Summary of key points regarding SHPA submission re Supply of chemotherapy drugs such as docetaxel

- Contemporary cancer treatment involves the delivery of complex protocols of multiple chemotherapy medicines administered both sequentially and in parallel, together with standard supportive care therapies.
- Patients with cancer may also have other conditions for which they take a range of medicines. Close consideration must be given to ensuring that the chemotherapy medicines don't interact with patients' usual medicines and vice versa – cancer pharmacists help to sort this out for individual patients, working very closely with cancer doctors and nurses.
- Chemotherapy medicines are not ordinary medicines – they have complex dosing regimens, have significant toxicities that can be prevented and managed in expert hands. They require preparation in special facilities that protect the product from microbial contamination and the healthcare workers from occupational exposure, close to the time, often on the same day that they are required for administration.
- The systems that have been developed allow patients to have their treatment either in private or public facilities and close to home rely on a fair and reasonable reimbursement of costs associated with the delivery of the medicines. Changes to the reimbursement price of some medicines like docetaxel have put this system at risk, particularly in the private sector.
- SHPA supports the Efficient Funding of Chemotherapy Drugs and the price disclosure arrangements. However these changes should be viewed in the context of:
    1. the cumulative impact of multiple changes to the funding of chemotherapy medicines
    2. that the funding construct (based on re-imbursement for the supply of the medicine) ignores the essential services that are required for these medicines to be safely and effectively administered to the patient. That is; the pharmacist review of the dose, dosing schedule and toxic effects of chemotherapy and the preparation of the chemotherapy into a ready-to-administer form and
    3. the considerable administrative burden for pharmacists entrenched in business rules for re-imbursement since the inception of the PBS.
- In 2009 the Commonwealth stated that savings generated through changed arrangements would be re-invested. The sector was expecting that if saving of $210million was made approximately $64million would be re-invested.
- The PBS was not set up to support the use of medicines in hospitals. Business rules from 1947 on the way a prescription must be written for reimbursement continue to drive how doctors and pharmacists provide services in hospitals in 2013. These systems need to be modernised.
- The current funding system discriminates between patients based on the type of ownership of the pharmacy. This is incompatible with contemporary cancer care and community expectations. Government funding should be contingent upon services required by individual patients, patient eligibility and the services actually delivered by the pharmacist.

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- SHPA's submission seeks:
  1. a transparent model that clearly identifies the four component costs: cost of the chemotherapy medicine, cost of consumables/devices necessary for the delivery of the medicines, a reconstitution fee and a pharmacy professional services fee
  2. that the same business rules and funding apply to both Section 90 and Section 94 pharmacies in private hospitals
  3. a revision of the business rules for the claiming of PBS medicines via Medicare Australia, specifically:
     - That paperless claims and streamlined authorities across the range of drugs within the Efficient Funding of Chemotherapy for public hospitals program be offered to all private hospital pharmacy providers
     - That all features of the Paperless Claiming Trial should be made available to all pharmacies licensed to supply PBS medicines in private hospitals irrespective of the medicine, type of hospital or care facility or the type of pharmacy service accessed by the patient.
- The providers of chemotherapy pharmacy services, that is the community and private hospital pharmacists, have continued to provide services to patients while negotiations have been ongoing. This has been a show of good faith by these pharmacists and pharmacy services and is based on advice that payments will be backdated to the 1st December once a resolution to the situation is reached.
- SHPA believes that this situation highlights that to avoid unintended consequences all stakeholders need to be involved when formulating and finalising policy decisions.

If asked:
In response to a question regarding where the money should come from:

SHPA believes that the additional funding for the safe provision of chemotherapy must come from the savings made to date from Chemotherapy reforms – the efficient funding of chemotherapy and the price disclosure program – this we believe is currently sitting at around $200million with more to come after the 1st April – the amount that is being requested to come back into the system is around $64million.

SHPA does not support finding this funding from the capped budget associated with professional services in the 5th Community Pharmacy Agreement.

Whilst the efficient funding of chemotherapy program was negotiated alongside of the 5th community pharmacy agreement, it is not a part of the agreement and was never meant to be.

The programs funded under the 5th CPA are important programs designed to improve the quality use of medicines for eligible Australians, we do not believe there is capacity in that funding for these measures to be funded in the long term. The recent increase in expenditure of one component of that program, HMRs is a demonstration of the way such programs are taken up over the life of an agreement.

Summary of key points regarding chemotherapy medicines in hospitals

Contemporary cancer treatment demands complex protocols of multiple chemotherapy medicines administered both sequentially and in parallel, together with standard support therapies (e.g. anti-emetics) and specific electrolyte replacements and hydrating fluids.

The use of all medicines has risks; the use of **chemotherapy medicines has significant inherent risks to the patient**, and of health professionals preparing and administering the chemotherapy, that must be managed. **Mistakes cost lives**.

Every dose of every chemotherapy medicine for every individual patient must be calculated within the protocol being used, confirmed as appropriate for that patient and then compounded and prepared for administration to minimise the risk to both the patient and the health professional administering the chemotherapy medicine.

Pharmacists have a key role in managing the risks associated with the use of chemotherapy medicines:

- **clinical pharmacy** services focus on the dose of every medicine in every course or cycle of therapy in the chosen chemotherapy protocol: the calculated dose of every chemotherapy medicine including the cumulative or acute toxicity the patient has experienced, the mode of delivery, the appropriate fluid for delivery, and appropriate support therapies such as anti-emetics, electrolyte replacement etc. This pharmacist review is the final confirmation step and is completed before the chemotherapy is prepared which minimises wastage.
- the **pharmacy manufacturing service** focuses on accurately preparing each chemotherapy medicine, in an appropriate delivery device, under controlled conditions to ensure that each dose is ready for administration without further manipulation (i.e. at no risk to the health professional administering the medicine)
- **medication safety pharmacists and pharmacy managers** are involved in system-wide strategies for preventing medication errors (e.g. ensuring appropriate prescribing protocols, electronic prescribing with decision support, checking procedures, transport of chemotherapy medicines)

The current remuneration model does not reflect contemporary cancer services. Business rules written for the PBS in 1947 continue to drive how doctors and pharmacists provide services in 2012. **Current business rules discriminate between patients based on the ownership of the pharmacy and hospital where they are treated.**

What is needed is a **sustainable, transparent and fair funding model** for the provision of chemotherapy medicines that is equally applicable across **all hospitals / types of pharmacy services**.

SHPA believes that such a model has four component costs and should be applied all private hospitals:

1. a **professional services fee covering the clinical pharmacy review** of each course or cycle of chemotherapy that would be payable <u>once</u> per course or cycle
2. the **cost of the chemotherapy medicine** payable for each medicine prepared
3. the **cost of consumables** used in the preparation of each medicine and if required by the chemotherapy protocol the cost of the delivery device payable for each medicine prepared
4. a **preparation fee** payable for each medicine prepared.

Services required for every cycle of chemotherapy

1. Diagnosis and chemotherapy protocol chosen

CP

1a) Pre-treatment interview by clinical pharmacist. Medication reconciliation, identification of potential medication issues (e.g. changes to diabetes control and previous ADRs). Counselling about pre and post treatment medicines.

1b) Pre-treatment review by clinical pharmacist. Working with medical and nursing staff to confirm doses based on weight and body surface area (BSA), manage anticipated medication issues (e.g. changes to diabetes control and previous ADRs), renal, cardiac and liver function

CP

2. Review of patient prior to each cycle of chemotherapy, medicines order confirmed

The clinical pharmacist focus on the dose of every medicine in cycle of therapy in the chosen chemotherapy protocol. Prior to each cycle of chemotherapy the patient's weight, BSA, renal function, FBEs, LFTs and U&Es are reviewed and if required, changes to the doses of chemotherapy and support medicines are made.
The pharmacist review is the final confirmation step and is completed before the chemotherapy is prepared which minimises wastage as un-required doses are not prepared.

CP

3. Manufacture of each chemotherapy medicine

The **pharmacy manufacturing service** focuses on accurately preparing each chemotherapy medicine, in an appropriate delivery device, under controlled conditions to ensure that each dose is ready for administration without further manipulation (i.e. at no risk to the health professional administering the medicine).

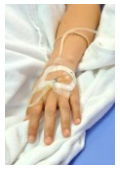
M

4. All chemotherapy, fluids and support therapies required that day are dispensed and made ready for patient

There is a final check that all the medicines required are labelled and ready for administration.

M

5. Chemotherapy and other medicines administered



6. Medicines provided on discharge

The patient receives discharge medicines including medicines to control nausea and vomiting and pre-medications to be taken prior to the next cycle of chemotherapy.
Clinical pharmacist counsels patient on the use of all of these medicines.

CP

CP: Clinical pharmacist

M: Manufacture of the chemotherapy so that dose is ready to administer

Summary of key points regarding claiming PBS chemotherapy medicines in hospitals

The PBS was not set up to support the use of medicines in hospitals. Business rules from 1947 on the way a prescription must be written for reimbursement continue to drive how doctors and pharmacists provide services in hospitals in 2013.

The administrative burden for pharmacists has been entrenched in business rules for re-imbursement since the inception of the PBS. **Revenue generated must cover the cost of doing business with Medicare Australia.**

This is an 'every day' issue across most public and all private hospitals, whether the patient is an inpatient, day patient or being discharged from the hospital. There are two business rules regarding the claiming of PBS medicines that substantially contribute to the administrative burden for pharmacists in hospitals that provide chemotherapy services.

1. Timely access to many chemotherapy medicines is compromised in private hospitals due to onerous authority requirements.

Australia's doctors and pharmacists working in hospitals must have an understanding of eight different authority categories within the PBS. The administrative burden is considerable, particularly in the treatment of cancers.

As the cost of these chemotherapy medicines is considerable, treatment is delayed until funding can be assured (i.e. authority is granted through Medicare Australia and appropriate prescription is received). These issues have been addressed in the public sector through the **Chemotherapy Pharmaceuticals Access program (CPAP). This program should be offered to all private hospital pharmacy providers.**

2. The re-imbursement rules require or presume a 'no script no drug' approach. Doctors must complete and sign two orders for every medicine for a patient to receive that medicine through the PBS from a hospital and for the pharmacy to receive cost reimbursement through Medicare Australia.

At best this is inefficient, wasting the time of doctors and pharmacists and delaying patient care. At worst this causes confusion, increases errors of omission and creates new opportunities for errors related to differences between the medication order and what is written on the PBS prescription. This error type is a well recognised risk any time that there is a requirement to transcribe the same order.

All features of the Paperless Claiming Trial (initiated in July 1998 but currently available in only seven private hospitals) should be made available to all pharmacies licensed to supply PBS medicines irrespective of the medicine, type of hospital or care facility or the type of pharmacy service accessed by the consumer.

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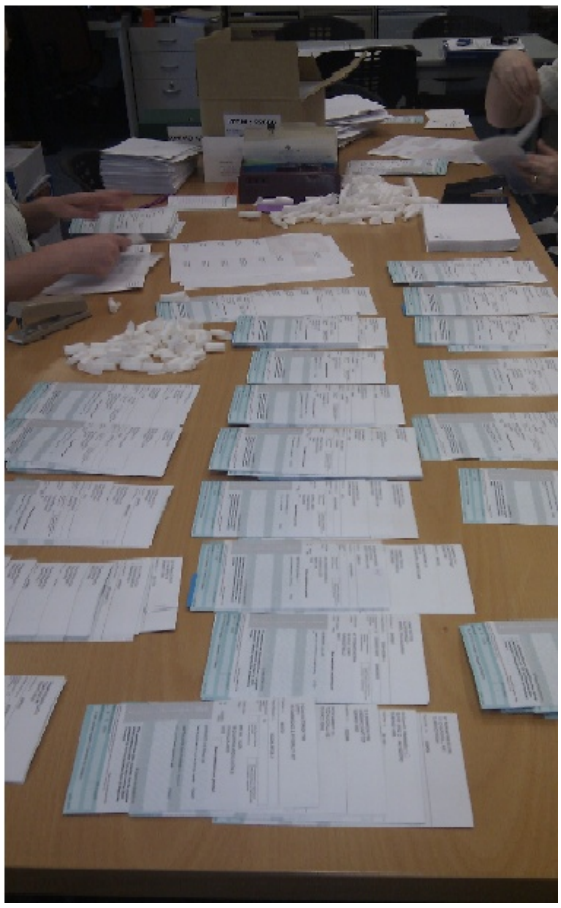
This is a photo of **one week's worth** of prescriptions generated from inpatient medication charts through a Section 94 pharmacy at a private hospital.

All of the medicines have already been ordered on the patient's hospital medication chart and have already been supplied.

This paperwork shown is additional and required only for the pharmacy to make a claim to Medicare Australia.

The introduction of the national inpatient medication chart (NIMC), with the associated improvements in medication safety, is problematic in private hospitals as use of the standard NIMC requires that doctors write both the medication order and another PBS prescription.

As shown in a picture from another hospital pharmacy each of these additional prescriptions must be:

- printed on approved PBS stationery obtained from authorised prescribers
- sorted, the relevant prescriber must be identified and the hardcopy prescription then must be sent to that prescriber
- signed by the prescriber
- sent back to the pharmacy and
- processed for claiming through Medicare Australia
- filed and stored separate from the patient's medical history for audit requirements

Frequently the pharmacy needs to reprint several hard copies of the prescription before it is signed by the prescriber.