROPOLITAN CHEMOTHERAPY SERVICES

Community pharmacies that provide chemotherapy drugs to their local hospitals in regional towns and cities, which service surrounding rural and remote areas, have particular concerns relating to the supply of chemotherapy drugs.

For example, in non-metropolitan areas it is more common for the dose (and any associated devices) provided by the third party reconstitution provider to not be used due to a last minute change in dosage or treatment. In this case no reimbursement is available from government and the pharmacy bears the cost. This is particularly common in non-metropolitan areas as the patient may travel 100km (or more) to see their oncologist so for logistical reasons the pre-treatment consultation with the oncologist does not occur until the morning of the scheduled chemotherapy

treatment. The dose has been ordered by the community pharmacy from the third party compounder and made available to the hospital or clinic, all costs being borne by the pharmacy, only for the dose to be changed following the morning consultation. The community pharmacy must then re-order the dose (and the infusor if applicable) and has no way of recouping the cost of the dose and infusor that was originally ordered. One community pharmacist, servicing one private hospital and one public hospital in the Albury-Wodonga area, reports that losses as a result of these changes can run to well over $10,000 per year.

Other concerns in more remote areas include the inability to access prepared doses in a timeframe that allows them to be provided to the patient before expiry. Some chemotherapy drugs have extremely short expiry following preparation. For example, according to Baxter Healthcare, short expiries include[17]:

- melphalan – 90 minutes
- natalizumab – 8 hours
- abatacept – 24 hours
- liposomal doxorubicin – 24 hours
- azacitadine – 6 hours (not currently part of the chemotherapy arrangements but is a cytotoxic drug dispensed by the same pharmacies)

This has been a particular problem in Tasmania. As some drugs cannot be transported from the nearest third party compounder (Melbourne) within the required timeframes to allow patient treatment, community pharmacies in Tasmania have been compelled to invest capital in their own reconstitution facilities to ensure patient access to chemotherapy in the state.

Regional cancer treatment centres exist in the following locations. If chemotherapy drug supply to any of these centres is discontinued cancer patients may be faced with much longer distances to seek treatment.

NEW SOUTH WALES

- Lismore
- Grafton
- Ballina
- Coffs Harbour
- Port Macquarie
- Newcastle
- Gosford
- Wagga Wagga
- Wollongong
- Albury
- Dubbo/Bathurst/Orange (public hospital services supplied by community pharmacy)

[17] *Shelf Lives of Cytotoxic and Anti-Viral Agents*, December 2011 (Baxter Medical Information Service)

VICTORIA

- Warrnambool
- Geelong
- Ballarat
- Bendigo

QUEENSLAND

- Cairns
- Townsville
- Mackay
- Rockhampton
- Bundaberg
- Maryborough
- Gladstone
- Sunshine Coast
- Noosaville
- Buderim
- Toowoomba
- Gold Coast

SOUTH AUSTRALIA

- Whyalla

TASMANIA

- Launceston
- Hobart (included as regional due to the difficulty of supplying some drugs in Tasmania)
- Burnie
- Latrobe

WESTERN AUSTRALIA

- Bunbury
- Geraldton

APPENDIX 1:
EXAMPLE & PHOTOGRAPHS OF A TGA LICENSED CHEMOTHERAPY RECONSTITUTION FACILITY

The photographs and descriptions in this section are designed to show the complete process the specialised staff go through in a reconstitution facility and the equipment they use. The process starts from an initial changing area and, eventually, staff can move through to the final sterile suite where the chemotherapy reconstitution takes place. Reconstitution is an extension of the manufacturing process. Without it, the drugs cannot be used, and unless reconstitution is performed in these strict conditions patient and pharmacist safety can be jeopardised.

1: ANTEROOM CHANGEROOM

An area built specifically for staff to change into designated scrubs at the beginning of their session.

2: GMP COMPLIANT ANTEROOM

This is where the picking and dispatch occurs, this environment is controlled and clean, but allowed to be ungraded as long as the gowning and cleaning is controlled. This area exists just outside the cleanroom.

3: GRADE D ENVIRONMENT

This is the very first room in the actual cleanroom suite, a Grade D environment. When staff leave this room they go into the Grade C room.

The second stage of gowning occurs in the Grade D environment with staff changing out of scrubs into low linting garments, washing and preparing for Grade C, and applying appropriate gloving prior to moving into the next room.

4: GRADE C ENVIRONMENT

This is where Preparation, 2nd stage decontamination and release occurs.

5: AIR LOCK BETWEEN GRADE C AND GRADE B AREAS

This is where gowning occurs before entering the sterile suite. This is the 3rd stage of gowning.

6: STERILE SUITE (GRADE B ENVIRONMENT) AND CABINET (GRADE A ENVIRONMENT)

As staff have now passed through all previous environments, this is where the reconstitution process finally occurs. The highly trained staff performs the process by inserting gloved hands into the cabinet. This all occurs in strictly sterile conditions to ensure the safety of the cancer patient for whom the dose is being prepared, and the safety of the staff working with these cytotoxic drugs.

Once prepared the infusion then passes back through the various stages so that it can be safely and efficiently transported to the patient for their treatment.