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Submission to the Medicines Australia Oncology Industry Taskforce on 'Access to cancer medicines in Australia'



National Secretariat

Level 2, 15 National Circuit, Barton, ACT 2600 Australia PO Box 7036, Canberra Business Centre, ACT 2610 Australia Telephone: + 61 2 6270 1888 · Facsimile: + 61 2 6270 1800 Email: guild.nat@guild.org.au · Internet: www.guild.org.au

## About The Pharmacy Guild of Australia

The Pharmacy Guild of Australia (the Guild) was established in 1928, and is registered under the federal Workplace Relations Act 1996 as an employers' organisation. The Guild's members are the owners of approximately 80% of the 5,350 community pharmacies in Australia. The Guild aims to promote, maintain and support community pharmacies as the most appropriate primary providers of health care to the community through optimum therapeutic use of medicines, medicines management and related services.

## Introduction

The Guild welcomes the opportunity to provide feedback on the 'Access to cancer medicines in Australia' report (Report) prepared by Deloitte Access Economics for the Medicines Australia Oncology Industry Taskforce. We note that the purpose of the Report is to provide a common platform for open dialogue among stakeholders on issues pertaining to patient access to cancer medicines in Australia.

### Comments

### 1. Report Deficiencies

We support the objective in developing this Report, but we note that there is a strong bias to providing background from the industry perspective, and to a lesser degree, hospital care. The Guild feels that if the Report is to act as a broad discussion platform for accessing cancer medicines in Australia, there must be more information regarding:

- Wholesale distribution of cancer medicines
- Delivery of cancer medicines, with greater differentiation of the issues faced by community pharmacy versus hospital pharmacy
- Dispensing and preparation of cancer medicines

We also note that the Efficient Funding of Chemotherapy (EFC) is referenced only once in the Report on page 68. As a discussion platform, we recommend some background be provided about the EFC. There would also have been value in obtaining some commentary from relevant stakeholders that were interviewed about actual or perceived limitations or benefits with EFC arrangements.

With respect to the deficiencies described above, for information about the wholesale distribution of cancer medicines the Guild advises consultation with the National Pharmaceutical Services Association (NPSA) as the representative body for the major

pharmaceutical wholesale distributors in Australia. Our submission will comment on the preparation of cancer medicines and their delivery through community pharmacy.

### 2. Delivery of Cancer Medicines through Community Pharmacy

We note in Appendix A that there is little representation from the community pharmacy sector. Three of the four pharmacist participants provide greater representation of the hospital pharmacy sector. We feel the Report lacks community pharmacy input and the little that is included appears to be from referencing the Guild's submission to the Senate Community Affairs Reference Committee Inquiry into the 'Supply of chemotherapy drugs such as docetaxel' in mid-2013.

The supply of chemotherapy medicines through community pharmacy can be categorised as follows:

- i. Interface Pharmacies the community pharmacy accepts and coordinates the processing and claiming of the prescription but the preparation of chemotherapy medicines is conducted by an external licensed third-party provider
- ii. Compounding Pharmacies the community pharmacy dispenses the prescription and prepares chemotherapy medicines for supply to its own patients
- iii. Licensed Pharmacies the community pharmacy has a Good Manufacturing Practice (GMP) licence from the Therapeutic Goods Administration (TGA) and can prepare chemotherapy medicines for dispensing to its own patients or for thirdparty supply to other pharmacies to dispense to their patients

Pharmacies from the two latter categories must have the necessary infrastructure and specially trained staff to prepare chemotherapy medicines. To provide a discussion platform, the Report should identify that community pharmacies operate as commercial businesses. The provision of pharmaceutical benefits is conducted as a Public Private Partnership with Government in which the community pharmacy provides the infrastructure, staffing and business resources to support the delivery of a Government subsidised medicine scheme.

The Guild believes that further updating of the Report would benefit from input from the three community pharmacy categories listed above in addition to those already represented.

Regarding delivery of cancer medicines through community pharmacy, the Guild believes there would be value in distinguishing between the public hospital and community pharmacy sectors. As a starting point, the following lists demonstrate some of the differences:

Public Hospital

- Staff are public service
- Purchase and maintenance of Infrastructure and equipment is funded by relevant Government (Commonwealth and/or State/Territory)

- Business costs such as rent and utilities are covered under hospital administrative budget and funded by Government
- Quality accreditation is managed under hospital accreditation system and funded by Government

**Community Pharmacy** 

- Pharmacy business funds staffing arrangements, including wages, superannuation, leave entitlements, workers insurance and training
- Pharmacy business purchases and maintain infrastructure and equipment
- Pharmacy covers business costs such as rent and utilities
- Pharmacy business funds implementation and maintenance of quality accreditation

### 3. Dispensing and Preparation of Cancer Medicines

The preparation and dispensing of medicines are at the core of the remuneration structure for the Pharmaceutical Benefits Scheme (PBS). The dispensing of cancer medicines usually involves more complexity than the dispensing of non-cancer medicines, however under current arrangements, the payment of a \$6.63 dispensing fee per infusion – which is the only fee that is currently paid for the professional and clinical aspects of dispensing cancer medicines – is not sufficient to account for the complexities involved. Adding to this, there is now a greater availability of biological cancer medicines which are more complex to prepare than many of the older cancer medicines, a greater need for specialty containers and devices (often at much higher prices) and sometimes discrepancies between the PBS listed price and the price available to pharmacy.

#### **Dispensing Activities**

The table below provides a snapshot of the dispensing activities undertaken in a community pharmacy with supplying cancer medicines as compared to standard (non-cancer) medicines for which both activities are recompensed at \$6.63.

| Dispensing activities with cancer medicines    | Dispensing activities with standard medicines |
|--|---|
| Referral form received by the Oncology         | Prescription presented at pharmacy by         |
| Clinic (first contact Oncology Clinical Nurse  | patient                                       |
| Consultant, then referral given to             |   |
| pharmacist                                     |   |
| Pharmacist assesses whether additional         |   |
| pathology tests are required prior to the      |   |
| patient commencing treatment                   |   |
| Collect and assess current and past patient    | Establish patient history prior to dispensing |
| clinical, drug and family history necessary to |   |
| design a pharmacotherapeutic plan              |   |
|  |   |

Table is continued on following page

| Dispensing activities with cancer medicines  | Dispensing activities with standard medicines   |
|--|---|
| Pre-treatment chart revision – pharmacist<br>checks the body surface area, dosages, pre-<br>treatment and take-home medicines  | Confirm history/dosage check on dispense system   |
| Pharmacist attends chemotherapy<br>drug/chart write up to consult with treating<br>specialists to discuss treatment  |   |
| Pharmacist participates in a multi-<br>disciplinary team meeting to establish<br>therapeutic goals in collaboration with<br>patient  | Contact prescriber if confirmation, dose checks or changes required to prescription                             |
| Pharmacist orders cancer medicines as per<br>the checked chart – including take-home<br>medicines  | Pharmacist assembles prescribed medicines   |
| Required dose of IV chemotherapy<br>medicine prepared aseptically by a<br>pharmacist using in-house facilities or<br>sourced form a TGA licensed third party<br>provider – this is a specialised task requiring<br>advanced equipment and specially trained<br>staff and must be performed in a controlled,<br>sterile environment |   |
| Assessment of the financial impact of the<br>selected treatment on the hospital as well<br>as for the patient  | Discuss generic options with patient if less expensive brand available  |
| Medicines prepared by external third party<br>licenced providers are checked upon arrival<br>for dose, container, compatibility and safety   | Check drug, brand, strength, form and quantity along with PBS status  |
| Cancer medicines are labelled and re-<br>checked   | Process, label and check medicines – scan<br>barcode, review expiry date, instructions<br>and cautionary labels |
| Prepare individualised patient medication<br>kits – includes treatment, pre-med and<br>supportive care medicines   | Organise counselling aids e.g. CMI  |
| For New Patients – during first visit to clinic,<br>patient provided with Patient Care Kit,<br>Cancer Council Kit and other relevant<br>information  | First time use counselling provided by pharmacist   |
| Assessment of physical signs of drug-related effects   |   |
| Table is continued on following page   |   |

| Dispensing activities with cancer medicines   | Dispensing activities with standard medicines   |
|---|---|
| Pharmacist, in collaboration with the<br>chemotherapy nurse, conducts a holistic<br>assessment of patient's well-being and any<br>non-drug related effects that may require<br>referral |   |
| Monitor compliance with medicines, diet,<br>sleeping, nausea, constipation, effect of<br>treatment on lifestyle, medicine<br>interactions – liaise with family members                  | Assess adherence and medicine-related issues when presenting for repeat prescriptions |
| Respond to medicine information requests<br>– liaise with nursing staff about drug issues   | Respond to any medicine information requests  |
| Liaise with prescribers to recommend newly<br>available medicines, extra therapeutic drug<br>monitoring or suggested management<br>techniques to improve patient outcomes               | Consult prescriber if potential changes to prescription identified                    |

#### **Remuneration Arrangements**

The Department of Health is currently reviewing the remuneration arrangements for chemotherapy medicines. On 5 May 2013, the Minister for Health announced interim funding arrangements while the review is undertaken. Under the new arrangements, community pharmacies are paid an additional \$60 per infusion to the Preparation Fee, after indexation. These revised arrangements are in addition to the \$6.63 Ready Prepared Dispensing Fee and recognise the specialist nature of preparing chemotherapy medicines.<sup>1</sup>

The interim funding arrangements in operation from 1 July 2013 until 31 December 2013 are as follows<sup>2</sup>:

• Diluent fee - \$4.91\*

Intended to cover the cost of the diluting agent used in the reconstitution process

- **Dispensing fee \$6.63**\* Standard Ready Prepared PBS Dispensing Fee
- **Distribution fee \$24.79**\* (replaces the whole-sale mark-up) Intended to cover the costs to pharmacy of the logistics and transport of the chemotherapy
- Preparation fee \$101.33\* (includes additional \$60)
  Intended to cover the cost of preparing the infusion so that the medicine can be dispensed and administered to the patient in the hospital or clinic
   [\* reflecting indexation from 1 July 2013]

<sup>&</sup>lt;sup>1</sup> http://www.pbs.gov.au/info/publication/factsheets/shared/revised-arrangements-for-chemotherapy

<sup>&</sup>lt;sup>2</sup> Explanatory Statement, National Health Act 1953, National Health (Efficient Funding of Chemotherapy) Special Arrangement Amendment Instrument 2013 (no.6); PB 36 of 2013

With regards to pharmacy supply and remuneration, the following points should be considered:

- Remuneration must compensate community pharmacy as a commercial business for the services provided
- Remuneration must cover the cost of supply, associated business risks with highcost medicines (expiry etc) as well as professional, business and administrative costs
- There is no legislation limiting what price pharmacies are charged for chemotherapy medicines by wholesalers or licenced third-party providers
- The above fees are paid per infusion whereas pharmacies purchase cancer medicines in vials – a single infusion generally uses multiple vials
- Single vials of chemotherapy commonly cost in excess of \$1,000
- Many pharmacies carry high inventory levels of high-cost medicines to meet critical timelines for patients – this is a significant cost to business which in other industries is generally off-set by higher margins
- Last minute changes to the dosing schedule may mean the supply cannot be used - this cost is borne by the pharmacy
- Capital and service costs in rural and regional locations are generally higher
- Reconstituted chemotherapy typically has a short expiry sometimes hours; this can impact availability in non-metropolitan locations
- Current PBS arrangements are very inefficient for pharmacy
  - $\circ$   $% \left( {{\rm{T}}_{{\rm{T}}}} \right)$  the medication chart acts as the order but a prescription is needed for claiming purposes
  - the capacity to check and cross-reference claims is complex and time consuming
  - o prescribers and pharmacists are often weighed down with clerical duties

#### **Standards and Quality Control**

While the Pharmacy Board of Australia expects pharmacy practice to be consistent with either the Professional Practice Standards<sup>3</sup> developed by the Pharmaceutical Society of Australia (PSA) or the Practice Standards developed by the Society of Hospital Pharmacists of Australia (SHPA)<sup>4</sup>, there is no quality assurance requirement for supplying PBS medicines. The Quality Care Pharmacy Program (QCPP)<sup>5</sup> is a quality assurance program for community pharmacy requiring a biennial assessment of pharmacy practice to maintain accreditation.

# Conclusion

Should the authors of the Report or the Medicines Australia Oncology Industry Taskforce be interested in consulting further with community pharmacists involved in the preparation and/or supply of cancer medicines, the Guild would be happy to provide recommendations.

<sup>&</sup>lt;sup>3</sup> <u>www.psa.org.au</u>

<sup>&</sup>lt;sup>4</sup> http://www.shpa.org.au/Practice-Standards

<sup>&</sup>lt;sup>5</sup> <u>www.qcpp.com</u>