



Community
Pharmacy
Chemotherapy
Services Group

Patients to be Impacted by Cuts to Chemotherapy Drugs:

The Case for Urgent Action



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Chemotherapy drug supply at imminent risk due to funding model

Background

- Community pharmacies prepare and supply chemotherapy drugs to patients through private hospitals and clinics throughout Australia.
- Medicare Australia PBS data shows that more than 13,000 life-saving infusions are prepared and dispensed by community pharmacies for cancer patients each week.
- The preparation of chemotherapy drug infusions is complex, requiring specialised skills and facilities. There are a limited number of community pharmacies in Australia that provide these specialist pharmacists and facilities.
- The current funding model for chemotherapy drugs 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 exhibited a severe lack of understanding of the way in which chemotherapy drugs are prepared for patients.
- Cancer patient groups, oncologists, private hospitals, pharmacists, wholesalers and manufacturers all fought the proposed model and, eventually, their views were heard.
- However, the government insisted on savings being made and would not finalise the Fifth Community Pharmacy Agreement with The Pharmacy Guild of Australia until an agreement was made in relation to chemotherapy.
- With this imperative an alternative proposal was put forward, however it warned that unless Price Disclosure savings were returned to the sector the model was only a short term solution. It was made viable only by discounts available to pharmacies from suppliers of some off-patent drugs, and these would be quickly eroded by Price Disclosure. These discounts cross-subsidised the supply of other drugs which were prepared by the pharmacy at a loss. Despite these warnings, the remuneration in the EFC was set at a level that did not cover costs or provide any return on capital invested on expensive facilities and equipment required for the safe and efficient preparation of infusions. This model was destined to fail.

Problems

- **Price Disclosure has already delivered substantial savings from chemotherapy drugs, but the funding model has become unviable for community pharmacies from 1 December 2012 due to a 76.2% price reduction on docetaxel. The problem will be deepened by an 86.9% price reduction that will apply to another frequently used chemotherapy drug, paclitaxel, on 1 April 2013. Ongoing care for Australian cancer patients is at risk.**
- As the EFC remuneration is inadequate the supplier discounts available to pharmacies on docetaxel and paclitaxel have been cross-subsidising the dispensing of other drugs. With the 1 December 2012 and 1 April 2013 price reductions these sources of cross-subsidy are being removed as the discounts available on these drugs are taken away. There are no other discounts or sources of income to replace this loss.

- **While it is not the first price reduction, nor will it be the last, the 1 December 2012 docetaxel price reduction was the final straw that resulted in an unviable system, and the paclitaxel price reduction will simply make the funding shortfall even larger.**
- Other problems exist with the current funding arrangements:
 - Unanticipated losses of mark-up: the algorithm for calculation of pharmacy mark-up was not implemented in the way the sector expected (based on discussions with DoHA) and had modelled.
 - The cost to pharmacies of some drugs is higher than the official reimbursement price. These continue to be supplied only because of the current cross-subsidisation from trading terms on other drugs.
 - As a result of the separate Expanded and Accelerated Price Disclosure (EAPD) policy that started in 2010, some chemotherapy drugs have been affected by Price Disclosure which were not anticipated to be affected when the alternative proposal was put to government in 2009.
 - The Price Disclosure calculations include prices paid for drugs which are supplied through third parties to the public hospital system. This is not the intention and leads to reimbursement prices being pushed lower than the private market price.
 - The costs of containers and devices, which can be over \$100 for a single infusion, are not reflected in the remuneration model.

Solutions

- **More than \$40 million has been taken from the sector through the docetaxel price reduction and a further \$15 million will be taken through the reduction on paclitaxel. This is a total of \$55m in funding that must be returned to the sector for it to remain viable.**
- **The solution is to increase the current Infusion Fee to a level that provides adequate funding. This would require new funding that would at least offset the loss that will be incurred due to price reductions on docetaxel, paclitaxel and other drugs. The government has already achieved more than \$150m in annual savings on chemotherapy drugs through price disclosure cycles prior to 1 December 2012, in addition to \$23m in savings through the EFC initiative and now over \$55m from these two major cancer drugs. Returning part of these savings is a necessary reinvestment to ensure sustainable cancer care.**
- In addition, the remuneration model should recognise and reimburse the cost of containers, devices and clinical services. Other problems with the EFC implementation must also be addressed.
- Price Disclosure on chemotherapy drugs should also be reviewed and modified so that it is not distorted by public sector purchases through third party compounders.

What will happen if nothing is done?

- The current system for the preparation and supply of chemotherapy drugs through private hospitals and private clinics is at risk of collapse.
- As a result, patient access to cancer treatment through the private system will reduce.
- The outcomes in the near future are likely to include one or more of the following:
 - An influx of cancer patients to the already stretched public hospital system.
 - The introduction of additional charges to enable the private system to remain viable. These charges may be levied by pharmacies either directly on patients or indirectly through private hospitals and clinics.
 - Severe disruption for patients, particularly those in rural and remote areas who may need to travel further for treatment or have delayed access to treatment.
- The public hospital system does not have the capacity to deal with such a failure in the private system.
- All of the above is avoidable, and should have been avoided if the proposal put forward in 2009 was implemented in full and as expected.

The Solution – a sustainable funding model

- The current remuneration per prescription comprises:
 - a ready-prepared dispensing fee (\$6.52)
 - a preparation fee (\$40.64)
 - a distribution fee (\$24.38), intended to cover the cost of supply by the pharmaceutical wholesalers.
 - a diluent fee (\$4.83)

In total the current fees add to \$76.37. This is grossly inadequate to cover the complex processes involved with the safe and effective preparation and dispensing of these drugs and the wholesale distribution chain. Until now the sector has only remained viable due to the discounts (extra margin) available on a small number of drugs.

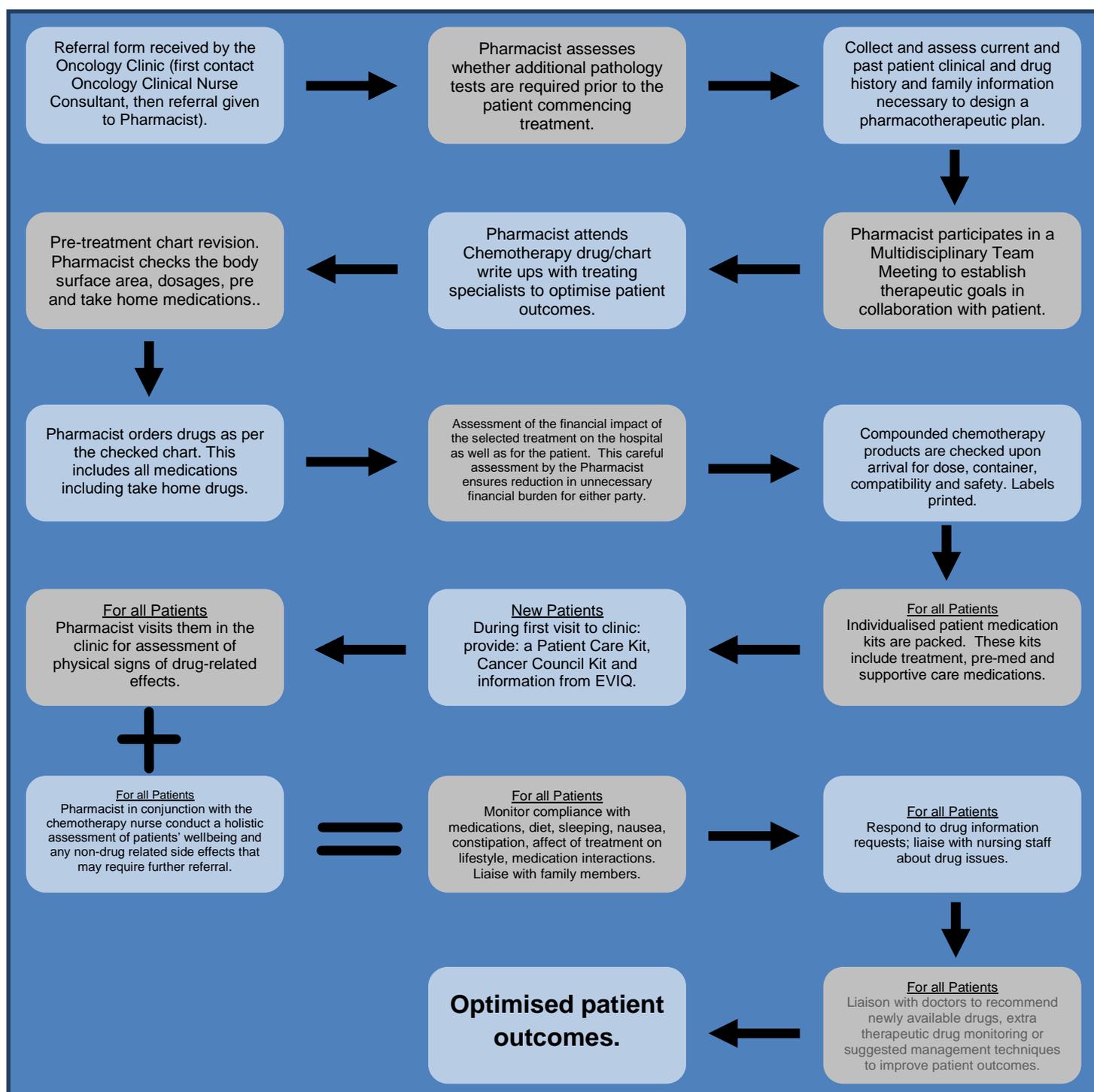
- Following the price reduction that has applied to docetaxel on 1 December 2012, and including savings already booked through the implementation of the new funding arrangements, the government will have removed an estimated \$217 million per year from the chemotherapy sector. There is more to come in 2013 through further reductions, with \$15m more already announced to be saved through the 86.9% price reduction on paclitaxel on 1 April 2013.
- A sustainable funding model must return a proportion of these savings, replacing the cross-subsidisation from trading terms. The model must properly recognise and provide remuneration for the following:
 - the cost of distribution from wholesalers
 - the costs of preparing doses (or the marginal cost of using a third party compounder)
 - the cost of associated services
 - the cost of consumables and dosage delivery devices
 - return on capital, in a sector that requires significant investment in facilities, equipment and training
- A sustainable funding model must also recognise that operating costs continue to increase in this highly technical area.

It is estimated that a fee increase of \$100 per infusion will be required to ensure a sustainable model of supply for chemotherapy drugs.

The role of an oncology pharmacist in a patient's care

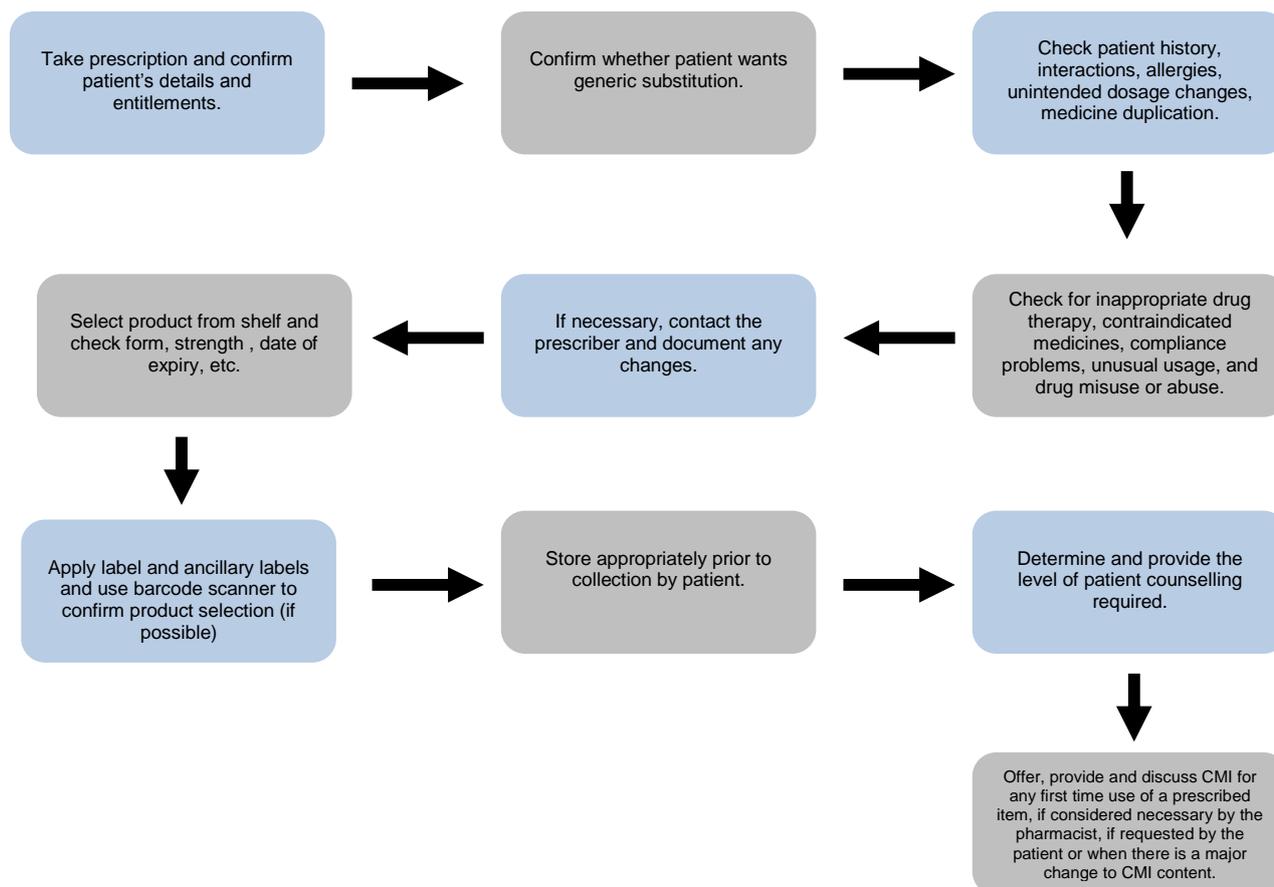
A patient's journey with cancer is a long and complex one. From screening and diagnosis through to treatment and supportive care, a patient will see countless medical professionals. In order to make this process easier patients are provided with a dedicated specialist Clinical Oncology Pharmacist who will guide them through the course of their treatment. Below is a snapshot of the role of an Oncology Pharmacist.

Costs including wages, extensive specialised training, facility capital, ongoing operation, rents, disposal, consumables, distribution and others are either paid for directly by the pharmacy or indirectly via purchasing from a third party.



The dispensing role of a community pharmacist

The role of a Community Pharmacist for most prescription medicines, while no less important to optimising the health outcomes from the patient's treatment, is not as in depth and involved as an Oncology Pharmacist's role. Below is a snapshot of a Community Pharmacist's dispensing role.



Example of Pharmacy Chemotherapy Supply (using 3rd party compounder)

Each month, Mrs BB, a 60 year old lady from regional Tasmania with advanced ovarian cancer has her neighbour drive her an hour and 10 minutes to be treated at her nearest day oncology unit in a private hospital. She is treated with Doxorubicin (Caelyx®) and Carboplatin. Her chemotherapy is ordered through the community pharmacy that supplies the private hospital that she attends. Due to its cytotoxic nature, Mrs BB's treatment is ordered through a TGA-approved third party compounder in Victoria the day before treatment and flown overnight to Launceston ready for administration.

The community pharmacy has a number of considerations when supplying Doxorubicin for Mrs BB:

- Doxorubicin only has a 24 hour expiry once compounded and must be flown interstate overnight
- Patients receiving Doxorubicin usually have to pass a blood test the day prior to treatment so these results need to be available before an order can be placed
- Due to a worldwide shortage of Doxorubicin, the pharmacy must order the stock from the drug company specifically for Mrs BB under a special patient supply program and have this sent to the third party compounder in time for the expected treatment day

This provides the pharmacist with only a very narrow window in which the Doxorubicin can be ordered so that the patient can receive treatment the following day – and remember her neighbour is driving her more than an hour to the oncology unit. The full cost of the Doxorubicin for Mrs BB is \$1,620. Carboplatin is less expensive and has a much better expiry.

The combined cost of chemotherapy treatment is \$1,694. As Mrs BB is a concession card holder she receives her treatment for \$11.60 (\$5.80 each) and her remaining repeat prescriptions are free as per the Efficient Funding of Chemotherapy (EFC) rules.

The current PBS reimbursement for the community pharmacy for this treatment under the EFC is \$1,712. **This is just \$18 for the pharmacist to perform all of the activities necessary to supply Mrs BB with her life saving medicines. At this low level of margin it is not viable to continue to supply this treatment. It has only continued due to the higher margins available on a small number of other drugs, primarily docetaxel and paclitaxel.**

Clearly, the treatment of Mrs B.B cannot be sustained without increasing the PBS remuneration for medicines listed on the PBS under the EFC program.

Isn't the current funding model based on a proposal supported by The Pharmacy Guild of Australia?

- A proposal put forward in 2009 was supported by a number of organisations, including The Pharmacy Guild of Australia. It was an alternative to the unsustainable arrangements that existed and the unworkable 2008 Budget measure. **The problem is that the new funding arrangements do not reflect that proposal.**
- The 2009 proposal stated:
 - *“It must be recognised that revenue currently derived from trading terms on a small number of off-patent items plays a crucial role in the viable operation of chemotherapy services... It is proposed that a risk share arrangement be entered into via the 5th Pharmacy Government Agreement or some parallel negotiations, that ensure a sizeable portion of savings from Price Disclosure are re-invested in the provision of service delivery.”*
- Pharmacists warned the Department of Health and Ageing that without this element the model was only a short term solution as it continued to rely on trading terms on some drugs cross-subsidising others which were being dispensed at a loss (after direct costs are considered). This was, and is, the commercial reality.
- This essential element of the proposal was ignored. Price disclosure has since removed almost all of the trading terms on these off-patent drugs, saving government about \$200m in the process. Price Disclosure has also been expanded and accelerated since the proposal was put forward.
- The last source of significant trading terms, docetaxel, was subject to a 76.2% price reduction on 1 December 2012. These are the primary reasons the current situation has come about and is why the arrangements are in urgent need of change.
- In May 2010 the signing of the Fifth Community Pharmacy Agreement was made conditional on support for the new chemotherapy funding arrangements. The Fifth Community Pharmacy Agreement determines the viability of over 5,000 pharmacies across Australia. The Guild could not delay that Agreement despite the new chemotherapy arrangements being unsustainable beyond the short term.

The current arrangements are flawed and unsustainable

- The new arrangements were implemented without recognition of the impact of Price Disclosure or the changes that took effect with the Expanded and Accelerated Price Disclosure policy in 2010. This left an unsustainable funding model that continued to rely on cross-subsidisation, which Price Disclosure has quickly eroded.
- The new funding model has also been implemented in a way that has resulted in significantly less remuneration than was expected:
 - A Department of Health and Ageing information release in April 2009 stated that “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 final arrangements. It did not. As a result, the mark-up component paid on some drugs is less than expected. For some drugs the funding algorithm means that the maximum expected mark-up (\$70) is never allocated for any prescription, no matter how many vials of the drug are used or how much those vials cost the pharmacy to purchase.
 - The Department of Health and Ageing insists that the mark-up is being calculated in the same way as other PBS drugs. This position fails to recognise that the new funding arrangements for chemotherapy differ from the standard PBS in many other ways. The arrangements have been established under section 100 of the *National Health Act*, which is intended to allow variations from the standard PBS.
- In addition, for many drugs the purchase price from manufacturers, wholesalers or third party compounders is above the PBS list price. This erodes the already inadequate remuneration base. One example is shown below:
 - cabazitaxel (Jevtana®) is PBS listed at a price of \$5,814.74
 - cabazitaxel cannot be purchased directly from the manufacturer
 - the lowest available price from a wholesaler is \$5,930.60
 - the average price from a third party compounder is approximately \$6,070
 - including all fees and mark-up, the amount the pharmacy receives for cabazitaxel is \$5,961.11
 - this means that the maximum total margin, from which all costs of compounding, supply, related services, consumables and capital are supposed to be met, is \$30.51 on a drug worth approximately \$6,000 per vial. If a third party compounder is used the pharmacy loses almost \$140 per prepared infusion, even before other costs are considered

Price Disclosure has hit chemotherapy drugs the hardest

- Price Disclosure was introduced in 2007. Manufacturers of PBS-listed drugs provide sales data to the government and the PBS price of the drugs is adjusted down to the average market price.
- Through Price Disclosure the government cost of chemotherapy drugs has already been reduced by a total of approximately **\$210 million per year** on a running annual basis (including the announced 1 April 2013 price reduction on paclitaxel). This is in addition to the approximately \$23 million per year saving produced by the new funding arrangements that started on 1 December 2011.
- 12 drugs listed under the chemotherapy funding arrangements have been subject to price reductions since December 2009, with the average total reduction being 67%.
- All of these price reductions have taken place since the CPCSG proposal was put forward to government in 2009.
- Since 2009, Price Disclosure has also changed with the introduction of Expanded and Accelerated Price Disclosure (EAPD) from December 2010. This resulted in some chemotherapy drugs being brought into Price Disclosure that were not expected to have been subject to that process when the proposal was put forward.
- The docetaxel and paclitaxel price reduction will bring the total saving through Price Disclosure on chemotherapy drugs to \$210 million per year (see attached appendix). After adding the savings generated from the new funding arrangements, **the total savings will exceed \$233million per year.**
- Of chemotherapy drugs that are off-patent, docetaxel was the final source of significant cross-subsidisation that offset the cost of preparing and supplying other chemotherapy drugs. From 1 December 2012 that came to an end.
- 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 and, when patents do expire, 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.



Appendix: Price Disclosure on Chemotherapy Drugs

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.

All of these price reductions have occurred after the alternative proposal was put to government in 2009. Three of the drugs listed below (carboplatin, epirubicin and methotrexate) have only been subject to Price Disclosure due to the introduction of Expanded and Accelerated Price Disclosure (EAPD) from 2010.

Chemotherapy Drugs Subject to Price Disclosure Reductions and Medicines Australia MOU

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

* Drugs brought into price disclosure as a result of Expanded & Accelerated Price Disclosure (EAPD)

~ Mandatory reductions as a result of Medicines Australia MOU

^ Ondansetron is not listed under the Efficient Funding of Chemotherapy program but is used for the management of nausea and vomiting in chemotherapy patients.