

# SHPA's Response to the Efficient Funding of Chemotherapy (EFC) Review Interim Report, October 2022

#### Introduction

The Society of Hospital Pharmacists of Australia (SHPA) is the national, professional organisation for the 6,100+ Hospital Pharmacists, and their Hospital Pharmacist Intern and Hospital Pharmacy Technician colleagues working across Australia's health system, advocating for their pivotal role improving the safety and quality of medicines use. Embedded in multidisciplinary medical teams and equipped with exceptional medicines management expertise, SHPA members are progressive advocates for clinical excellence, committed to evidence-based practice and passionate about patient care.

Since the initial consultation to the Review of the Efficient Funding of Chemotherapy (EFC) Program Discussion Paper which SHPA made a <u>comprehensive submission</u> on behalf of its members who compound chemotherapy medicines and provide cancer services for Australian cancer patients, there have been several key pieces of work which further impact on and discuss the provision of cancer services for Australians.

# Concurrent reviews and reports relevant to EFC Review

There are several current ongoing reviews which impact on the EFC Review, which SHPA would appreciate being mentioned in the Final Report to understand how these aspects of Australia's cancer care and healthcare system interplay with one another to support safe, quality and efficient cancer care delivery.

At the start of 2022, the Department of Health and Aged Care (Department) also consulted on a proposed <a href="The Australian Cancer Plan 2023-2033">The Australian Cancer Plan 2023-2033</a>, with a further consultation on the draft Australian Cancer Plan flagged for the end of 2022. SHPA anticipates that this work would likely impact on or discuss the provision of chemotherapy medicines for cancer patients, and believes its omission in the Interim Report should be reconsidered in the Final Report such that stakeholders can understand the Department's view on how the EFC program relates to the Australian Cancer Plan.

Similarly around the same time, the Department also began its Review of Pharmaceutical Reform Agreements (PRA), to which SHPA also made a <u>comprehensive submission</u>. The PRA Review is yet to be finalised, but understandably its outcomes will have a large impact on the EFC and whether patient access to chemotherapy medicines is provided in an efficient and cost-effective manner. The majority of EFC is supplied by section 94 approved hospital authorities (hospital pharmacies) and the PRAs determine the arrangements for remuneration and supply for PBS medicines for public hospital pharmacies. These remuneration arrangements have a demonstrable impact on the viability of cancer services in public health services, which is relevant to the EFC Interim Report as it discusses viability of cancer services in public and private settings, metropolitan and non-metropolitan settings.

Again in March 2022, the Australian Government undertook a consultation on the National Medicines Traceability Framework (NMTF), which explicitly discusses the efficiency and responsiveness of supply chains and the provision of accurate and secure data that can be used by the supply chain to support payment reconciliation. In SHPA's submission to this consultation, SHPA was broadly supportive of a NMTF to support pharmacovigilance and transparency. Most importantly, the need to serialise medicines would assist with hospitals achieving closed loop medicines management to reduce the incidence of medication-related errors.

In July 2022, SHPA launched Pharmacy Forecast Australia 2022, a strategic thought leadership piece on emerging trends and phenomena forecasted to impact pharmacy practice and the health of Australian patients to 2027 developed by SHPA, informed by the views of leading Australian pharmacists who are Forecast Panellists. Theme 5 of Pharmacy Forecast Australia 2022 is Funding Models and discusses the cost of providing

chemotherapy. The most pertinent excerpts from Pharmacy Forecast Australia 2022 relating to the EFC Review are quoted below:

"Provision of chemotherapy is one of the highest risk medication services; and, due to the high cost of the medicines involved, is also an area where there is constant pressure to manage costs of care...

...Chemotherapy costs extend beyond the cost of dispensing and compounding; funding also needs to recognise the need for clinical pharmacist review at every step of service delivery, not just supply, to avoid patient harms from treatment errors such as those that have occurred in Australian hospitals in recent years...

...It is therefore highly concerning that the vast majority (71%) of FPs consider it likely that remuneration for PBS-funded chemotherapy will have fallen below the point at which it can be safely provided."

SHPA acknowledges the Interim Report's remarks that matters such as funding for the administration of cancer medicines to patients, clinical management and infrastructure "do not relate directly to the EFC" as it is a legislative instrument, and strongly appreciates the clarity in Table 3. Activities in the provision of cancer medicines regarding what is and is not within the scope of EFC. However, all elements described within Table 3 do impact on continuing access to medicines and whether patient access to chemotherapy medicines is provided in an efficient and cost-effective manner, which is purpose of the EFC Review.

For example, it is impossible to discuss the provision of chemotherapy medicines under the EFC program, without also discussing the importance of checking critical patient factors such as determining drug regimen and dose, checking patient vials and blood-levels, patient clinical and mediation history, all of which are technically out of scope of the EFC according to Table 3.

Tacitly endorsing the detachment of the clinical pharmacy service elements that promote safety and quality, from the funding and provision of chemotherapy medicines under the EFC program, risks patient safety and their right to receive high quality care. It further undermines health service's abilities to achieve the <a href="National Safety and Quality Health Service">National Safety and Quality Health Service</a> (NSQHS) Standards, in particular the Comprehensive Care Standard and Medication Safety Standard, when providing care for cancer patients. Such approaches continue the recurring theme of cost-shifting between federal and state governments, cancer service providers and consumers, which ultimately do not place patient access, safety and quality at the centre.

Therefore, while SHPA agrees in principle with the Interim Report's overarching view that the EFC continues to be an appropriate policy response for the specialised nature of cancer care, its remit should be broadened not just to ensure access to cancer medicines can be maintained, but also that its access is guaranteed to be provided in a safe and high-quality manner for Australian cancer patients.

If you have any further queries or would like to discuss our submission, please contact Jerry Yik, Head of Policy and Advocacy at <a href="mailto:jvik@shpa.org.au">jvik@shpa.org.au</a>.

SHPA has addressed each recommendation made in the Efficient Funding of Chemotherapy (EFC) Review Interim Report under its key themes.

Chemotherapy as a 'speciality service'

- 1. Short-term: Modify the EFC legislative instrument to recognise that the program funds more than chemotherapy and intravenous cancer medications. Consideration should be EFC Review Interim Report July 2022 202 given to the following suggestions:
  - a. 'Efficient Funding of Cancer Medicines';
  - b. 'Cancer Medicines Funding Program'

SHPA provides in principle support for this recommendation to modify the EFC legislative instrument to encompass all medications used in cancer care, however, we reiterate the importance of the title reflecting the safety and quality of chemotherapy services and chemotherapy medicines delivered to patients.

SHPA agrees that this recommendation is appropriately classified as a short-term change.

2. System change: Investigate system changes with respect to alternative funding mechanisms for the delivery of cancer medicine services that better integrate all aspects of the care pathway (including assessment for treatment, treatment preparation and delivery, and follow-up care).

SHPA is pleased to see the EFC Review Interim Report acknowledge SHPA's recommendation to investigate alternative funding mechanisms that integrate all aspects of the care pathway. This should include care provided in the acute setting when patients become too unwell and need to be admitted to hospital as inpatients. SHPA would like to emphasise that these funding changes should not result in net-negative funding compared to existing remuneration models so as not to threaten the safety and quality of cancer therapy, and the viability of cancer services. Furthermore, any changes should not unintentionally create more cost-shifting between federal and state governments, cancer service providers and consumers, which ultimately do not place patient access, safety and quality at the centre.

Current PRA and Pharmaceutical Benefit Scheme (PBS) rules dictate that PBS medicines can be provided to patients who are in the community or outpatient setting. Given the critical nature of delivering timely chemotherapy medicines according to prescribed chemotherapy protocols, if a patient's hospital admission coincides with their chemotherapy treatment day, hospitals are forced to choose between administering these high-cost medicines to hospitalised patients and forgoing the eligibility to claim for these medicines from Services Australia or wait until the patient has been discharged and provide delayed chemotherapy treatment. These medicines can cost thousands of dollars per dose, and despite them being non-PBS as it is inpatient use, these costs are not passed on to the patient in public hospitals, but rather absorbed by the hospitals from their already constrained budgets. This is not possible for smaller and/or regional, rural and remote hospitals and can compromise continuity and quality of care.

SHPA would like to reiterate that the lower the renumeration for supplying PBS medicines, the less funding there is for high quality clinical pharmacy services, dispensing services and compounding services to be delivered to patients requiring chemotherapy. The development of an alternative funding model will require all aspects of the cancer care pathway, including the clinical pharmacy service, to be mapped out and costed accordingly.

SHPA agrees that this recommendation is appropriately classified as a system change however, it is important to recognise that this may need to occur before other recommendations are able to be actioned. An alternative funding model will impact on several areas and suggested recommendations, including proposed solutions to vial sharing.

### **Service Viability**

3. System change: Consider the potential for the Commonwealth to purchase medicines directly from manufacturers as a means of increasing system efficiency and reducing pharmacy/hospital exposure to cost pressures associated with purchasing and carrying EFC-listed stock.

SHPA does not support the recommendation that the Commonwealth purchase medicines directly from manufacturers and supply them to pharmacies/hospitals.

The COVID-19 pandemic has seen hospitals greatly involved with the National Medical Stockpile regarding the procurement and supply of COVID-19 oral and intravenous antivirals, as well as the procurement and disbursement of COVID-19 vaccines, which are likely similar central systems to what this recommendation is supporting. Experiences over the COVID-19 pandemic have demonstrated that a centralised acquisition and distribution model, or a model in which the government acts as a purchaser, is not efficient and is likely to add to the complexity of an already complex system. Several issues stemming from these types of arrangements, some of which continue to this day, include:

- Transparency and awareness of stock levels in the NMS, wholesalers and health services
- Confusing guidance and rules and variable interpretation regarding patient eligibility
- Unreliable stock delivery
- The need to maintain several medicine lines/bins for the same medicines procured from different sources in inventory management systems, as well as for different funders (i.e. PBS vs non-PBS)
- Administrative burden to reconcile orders and supplies of medicines via manual paperwork for reporting back to authorities

The suggested centralised model does not address the non-PBS or off-label use of medicines and will not support States and Territories that are non-PBS signatories. It does not clearly state who will be financially accountable for expired stock at health services and for wastage. This model will increase the administrative burden on an already stretched workforce and adding to its complexity will likely inadvertently cause wastage and inefficiency.

While SHPA notes the EFC Interim Report's comments that the World Health Organisation recommends such system changes can increase system efficiency and transparency, as well as citing example countries such as Denmark and Norway as having implemented these changes, the design of local healthcare systems must be considered. For example, Australia's federated healthcare system with multiple funding frameworks and multiple funders and purchasers – both public and private – would be challenges to assimilate such a radical system change into.

#### **EFC** remuneration

4. Short-term: Maintain the EFC's existing fee structure and level as currently legislated, subject to indexing arrangements.

SHPA supports this recommendation, however, we note the lack of a compounding fee for non-cancer biologicals, despite fees being paid when the indication is for cancer. This again demonstrates the complexity and lack of consistency in current funding frameworks. While theoretically these types of costs can potentially be built into and picked up by Efficient Price calculations under the work of the Independent Hospital Pricing Authority (IHPA), as is alluded to when the Interim Report discusses per-mg funding in a latter section, it is yet another example of cost-shifting between programs that are both the remit of the Commonwealth.

Whilst we agree that this recommendation change should not require an extended period of time to action, consideration should be given to the transition period as pharmacy software is being updated. A stepped approach may be appropriate.

- 5. Long-term: Consider amending the EFC fee components and levels (subject to an analysis of stakeholders' empirical cost data) to add specific payments with respect to:
  - a. Infusion devices (e.g., elastomeric infusors, Cadd devices) required for the administration of the compounded pharmaceutical product;
  - b. Verification of the distribution fee (in lieu of a specific wholesaler payment);
  - c. Recognition of the activity required for repurposing/reissue of compounded medicines. Current evidence suggests a payment of \$10 per repurposed item. Evidence is required of the proportion of PBS claims to which repurposing might apply to allow this incentive payment to be included on a weighted basis as part of the standard EFC fee arrangements; and
  - d. Provision of cancer medicines in rural areas, as a means of recognising the additional barriers faced by providers in those areas in maintaining appropriate workforces required to request, dispense and administer cancer medicines, and for the additional logistics costs associated with provision of cancer medicines in rural/regional areas.

SHPA provides in principle support for this recommendation. SHPA notes that the current system cannot withstand a decrease in investment which threatens service viability, and that amendments stemming from this recommendation must be additional investments that do not draw from current funding already allocated to existing EFC fee components. The recognition of additional barriers faced by cancer service providers in rural areas is much welcomed. These service providers need to be supported as their closures – which have occurred in some areas – would push patients onto metropolitan areas at a time where these services are struggling with service capacity and would also significantly represent an impost to patients and their adherence to treatment.

EFC fees should represent the true cost base of the service being provided, recognising that rural and remote services often do not have an opportunity to repurpose compounded medicines. The cost involved in compounded medicines does not account for common practice in rural and remote settings where pharmacy technicians utilise the same amount of consumables as most other sites, yet only manufacture one or two products as needed.

SHPA agrees that this recommendation is appropriately classified as a long-term change.

6. Long-term: Consider amending the EFC fee level associated with the distribution fee in lieu of a specific wholesaler payment. Further negotiations of the Community Services Obligation (CSO) should consider whether the supply of EFC medicines can be captured as a means of simplifying arrangements for the payment of distribution and wholesaler payments.

SHPA would like to further understand how distribution fees and wholesaler payments would be arranged and to what extent under this recommendation. As mentioned above, SHPA would like to emphasise that these funding changes should not result in net-negative funding compared to existing remuneration models so as not to threaten the safety and quality of cancer therapy, and the viability of existing cancer services.

Furthermore, it is important to note that public and private hospital pharmacies are not covered under CSO arrangements which support the timely supply of PBS medicines in the community. Given that hospital pharmacies are responsible for approximately a quarter of all PBS expenditure, and the majority of PBS-funded chemotherapy, SHPA would be interested to hear whether the Review believes the CSO could be extended beyond its current remit, and notes that the next CSO will be renegotiated soon with the upcoming expiry of the Seventh Community Pharmacy Agreement.

#### Administrative burden

7. Short-term: Continue the operation of the Medicare Prescribing chart for online prescribing and claiming.

SHPA supports this recommendation.

SHPA agrees that this recommendation is appropriately classified as a short-term change.

8. Short-term: Expand the medicines covered under the EFC to include all compounded cancer medicines listed for cancer indications on the PBS.

SHPA provides in principle support for this recommendation. Refer to comments under recommendation 1.

SHPA agrees that this recommendation is appropriately classified as a short-term change.

- 9. Short-term: Develop an education program targeting all system stakeholders to focus on:
  - a. The basis on which the PBAC makes recommendations for cost-effectiveness, including how PBS authority and listing requirements support the principles of cost-effectiveness;
  - b. the scope of the existing EFC arrangements, including that EFC funding extends to supportive therapies as covered under Schedule II of the enacting legislative instrument.

SHPA supports the need for a targeted education campaign to all relevant stakeholders. SHPA notes that Medical Software Industry Association (MSIA) should be included as stakeholders. SHPA also advocates for better understanding by decision and policy makers around the impacts of their decisions across the system.

SHPA agrees that this recommendation is appropriately classified as a short-term change.

# Compounding

- 10. Short-term: It is essential that all compounding sites (TGA and non-TGA licensed) be appropriately recognised for the investment associated with complying with regulatory requirements and good manufacturing practice.
  - a. The payment of the CCPS should be expanded to all compounding facilities and made subject to an annual review of compliance with relevant regulatory guidelines and practice (Pharmacy Board Guidelines/USP 797).
  - b. Payment of the CCPS fee should be uncoupled from service volume and made on an annual grant basis.

SHPA provides in principle support for this recommendation, noting that no additional regulatory burden should be placed on Therapeutic Goods Administration (TGA) and non-TGA licensed compounders. Compliance with current standards is sufficient to maintain quality compounding services.

A significant number of Australian hospitals, including larger urban hospitals, already have outsourced the manufacturing of their cancer therapies to a third party TGA-licenced compounder in order to remove the need for unfunded capital investments to bring existing facilities in line with standards. Additional regulatory requirements may make this even more unsustainable for those who do currently compound and may risk the cancer care services being delivered, therefore, changes to requirements will require a review of annual grants.

As cancer care continues to become more complex with the advent of new medicines and technologies, the ability to compound locally is increasingly a concern for timely and efficient cancer care, particularly in regional and remote locations. SHPA members report that growing regulatory requirements along with increasing fiscal constraints have made it extremely challenging to maintain an appropriate, up-to-standard cytotoxic compounding facility. Access to in-house cytotoxic compounding services are essential to support access to cancer therapies with short expiries in rural and remote areas and to accommodate last minute changes to therapies in all settings. SHPA advocates for adequate financial incentives for facilities to set up a compliant compounding unit, and suitable reimbursement for running costs when there are poor economies of scale in smaller, non-urban hospitals, to encourage broader uptake of the compounding service. Further discussion on eliciting the true costs and overheads for chemotherapy manufacture are in SHPA's submission to the EFC Review discussion paper.

SHPA agrees that this recommendation is appropriately classified as a short-term change.

11. Long-term: Government should investigate the requirements and feasibility of establishing a National Centre for Stability Testing to increase the shelf-life of compounded products under conditions that can be replicated by local compounders.

SHPA supports this recommendation for the Government to investigate the requirements and feasibility of establishing a National Centre for Stability Testing. SHPA members believe Australian specific data would be invaluable to support current practice and ensure optimal use of medications. Noting that all data should be made readily available to the public. Consideration of common closed system transfer devices and compatibility should also be included as these are used for increased operator safety.

An independent body determining the stability of compounded products is likely to impact on wastage during natural disasters and/or pandemics, especially in rural and remote locations. Not having this information currently available impacts on tender and contract processes in these locations as different compounding companies have varying stabilities for the same product.

Rural and remote facilities providing cancer therapies currently compound low stability or short-expiry medications in-house which adds costs associated with commissioning compounding facilities, maintaining and staffing these facilities with a suitably trained pharmacy workforce for a limited number of patients. If data from a National Centre for Stability Testing proved these compounded products had a longer shelf-life, it would improve access to quality chemotherapy for patients living in rural and remote locations.

Furthermore, hospital pharmacists have been increasingly discussing the impact of weather events and the climate on safe and appropriate medicines transport and storage, particularly cold chain items. During the COVID-19 pandemic, issues regarding supply of cold chain medicines to warm, remote parts of Australia were exacerbated with cold chain breaches of vaccines and antivirals for COVID-19, and in reality had already been occurring for a long time for other medicines. A National Centre for Stability Testing would potentially also be able to ascertain stability data to minimise wastage in the Australian environment.

# Wastage (and vial-sharing)

12. Short-term: Continue the current system of reimbursement on the basis of the most efficient combination of vials.

SHPA supports this recommendation.

SHPA agrees that this recommendation is appropriately classified as a short-term change.

13. Medium-term: Investigate the introduction of a PBS Dose-Banding chart for cancer medicines to facilitate ease of prescribing within bands (with an aim to reduce wastage on a per-patient basis). Reimbursement would continue to be based on the most efficient combination of vials (ad-interim).

SHPA is pleased to see the EFC Review Interim Report acknowledge SHPA's recommendation to explore the appropriateness and feasibility for using a dose banding strategy for chemotherapy medicines to minimise wastage. These strategies are broadly used internationally and provide a solid foundation for its potential implementation in Australia.

SHPA members have reported that dose banding is often met with resistance from medical and nursing staff concerned about the accuracy and efficacy of the dose being provided, despite assurances provided by the literature. SHPA recommends an education campaign for prescribers, nurses and patients to inform them of the evidence behind this strategy.

SHPA agrees that this recommendation is appropriately classified as a medium-term change.

14. Long-term: Adopt a per-mg reimbursement model as the most efficient use of cancer medicines and may support the reconciliation of sales with manufacturers. This is predicated on broader system change with respect to the interface between PBS reimbursement for drug supplied and the flow of funds to states for hospital funding through the Australian Hospital Agreements. The aim would be to allow hospital-based pharmacies to remain viable in the face of short-term reductions in cash-flow (due to a decline in PBS receipts).

SHPA does not support this recommendation to adopt a per-mg reimbursement model. SHPA members are concerned that this model will result in more wastage and therefore, increased cost of compounded medicines. This model will undermine the viability of the cancer service being provided ultimately impacting negatively on the quality of the service received by patients.

A per-mg model will not be efficient in hospital settings and especially for those in rural and remote locations. Hospitals will not be able to afford purchasing cancer medicines where the full vial is not being used, as the cost of the unused medicine is not being accounted for or reimbursed. This in turn will restrict the service being provided and impact on the quality of cancer care.

This model will not only increase wastage of medicines, it does not at all support the use of medicines with short stability data, or those that are used infrequently. For example, melphalan, a less common chemotherapy medicine with short stability, comes in 100mg vials. In the proposed per-mg reimbursement model, a dose of 120mg (2 x 100mg vials) will result in an 80mg wastage. If this wastage is not financially accounted for, hospitals will have to either underdose patients with 100mg (1 x 100mg vial) or carry the cost of the 80mg wastage, which is not viable especially for high-cost medicines, and will threaten the viability of cancer services, especially in smaller hospitals and hospitals in rural and regional areas that are unable to achieve economies of scale.

SHPA acknowledges that in the Interim Report's discussion of the per-mg reimbursement model, costs to the Australian government are lower. SHPA does not dispute this, however it does not adequately describe the potential wastage associated with this, particularly for smaller cancer services with small patient loads. Furthermore, while costs to the Australian government are indeed lower, what it explicitly results in is cost-shifting back on to other funders – such as states and territories, private providers and ultimately consumers – who will not be subsidised or remunerated for any quantity of medicine that is not used and discarded from a vial. These

changes would create more cost-shifting between federal and state governments, cancer service providers and consumers, which ultimately do not place patient access, safety and quality at the centre.

Not only would this cost-shifting be unfair to other cancer patients and service providers, it would also encourage adding further to cytotoxic waste which has an environmental impact. The intersection of hospital care and pharmaceuticals already accounts for the majority of Australia's healthcare related carbon footprint, and measures that increase pharmaceutical waste will only add to this. Theme 1 of <a href="Pharmacy Forecast Australia 2022">Pharmacy Forecast Australia 2022</a> is Environmental Sustainability and the majority of Forecast Panellists anticipate that by 2027, hospitals will increase budget allocations to support new medication-related inventory and distribution technology solutions to reduce wastage.

15. Medium-term: Upgrade PBS data collection and reporting systems to ensure information on the form and strength of vials used in estimating the most efficient combination of vials can be readily extracted from the system.

SHPA provides in principle support for this recommendation, however, is concerned that this recommendation will place an unnecessary additional administrative burden on an already stretched pharmacy and compounding workforce. This recommendation can only be realised if the procurement, dispensing, compounding and clinical systems used along the entire continuum of cancer care, are integrated to prevent manual transcription of data, which is likely to contribute to reporting errors anyway.

16. Long-term: Serialise vials to facilitate reconciliation of drugs transacted with PBS claims. Feasibility of such an arrangement is subject to requisite infrastructure (e.g., sterility compliant scanning devices in compounding facilities, pharmacy scanning software) and financial capital investment.

SHPA provides in principle support for this recommendation, and strongly appreciates that it acknowledges that its feasibility is subject to requisite infrastructure. While SHPA is supportive of increased serialisation and tracking of medicines, to support <u>closed loop medication management</u>, it must be acknowledged the current disparate and complex patchwork of procurement, dispensing, compounding and clinical systems used along the entire continuum of cancer care would make it immensely difficult to achieve accurate tracking of serialised medicines.

Alongside an additional workload, serialising vials will also add complexity, cost and infrastructure to those providing the service. Data entry may be required at multiple sites, at the point of compounding and again at point of claiming and dispensing, if these are two separate locations as is often the case in rural and remote settings. Additional workload must be accounted for, and the process must be electronically integrated across the whole system to avoid transcribing which will not only be resource intensive but also increase the risk of errors.

Furthermore, the Interim Report does not discuss with respect to serialising vials, how this would impact on cancer services who routinely provide chemotherapy for non-PBS indications, or for settings of care where PBS subsidy is ineligible such as inpatient settings. SHPA raised these issues when Special Pricing Arrangement reforms were proposed a number of years ago, and reiterates that any changes to medicines reimbursement, funding and tracking must take into account its impacts on medicines use outside the PBS. As the COVID-19 pandemic experience has exacerbated, maintaining multiple bins/lines in procurement and inventory systems for the same medicine is inherently inefficient and adds to complexity for health services, which ultimately contribute to errors and inaccuracies both in the supply chain and in patient care.

17. System change: Consider the potential for the Commonwealth to purchase medicines directly from manufacturers as a means of increasing system efficiency and more directly align the purchase and reimbursement of PBS medicines.

SHPA is against having the Commonwealth purchase medicines directly from manufacturers. As outlined in our response to recommendation three above, a centralised model does not address the non-PBS or off-label use of medicines, and will not support States and Territories that are non-PBS signatories. It does not clearly state who will be financially accountable for expired stock at health services and for wastage. This model will simply increase the administrative burden on an already stretched workforce.

# Patient access and safety

18. Short-term: Remove the distinction between public and private hospital prescribing as a means of rationalising patient co-payments. There should be no distinction between out-of-pocket costs to patients based on the settings in which prescribers are authorised.

SHPA supports this recommendation.

SHPA agrees that this recommendation is appropriately classified as a short-term change.

19. Short-term: Expand the availability of the Closing the Gap arrangements to all eligible Indigenous peoples accessing cancer medicines listed in Schedule 1 or Schedule 2 of the EFC, irrespective of the setting from which those medicines are prescribed.

SHPA supports this recommendation to improve access by expanding the availability of Closing the Gap arrangements to all eligible Indigenous peoples accessing cancer medicines listed in Schedule 1 or 2 of the EFC irrespective of the setting from which they are prescribed.

SHPA also recommends improving chemotherapy service delivery to Aboriginal and Torres Strait Islander People by addressing health literacy and developing culturally appropriate resources on chemotherapy medicines and cancer care in hospitals, through co-design and consultation with Aboriginal and Torres Strait Islander Peoples and Indigenous Health peak bodies and practitioners. Culturally and linguistically diverse medication information resources are not currently available for chemotherapy and supportive non-chemotherapy medications. These resources would support these important conversations and help improve cultural perspectives on hospitals and cancer treatment options.

SHPA agrees that this recommendation is appropriately classified as a short-term change.

20. Short-term: Extend the current co-payment arrangements for EFC Schedule I medicines to Schedule II medicines to ensure patients are not differentially affected by co-payments.

SHPA supports this recommendation.

SHPA agrees that this recommendation is appropriately classified as a short-term change.

21. Medium-term: Conduct a system wide consultation on the provision of cancer services to consider initiatives that may improve access to care. This will necessitate the combined consultation of State/Territory and Commonwealth Governments, and key health organizations.

SHPA supports this recommendation.

SHPA agrees that this recommendation is appropriately classified as a medium-term change.

#### Standards - Pharmacy

- 22. Short-term: The Review reiterates the findings of the King Review (2017) with respect to the establishment of consistent standards as they apply to the compounding and supply of cancer medicines. There should be a clear and uniform minimum set of standards for all approved cancer medicine compounding facilities. These minimum standards should:
  - a. Be developed based upon current Good Manufacturing Practice and the Pharmacy Board of Australia compounding standards, therefore ensuring all TGA licensed and non-TGA licensed facilities will meet the minimum standards;
  - b. Not require that a compounding facility be TGA-licensed to meet minimum requirements;
  - c. Reflect the various settings that are appropriate for the preparation of cancer medicines, including 'urgent' preparations in a hospital or community pharmacy setting;
  - d. Detail specific and measurable requirements that will be audited to maintain approval to operate as a cancer medicine compounding facility; and
  - e. Articulate the distinction in standards required for cytotoxic and non-cytotoxic cancer medicine compounding.

The Pharmacy Board of Australia, or appropriate regulatory authority, should be adequately resourced to monitor compliance with these national standards.

SHPA supports this recommendation on the proviso that it does not place an additional regulatory burden on a stretched and under-resourced workforce.

SHPA as the professional organisation for pharmacists practicing in Australian hospitals and across the healthcare system, and our members who are experts in Oncology and Compounding, should be involved in ensuring these standards are relevant, up-to-date, and clearly articulate requirements for health services. Relevant to this recommendation is SHPA's <u>Guidelines for Medicines Prepared in Australian Hospital Pharmacy Departments</u>, which is currently being reviewed.

SHPA agrees that this recommendation is appropriately classified as a short-term change.

#### Public vs private settings

23. Short-term: Remove the distinction between (s94) public and private hospital settings with respect to PBS item codes.

SHPA is pleased to see the EFC Review Interim Report acknowledge SHPA's recommendation to address the discrepancy between s94 public and private hospital settings with respect to PBS item codes. Fundamentally, the lower the renumeration for supplying PBS medicines, the less funding there is for high quality clinical pharmacy services, dispensing services and compounding services to be delivered to patients requiring chemotherapy.

SHPA agrees that this recommendation is appropriately classified as a short-term change.

24. Short-term: Remove the distinction between (s94) public and private hospital providers with respect to the EFC fees paid for the supply of cancer medicines.

SHPA is pleased to see the EFC Review Interim Report acknowledge SHPA's recommendation to address the discrepancy between section 94 public and private hospital providers with respect to the EFC fees paid for the supply of cancer medicines. The distinction in fees paid impacts on the viability of chemotherapy services which have comparably larger fixed and ongoing costs compared to other PBS medicines.

It is imperative however, that this recommendation sees public hospitals being provided comparable EFC fees to section 90 community and section 94 private hospital providers, and not a reduction in funding to those settings to meet that of the public health sector.

SHPA agrees that this recommendation is appropriately classified as a short-term change.