July 2013
Submission to PBS Chemotherapy Medicines Review

The Pharmacy Guild of Australia welcomes the opportunity to contribute to this review, which is of vital importance to current and future cancer patients. As the Department has acknowledged, the Guild has previously provided a wide range of detailed information on issues relevant to this review. The Guild’s submissions to the Senate Community Affairs Reference Committee Inquiry (“Senate Inquiry”) into the Supply of chemotherapy drugs such as docetaxel should be considered as comprehensive, current and relevant to the current review. These submissions are attached as Appendix 1 and Appendix 2. The Guild acknowledged a minor error of fact in its submissions to that Inquiry. Appendix 3 is copy of the Guild’s letter to the Chair of the Senate Community Affairs Reference Committee, explaining that this error did not in any way diminish the Guild’s position.

Core Issues

The Guild encourages the current review to place its primary focus on two core issues. These are the deficiencies that exist in current remuneration for (1) the preparation and (2) the dispensing of chemotherapy drugs under the Efficient Funding of Chemotherapy (EFC) arrangements.

Models of patient care differ between business models, hospitals and clinics, states and territories, and the public and private hospital environments. However these two elements – preparation and dispensing – are universal and are elements that are at the core of the Pharmaceutical Benefits Scheme. The Guild acknowledges that issues such as the costs and method of the provision of clinical services are within the scope of this review. However the Guild considers that these are of secondary importance to the immediate shortfall in remuneration for preparation and dispensing. It is this shortfall that must be adequately and permanently addressed to ensure that the supply of chemotherapy for cancer patients across Australia is viable beyond 31 December 2013.

The infusion preparation function is largely homogenous. Whether it is performed in-house or outsourced, significant costs are incurred and are borne by the community pharmacy. As has been previously documented, these costs are substantially in excess of the preparation fee paid under the EFC arrangements.

While there can be some debate about where the dispensing function ends and where other clinical activities intersect, it is true to say that the dispensing of chemotherapy drugs usually involves more complexity than the dispensing of non-chemotherapy drugs. The payment of a $6.63 dispensing fee per infusion – which is the only fee that is currently paid for the professional and clinical aspects of dispensing chemotherapy drugs - is not sufficient to account for the complexities involved. These two essential and universal activities must be properly funded. The Guild encourages the review team to focus on these core aspects of chemotherapy supply and to recommend the
permanent introduction of increased fees for preparation and dispensing, in line with the Guild’s submission to the Senate Inquiry.

Related Issues
In determining the appropriate remuneration for preparation and dispensing of chemotherapy drugs a number of related costs and issues must be either addressed or considered. Most of these costs and issues have been raised in previous Guild submissions, and include:

- all costs associated with preparation and dispensing, including but not limited to highly trained staff, maintenance of sterile facilities, quality control, rent, consumables, containers, diluent, specialised computer software, insurance, delivery and PBS administration;
- the cost of purchasing from third party compounders, including fees and mark-ups on the drug price, and the lack of regulation around this pricing;
- the complexity of dispensing activities related to chemotherapy drugs;
- the need for an adequate return on capital invested, accounting also for the risk of that investment;
- the current inability to purchase some drugs at the PBS-listed prices that have been negotiated between the Government and manufacturers, resulting in some drugs being prepared and dispensed at a loss even before costs are considered;
- the shortfall in mark-up, compared to that expected, arising from the manner in which the chemotherapy algorithm has been implemented;
- the trend toward more rigorous regulation and standards for facilities engaged in preparing chemotherapy infusions and other complex compounding; and
- the trend towards more prescribing of newer drugs that are more complex to prepare and dispense.

Funding Source
The Guild takes this opportunity to reaffirm its position that the 5\textsuperscript{th} Agreement is not the appropriate source of funding for the chemotherapy shortfall.

Negotiations for the 5\textsuperscript{th} Agreement concluded with the signing of that agreement on 3 May 2010. The 5\textsuperscript{th} Agreement contains no reference to the funding or fees associated with the EFC arrangements. The 5\textsuperscript{th} Agreement superseded all other agreements that had been entered into between the Guild and the Commonwealth.

The root causes of the chemotherapy funding shortfall – the original Price Disclosure arrangements and the 2008 and 2010 Commonwealth Budget measures relating to chemotherapy – are separate to the 5\textsuperscript{th} Agreement and are also separate to the Commonwealth’s Memorandum of Understanding with Medicines Australia.

The sheer amount of the chemotherapy funding shortfall – which is somewhere between $60 million and $100 million per year – makes it impossible to conclude that this issue could have been dealt with as part of the 5\textsuperscript{th} Agreement negotiations. Clearly it could also not have been dealt with through the separate negotiations of the EFC arrangements, given that those arrangements were required to deliver Government savings.
The Guild will not accept that it is appropriate for the shortfall to be borne by the more than 5,000 community pharmacies that have no involvement with chemotherapy and have provided savings of $1 billion through the 5th Agreement, plus significant unaccounted savings due to the serious underestimation by a Department of Health and Ageing-commissioned report in 2010 of the savings that would flow from Price Disclosure during the period of the 5th Agreement.

The Guild noted that the Final Report from the Senate Community Affairs Reference Committee (“the Committee”) refers to “an amount of $277 million subsequently injected into a range of clinical services for patients as a consequence of the impact of Price Disclosure”. It appears from this statement that the Committee may have been of the view that this funding was related to chemotherapy drugs and could have, or should have, been used to provide extra funding for pharmacy remuneration relating to chemotherapy drugs. This is not the case. The following are the facts relating to this $277 million:

- The amount related only to the direct impact on 5th Agreement funding through reductions in the mark-up components of remuneration.
- The $277 million estimate was provided by the Department of Health and Ageing to the Guild and was not a negotiable figure.
- No breakdown of the $277 million (for example by drug, by drug group or by period) was provided to the Guild during the 5th Agreement negotiations, or since those negotiations.
- The Guild has never been provided with any evidence that the calculations took into account price reductions on chemotherapy drugs.
- Even if the Department’s calculation of the $277 million did include chemotherapy drugs, only the three chemotherapy drugs that were added to Price Disclosure as a result of the introduction of Expanded and Accelerated Price Disclosure (EAPD) in 2010 would have been in scope for this calculation. These three drugs – carboplatin, epirubicin and methotrexate - represent less than 10 per cent of the savings that the Government is now deriving from Price Disclosure on chemotherapy drugs.
- The remaining 90 per cent of chemotherapy drug savings relate to the original Price Disclosure arrangements. The impact of those original Price Disclosure arrangements was not part of the calculation of the $277 million.
- The government would not agree to the $277 million being applied to any form of pharmacy remuneration for dispensing. It would only agree to direct these funds to support the provision of professional services or quality measures for payments through practice payments to accredited community pharmacies.
- In line with this direction from government the $277 million was applied to patient-focussed services delivered by accredited community pharmacies through the Pharmacy Practice Incentives Program, and to other initiatives including the development of an electronic recording and reporting system for controlled drugs and the introduction of PBS claiming from a medication chart in Residential Aged Care Facilities.
- The $277 million has been directed, entirely appropriately and as agreed with the government, to the pharmacies that are experiencing the reductions in remuneration from which the funding is derived. It would not have been fair, reasonable or appropriate to have redirected these funds to any other area, including chemotherapy drugs. This continues to be the case as the negative impact of Price Disclosure on non-chemotherapy community pharmacy has in fact grown beyond expectations.
• The 5,000-plus non-chemotherapy community pharmacies in Australia also provided $1 billion in savings to taxpayers over the five years of the 5th Agreement, and have suffered a decrease of more than 10 per cent in real remuneration per prescription over the first three years of the 5th Agreement. Further decreases are certain to occur over the remaining two years as Price Disclosure cycles continue.

The Guild has also noted that the Consumers Health Forum (CHF) has been engaged by the Department to consult directly with consumers and consumer groups as part of this review. The Guild supports and encourages the involvement of fully informed consumers and those with experience and expertise in this complex area. However, prior to being formally engaged by the Department the CHF has made several incorrect statements regarding chemotherapy funding arrangements. These have included the following in a recent CHF media release:

  o “the guild had already agreed to additional payments from the government to compensate pharmacists for chemotherapy drug price changes”
  o “the Guild had received inflated payments for these chemo drugs for years…had planned for this reduction and had received $277 million to help compensate for the likely impact”.

As has been explained above, the $277 million is not associated with the chemotherapy issue. Any statement to the contrary must show evidence of the breakdown of that $277 million, evidence of the true contribution of chemotherapy drug price reductions to that component of 5th Agreement funding, and evidence of this funding pool being allocated to chemotherapy services. No such evidence exists. These and other CHF statements are not a sound footing for a properly informed consumer consultation process.

As outlined on pages 20 to 21 of the Guild’s Senate Inquiry submission, a Government-commissioned report released in February 2010 has now been proven to have profoundly underestimated the impact of Price Disclosure, particularly on chemotherapy drugs. The financial modelling underlying the 2010 Budget and the 5th Agreement negotiations relied on this flawed report. The actual savings – which include direct reductions in the mark-up components of community pharmacy remuneration and an indirect impact through reduced trading terms - now far exceed the projections published and used in 2010. None of the excess impact has yet been returned to any community pharmacy.

The savings from chemotherapy drugs alone in 2013-14 will exceed $210 million, which is more than the estimate in that 2010 report for savings from the entire PBS (that is, from non-chemotherapy drugs and chemotherapy drugs). It is this pool of Government savings that is the appropriate source of funding to address the chemotherapy shortfall. Less than half of the savings from chemotherapy drugs are needed to be re-invested. This re-investment will ensure the future viability of Australia’s safe, efficient, high quality and professional chemotherapy infusion preparation and dispensing system through community pharmacy, enabling the continuance of the life-saving services provided to more than 13,000 cancer patients throughout all areas of the country every week.
Appendix 1

Submission to Senate Community Affairs Committee Inquiry, March 2013
Submission to
Senate Community Affairs Committee
Inquiry:

*Supply of chemotherapy drugs such as docetaxel*

March 2013

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The Pharmacy Guild of Australia
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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 all chemotherapy drugs, not just docetaxel, paclitaxel or others that have been, or will be, subject to price reductions. Ongoing care for all 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.

<table>
<thead>
<tr>
<th>Issue</th>
<th>Section/Page</th>
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<tbody>
<tr>
<td>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 compounding pharmacy.</td>
<td>Section 3, pages 13-14</td>
</tr>
<tr>
<td>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.</td>
<td>Section 3, page 14</td>
</tr>
<tr>
<td>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.</td>
<td>Section 6, pages 20-21</td>
</tr>
<tr>
<td>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.</td>
<td>Section 6, page 22</td>
</tr>
<tr>
<td>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.</td>
<td>Section 6, page 23</td>
</tr>
<tr>
<td>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.</td>
<td>Section 6, pages 27-29</td>
</tr>
<tr>
<td>The minimum cost to pharmacies for some prepared infusions of off-patent drugs is now higher than the amount received.</td>
<td>Section 6, page 22</td>
</tr>
<tr>
<td>Unanticipated losses of mark-up have been incurred due to the payment algorithm being illogical and not implemented as the sector had expected.</td>
<td>Section 6, pages 24-27</td>
</tr>
<tr>
<td>The remuneration arrangements fail to adequately recognise the costs associated with meeting the increasingly stringent standards required for preparation of chemotherapy.</td>
<td>Section 6, pages 29-31 and Appendix 1, pages 34-39</td>
</tr>
<tr>
<td>The costs of containers and devices, which can be over $100 for a single infusion, are not reflected in the remuneration model.</td>
<td>Section 6, page 31</td>
</tr>
<tr>
<td>Specific concerns that relate to non-metropolitan areas.</td>
<td>Section 6, pages 31-33</td>
</tr>
</tbody>
</table>
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 all chemotherapy drugs, due to the availability of trading terms on a few 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>
<thead>
<tr>
<th>Oncology Pharmacy Dispensing Activity</th>
<th>Corresponding Activity in non-Chemotherapy Community Pharmacy Dispensing</th>
<th>Private Hospital Clinical Service</th>
</tr>
</thead>
<tbody>
<tr>
<td>Referral form received by the Oncology Clinic (first contact Oncology Clinical Nurse Consultant, then referral given to pharmacist).</td>
<td>Prescription presented at pharmacy by patient.</td>
<td>Yes</td>
</tr>
<tr>
<td>Pharmacist assesses whether additional pathology tests are required prior to the patient commencing treatment.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Collect and assess current and past patient clinical, drug and family history necessary to design a pharmacotherapeutic plan.</td>
<td>Establish history of patient at the counter prior to dispensing.</td>
<td></td>
</tr>
<tr>
<td>Pre-treatment chart revision. Pharmacist checks the body surface area, dosages, pre-treatment and take home medications.</td>
<td>Confirm history/dosage checks on dispensing system.</td>
<td></td>
</tr>
<tr>
<td>Pharmacist attends chemotherapy drug/chart write up to consult with treating specialists to discuss treatment.</td>
<td></td>
<td>Yes</td>
</tr>
<tr>
<td>Pharmacist participates in a multidisciplinary team meeting to establish therapeutic goals in collaboration with patient.</td>
<td>Contact doctor if confirmation, dose checks or changes required to prescription.</td>
<td></td>
</tr>
<tr>
<td>Pharmacist orders drugs as per the checked chart. This includes all drugs including take home drugs.</td>
<td>Dispensing continues with drug selection and labelling.</td>
<td></td>
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</tbody>
</table>

TABLE IS CONTINUED ON FOLLOWING PAGE
<table>
<thead>
<tr>
<th>Oncology Pharmacy Dispensing Activity</th>
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<th>Private Hospital Clinical Service</th>
</tr>
</thead>
<tbody>
<tr>
<td>Required dose of IV chemotherapy drugs prepared aseptically by a pharmacy using in-house facilities or sourced from a TGA Licensed third party compounding.</td>
<td>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.</td>
<td></td>
</tr>
<tr>
<td>Assessment of the financial impact of the selected treatment on the hospital as well as for the patient.</td>
<td>Once price/co-payment is confirmed any financial issues will be discussed with the patient.</td>
<td></td>
</tr>
<tr>
<td>Compounded chemotherapy products are checked upon arrival for dose, container, compatibility and safety. Labels printed.</td>
<td>Pharmacist checks dispensing – labelling, drug selection, etc.</td>
<td></td>
</tr>
<tr>
<td><strong>For all Patients</strong> Individualised patient medication kits are packed. These kits include treatment, pre-med and supportive care medications.</td>
<td>Any supportive material provided (for example, Consumer Medicines Information).</td>
<td></td>
</tr>
<tr>
<td><strong>New Patients</strong> During first visit to clinic: provide a Patient Care Kit, Cancer Council Kit and information from EVIQ (an online cancer treatment information resource).</td>
<td>First time use counselling provided by pharmacist.</td>
<td></td>
</tr>
<tr>
<td><strong>For all Patients</strong> Assessment of physical signs of drug related effects.</td>
<td>Part of the next visit for the repeat prescription.</td>
<td></td>
</tr>
<tr>
<td><strong>For all Patients</strong> 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.</td>
<td>Yes</td>
<td></td>
</tr>
</tbody>
</table>

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

**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.” 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
<table>
<thead>
<tr>
<th>Remuneration Component</th>
<th>Amount</th>
<th>Description</th>
<th>Comments/I issues</th>
</tr>
</thead>
</table>
| 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 compounding.  

*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 compounders 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. |
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

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

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 document3 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 report4 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 instrument6 also contains no reference to
the 5th Agreement.

The current information regarding the new arrangements on the www.pbs.gov.au website7 includes
no reference to the 5th Agreement.

The Explanatory Memorandum8 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.

3 Overview of the Fifth Community Pharmacy Agreement
4 Consumers Health Forum Analysis of the Fifth Community Pharmacy Agreement, May 2010
7 http://www.pbs.gov.au/info/browse/section-100/chemotherapy and
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”.
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, 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**

<table>
<thead>
<tr>
<th>Drug</th>
<th>Dec-09</th>
<th>Apr-10</th>
<th>Aug-10</th>
<th>Feb-11*</th>
<th>Apr-11</th>
<th>Aug-11</th>
<th>Apr-12</th>
<th>Aug-12</th>
<th>Dec-12</th>
<th>Apr-13</th>
<th>Total Reduction on original price</th>
<th>Approximate total annual reduction in government cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>DOXETAXEL</td>
<td>-2.00%</td>
<td>-72.54%</td>
<td>-51.76%</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>$76.20%</td>
<td>$41,831,627</td>
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<tr>
<td>OXALIPLATIN</td>
<td>-2.00%</td>
<td>-52.58%</td>
<td>-64.63%</td>
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<td></td>
<td></td>
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<td></td>
<td></td>
<td>$68.05%</td>
<td>$38,928,432</td>
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<tr>
<td>PACITAXEL</td>
<td>-2.00%</td>
<td>-61.40%</td>
<td>-53.65%</td>
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<td></td>
<td></td>
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<td></td>
<td></td>
<td>$59.30%</td>
<td>$35,870,062</td>
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<tr>
<td>IRINOTECAN</td>
<td>-2.00%</td>
<td>-37.00%</td>
<td>-32.97%</td>
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<td></td>
<td></td>
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<td></td>
<td></td>
<td>$58.30%</td>
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<tr>
<td>GEMCITABINE</td>
<td>-2.00%</td>
<td>-37.00%</td>
<td>-32.97%</td>
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<td></td>
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<td></td>
<td>$58.30%</td>
<td>$21,232,439</td>
</tr>
<tr>
<td>DOXORUBICIN</td>
<td>-63.54%</td>
<td>-34.62%</td>
<td>-2.00%</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>$84.34%</td>
<td>$20,505,664</td>
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<tr>
<td>CARBOPLATIN*</td>
<td>-2.00%</td>
<td>-66.41%</td>
<td>-32.97%</td>
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<td></td>
<td>$67.08%</td>
<td>$9,962,596</td>
</tr>
<tr>
<td>EPIRUBICIN*</td>
<td>-2.00%</td>
<td>-78.05%</td>
<td>-32.97%</td>
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<td></td>
<td></td>
<td>$78.49%</td>
<td>$9,003,485</td>
</tr>
<tr>
<td>CISPLATIN</td>
<td>-2.00%</td>
<td>-26.02%</td>
<td>-21.52%</td>
<td></td>
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<td></td>
<td></td>
<td>$58.30%</td>
<td>$2,890,694</td>
</tr>
<tr>
<td>VINORELINE</td>
<td>-2.00%</td>
<td>-63.87%</td>
<td>-11.61%</td>
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<td>$59.30%</td>
<td>$2,687,950</td>
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<tr>
<td>METHOTREXATE*</td>
<td>-2.00%</td>
<td>-20.20%</td>
<td>-21.14%</td>
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<td></td>
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<td></td>
<td></td>
<td></td>
<td>$58.30%</td>
<td>$442,467</td>
</tr>
<tr>
<td>LINTIRIZPAM*</td>
<td>-12.57%</td>
<td>-1.01%</td>
<td>-21.51%</td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>$59.30%</td>
<td>$50,294</td>
</tr>
<tr>
<td>MITOZANTRONE</td>
<td>-34.42%</td>
<td>-13.33%</td>
<td>-2.00%</td>
<td>-10.61%</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>$59.30%</td>
<td>$368,723</td>
</tr>
</tbody>
</table>

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

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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.

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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 compounding 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. 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.

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.”,
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\(^\text{12}\) 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 these 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 5\(^\text{th}\) 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.”

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**

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

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.” 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

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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.”

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. 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 compouder” 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

<table>
<thead>
<tr>
<th>Brand</th>
<th>Vial Size</th>
<th>PBS Listed Manufacturer’s Price per Vial</th>
<th>Price from manufacturer</th>
<th>Price from wholesaler*</th>
<th>Price from third party compounder</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jevtana</td>
<td>60mg</td>
<td>$5,814.74</td>
<td>Cannot be purchased</td>
<td>$5,930.60</td>
<td>$6,069.35</td>
</tr>
<tr>
<td>Abraxane</td>
<td>100mg</td>
<td>$401.48</td>
<td>Cannot be purchased</td>
<td>$431.67</td>
<td>$453.25</td>
</tr>
<tr>
<td>Alimta</td>
<td>500mg</td>
<td>$1,559.86</td>
<td>Cannot be purchased</td>
<td>$1,591.68</td>
<td>$1,695.00</td>
</tr>
<tr>
<td>Erbitux</td>
<td>500mg</td>
<td>$1,705.00</td>
<td>Cannot be purchased</td>
<td>$1,773.20</td>
<td>$1,975.00</td>
</tr>
<tr>
<td>Muphoran</td>
<td>208mg</td>
<td>$1,084.33</td>
<td>Cannot be purchased</td>
<td>$1,132.50</td>
<td>$1,185.00</td>
</tr>
</tbody>
</table>

* 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 compounding (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 compounding 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 compounding center 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:\footnote{Shelf Lives of Cytotoxic and Anti-Viral Agents, December 2011 (Baxter Medical Information Service)}:

- 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 compounding center (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)
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.
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.
Appendix 2

Supplementary Submission to Senate Community Affairs Committee Inquiry, April 2013
Supplementary submission to
Senate Community Affairs Committee Inquiry:
Supply of chemotherapy drugs such as docetaxel

April 2013

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This supplementary submission should be read in conjunction with The Pharmacy Guild of Australia’s (‘the Guild’s’) original submission to this Inquiry (March 2013). The Guild is providing this supplementary submission to ensure that the Committee is fully informed and to respond to the Department of Health and Ageing (DoHA) submission that was released on 5 April 2013. We urge the Committee to consider the content of this supplementary submission when compiling its report.

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SECTION 1:
THE EFFICIENT FUNDING OF CHEMOTHERAPY (EFC) BUDGET MEASURE IS SEPARATE FROM THE FIFTH COMMUNITY PHARMACY AGREEMENT

Overwhelming documentary evidence from 2008 onwards that the chemotherapy arrangements are separate to the Community Pharmacy Agreement.

Confirmed by DoHA in April 2010.

No attempt was made to recoup from the 5th Agreement the reduction in anticipated savings from the EFC measure announced in the 2010 Budget.

No references to chemotherapy in 5th Agreement or official Agreement-related information. No references to 5th Agreement in EFC arrangements or related information.

In its submission to this Inquiry DoHA contends that “the Fifth Community Pharmacy Agreement has been identified by the Government as the appropriate source for funding chemotherapy fee changes” on the basis that it “was negotiated in the context of three interlinked measures (including the Fifth Community Pharmacy Agreement)”. DoHA cites as evidence the fact that while the Efficient Funding of Chemotherapy Measure (EFC) was first announced in the 2008-09 Budget entirely separately to any Community Pharmacy Agreement, it was renegotiated in parallel with the Fifth Community Pharmacy Agreement. DoHA refers to an alternative funding model for chemotherapy being agreed by the Commonwealth and the Guild in negotiations that ran parallel to the Agreement negotiations and asserts that details of the EFC were announced in the 2010-11 Federal Budget as part of a wider announcement of the Agreement, despite the fact the Agreement was announced separately and prior to the Budget without any mention of the EFC.

The Guild and its members cannot and will not accept the Department’s position in relation to the source for funding chemotherapy fee changes. It would result in a significant and totally unfair impost on Australia’s 5,240 community pharmacies, 98% of which do not deal with chemotherapy medicines and are struggling with the increasing impact of price disclosure. The claim by DoHA that the Community Pharmacy Agreement is “the appropriate source for funding chemotherapy fee changes” has no legal or factual basis and would require a retrospective and unilateral rewriting of the Agreement to the considerable detriment of Australia’s community pharmacies, which are separately already providing savings to the Government under the Agreement of over $1 billion between 2010 and 2015 as well as indirect savings through price disclosure. These pharmacies have already experienced a 10.8% real reduction in remuneration over the past three years, and further reductions are likely to flow from price disclosure over coming months and years.

Given the DoHA submission and evidence to the inquiry, it is important to put all the pertinent facts on the table on the question of whether the chemotherapy shortfall should be funded from the Agreement. The original EFC budget measure was announced in May 2008 separately to any Community Pharmacy Agreement. It was postponed because of its flawed nature, first to enable further consultation with stakeholders and again to be considered in the context of the 5th Community Pharmacy Agreement. In late 2009, the Government and the Guild expressed an agreed intent to achieve $120.6m in savings from the EFC over 5 years, with any shortfall in these savings to be applied to pharmacy remuneration. At the same time, the Government and the Guild expressed an agreed intent that community pharmacies would receive additional funding for professional services or quality measures (not remuneration) in lieu of the flow-on impacts of the proposed price disclosure MOU which was separately being negotiated with Medicines Australia.
The latter expression of intent in relation to the Medicines Australia MOU was carried through to the Fifth Agreement; however there is no provision in the Agreement for the amount provided for professional services or quality measures to now be redirected to address the loss of remuneration from the chemotherapy shortfall and, in any event, the amount of funding available would be clearly insufficient to meet this shortfall without emasculating these programs. In stark contrast, the expression of intent in relation to chemotherapy savings was never followed through by the Government either in terms of maintaining the levels of savings or imposing a requirement in the Agreement or elsewhere that any shortfall be sourced from pharmacy remuneration.

In the May 2010 Budget, the Government announced that the EFC would reduce the previously booked savings (from the 2008 Budget measure) by $95.3m over 5 years. There was no reference in either the EFC budget measure or in the already announced 5th Community Pharmacy Agreement and the accompanying collateral of any funding interlinking between the two initiatives. On the contrary, a matter of days prior the public announcement of the 5th Community Pharmacy Agreement, the Department confirmed in writing that the EFC model had been agreed and was separate from the Agreement. Nor did the Government at the time or subsequently ever approach the Guild to seek recoupment of the EFC shortfall between the $120.6m agreed in-principle in late 2009 and the 2010 Budget announcement which reduced the savings to below $100m.

It is important to point out that Clause 33 of the Fifth Agreement states that “this Agreement constitutes the entire agreement of the parties about its subject matter and supersedes all previous agreements.” The importance of this provision is that it makes clear that unless a matter is covered by the Agreement, it is outside of it regardless of whether it was the subject of earlier consideration or not. This is a fundamental element of the Agreement and of prior agreements, which is included to provide certainty to both parties during the life of the Agreement. For any shortfall in chemotherapy remuneration to be recouped from the Agreement, this would need to have been expressly provided for in the Agreement, and the fact that it was not is hardly surprising given the EFC, which seeks to fund the unique costs incurred by chemotherapy pharmacists, was always a budget measure separate to the Agreement, as confirmed by DoHA shortly before the Fifth Agreement announcement.

It is also important to point out to the Committee that the funding shortfall now facing chemotherapy pharmacists is a direct result of their loss of trading terms due to the impact of the price disclosure arrangements on chemotherapy medicines. These price disclosure arrangements and the savings the Government is deriving from them are separate both from the Agreement and the EFC. The level of savings being derived by the Government from the impact of price disclosure on chemotherapy medicines far exceeds the savings attributed to the EFC. In fact, the Guild estimates that the savings from the impact of price disclosure on chemotherapy medicines will be $210m in 2013-14 alone.

Finally, given the statements in the DoHA submission that the Agreement is “the only other source of available funding” and “the appropriate source for funding chemotherapy fee arrangements”, it is important to emphasise the difficult position in which chemotherapy pharmacists find themselves in seeking to find a solution to their shortfall. Unlike other pharmacists whose remuneration is covered by the Agreement and medicine innovators and generic medicine providers who are subject to the Medicines Australia MOU, the chemotherapy pharmacists have no formula, established process or
designated time that they can rely upon to have their remuneration issues reviewed or reconsidered. They face a situation where they have, as a result of significant reductions in their remuneration, reached a point where their businesses are increasingly unviable, but have no recourse other than to request direct assistance from the Government.

In summary, both the source of the problem facing chemotherapy pharmacists (price disclosure and inadequate funding for the costs entailed in preparing and dispensing chemotherapy medicines once the trading terms cross subsidy has been eliminated) and the measure to resolve the problem (enhancements to the EFC which funds these costs) are separate to the Fifth Community Pharmacy Agreement. There is no legal or factual basis for asserting that there is a funding link between the Agreement and the EFC. Any attempt to derive the shortfall from the Agreement would come at the expense of community pharmacies who have no involvement in chemotherapy; are already providing over $1 billion in savings separately to the Government through the Agreement; and who themselves are increasingly being impacted by the multiple billions of dollars in savings the Government is deriving from price disclosure.

The claim by DoHA that the Agreement is “the only other source of available funding” may be their view of the current budgetary environment. However, in reality the most “appropriate” means of addressing this issue would be to return what would amount to a relatively small proportion of the savings generated from price disclosure to cover this shortfall in remuneration.

The table below details the history of the Efficient Funding of Chemotherapy (EFC) budget measure and the separate 5\(^{th}\) Agreement.

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<tr>
<th>Date</th>
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| 13 May 2008     | Government announces a budget measure that “more efficient arrangements” will be implemented for chemotherapy drugs, saving $96.9m over four years to 30 June 2012. | 1. The Guild was not consulted in the lead-up to the budget and knew nothing about the measure until it was announced.  
2. The Government did not link this budget measure to the 4\(^{th}\) Agreement in any way.  
3. No funds were allocated back to the 4\(^{th}\) Agreement as a result of this savings measure.  
4. The Guild recognised that chemotherapy was not part of the 4\(^{th}\) Agreement so did not contend that the introduction of this measure would be a breach of that agreement. |
<p>| 26 April 2009   | Minister announces delay “to enable sufficient time to negotiate with industry stakeholders”. | 5. No linkages were drawn to the 4(^{th}) Agreement in this announcement. |
| 20 August 2009  | Minister announces further delay “to discuss the measure further in the context of negotiations for the Fifth Community Pharmacy Agreement”. | 6. As shown by this statement, it remained a separate measure. |
| Late December 2009 | The Guild and Minister agree to continue to discuss a proposal with an intended target savings | 7. The $120.6m savings target was expressly in addition to, and separate to, the $1,001.0m in savings to be generated from the 5(^{th}) Agreement. |</p>
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|              | level of $120.6m over the five years to 30 June 2015, a reduction of $68.4m in savings compared with the 2008 budget measure over this five year period. | The chemotherapy arrangements remained a separate budget measure.  
8. The $120.6m was an intended target at this time but was further reduced through the 2010 Budget (see below). The difference was not recouped from the 5th Agreement funding pool.  
9. The negotiations anticipated that community pharmacy may receive additional funding for professional services or quality measures (not remuneration) in lieu of the flow-on impacts of price disclosure, which was carried through to the Agreement  
10. There was however no such arrangement pursued in the Agreement to meet any shortfall in the budget savings from the EFC. |
| February 2010 | Additional financial model information from Community Pharmacy Chemotherapy Services Group (CPCSG) | 11. In this revised paper provided to the Government by the Guild on behalf of the chemotherapy pharmacists, the savings for chemotherapy over five years (as estimated by the CPCSG) were reduced to $95m. While this amount was significantly lower than the late 2009 discussion, no adjustment to the Community Pharmacy Agreement was anticipated nor made. |
| March-April 2010 | Drafts of the 5th Agreement produced by DoHA. | 12. Neither the first draft nor any subsequent draft contained any reference to chemotherapy fees or any arrangements to recoup any shortfall in the EFC savings. |
| Late April 2010 | The Guild receives confirmation in writing from DoHA that “the measure remains separate from the Fifth Agreement”. | 13. This was final confirmation that the chemotherapy arrangements were not part of the Agreement and remained completely separate to it.  
14. It also confirmed that the proposal from the Community Pharmacy Chemotherapy Services Group had been accepted but final calculated savings were not provided to the Guild prior to the Budget. |
| 3 May 2010 | 5th Agreement signed by Guild and Minister | 15. The 5th Agreement contains no reference to chemotherapy arrangements or fees.  
16. The Pharmacy Remuneration element of the funding table in the 5th Agreement lists all fees that are part of the agreement but does not mention the chemotherapy fees.  
17. The 5th Agreement information document released by DoHA following the signing of the agreement contains no reference to chemotherapy.  
18. The savings generated by the chemotherapy measure are not announced with the 5th Agreement and are not included in the $1,001.0m savings flowing from the 5th Agreement. |
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<tbody>
<tr>
<td>9 May 2010</td>
<td>EFC measure announced in Budget.</td>
<td>19. Clause 33 states that “This Agreement constitutes the entire agreement of the parties about its subject matter and supersedes all previous agreements.”</td>
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<td>20. Budget paper references to the EFC made no link with the 5th Agreement.</td>
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<td></td>
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<td>21. This budget reduced the savings from the 2008 budget measure by $95.3m over the five years to 30 June 2010. This reduction was $26.9m more than the target established in late December 2009 (see above). The Guild was unaware of this final figure until the Budget and there was no approach made by the government to seek to recover this $26.9m shortfall from the 5th Agreement. The EFC had remained a separate measure, as it was in 2008, and as had been confirmed in writing in late April 2010.</td>
</tr>
<tr>
<td>Late 2010 to 2011</td>
<td>DoHA and the Department of Human Services publish various materials on the EFC.</td>
<td>22. None of these EFC materials contain reference to the 5th Agreement.</td>
</tr>
<tr>
<td>1 December 2011</td>
<td>EFC implementation date.</td>
<td>23. The new arrangements and fees took effect from this date. No amendments were made, or suggested to be made, to incorporate the fees and arrangements into the 5th Agreement.</td>
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</table>
SECTION 2: COMMUNITY PHARMACIES CANNOT PAY FOR THE CHEMOTHERAPY SHORTFALL

Community pharmacy contributed $1 billion through 5th Agreement, plus additional impact from PBS Reforms and other price reductions.

Remuneration per prescription for non-chemotherapy dispensing down almost 11% in real terms since 2009, and is likely to drop further with more price reductions to come.

Weak and declining retail sales and intense competition from pharmacies and other retailers.

Record levels of bankruptcies and receiverships in general community pharmacy, including new announcements this month.

The previous section listed the documented evidence that the EFC arrangements are a separate and unrelated budget measure with no linkages to the 5th Agreement. It is also important to recognise that the approximately 97% of community pharmacies that dispense no chemotherapy are not in a position to pay for the shortfall that has been created by underfunding of chemotherapy.

Savings of $1 billion were derived directly from community pharmacy over the term of the 5th Agreement. These savings included the direct impact of PBS Reform price reductions on 1 February 2011 and 1 April 2012 (as a result of the government’s Memorandum of Understanding with Medicines Australia) however they did not account for the indirect impact of those reductions on trading terms. Nor did those savings include the additional loss in income that has resulted from more recent price reductions such as those in December 2012 to the top two drugs on the PBS, the reductions on 92 drugs on 1 April 2013, an uncertain number (likely to be around 50) on 1 August 2013, with many more to come over the remainder of 2013 and beyond.

For regular (non-chemotherapy) PBS dispensing, community pharmacy remuneration per prescription through the 5th Agreement is lower today than in 2009, even without adjustment for inflation over this period. In real terms the reduction in remuneration per prescription since 2009 is 10.8%. Further reductions in PBS prices that will occur throughout the remaining two years of the 5th Agreement are likely to result in even lower levels of overall remuneration. This is difficult enough for community pharmacies to sustain without also being asked to fund a shortfall that has no relationship to more than 97% of those pharmacies and no relationship to the agreement that determines their remuneration.

Community pharmacies have also been significantly affected by a variety of increases in labour, leasing and other costs, that with the highly regulated nature of the PBS they are not able to pass on like other businesses. They are also impacted by the current weak retail conditions, with a reduction in retail sales of 2.3% recorded for the 2012 calendar year and margins weakening in the face of intense competition both within pharmacy and from supermarkets and other retailers.

Community pharmacy receiverships and bankruptcies are running at record levels. Only this month it has been announced that a highly regarded and well-established group with 15 pharmacies across four states and territories (Harrisons Group) has been put into receivership.

Community pharmacy simply cannot afford to fund a chemotherapy shortfall on top of the impact of the 5th Agreement, ongoing PBS Reforms, intense competition, increasing running costs and a prolonged and severe slowdown in retail.
The Guild wishes to ensure that members of the Committee are reminded of the additional issues listed below. While not gaining significant attention at the Inquiry Hearing on 28 April or in other submissions, these do require consideration in order to establish a transparent funding model that is sustainable and workable for the long term. Funding for many of the items has historically been attained through the trading terms for chemotherapy. This is no longer the case because of the new price disclosure arrangements. The issues below are in addition to the fundamental shortfall in the preparation fee and dispensing fee, compared with the costs associated with preparation and dispensing.

The additional issues include and are not limited to:

1. possible cost-shifting from state/territory governments to the Commonwealth, increasing the costs of the PBS;
2. possible cost-shifting from private health insurers to the PBS for services provided by private hospitals/clinics;
3. the lack of visibility of cost structures in some vertically integrated corporate models of chemotherapy supply;
4. the absence of monitoring of, or protection against, arbitrary price rises applied, independently of drug cost, by third party chemotherapy compounders who supply the pharmacies (or other purchasers). This can effectively force the supply pharmacies to supply the final prepared medicine infusion at a loss;
5. the absence of a mechanism to ensure that prices paid by pharmacies (or other purchasers) for chemotherapy drugs are limited to the price agreed between the manufacturer and the Commonwealth (again, this can force the supply pharmacies to supply at a loss);
6. a shortfall in mark-up, compared with the levels expected by the sector, due to the algorithm having been implemented in an illogical manner inconsistent with PBS policy intent;
7. the lack of any specific reimbursement for containers and drug delivery devices;
8. the lack of consideration in the price disclosure mechanism for the differences in the supply chain that exist with chemotherapy drugs, where most purchasing of drugs from manufacturers is by third party compounders and does not reflect the prices paid by community pharmacies.
Appendix 3

Letter to Secretary, Senate Community Affairs Committee, May 2013
Re: Senate Community Affairs Reference Committee report (Inquiry into Supply of chemotherapy drugs such as docetaxel)

Dear Dr Holland

The Guild notes that the final report of the Senate Community Affairs Reference Committee Inquiry into the Supply of chemotherapy drugs such as docetaxel points out that one statement made by the Guild in our original submission to the Inquiry was incorrect. The Guild apologises for this inadvertent error which we are now correcting at the earliest opportunity.

Unfortunately the Guild was not given the opportunity to clarify this matter prior to the Final Report. Had the Guild been offered this opportunity we would have been able to assure the Committee that the two references to the Fifth Community Pharmacy Agreement (5th Agreement) in the Explanatory Memorandum to the National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2010 contained no new information. The Guild had already pointed out, on page 16 of our original submission to this Inquiry and on page 2 of our supplementary submission, that the chemotherapy measure in the 2008 Budget had been postponed to be considered “in the context of the Fifth Community Pharmacy Agreement”. This was never in dispute. Further, the Guild would have been able to point out to the Committee that the National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2010 did indeed include amendments to the Act that related to a measure that was agreed to as part of the 5th Agreement – that being the Collection of Under Co-Payment Data measure.

The references in the Explanatory Memorandum do not alter the Guild’s strongly held view that the chemotherapy measure was, and remains, a budget measure separate to the 5th Agreement and that the 5th Agreement does not include funding to cover the chemotherapy shortfall.

Yours sincerely

David Quilty
Executive Director

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