Submission for Senate Inquiry

Supply of Chemotherapy drugs such as Docetaxel

APHS Pharmacy Group

20 March 2013

Your Pharmacy Partner

Introduction

APHS Pharmacy welcomes the opportunity to provide this submission regarding the safe supply of chemotherapy drugs to Australians with cancer.

The APHS Pharmacy Group operates in Queensland, New South Wales, Victoria, South Australia, Western Australia and the Australian Capital Territory. APHS pharmacies specialise in the provision of pharmaceutical care to inpatients of private, public and day treatment hospitals, with the majority of our pharmacies involved in the preparation and dispensing of chemotherapy items.

Cancer is now the greatest burden of disease in Australia. With more than 120,000 new cases of cancer estimated to have been diagnosed in 2012, and continuing gains in life efficiency seeing approximately 1 in 2 males and 1 in 3 females diagnosed with an incidence of cancer before the age of 85[1], this is unlikely to change in the foreseeable future.

As such, APHS Pharmacy believe that continuing and expanding access to chemotherapy services in a safe and sustainable manner becomes an essential requirement of the Australian health care system.

Australia's Cancer Care System is Number 1: let's keep it that way

Recent media reports have lauded the fact Australia has the highest five-year cancer survival rate in the world, a reflection of the quality of our current cancer care system. The statistics indicate a five-year survival rate of 67 cancer patients for every 100 new cases of cancer, a noteworthy achievement when benchmarked against peer healthcare economies like the US, which reported only 38 survivors per 100 new cases in the same period[2].

Affordable access to primary care, developed public and private specialist referral networks, medicines subsidised through our leading Pharmaceutical Benefits Scheme, and a sustainable model of private health insurance, ensure the majority of Australians receive the treatment they require at an appropriate stage in their disease. These factors combined with early detection and lifestyle education programs, are the primary drivers behind Australia's world leading cancer survival rate.

APHS Pharmacy hold a definite view that the system is working in Australia, and, given the central role that chemotherapy regimes play in the majority of cancer care plans, we are proud to be a contributor.

The actions this Senate Inquiry will ultimately recommend on are not about pharmacy profits, private hospital profits, public hospital sustainability or budget surpluses, they are about families, communities, and cancer patients. A long-term, sustainable funding model for chemotherapy drugs will ensure patients continue to receive safe access to chemotherapy treatment in both private and public settings, keeping Australia at the top of the cancer survival table and our people alive.

[1] *Cancer in Australia: an overview 2012*, Australian Institute of Health and Welfare, p12-14.
[2] Based on GLOBOCAN data, 2008, *Cancer in Australia: an overview 2012*, Australian Institute of Health and Welfare, p58-59.

Price Disclosure: friend or foe of the cancer patient?

Weighted Average Disclosed Price ('Price Disclosure') was introduced in 2007 as the centrepiece of a PBS reform platform. The current process of Price Disclosure is extremely effective in reducing the price paid by government through leveraging market competition opportunities created around price when a drug moves off-patent. Pharmacy derives a short term benefit from these pricing opportunities, which essentially acts as the incentive to undertake the substitution of the original brand with the competitor, while the taxpayer (as ultimate funder) extracts the long-term benefit of a reduced price.

APHS fully supported PBS Reforms as an effective tool to maintain the cost affordability of medicines and allow the government to continue making appropriate funding decisions in the health sector. The decision of the Federal Government to enter into a Memorandum of Understanding with Medicines Australia in 2010, and expand and accelerate Price Disclosure, was also intended to provide further savings that enabled new medicine listings on the PBS. Many of these medicines were designed to increase the range and quality of treatment options for cancer patients, a move that was embraced by APHS and the wider cancer care community.

While pharmacy has been receiving short term pricing benefits via the chemotherapy supply system since PBS Reform was introduced five years ago, these benefits have been masking the fact that the vast majority of chemotherapy drugs provided, particularly the newer and more expensive items, are being remunerated by the PBS at a substantially lower rate than the cost associated with the safe preparation and supply of these items. As a result, savings on a small number of chemotherapy items were 'cross subsidising' the supply of a substantial number of loss-making items.

When the May 2008 Federal Budget sought to introduce a further set of PBS reforms, the 'cross subsidisation' issue was highlighted and the wider chemotherapy supply sector entered into dialogue with the Government regarding a solution. The solution tabled was to partially reinvest some of the Price Disclosure savings from chemotherapy drugs in order to maintain an economically viable system for pharmacy operators and continue delivering cost efficiency improvements.

This Alternate Proposal for chemotherapy funding put forward by the Community Pharmacy Chemotherapy Services Group in July 2009, and endorsed by key cancer patient advocacy groups, private and public hospital peak bodies, the Pharmacy Guild of Australia and other industry stakeholders, included a series of proposed actions to ensure a sustainable chemotherapy remuneration program that was equitable and safe for all Australian cancer patients going forward.

During the consultation process and the development of this Alternate Proposal in 2009, APHS were fortunate to host the then Acting First Assistant Secretary, Stephen Dellar from the Department of Health and Ageing and Sue Campion from Medicare for an open and honest discussion. Data provided in this meeting illustrated the risk to long term chemotherapy supply that had emerged from a reliance on the generic trading terms of a few drugs to cover the losses generated on most new drugs. The willingness of department staff to engage with and expand their understanding of a highly specialised sector was warmly welcomed, and befitted the importance of implementing appropriate policy decisions in this area.

Following the 2009 Alternate Proposal, the Government implemented a reform known as Efficient Funding of Chemotherapy (EFC). Broadly based on three measures contained in this Alternate Proposal, the EFC reform delivered the requested $120M in savings and deferred action on the two remaining measures in this Alternate Proposal. The first deferred action was focused on delivering a long term sustainable funding arrangement for the sector and the second aimed to deliver efficiency improvements for cancer care specialists.

After the forthcoming 1 April 2013 price reductions, Price Disclosure on chemotherapy drugs will be delivering over $200M in annual savings to the government. In parallel with this, the sustainability of the sector remains extremely tenuous. With no drugs moving off-patent since Docetaxel in March 2011, the ability for the sector to

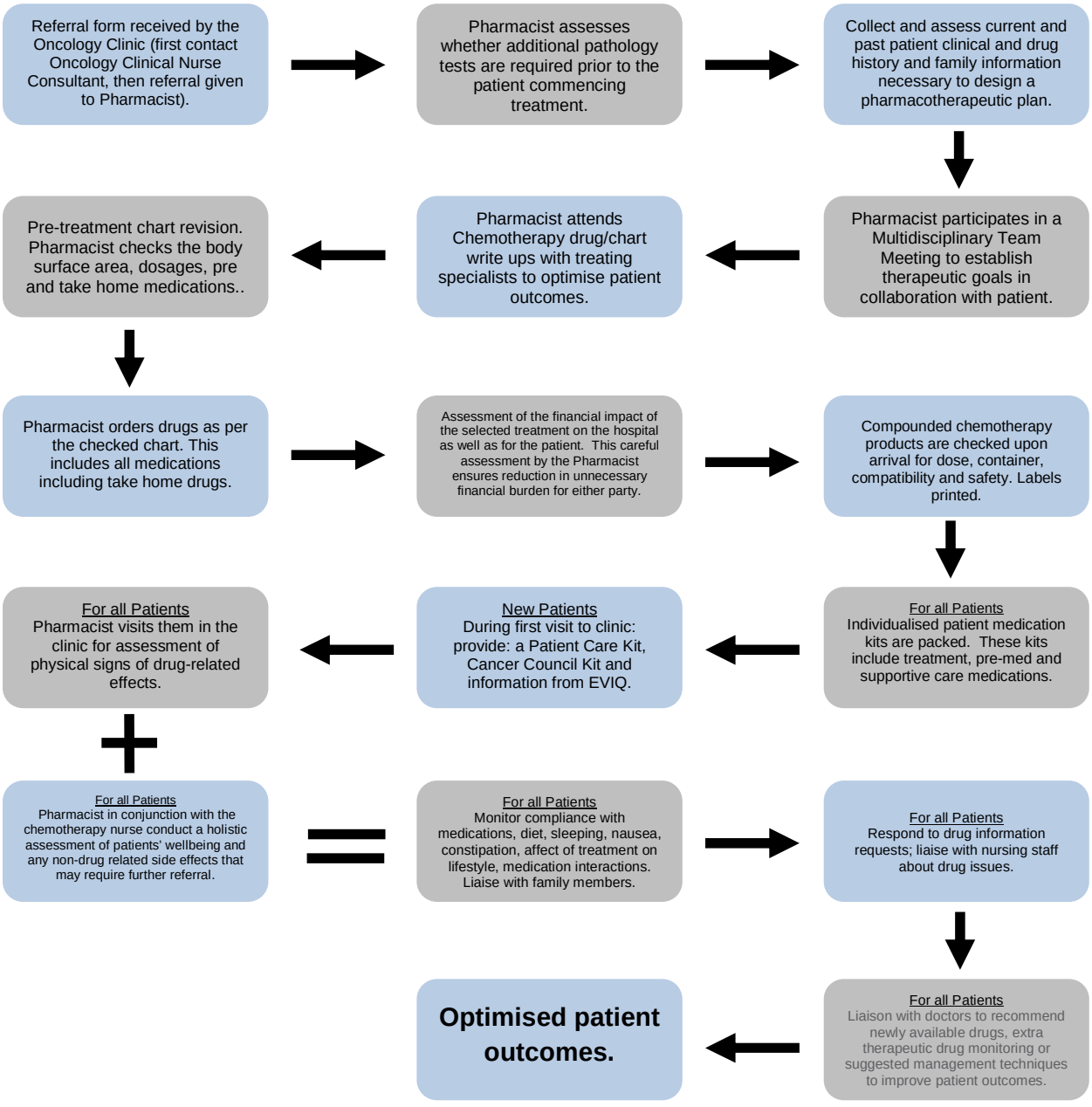
remain sustainable through new generic products coming to market and 'cross subsiding' loss makers has passed. Further to this, the price reductions achieved by the Government during 2012/13 cuts have removed the very contribution that has allowed the sector to maintain services and patient safety.

Price Disclosure savings, which enable new cancer therapies to be listed on the PBS so they are affordable for everyday Australians, are a friend of cancer patients. Unfortunately, if the appropriate actions to reinvest some of the savings back into the sector do not now occur, it may become an unwilling foe with serious negative consequences for patient safety and access to treatment.

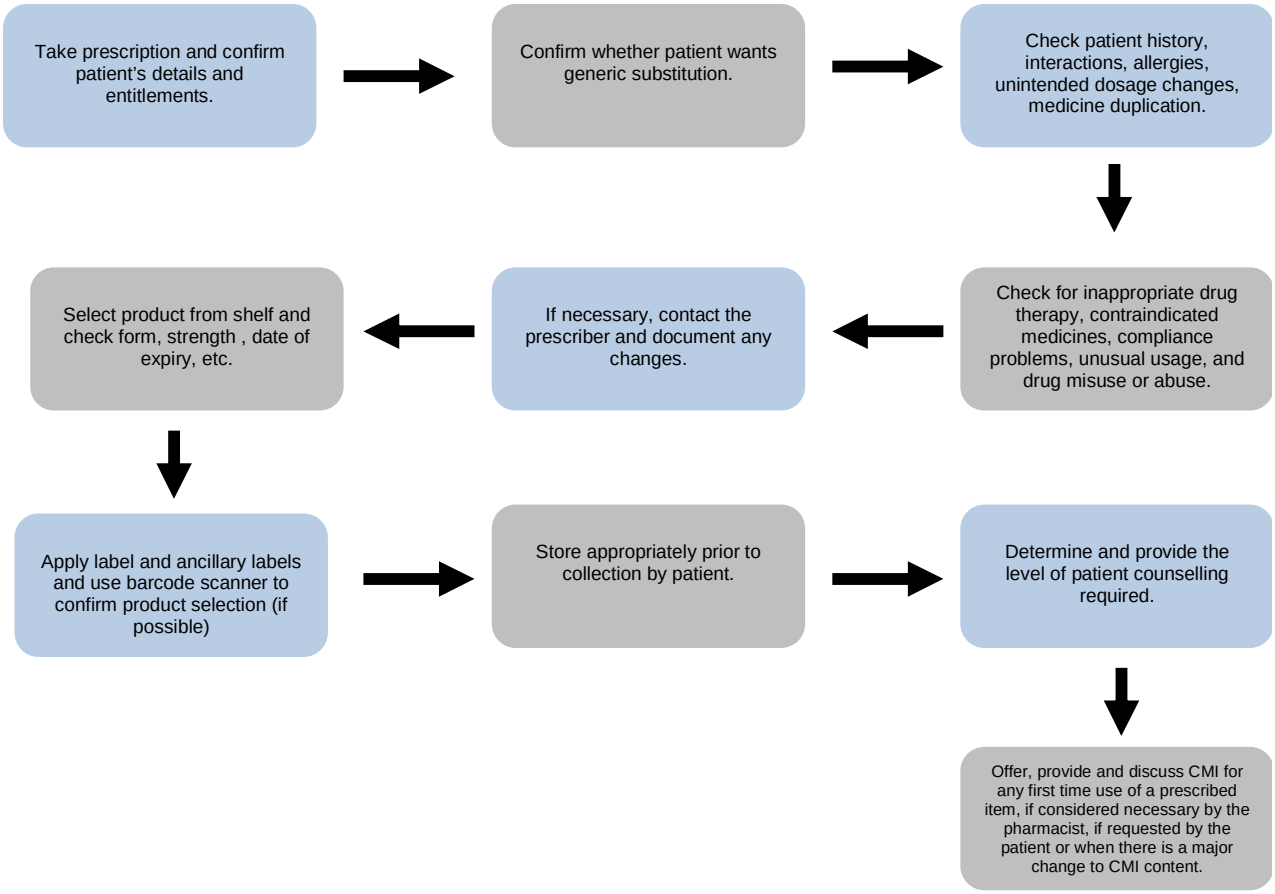
Supply of Chemotherapy: compensation that doesn't compromise patient safety

The supply of chemotherapy is a vastly complex process. Dealing with highly toxic drugs requires numerous steps and highly trained staff to ensure supply supports optimum patient safety and outcomes. Following are two flowcharts; the first outlines the complex role of the oncology pharmacist and the second shows a comparative role of a pharmacist dispensing medication in an average community pharmacy.

The role of an oncology pharmacist: a comprehensive overview



The role of a pharmacist: the dispensing process



The PBS ensures most Australians have affordable access to their cancer treatment. Approximately 60% of chemotherapy treatments are currently delivered in private hospitals, where funding for the drug is dependent on the PBS. Thus the remuneration model for chemotherapy under EFC needs to be sufficient to cover all of the steps required in the supply process if the system is to remain sustainable. As the flowcharts demonstrate, this process is far more complex than dispensing ordinary medicines, such as antibiotics or anti-inflammatories, which are supplied in their original manufacturers packaging and usually in a single interaction with the patient.

The cost of compounding

The 'compounding' aspect of the supply process, which involves conversion of a manufacturer's originally packed active chemotherapy agent into a form that is ready for infusion, has historically been prepared by the pharmacy in-house or outsourced by them to a third-party who specialises in compounding.

In-house preparation requires investment in infrastructure, processes and training, due to the nature of the drugs involved, while outsourcing requires a margin to be paid above the drug cost and direct labour involved, to compensate the third party for their investment in those same areas.

Across APHS pharmacies, which have differing proportions of in-house versus third party compounding to meet the requirements of the location, the true cost of compounding (including cost of the wholesale supply chain) averages around $100. The EFC model currently provides $40 to cover the cost of compounding and $4.83 for diluent, we believe this compounding fee should be increased by $60 from $40 to $100.

Ensuring sufficient funding to reflect compounding costs, as well as dispensing and other costs, is vital to ensure safety is not compromised. The pharmacy industry is acutely aware of the tragic consequences witnessed at the New England Compounding Centre in the USA last year. A business decision to drive down the cost of supply led to changes in the nature of compounding activity undertaken. Tragically, this compromised the safety of the product and is linked to more than 40 deaths. APHS don't believe any funding model in the Australian healthcare environment should place pharmacy or hospitals at risk of having to contemplate similar patient safety exposure.

Dispensing, administration and overhead costs

Dispensing, administration and overhead costs average around $70 in APHS pharmacies. EFC items currently attract the standard $6.52 dispensing fee and a $24 distribution fee.

An increase of $40 in fees is necessary to support these range of activities. APHS believes the $40 may be comprised of multiple fees reflecting the different service and activity levels that contribute to costs.

APHS propose that at least $25 of the required $40 be allocated to an increased dispensing fee in order to cover the core service provisions that occur in all treatment settings.

There has been much discussion with the Government and wider sector over the past few months regarding the 'final mile' of services delivered directly to the patient by a multi disciplinary team (oncologist, nurses, surgeons, allied health professionals). Led by an oncology pharmacist, these services are vital to the safe supply of chemotherapy and essential for a positive patient outcome. Due to the different settings in which APHS operate pharmacies across Australia, we have the opportunity to comment on the true cost contribution that this aspect of pharmacy service incurs. In this context, 'final mile' clinical services are the direct interactions between patient and pharmacist on the hospital ward, whether at the bedside or in the chair. At APHS we fulfil a number of contracts where the hospital provides their own clinical service and our pharmacy role is limited to dispensing and supply of compounded items. From evaluating the performance of these contracts, APHS believes our dispensing, administration and overhead costs are in the range of $10-15 lower per infusion when the 'final mile' service is not provided.

From this evaluation, APHS would propose that any newly introduced fee recognising the 'final mile' of clinical service (an important distinction because many of the fundamental dispensing and supply steps in this complex and specialised area of practice also involve clinical activity) should be in the in the vicinity of $15 per infusion.

This would ensure that pharmacy is not inadvertently remunerated for services government is already paying for in the form of wages, particularly in the public hospital setting. However, APHS would contend that the additional margin on these services is currently transferred to the public hospital authority via lower service pricing for the dispensing and supply function. Thus the potential 'double dip' is more theoretical than actual.

Based on learnings from previous chemotherapy funding models, APHS proposes that hospital executive are required to confirm service delivery of 'final mile' clinical services over a given period, based on eligible infusions provided for that period, before payment is made for this clinical service fee. If the payment model for the clinical service fee is not based on individual infusions provided, we may find ourselves reinstating a similar issue that EFC addressed by changing payment from a per prescription model, where payment was received at the start of a treatment cycle to cover multiple infusions despite the fact a patient may not ultimately complete the full cycle of treatments, to a per infusion model. Upfront payments would be an inefficient option for government, as it would lead to either overpayment where the full treatment cycle is not completed, or potentially underfunding of services for patients who do complete their full treatment cycle.

Differences in pharmacy remuneration: do they add up?

S.94 pharmacy remuneration

The 2010-11 Federal Budget introduced changes to s.94 private hospital remuneration, which were intended to better align remuneration arrangements with operational requirements. The core tenants of this change were to replace the wholesale mark-up of 7.52% with an 11.1% storage and handling mark-up, and the tiered pharmacy mark-ups (6 levels of mark-up with a maximum $70) to a flat 1.4% private hospital mark-up.

Fact sheet 4368.09.10 issued by Medicare Australia provided further information in relation to these changes, specifically noting that medicines supplied under the Intravenous Chemotherapy Supply Program (ISCP) would not be affected by these changes.

When ICSP was subsequently replaced by the adoption of EFC, there was no indication that the communicated exclusion of ICSP from the changed mark-up arrangements would not be carried forward under EFC.

However, in the final implementation of EFC this exclusion was not carried forward and s.94 pharmacies in a Private Hospital had the 11.1% storage and handling mark-up replaced by the $24 distribution fee contained in the EFC model, while continuing with a flat 1.4% mark-up. In essence, s.94 pharmacies lost the compensation of a higher storage and handling mark-up that had offset a lower product mark-up and were left worse off with a remuneration reduction of approximately $27 per infusion.

s.90 mark-up algorithm

There were also unintended consequences in the application of the mark-up algorithm for s.90 pharmacies when EFC was implemented. The concept of maximum prescribable dose (in mg) was introduced and the regular s.90 pharmacy mark-up became pro-rated against the maximum dose. Instead of receiving the capped $70 mark-up on a chemotherapy item costing more than $1750, as had historically been the case, the mark-up now varies for different drugs and doses where drug cost exceeds $1750, but rarely approaches $70. For s.90 pharmacies, the introduction of the maximum dose concept reduced the mark-up component of their remuneration by approximately $20 per infusion.

APHS believe it is important to note that in the development of the Alternate Proposal, neither of these additional savings to the Government was factored into modelling or forward estimates of savings by either the Government or the CPCSG, to the best of our knowledge. When the industry realised these changes, the Government was notified of the additional reductions to remuneration with an expectation that they were an unintended outcome. However, they have continued to exist since 1 December 2011.

Administrative costs: government savings to be made

Management of prescriptions in the chemotherapy sector is a complex and unnecessary administrative burden for doctors and pharmacy. Due to the setting in which chemotherapy treatment occurs, the prescription is a duplication of information the doctor has already recorded on the patient's medication chart and thus open to the risk of error. Further to this, not all items are available for prescribing under the streamlined authority system. This causes significant interruption to a doctor's ability to prescribe treatment for a patient when an authority code must be obtained, as well as the workload and cost that the authority process places on Medicare.

Knowing 'trial sites' in Victorian private hospitals have operated using the medication chart as the prescription for more than a decade, a wider adoption is well overdue. APHS believe Medicare, doctors and pharmacy would all benefit from removal of the current authority system, as well as adopting the medication chart as the script. This would deliver financial savings to Medicare, while doctors and pharmacy would benefit from an increase in their availability for patient care from reduced paper chasing.

A case study: the cost burden

St Andrews Hospital Toowoomba received attention in the print media in the lead-up to 1 December 2012, when it raised concerns about the impact of the 1 December price cut to Docetaxel.

As the pharmacy provider at this hospital, APHS are very familiar with the hospital's concerns. When the Department and the Pharmacy Guild indicated productive discussions were taking place, the hospital was able to reassure residents in Toowoomba and the wider Darling Downs area that they would maintain cancer services past 1 December. Due to the same reassurances, APHS subsequently informed the hospital that we would delay the imposition of fees on the hospital for chemotherapy services.

Unfortunately the current status of impasse in Department/Guild negotiations required this decision to be reviewed. APHS wrote to the hospital during February to advise that unless a government funding solution was implemented, pharmacy could not continue to absorb the shortfall and would have to commence charging an $85 fee per infusion from 1 March that would increase to $100 from 1 April (to reflect the increased shortfall delivered by the Paclitaxel price reduction) if a solution was not forthcoming.

Currently the hospital is absorbing this charge, which we understand remains a challenge to the financial metrics of their Cancer Centre. This is a difficult scenario for the hospital and APHS. The St Andrew's Hospital Pharmacy owned by APHS has been a provider of care in the community over many years, and has worked positively with the hospital to be a vital part of the healthcare landscape in the Darling Downs region. The necessity to take the step of charging a fee to the hospital is reflected in the numbers below.

Chemotherapy Services
St Andrews Pharmacy Toowoomba
Financial Summary – Jul to Sep 2012

	Actual Result		With Price Disclosure impact applied		With $100 fee introduced
Revenue	1,344,067		1,159,183		1,315,283
Gross Profit	252,749		67,865		223,965
Direct wages*	51,372		51,372		51,372
Operational & administrative costs, incl income tax	115,625		41,094		102,241
Surplus/(Deficiency)	85,752		(24,601)		70,352
Per infusion	54		(16)		45
%age of revenue	6.38%		-2.12%		5.34%

* This pharmacy benefits from a large professional team supporting the needs of the wider hospital and medical centre on the hospital campus. As a result, not all administrative requirements of the service are recorded in these costs, and the cost of staff cover for annual and personal leave and to provide additional support on the busier days in the Cancer Centre is not captured here.

Recommendations

1. Increase remuneration to all pharmacy operators

Introduction of **additional fee remuneration totalling $100** restores sustainability to the sector and ensures continuing safe access to chemotherapy for patients. APHS believe the fee model should be per infusion, providing a low-cost administrative model (each infusion is already processed as a prescription), and reflecting the nature of pharmacy interaction being principally related to activities that occur around an infusion.

2. Reinstate consistent application of PBS mark-ups

Pharmacy departments should receive the same remuneration to cover their services where the core service is the same. This means restoring s.94 private hospital pharmacies to the same mark-up structure as community pharmacies. In addition, the basis for calculation of the mark-up for all pharmacies should return to being the cost of the drug, not a reduced payment to reflect the dose provided compared to a theoretical 'maximum dose'.

3. Reduce administrative burden

We believe doctors and Medicare will both benefit from reduced administrative overhead when replacing the prescription with the medication chart occurs, and would advocate for removal of the current authority system at the same time.

Conclusion

Australia has much to be proud of in its health system, particularly in relation to topics of cost and access to treatment.

Our safety record is impressive, and ensuring pharmacy is maintained as a viable part of the health landscape is an important component of this.

In the specialised area of chemotherapy, we have reached (and now passed) the junction at which effective measures to reduce cost of medicines have made the existing remuneration model insufficient in this important segment of the market.

As identified in 2009 when industry engaged with government regarding the proposed ICSP, introducing new remuneration arrangements to progress towards a sustainable model is critical to ensuring safe and equitable access to chemotherapy.

APHS Managing Partner and Executive Chairman Stuart Giles will be attending the hearing in Sydney on 28 Marc, and would welcome the opportunity to provide additional support to this submission. The other pharmacy owners who have contributed to this submission, Cathie Reid, Tom Khoo and Russell Hill, would also be willing to make themselves available to the hearing if requested.

Submitted by Andrew Reid, APHS CEO, in conjunction with Stuart Giles, Cathie Reid, Tom Khoo and Russell Hill, owners of pharmacies in the APHS Pharmacy Group.