

**Head Office**

14 Palmer Court  
Mount Waverley, Victoria 3149

Telephone 03 9565 4400

Facsimile 03 9565 4488

[www.slade.net.au](http://www.slade.net.au)

Mr Mike Wallace  
Chair of the Chemotherapy Review Team  
Department of Health and Ageing  
Chemotherapy Review  
MDP 901  
GPO Box 9848  
Canberra ACT 2601

Dear Mr Wallace,

**Re: Review of funding arrangements for chemotherapy services**

I am pleased to submit the following responses in relation to the discussion paper into the review of funding arrangements for chemotherapy services.

Whilst there are different models of care in the cancer setting it is internationally recognised that providing cancer services and preparing sterile infusions is a complex and high risk activity where quality of service and the involvement of specialist pharmacists is of paramount importance.

**Executive Summary**

- The government has made substantial savings on the PBS as a result of price disclosure on chemotherapy medicines. These savings are in excess of \$200m. A portion of these savings needs to be reinvested back into the system to ensure a safe and viable chemotherapy supply chain;
- The appropriate way to fund chemotherapy services is to provide a transparent 'fee for service' which recognises the critical components in the chemotherapy supply chain;
- The fee should cover all the costs associated with reviewing, preparing, delivering, dispensing a safe and high quality chemotherapy infusion to a patient in either a regional or metropolitan area, private or public hospital;
- Cancer medicines are expensive and the costs associated with purchasing, storing and holding the medicines must continue to be recognised;
- The fee should be split into a 'clinical & dispensing' and 'preparation' component;
- The fee should be set at a value which recognises the high risk in reviewing, preparing, delivering and dispensing chemotherapy, the significant cost associated with sterile facilities, equipment and highly skilled personnel required to prepare infusions and the cost for the provision of advanced care pharmacists who provide clinical services in this area;
- Providers of chemotherapy services should be quality accredited in order to receive the respective component fees from the Commonwealth;
- Whilst the PBS remunerates pharmacists for the original drug cost ex-manufacturer, this does not represent the cost of the prepared and delivered infusion to the pharmacy. The PBS price must be an all inclusive price to ensure chemotherapy is not being supplied at a loss by pharmacies;

- The administrative burden associated with the collection of all paper prescriptions (Authority and standard) should be removed by allowing the chemotherapy drug chart to be accepted as the prescription;
- The PBS algorithm for the calculation of the payment for high cost medications pharmacists must be corrected.

I would welcome further discussion with the Department on any aspect of this discussion paper to support the review into the appropriate funding of chemotherapy to patients.

Yours sincerely,



**David Slade**  
**Managing Partner/Director**

**Terms of Reference 1 and 2: How chemotherapy medicine infusions are provided, the role of each sector, and how services and funding roles have changed over time**

1. *Describe the model of care for the provision of chemotherapy medicine infusions that apply in your healthcare sector or the institution in which you practice. Please consider all components from the clinical decision to order an infusion to follow-up after the course or cycle has been completed.*

Slade Pharmacy (Slade) provides clinical pharmacy and dispensing services associated with chemotherapy and also operates its own Therapeutic Goods Administration (TGA) licenced compounding facility which prepares and supplies sterile infusions.

In the private hospitals serviced by Slade, the private hospital completely outsources its chemotherapy pharmacy requirements and relies on the Slade team to work with the nursing and medical staff in the management of chemotherapy medicines for patients.

Slade, is responsible for all aspects of chemotherapy supply and management which includes *inter alia*:

- the provision and management of specialist onsite pharmacy personnel in accordance with Australian Pharmacy Board Guidelines;
- providing clinical pharmacy services to patients, nursing and medical staff of the hospital;
- coordinating the review, ordering and management of the chemotherapy infusions;
- checking the scheduling of the chemotherapy cycles to ensure an appropriate amount of time has passed between cycles of chemotherapy in accordance with the relevant chemotherapy protocols;
- providing counselling and medicine information to patients;
- coordinating the administrative tasks associated with the management of chemotherapy items;
- communicating and coordinating supply with the Slade TGA accredited sterile compounding suite;
- preparing chemotherapy infusions at Slade's TGA compounding suite.

In all settings, the role of the pharmacist commences once the doctor has placed the order and continues to when the patient has been discharged and leaves the facility.

The pharmacists follow Society Hospital Pharmacists Australia (SHPA) standards for the practice of Clinical Pharmacy Services in hospitals and the SHPA standards for the Provision of Clinical Oncology Pharmacy Services.

The sterile compounding suite operates in accordance with Good Manufacturing Practice (GMP) Standards and Guidelines and is licenced by the TGA for the

preparation of sterile infusions. Specifically the TGA facility operates in accordance with and is audited against the following:

1. Guide to good manufacturing practice for medicinal products part I PE 009-9 (part I) 1 September 2009
  2. Guide to good manufacturing practice for medicinal products part II PE 009-9 (part II) 1 September 2009
2. *Describe the professional and administrative practices for the provision of chemotherapy medicine infusions within the healthcare sector/s in which you participate and the business model/s which support them.*

There are many professional and administrative practices associated with the provision of chemotherapy infusions within the hospitals in which Slade operates.

The professional practices undertaken by Slade Pharmacy personnel are in accordance with widely and publicly documented practice standards - the details of which can be found in the **SHPA Standards for Clinical Pharmacy Services**, the **SHPA standards for the Provision of Clinical Oncology Pharmacy Services** or the **Clinical Oncological Society of Australia (COSA) guidelines** for the safe prescribing, dispensing and administration of cancer chemotherapy:

As part of this practice the responsibilities of the pharmacist both professional and administratively include:

1. The clinical verification of the drug order including chemotherapy, targeted therapy and supportive medications, according to the protocol, the patient's treatment plan and patient parameters;
2. Checking the dose against the patient's BSA (body surface area); and the appropriateness of each drug according to the relevant protocol including:
  - i. Drug
  - ii. Strength
  - iii. Dose
  - iv. Route
3. The clarification and resolution of any identified discrepancies with the protocol;
4. The accurate dispensing of chemotherapy, targeted therapy and related treatment including supportive care therapies. This includes a review of pre-treatment and post treatment medications, treatment scheduling: time between cycles, multi-day and multi-drug treatments, review of blood counts and other relevant biological and physiological marker tests, drug interactions and adverse drug reactions. Additionally, patients are counselled regarding possible side effects of their chemotherapy and how best to manage some of the side effects;
5. Ensuring the appropriate preparation of the infusion;
6. Ensuring that all components of the prescription are dispensed in a timely and safe manner;
7. Ensuring that all professional and legal responsibilities with respect to dispensing are met;

Some of the administrative practices include:

1. Purchasing and storage of high cost medication: Most cancer medicines are very expensive and require strict temperature controlled environments for their storage. Appropriate refrigeration needs to be in place for medication storage and systems which provide alerts when temperatures go out of range must be installed. The installation and maintenance of these systems comes at a significant cost.
2. General Prescription processing and management: keeping patients prescriptions on file and ensuring their validity for each treatment cycle;
3. Owing prescription management – ensuring doctors provide standard PBS prescriptions for any medication written on the patient’s medication therapy chart.
4. Authority prescription management - ensuring doctors provide, prior to supply, valid PBS Authority prescriptions for any medication written on the patient’s medication therapy chart;
5. Streamlined Authority prescription management – advising doctors, prior to supply, on valid PBS Authority prescriptions with appropriate streamline codes for medication written on the patient’s medication therapy chart;
6. Drug chart signing - ensuring the correct PBS details are certified on the patients medication chart when a PBS supply is made;
7. Scheduling of orders in line with patient bookings;
8. Compiling individual treatments to orders to be placed with sterile compounding suite;
9. Liaising with the sterile compounding suite for late adjustments to chemotherapy orders;
10. Liaising with sterile compounding suite for approving orders previously placed ‘on hold’;
11. Ensuring on time delivery of chemotherapy drugs and following up on any delayed treatment;
12. Marking off delivered chemotherapy drugs and checking delivered products matches patient order (right patient, right drug, right dose, right route);
13. Updating patient medical files relating to medications;
14. Dispensing: including pre-medication drugs, chemotherapy treatment drugs and post-treatment drugs.

3. *Can you identify and describe any changes to the provision of chemotherapy medicine infusion services over recent years? Have these changes (if relevant) affected consumer access to services and, if so, how?*

There are more patients being admitted to private cancer care facilities over time. With newer, more expensive and more complex medicines being available, the increasing use of complementary medicines with the potential for interactions, pharmacists are being relied upon more heavily to ensure appropriate medication screening of patients and their regimen to ensure their chemotherapy medicines are safe and appropriate. This places more pressure on the pharmacists to review each patient's complete medication regimen, including their regular medicines and to check them for any potential side effects with their chemotherapy.

Chemotherapy is highly toxic medication and the personnel involved with handling and administering the medication must be protected from any occupational exposure. Hospitals and compounding facilities must provide the appropriate equipment and clothing to ensure personnel are protected. The relevant state guidelines on Workplace Health and Safety are explicit in their requirements – refer to the South Australian guidelines for “Safe Handling of Cytotoxic Drugs and Related Wastes: Guidelines for South Australian Health Services 2012”.  
<http://www.sahealth.sa.gov.au/wps/wcm/connect/f8aa68004b3f6cf6a340afe79043faf0/SafeHandlingOfCytotoxicDrugsRelatedWastesGuideline-PHCS-120515.pdf?MOD=AJPERES> , (accessed July 26<sup>th</sup> 2013).

There is also a growing trend for chemotherapy infusions to be prepared and supplied with a closed system transfers devices to reduce the risk of exposure to personnel. The attachment of these devices adds a further step in the process of manufacture and administration and further cost to the treatment.

4. *If third party compounders of chemotherapy medicines are used within your sector or institution please describe where and how they are incorporated within the practice and business model. Also discuss the reasoning for the decision to involve a third party compounder in preparing the chemotherapy infusions.*

Slade operates a sterile compounding facility licensed by the TGA to prepare sterile infusions. The TGA licenced compounding facility was opened in 2012 in Mt Waverley in response to hospital quality requirements which required patients' sterile infusions to be prepared in TGA accredited facilities. The TGA certification provides an extremely high level of assurance for product quality. TGA licensed facilities providing sterile infusions are routinely and independently audited by the TGA as they fall into the highest risk category of manufacturing.

The pharmacies work closely with the sterile compounding facility by placing their orders for compounded products daily. The compounding team purchases and stores the medication, prepares the infusions and provides information to the pharmacy team on product stability, ingredient compatibility, shelf life, delivery and storage.

Given the significant investment in establishing and operating a TGA licenced sterile facility, it is not commercially viable to have a compounding centre at each hospital where cancer services are provided. Therefore, economies of scale are achieved by using the one compounding centre to provide infusions to a number of day clinics.

5. *Please describe the components of dispensing and clinical services provided in relation to infusible chemotherapy medicines? It may be useful to provide a comparison with dispensing practice for non-infusible medicines, such as tablets. Please consider the differences in relation to costs, time involved, skills required, outcomes achieved and activities undertaken?*

The process and components for dispensing and associated clinical services provided in relation an infusible chemotherapy medicine are well established and documented in the both the SHPA standards for Clinical Pharmacy Practice, SHPA standards for the provision of Oncology Services and the COSA guidelines on the prescribing, dispensing and administration of chemotherapy cancer medicines.

Furthermore, the Guild submission to the Senate Committee Inquiry into the supply of chemotherapy drugs such as docetaxel earlier this year clearly outlines the components of dispensing an infusible chemotherapy medicine compared to a standard medicine.

Should more information be required, Slade can provide this on request.

6. *Describe in detail one or more possible options for:*
- *possible funding models for the preparation and supply of chemotherapy medicine infusions;*

Funding models should include the following key principles and considerations:

1. A fee per infusion of chemotherapy which recognises the 'preparation' and 'clinical & dispensing' components associated with each dose of chemotherapy supplied;
2. The fees should be paid to 'approved' accredited suppliers of chemotherapy services;
3. The quality of the providers should be subject to audit;
4. The fee should recognise the high risk nature of preparing sterile chemotherapy infusions and the significant investment required in building and maintaining such facilities and training personnel;
5. The fee should recognise the importance of the pharmacist in clinically reviewing, checking and dispensing the chemotherapy;
6. Whilst the PBS remunerates pharmacists for the original drug cost ex-manufacturer, this does not cover the cost of the compounded and 'delivered to patient' infusion. The PBS price to pharmacist must reflect a 'compounded' and 'delivered' drug cost;
7. The fee should be split into a 'clinical & dispensing' and 'preparation' component;

- a. The 'preparation' component should only be paid where an accredited facility / pharmacy operating to a recognised standard is used to prepare the infusion.
    - i. The fee would cover the cost of drug preparation, storage and validated temperature controlled delivery;
  - b. The 'dispensing and clinical' component should be paid in accordance with agreed standards relating to chemotherapy pharmacy service provision.
    - i. The standards which apply for the accreditation already exist and the administration of the accreditation could be conducted by various professional organisations ie The Pharmacy Guild QCPP program, Society Hospital Pharmacists Australia or Pharmaceutical Society of Australia;
  - c. The fees for each would be a fixed amount regardless of drug prepared;
  - d. The fee would be indexed each year;
  - e. The fee is payable per each PBS infusion ordered, prepared and supplied in good faith.
8. A mark up on the cost of the drug must be applied to recognise the costs involved in purchasing, storing and holding the medication.
  9. 'Approved suppliers' need to be accredited / audited for each component of the service they provide;
  10. Removal of the administrative burden associated with the collection of all paper prescriptions (Authority and standard prescriptions) by allowing the chemotherapy drug chart to be accepted as the prescription.



- the appropriate level and source of funding for each component of practice (described in response to Q6).

Component	Current Fee	New Fee	Source of Funding
<b>Dispensing and Clinical Fee per infusion</b>			
Dispensing Fee	\$6.63	\$6.63	Existing
Clinical Fee	-	\$20.00	Additional new funds out of PBS savings on price disclosed chemotherapy medicines
<i>Sub total</i>	\$6.63	\$26.63	
<b>Preparation Fee per infusion</b>			
Dist. Fee	\$24.79	\$24.79	Existing
Diluent Fee	\$4.91	\$4.91	Existing
Preparation Fee	\$101.33	\$121.33	Additional new funds out of PBS savings on price disclosed chemotherapy medicines
<i>Sub Total</i>	\$131.03	\$151.03	
<b>Total</b>	<b>\$137.66</b>	<b>\$177.66</b>	

In addition to the above fees, a mark-up is currently paid to the pharmacy which recognises the holding and administrative costs associated with buying, storing and managing the medicines. This mark-up must continue to be paid.

### **Part C: Source of funding**

The saving achieved by the PBS as a result of ongoing price disclosure on chemotherapy medicines alone has been substantial. These savings are ongoing and will continue to increase over the coming years.

To date, the government has saved over \$200 million dollars and the aforementioned fees represent a 30% reinvestment of the savings back into the cancer sector.

It is inappropriate for the funds to be in any way related or come out of the 5<sup>th</sup> Community Pharmacy Agreement. The majority of chemotherapy supplied

comes from specialist hospital pharmacy service providers or departments who operate in the public or private hospital system.

## **COSTS AND COMPLEXITIES INVOLVED IN THE PROVISION OF CHEMOTHERAPY DRUGS**

- *Are there significant differences in the processes or costs of compounding certain infusible chemotherapy medicines? If so, please identify those medicines; describe the different practices or processes and evidence to support your position.*

The processes and costs to compound infusions are complex. The medicines are toxic and strict sterile conditions need to be maintained at all times during the compounding process. The facilities and equipment required for the preparation of the infusion are extensive and costly to install and maintain. Furthermore, the personnel who handle the medicines need to be protected from exposure to the medicines.

The process to compound a sterile infusion must be regulated such that the quality of the prepared product is assured and patient safety maintained. There are well documented international and Australian standards which can and should apply to all facilities preparing such medicines. These have been referenced throughout this document.

Certain drugs, due to their particular stability, chemical or biological composition require special and different handling.

For example, such medicines include:

<b>Drug/Device</b>	<b>Indication</b>	<b>Issue</b>
Bacillus Calmette and Guerin (BCG, strain Tice). Live attenuated mycobacterium	Carcinoma of the bladder	2 hours stability once prepared. Must be transported and then infused into the bladder within this time frame otherwise treatment ineffective. Requires separate biohazard drug safety cabinets for its preparation. Temperature sensitive product requiring refrigeration during transport
Paclitaxel Nano (Abraxane®)	Treatment of metastatic breast cancer	It takes 15 minutes to reconstitute this item and ensure it dissolves, before it can be prepared as an infusion
Monoclonal Antibodies which include: <ul style="list-style-type: none"> <li>- Trastuzumab</li> <li>- Rituximab</li> <li>- Bevacizumab</li> <li>- Cetuximab</li> </ul>	Various cancer types	Due to their sensitive nature and composition, these products can not be shaken to assist with the reconstitution process. They can take longer to prepare. Instructions for dissolution often include requirements for product to stand for some minutes prior to withdrawal and dilution. Temperature sensitive product requiring refrigeration during transport
Continuous Ambulatory Delivery Device (CADD)	Mechanical device used for the delivery of chemotherapy to an ambulatory patient over an extended period	The device takes longer to fill and requires specially trained staff to prepare. The device

		cannot contain air bubbles within the bladder or tubing.
Elastomeric Devices	Balloon device used for the delivery of chemotherapy to an ambulatory patient over an extended period	The device takes longer to fill and requires specially trained staff to prepare.
Cyclophosphamide/ifosfamide	Multiple cancer types	It takes approximately 6 minutes of constant agitation to dissolve one vial of product. Then additional time to withdraw and prepare the infusion.
Gemcitabine Powder for injection	Multiple cancer types	Takes 6 minutes to dissolve and prepare an infusion
Azactidine (Vidaza ®)	Multiple cancer types	Takes 6 minutes to dissolve. The reconstituted solution must be transported and administered to the patient within 1 hour when made for IV use
Refrigerated drug lines include <i>inter alia</i> : Herceptin® Avastin® Vidaza® BCG Etc All drugs must be stored between 2 and 8 degrees Celsius.		The prepared infusions must be stored at the appropriate temperature to maintain their viability. Exposure to high or low temperatures can render the product inactive. Considerable additional costs are associated with validated temperature controlled packaging
Cabazitaxel (Jevtana®)	Metastatic prostate cancer	Takes 8 minutes to dissolve and prepare infusion. Cannot be shaken to aid dissolution as product will foam.

Carmustine	Multiple cancer types	Two step dissolution process, takes 15 minutes to dissolve and prepare an average dose infusion
Drugs with small vial sizes relative to commonly prescribed doses, including: Herceptin® (e.g.dose of 540mg) Dacarbazine (dose of 2000mg)	Multiple cancer types	Products with many vials going into one product take longer to compound than those with smaller vial: product ratios. E.g. Herceptin 540mg dose uses 2x150mg and 4x60mg, dacarbazine 2000mg uses 10x200mg.
High administrative compliance dispensing e.g. Lifesaving Drugs Program HIC Herceptin® (late stage metastatic breast cancer) Program	Multiple cancer types	Additional compliance burden for each unit produced (raw material reconciliation etc)
Intrathecal dosing e.g. Methotrexate Cytarabine	Multiple cancer types	Most facilities require infusions for intrathecal administration are filtered through a 0.22 micron filter during the compounding process

The more complex products and ambulatory devices take more time to manufacture and prepare. Personnel involved in their preparation require more expertise and training. Therefore these infusions have greater costs associated with their preparation.

Temperature sensitive products require special packaging during transport. This is critical when transporting infusions over long distances to rural and regional areas. Overly hot or cold days or incorrect storage conditions can affect the stability of the product resulting in it being unusable for patients once it arrives at the facility. This is particularly relevant when sending infusions overnight or over the weekend where the products can be in transit in non-temperature controlled warehouses for an extended period.

Whilst refrigerated original vials/packs are often transported from the manufacturer to the pharmacy compounding facility in special temperature

controlled packaging, the same type of packaging must be used when transporting the prepared infusion to the hospital / facility where the patient is being treated. The packaging insulates the product and guarantees a particular temperature range over a defined time period. The use of this packaging is likely to be mandated by the TGA at accredited compounding facilities.

The cost for this packaging ranges from \$25 – \$96 per box depending on its size. This includes the outer cardboard lining and the insulating gels used to regulate the temperature. Whilst the boxes and insulating material are reusable for a period of time, compounding suppliers need to organise 'reverse logistics' in an endeavour to get the boxes back which is an expensive process. The boxes often are damaged or they are misplaced by the customer and don't end up being returned.

## **QUALITY OF INFUSION PREPARATIONS**

- *What are the range of relevant guidelines and standards that apply to chemotherapy services across States and Territories? How are these standards enforced – i.e. regulations, on-site audits? Which if any of these standards should apply where drugs are being compounded on-site, or purchased from a third party, or prepared days before the infusion is delivered? How are adverse events monitored and reported?*

### **Relevant guidelines and standards for providing chemotherapy services**

1. SHPA Guidelines for Medicines Prepared in Australian Hospital Pharmacy Departments
2. SHPA Standards of Practice for the Provision of Clinical Oncology Pharmacy Services
3. SHPA Standards of Practice for the Safe Handling of Cytotoxic Drugs in Pharmacy Departments
4. SHPA Standards of Practice for the Transportation of Cytotoxic Drugs from Pharmacy Departments
5. PIC/S Guide to good practices for the preparation of medicinal products in Healthcare Establishments PE 010-3 1 October 2008 (hospital pharmacy)
6. PIC/S Guide to good manufacturing practice for medicinal products part I PE 009-9 (part I) 1 September 2009 (TGA licenced facility)
7. PIC/S Guide to good manufacturing practice for medicinal products part II PE 009-9 (part II) 1 September 2009 (TGA licenced facility)

The above guidelines document all the quality requirements, processes validations and certification requirements of facilities and people when providing chemotherapy.

### **Enforcement of Standards**

The TGA enforces the PIC/S Guides (Part I and II) and conducts regular onsite audits of 3<sup>rd</sup> party compounders.

Currently pharmacies (public and private) are not subject to routine onsite audits. However should audits be introduced they would be subject to onsite audits of points 1. – 5.

- *Should meeting any of these standards be a mandatory requirement for Commonwealth funding? If so, which? How would this be managed or enforced? Are there different standards that should be met depending on the circumstances under which the infusion is prepared? What would the effect of any changes be for consumers, in terms of access to and quality of chemotherapy services?*

*Should meeting any of these standards be a mandatory requirement for Commonwealth funding?*

Yes. Pharmacies and compounding facilities must meet the relevant PIC/S / SHPA standards and guidelines in claiming Commonwealth funding.

*How would this be managed or enforced?*

The TGA currently enforce the standards for 3<sup>rd</sup> party compounding facilities.

The Australian Pharmacy Board or relevant state Pharmacy Authority could enforce the relevant standard for pharmacies with in-house sterile compounding facilities. A transition period may need to apply to allow the audit framework to be developed and resources implemented.

*Are there different standards that should be met depending on the circumstances under which the infusion is prepared?*

No. if the infusion is not prepared in accordance with an agreed and recognised quality standard, there should be no commonwealth funding for that infusion.

*What would the effect of any changes be for consumers, in terms of access to and quality of chemotherapy services?*

Provided there is appropriate funding which ensures infusions are not being provided by pharmacists at a loss and specifically recognises the higher transportation and temperature storage costs to rural and remote areas, there should be minimal impact for consumers in terms of access to and quality of chemotherapy services. However consideration for the preparation of drugs with very short expiries also needs to be made.

## **OTHER MATTERS PERTINENT TO FUNDING FOR CHEMOTHERAPY INFUSION PREPARATION**

- *Are there any concerns in relation to current administrative processes surrounding the provision and claiming of PBS chemotherapy medicines and infusions?*

### **PBS Prescription management**

Yes. There is an enormous and unnecessary administrative paper based burden placed on pharmacy and medical staff regarding the provision and claiming of PBS chemotherapy medicines and infusions.

Most pharmacies around Australia will supply a chemotherapy medicine based on the verbal or written order of an Oncologist which is provided on the drug therapy chart. The oncologist or medical practitioner then provides a prescription to the pharmacist.

Even though supply may have been made to the patient, the pharmacy does not get paid for the medication by the Commonwealth until the prescription has been provided. This creates a significant financial impost on the pharmacy.

In addition there is an enormous amount of time and resource allocated to chasing and writing prescriptions when a valid written order already exists on the patient drug therapy chart.

This is time which could be better spent providing patient focused services.

The Drug Therapy Chart should be used as the PBS prescription for all chemotherapy related items. This is the current practice in Victorian public hospitals and a similar process should be put in place in the private setting.

Medicare can conduct regular audits on the pharmacy and doctors to ensure appropriate prescribing and claiming of the infusions. The drug chart provides independent evidence that the medication has been supplied and administered to patients. The doctors (and or pharmacists) could be required to write the indication for use on the drug chart next to each drug. Note this is a current standard for the National Inpatient Medication Chart.

There should be no requirement for Oncologists to contact Medicare for telephone approval for any authority required items. All items should be streamlined authorities.

### **Section 100—Special Authority Program for Trastuzumab (Herceptin®) for early breast cancer**

There is also a significant administrative overhead associated with the ordering of Herceptin® for the treatment of late stage metastatic breast cancer.

The process in place places an unnecessary and time consuming administrative burden on doctors and pharmacists. The details of the program can be found on the following website: <http://www.medicareaustralia.gov.au/provider/patients/late-breast-cancer.jsp> (accessed July 25th 2013).



The problems with the program are that the same product, Herceptin®, when used for different clinical indications (early stage breast cancer v late stage breast cancer) has to be ordered, managed and funded differently. Under the late stage metastatic program, the process for reordering is timely and convoluted. Pharmacists cannot order the medication and can only ring up Medicare to find out if stock has been ordered. If Doctors do not order the medication the patients will not have access to their treatment. Pharmacists routinely have to use their own 'purchased' vials to supply patients. When this occurs, Medicare do not replace stock supplied by the pharmacists in good faith.

Other issues include the nominated delivery address of the pharmacy may not be the actual address of the facility where the product needs to be prepared. Therefore further transport costs are incurred to ship the products to the compounding centre.

A suggested way forward would be to allow the doctors to register the patient with Medicare, write the order on the medication therapy chart with the patient ID number, write the relevant indication on the drug chart and allow the pharmacist to liaise with Medicare and the manufacturer via an online portal as to the ordering, delivery and funding of the medication.

The use of an online portal is common practice with many drug companies administering patient access programs for their medications.