Australian Government

Department of Health and Ageing

Submission

to the Senate Standing Committees

on Community Affairs

Inquiry into the supply of chemotherapy drugs such as Docetaxel

April 2013

Senate Inquiry – Terms of Reference

On 7 February 2013, the Senate referred the following matters to the Senate Community Affairs Committees for inquiry and report:

(a) the supply of chemotherapy drugs such as Docetaxel, particularly in relation to:

(i) patient access to treatment,

(ii) cost to pharmacists and suppliers, and

(iii) cost to the private and public hospital systems;

(b) any long-term sustainable funding models for the supply of chemotherapy drugs, including Docetaxel; and

(c) any related matters.

The Department's submission was delayed by analysis of recently received information from providers on the complexities of business arrangements for chemotherapy and work to extract data to inform the Senate regarding the impact of price changes to the drug docetaxel and other chemotherapy drugs.

Chemotherapy in Australia

Chemotherapy drugs are chemical treatments that bind to and kill microbes and tumour cells. Cancer drugs are highly toxic and due to this toxicity, and the processes associated with managing the toxicity and short half-life of chemotherapy drugs, these drugs are managed under different funding arrangements to other drugs on the Pharmaceutical Benefits Schedule (PBS), with separate fees for the services involved.

Chemotherapy treatment involves several steps. Firstly, the appropriate dosage and mix of medications for the treatment of the particular condition must be personalised for the individual patient by the referring specialist. Once that dosage is determined, an infusion must be prepared with the appropriate mix of drugs, having regard to the body dimensions and organ function of the person receiving the drug and the potential for misadventure. These quality assurance steps are managed by a pharmacist or pharmacists, either at the time of preparation or at the time of application.

Preparation is a skilled task and requires significant infrastructure in ensuring the safety of the pharmacist, technicians and the patient themselves. The infusion is then delivered and administered intravenously for the patient. Chemotherapy infusions are either prepared in-house by the dispensing pharmacy or hospital, or by third-party compounders that specialise in preparing infusions.

PBS funding of Chemotherapy drugs

There are currently 36 drugs funded through special arrangements set out under the Efficient Funding of Chemotherapy (EFC) initiative. The amount paid by the Australian Government for chemotherapy drugs is expected to be over $570 million in 2012-13.

Chemotherapy is an effective treatment for many cancers. The Government has recognised this by providing new funding for a range of chemotherapy treatments. For example, since 2007, 30 new medicines to treat 15 different types of cancers have been listed on the PBS, at a cost of $1.3 billion. On 1 December 2012, the Government began subsidising temozolomide, a treatment for brain cancer that if not subsidised would cost patients over $7,000 per treatment. Other recent new cancer medicines listed on the PBS include cetuximab to treat bowel cancer costing the taxpayer $272 million dollars, cabazitaxel, a treatment for prostate cancer, which will cost $26 million dollars and save cancer patients nearly $6,000 per treatment and rituximab for leukaemia, which will cost $47 million dollars.

Background - funding for chemotherapy services

In addition to funding PBS drugs, the Australian Government also funds the cost of chemotherapy services relating to the preparation of infusions and dispensing of the drugs to patients.

Prior to the Fifth Community Pharmacy Agreement, funding for chemotherapy services was provided through a per-script rate, with a dispensing fee ($6.52) paid per script, no different to any other medicine, along with any mark-up on top of the cost of the drug. These arrangements in some cases caused wastage, where for example the doctor wrote up a script for a course of treatment with a particular drug, and the patient had to discontinue treatment partway through. This can happen because the patient changes therapies or, in some cases, because the patient has passed away.

The current funding model for chemotherapy drugs was put in place through the EFC measure. This measure was negotiated in the context of three interlinked measures – the Expanded and Accelerated Price Disclosure measure; EFC, and the Fifth Community Pharmacy Agreement (the Agreement).

The current funding model for chemotherapy emerged from the PBS reforms that commenced in 2007 and negotiations between 2009 and 2010 on the measures above.

Introduction of Efficient Funding of Chemotherapy

As part of the 2008-09 Budget, the Government announced a proposal to implement the Intravenous Chemotherapy Supply Program (ICSP) to reform funding arrangements for chemotherapy infusions. The aim of the program was reduce wastage across both the public and private sectors.

The Government subsequently agreed on 10 September 2009 to delay implementation of the ICSP. This was to enable the remuneration component of the ICSP to be negotiated within the context of all relevant policy measures for the remuneration of pharmacy, particularly the then upcoming Agreement, which provides for the fees associated with chemotherapy remuneration, as distinct from payments for the cost of chemotherapy drugs.

As part of the Fifth Agreement negotiations, the Pharmacy Guild submitted an "Alternative Funding Model for Chemotherapy". During the agreement negotiations the Commonwealth and the Guild agreed on this alternative funding model, and it formed the basis for the new EFC funding model. Details of the new EFC funding were announced in the 2010-11 Federal Budget as part of the Fifth Community Pharmacy Agreement Budget announcement.

The revised arrangements for the Efficient Funding of Chemotherapy Drugs (EFC) commenced on 1 December 2011. The aim of these revised arrangements was to achieve greater efficiency in the use of injectable and infusible chemotherapy medicines used in the treatment of cancer. Medicines used in cancer therapy dispensed via vials are expensive, with some drugs costing thousands of dollars per script. Specifically the revised arrangements:

- Require prescribers of chemotherapy medicines to write dose specific prescriptions measured in milligrams, without specific reference in the prescription to forms or strength of medications. That is, prescriptions must specify the individual patient does expressed in the appropriate unit of measure, rather than in vials, and the quantity and number of repeats on the prescription will be clinically appropriate for a single treatment cycle as set out by the Pharmaceutical Benefits Advisory Committee (PBAC); and
- Pay approved chemotherapy suppliers/pharmacies for the combination of vials of medicines that most cost efficiently makes up the required patient dose of chemotherapy medicine.

The revised EFC arrangements were implemented through a new 'special arrangement' under Section 100 of the *National Health Act 1953*. All relevant forms and strengths of drugs chemotherapy medicines, including trastuzumab for treatment of early stage breast cancer, are covered by the revised arrangements. Prescribers are no longer able to write prescriptions ordering particular forms or strengths of a drug, nor may they order enough drug for a course of treatment in a single prescription; they can only order enough for one infusion.

This revised approach to writing prescriptions is reducing wastage by limiting the amount of a drug prescribed to the amount required for one infusion/injection. Any combination of chemotherapy vials may be dispensed, but an algorithm covering all chemotherapy medicines determines the remuneration pharmacies will receive based on the most cost efficient combination of vials that make up a patient dose of medicine. To assist pharmacists in minimising the costs of infusions (because payment is now based on the least-cost combination of vials), these algorithms have been integrated into dispensing software to calculate, for each infusion, the most efficient combination of vial sizes.

Patients, pharmacists and EFC

Under the revised arrangements, cancer patients pay only one PBS co-payment amount ($5.90 for concessional patients, and $36.10 for general patients) for each original prescription dispensed, with no patient costs for any repeat prescriptions. This means that a cancer patient will only pay either $5.90 or $36.10 for the first injection/infusion on a chemotherapy medicine script. Co-payment amounts paid for chemotherapy medicines count towards a patient's PBS Safety Net.

Patients cannot be charged any additional payments above the co-payment amount by private or public hospitals for the supply of their required PBS chemotherapy medications.

New remuneration arrangements were also put in place for pharmacists that recognise the skill and complexity of preparing chemotherapy medicines for individual cancer patients. While other drugs generally only attract the ready-prepared dispensing fee ($6.52), the complexity of chemotherapy has been recognised with the implementation, from 1 December 2011, of the following current payments and fees:

- Ex-manufacturer price of the least-cost combination of vials;
- Retail mark-up on the ex-manufacturer price;
- $40.64 infusion preparation fee;
- $24.38 distribution fee (replaces the wholesale mark-up);
- $4.83 diluent fee; and
- $6.52 dispensing fee.

The total of current fees is $76.37; with the average mark-up of around $15 added, the Government currently pays around $91.37 per chemotherapy infusion on top of the medicine price, which can in some cases be thousands of dollars.

Background - Price Disclosure and Expanded and Accelerated Price Disclosure

The aim of price disclosure is to ensure that Australian taxpayers benefit from discounts and incentives provided by manufacturers for medicines where more than one brand is listed on the PBS. Once the patent on older medicines expires, the medicine can be sold under a number of different brand names. Manufacturers often sell these brands at prices much lower than the Government approved price in order to compete for market share, however prior to the introduction of price disclosure, the Government was still paying the full price. Price disclosure brings the Government price in line with the market price, benefitting both taxpayers and consumers.

In addition to statutory price reductions of PBS medicines, the PBS reform process introduced price disclosure for all Formulary 2 (F2) PBS medicines subject to competition from August 2007. F2 generally consists of medicines where the patent has expired and two or more brands are listed on the PBS.

In December 2010, the Enhanced and Accelerated Price Disclosure (EAPD) measure was introduced. This measure is different from the original price disclosure measure in regard to the removal of the requirement for a new brand of medicine listing on the PBS to 'trigger' data collection and the possible application of a price reduction. The EAPD framework was agreed between the Government and Medicines Australia via a Memorandum of Understanding signed in May 2010.

Under EAPD, pharmaceutical manufacturers submit sales revenue, sales volumes, and the value of incentives (for example, price discounts and bonus stock) for each of their brands of their brands of pharmaceutical medicines subject to price disclosure. An external service provider undertakes the data collection and performs all calculations on behalf of the Department.

Using this data, a disclosed price is calculated for each brand of a pharmaceutical item – that is the price the manufacturer is actually selling the medicine net of incentives. A weighted average disclosed price is then calculated based on the difference between the current ex-manufacturer price and the disclosed prices, weighted by volume across all brands and manner of administration. If there is more than a 10% difference between the current ex-manufacturer price and the weighted average disclosed price for a medicine, the ex-manufacturer price is adjusted to be equal to the weighted average disclosed price. All price disclosure calculations also undergo an independent third party quality assurance checking process.

Price disclosure and the price impact for patients

Some medicines that take price disclosure reductions will become cheaper than the co-payment amount. For example, if a medicine currently costs $60 and if via price disclosure the price reduces to $25, the patient will pay this amount rather than the higher co-payment amount. However not all formulations of medicines affected by price disclosure will result in direct savings for patients. For example, if a formulation of a medicine currently costs $100 and as a result of price disclosure, the price of the medicine is reduced to $50 (above the co-payment paid by patients), the patient would continue to pay the co-payment amount. However, the cost to the Government and taxpayers for this the medicine would be reduced.

It should be noted that not all chemotherapy drugs have received a price cut or will receive a price cut in a particular price disclosure round. For example, the upcoming 1 April 2013 price disclosure round will involve price reductions to only 5 of 36 listed chemotherapy drugs funded through Section 100 of the *National Health Act 1953*.

1 December 2012 price reduction to Docetaxel

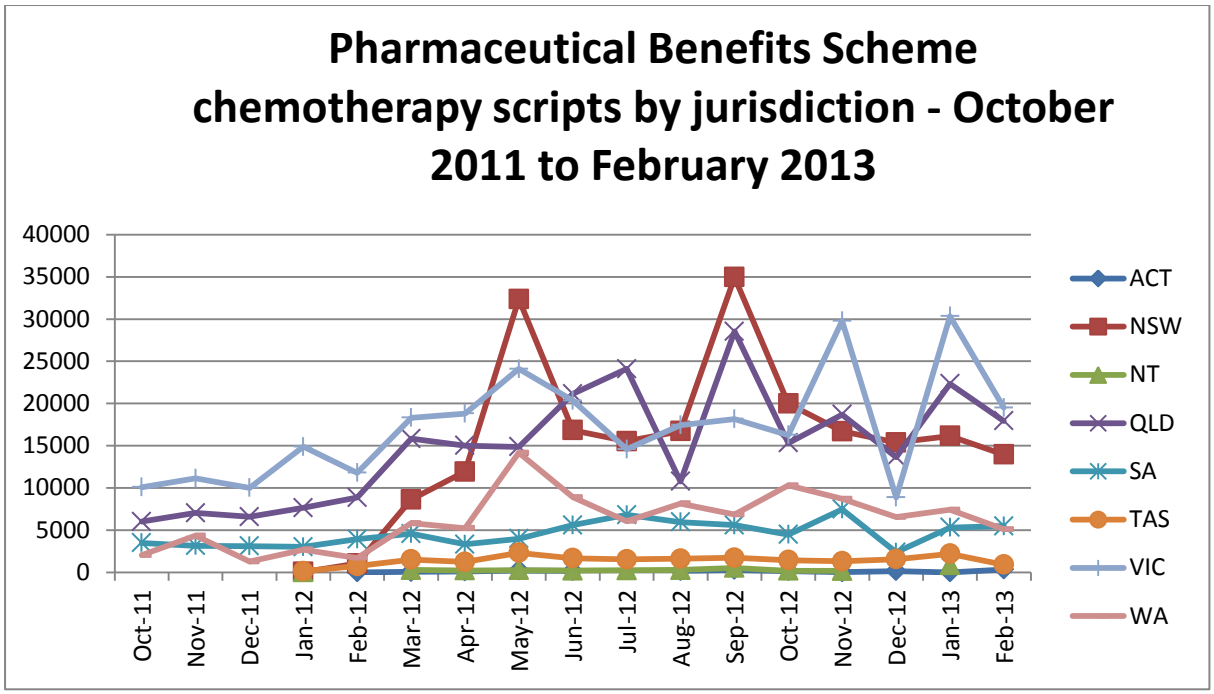
On 1 December 2012, the price the Government pays for Docetaxel was reduced by 76 per cent, bringing this price in line with the market price for this chemotherapy medicine. Docetaxel is a clinically well-established anti-mitotic chemotherapy medicine and it is primarily used for the treatment of breast, ovarian, prostate and non-small cell lung cancer. Up until that date the Commonwealth had been paying from 20 to 75 percent above the market price for this medicine resulting in the Government paying up to $2,800 above the market price per infusion. The price reduction of Docetaxel reflects the manufacturer discounts on different brands of Docetaxel since the first generic brand was listed on the PBS.

Price disclosure has had the effect of reducing the price the Commonwealth pays for chemotherapy medicines. As at 31 December 2012, EAPD had reduced the overall cost to the Commonwealth of chemotherapy medicines by approximately $165 million.

Ensuring transparent pricing arrangements is key to supporting the sustainability of the PBS, including the supply of chemotherapy medicines. A key aim of price disclosure is underpinning the sustainability for the PBS by ensuring that funds are available to support the listing of new medicines (including new chemotherapy medicines) on the PBS.

The effect of the 1 December 2012 Docetaxel price reduction

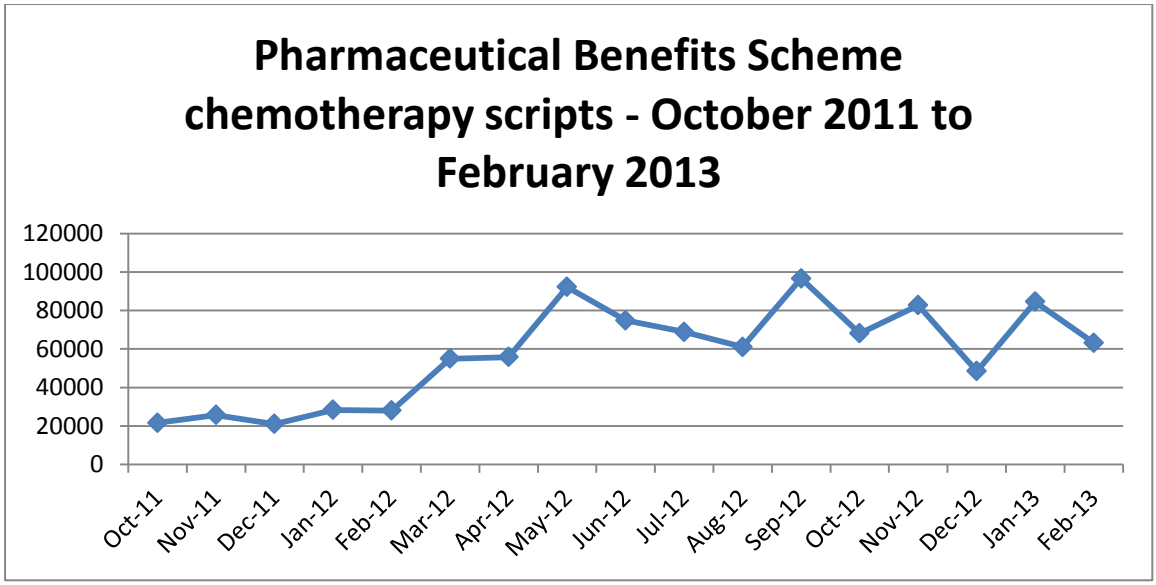
The Department has sought information and evidence to analyse the extent to which the reduction in the recently disclosed cross-subsidisation has affected pharmacies and hospitals providing chemotherapy.



Source: Department of Health and Ageing PBS data

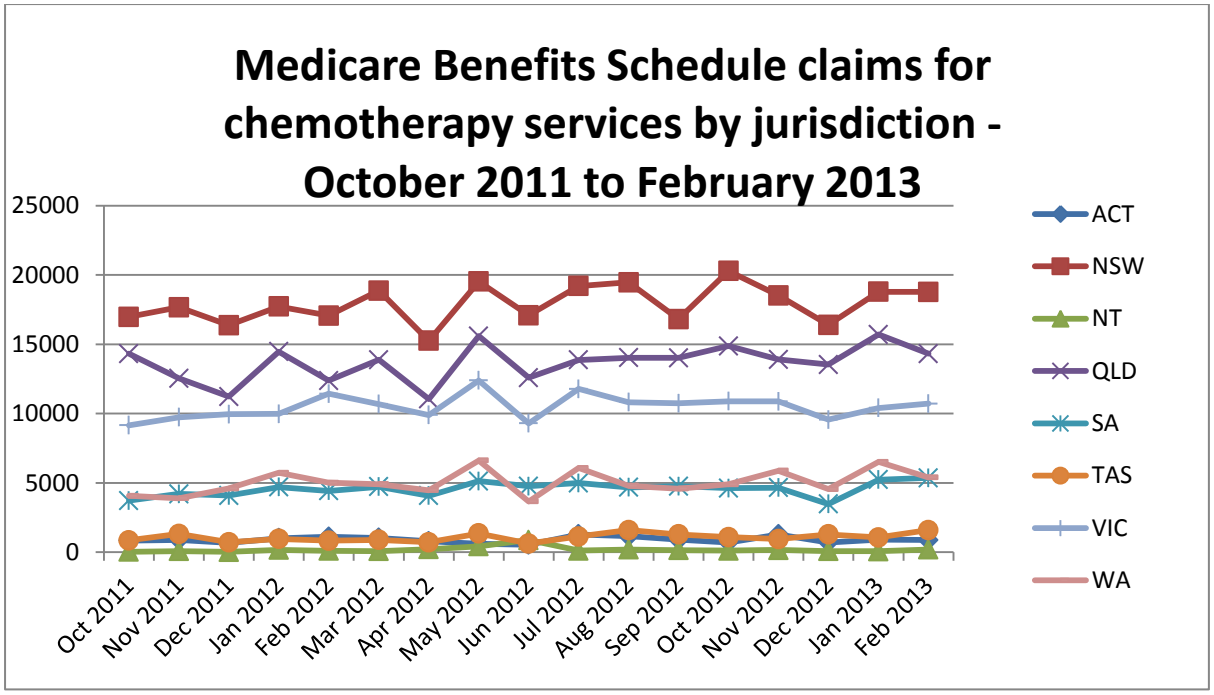
The above chart details the numbers of scripts claimed over the period October 2011 to February 2013. It should be noted that the initial period of the chart is prior to the introduction of the EFC measure on 1 December 2011. Prior to that date, a script for chemotherapy was equal to one vial of a chemotherapy drug rather than the current arrangements which require specification of a dose per milligram of relevant chemotherapy drugs. Therefore, script counts for October 2011 to February 2012 are not directly comparable to the months afterward and are included only for historical interest.

As can be seen in the fluctuations in script numbers over time, there seem to be significant seasonal or patient-related effects that lead to large variations in the amount of chemotherapy drugs claimed. December is a known period during which the holiday season and staff leave can result in lower numbers of drugs or services being provided. At this stage, there is no statistically significant variation to suggest that the amount of chemotherapy drugs being dispensed has changed due to the Docetaxel price reduction.



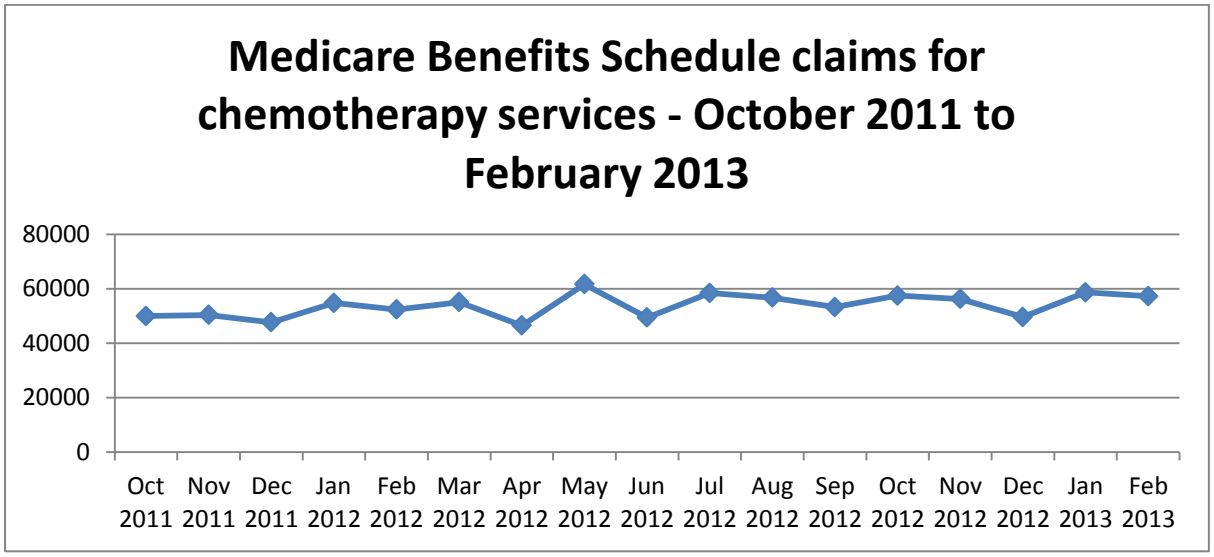
Source: Department of Health and Ageing PBS data

The chart above indicates similar seasonality effects to the State/Territory data. As per the previous data, caution should be taken in interpreting trends across the range of months, because the initial period involved PBS arrangements different to those in place from 1 December 2011 onwards.



Source: Department of Health and Ageing MBS data

The chart above shows Medicare Benefits Schedule item claims for cytotoxic chemotherapy services provided by oncologists over the same period. Again, seasonal effects can be seen in December 2012, but there is a resumption of average claims in January 2013 onwards. Unlike the PBS data presented above however, there was no change in MBS funding arrangements in December 2011.



Source: Department of Health and Ageing MBS data

The chart above reflects similar seasonality effects to the State/Territory MBS data, although the quantum of fluctuations in claims is significantly smaller than shown in the PBS data on pages 9 and 10.

In addition to the data above, the Department has received some anecdotal advice from stakeholders on the effect of the price reduction. The Department is not aware of any cessation of services.

Actions taken by the Department in response to concerns

The Department has worked to identify the extent to which the price reduction of Docetaxel, and subsequent reduction in cross-subsidy for chemotherapy services will affect pharmacies, hospitals and consumers.

As a result of concerns about the impact of the price reduction of Docetaxel raised by a number of stakeholders, the Minister for Health, the Hon Tanya Plibersek MP requested that staff from the Department visit key organisations to gain a first-hand understanding of the possible impact of the Docetaxel price reduction on the provision of chemotherapy medicines. In late 2012, senior staff from the Department visited a number of chemotherapy suppliers, third party chemotherapy compounders, and private hospitals with chemotherapy services, across Australia to understand this issue.

The Department has sought information widely, including from hospitals and pharmacies, the Australian Private Hospitals Association (APHA), the Society of Hospital Pharmacists of Australia (SHPA) and from the Pharmacy Guild of Australia (the Guild).

In addition to the evidence recently gathered by the Department, the Expanded and Accelerated Price Disclosure (price disclosure) measure has also played an important role in clarifying, through greater transparency, the total funding being provided for chemotherapy in Australia.

As well as site visits, the Department also commenced a process of regular meetings and teleconferences with members of the Guild. A key early outcome of these meetings was the agreement for the Guild to collect cost data from a wide sample of third party chemotherapy compounders, hospital pharmacies and community pharmacies and provide this to the Department. A wide group of organisations and individuals provided sensitive commercial information documenting the costs of key elements in chemotherapy supply.

Initial findings from visits and evidence gathering

The site visits the Department undertook and data obtained provided a firsthand understanding of the current costs for the supply of chemotherapy medicines in a number of settings. The visits provided anecdotal evidence, for the first time, that the price that the Government was paying for PBS chemotherapy medicines was not only being used to subside the costs of the supply of chemotherapy medicines; but also being used in a number of ways to underpin the costs of a range of other mainstream elements of the Australian healthcare system.

It is clear, based on the available evidence, that supplier discounts from Docetaxel and other drugs subject to EAPD have helped to subsidise the cost of chemotherapy services.

Specifically, information provided to the Department has identified that the pre-price disclosure pricing of PBS chemotherapy medicines was being used in different ways to cross-subsidise the following activities in the Australian health system:

- The funding via the PBS prices for chemotherapy medicines of a number of additional clinical services in private hospitals, aimed at ensuring the right patient gets the right dose of chemotherapy and reducing the risk of medication misadventure. Traditionally such services have been funded by private health insurance; and
- Through the outsourcing by public hospitals of their chemotherapy services to private providers, the increase in the funding of these services via the PBS.

Clinical services relate principally to:

- multidisciplinary liaison i.e. between pharmacists, oncology specialists, nursing staff and other healthcare providers;
- determining and preparing the appropriate dosage and mix of chemotherapy drugs, having regard to the body dimensions and organ function of the person receiving the drug and the potential for misadventure; and
- any follow-up required after the dose has been provided.

These clinical services are provided by a pharmacist or pharmacists, either at the time of preparation or at the time of application.

Initial evidence gathering did not indicate any short-term impact from price disclosure on the provision of chemotherapy services. However, it did reveal that chemotherapy services are underpinned by complex funding arrangements in the public and private health systems, and provided through a range of business models.

The private health system provides around 60% of all chemotherapy services. The majority of infusions supplied in the private health system are outsourced to third-party compounders. Where a third-party compounder is used, the community pharmacy sometimes acts as a wholesaler – that is, purchasing infusions from a compounder to on-sell to a hospital. The drugs are generally administered to patients in out-patient settings.

Chemotherapy infusions are also prepared in-house by hospitals and a very small number of community pharmacies. The other model of service provision in the private health system is a vertically integrated model, which may include clinics providing imaging services, oncology services, cytotoxic preparation services and chemotherapy-related clinical services under the umbrella of a single business.

Outside of the cost of infusions, the Department has been advised that the cost of clinical and associated services has been managed to date by hospitals in private and public settings via the cross-subsidisation of hospital services from the price the Commonwealth has paid for chemotherapy medicines.

The public health system provides a relatively small proportion of all chemotherapy services, in terms of funding provided through the Health Care Agreements. The notable exceptions are in New South Wales and the Australian Capital Territory. These Governments have not signed pharmaceutical reform agreements and therefore public hospitals in these two jurisdictions are ineligible to apply to become PBS providers. In all other States and Territories, hospitals can provide chemotherapy infusions under the PBS and claim the

relevant fees. Those public hospitals claiming the PBS operate under the same three models present in private settings.

Current situation

Discussions with stakeholders and confidential data have identified three key aspects to the provision of a chemotherapy drug:

- The preparation of a chemotherapy infusion;
- Processes associated with the management and dispensing of the chemotherapy infusion; and
- Clinical services associated with the safe delivery of chemotherapy drugs.

Costs for providers vary in relation to each of these key areas, based on the particular business model used, whether a third party is sourced to provide infusions, and economies of scale.

The Department and Guild continue to work in good faith towards agreeing a cost basis for these three aspects of chemotherapy funding and a source of funding for any changes.

Questions raised at 28 March Senate Inquiry hearing

Several questions were raised at a 28 March 2013 hearing that the Senate requested be addressed in the Department's submission.

Senator Fierravanti-Wells asked:

> *"Let us take the next step. At the moment let us assume that the cost is, as we were told, $97 – say $100 – which works out to 800,000 doses and $80 million. If you have a situation where the state hospitals then take over some of this work then that means that it will come within the basis of activity-based funding and, therefore, we are potentially going to see the same amount of money being paid, only it is going to go via the state hospital systems for them to be able to provide this service currently provided by the private sector. Is that a fair estimation of the situation?"*

Answer:
As indicated during the hearing, the transfer of services from the private to the public sector remains a hypothetical outcome. In that context, it is only possible to comment generically, noting that circumstances may vary significantly between providers and across locations.

The services provided in the public and private sector are not easily comparable. In the private sector, there are a range of funding sources for the costs of chemotherapy, including the price paid by the Commonwealth for the cost of the drug, the associated fees for the dispensing of chemotherapy medicines, and separate payments for any clinical services. These services may be funded through the Medicare Benefits Schedule, private health insurance or in some occasions may be directly paid for by the patient.

In the public sector, an episodic payment is made for chemotherapy which is designed to cover the continuum of care needed for each chemotherapy episode. It may cover a different range of clinical and other services provided in the private sector.

Senator Xenophon asked:

> *"And I have a question on notice; given the capping of public hospital funding, what the impact will be on the public lists – what the waiting times would be."*

Answer:
The Department is not in a position to quantify the possible effect on waiting lists of chemotherapy patients moving between the private and public health sectors. The most current available data on public hospitals from the Australian Institute of Health and Welfare is for 2010-11.

The Department does not have access to detailed financial information for the nearly 300 providers that undertake chemotherapy services in Australia. Without such information, the Department cannot predict whether certain providers are intending to refer patients from the private to the public system, the number of patients that may be referred, nor over what timeframe this might occur.

Closing comments

Chemotherapy services, and cancer treatments generally, are complex, and delivered in a range of settings through a range of different business models. Cancer treatments are multi-layered and multidisciplinary, involving a number of health professionals who work together to ensure the safe and effective treatment of patients with this disease.

In the context of the range of funding models for cancer treatments, the arrangements for EFC were put in place to ensure that patients can continue to access vital cancer drugs at a price that is affordable for the Government and taxpayers. These arrangements were developed in parallel with the EAPD measure and the Fifth Community Pharmacy Agreement, to form an interlinked set of measures for the ongoing funding of pharmacy services. The EFC arrangements did not contemplate a cross-subsidy for chemotherapy services.

There have been no suggestions from any stakeholders that the efficiencies generated for taxpayers by the EFC and EAPD measures are inappropriate. As the only other source of available funding, and the structural model for remuneration for pharmacy services, the Fifth Community Pharmacy Agreement has been identified by the Government as the appropriate source for funding chemotherapy fee changes.

The Department is committed to ensuring the long-term viability of cancer treatments, including chemotherapy drugs. To this end, when concerns were first raised about a likely shortfall in funding subsequent to the price disclosure of Docetaxel, the Department sought a range of information and evidence to determine the extent to which this was the case, and what actions might be required to ameliorate this issue.

The Department continues to work in good faith with the Pharmacy Guild to reach a speedy resolution to this issue.