SHPA response to TGA consultation on Extemporaneous Compounding of Emergency Medicines - Proposal to improve patient access to critical medicines in acute-care settings – via online survey

1. **Do you think that proposed change, to allow pharmacists to extemporaneously compound certain medicines without a named patient, is necessary?**

SHPA believes that the proposed change to allow pharmacists to extemporaneously compound certain medicines without a named patient is vital and necessary to ensure life-saving medicines or medicines preventing disability, significant loss of function or significant and permanent decrease in quality of life, are administered to hospital patients in a timely manner.

At present, existing approval pathways in the therapeutic goods legislative framework such as Authorised Prescriber and Special Access Scheme, would not allow for timely access to extemporaneously compounded medicines in emergency situations.

Members have expressed that this practice is necessary for a large range of medicines, some of which are not commercially available in Australia. This is especially true of medicines required for neonates and small children. This includes anti-infective medicines for the treatment of traumatic eye and ear injuries and furosemide and spironolactone oral liquid to treat oedema in heart failure, where a delay in treatment can have life-threatening consequences. The unpredictable and urgent nature of these kinds of admissions means that it would have serious implications to await a prescription before treatment can be prepared. This risk would be greater during evenings or weekends where reliance would be on the medical team and on-call pharmacist, not only delaying treatment but also giving way to the potential for medication errors.

Current legislation has also been limiting for preparing products to mitigate the impacts of known and long-term medicines shortages. An example being dexamethasone liquid for croup, which has been out of stock for over a year. Members report that the new proposal would allow this item to be prepared in advance and allow timely treatment for their patients.

2. **Do you believe the suggested approach is fit-for-purpose?**

SHPA supports the proposed approach for a new exemption and believes it is fit-for-purpose to achieve its aims. The four specific circumstances described by the proposal are appropriate for when the new proposed new exemption would apply. As this proposal seeks to address timely medicines access in acute settings, it is appropriate this exemption is limited to pharmacists employed in hospital settings, as they are familiar with working within robust governance frameworks.

All medicines use and supply in hospitals is governed by Drugs and Therapeutics Committees (DTC). DTCs provide expert multidisciplinary governance and evaluation around the approval of medicines and the system. Guiding principles for the roles and responsibilities for DTC are set out by the Council of Australian Therapeutic Advisory Groups (CATAG) to ensure uniform functions and compliance with appropriate standards, principles and statutory requirements and whose members represent DTCs around the country.

Furthermore, the Clinical Governance Standard and the Medication Safety Standard of the National Safety and Quality Health Service (NSQHS) Standards health service organisations have governance arrangements in place to support the safety and quality of medicines. The NSQHS Standards Guide for Hospitals also specify that health service organisations should include a governance committee that is responsible for medicines management, including the compounding of medicines.

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3. **Do you think proposed amendment will achieve desired patient outcomes?**

Our members welcome the proposed amendment that would allow hospital pharmacists to prepare extemporaneously compounded medicines prior to a patient being identified to prevent delay in treatment in emergencies. Patients can receive timely access to life-saving medicines out of hours without having to wait for a doctor to prepare the prescription and then await an on-call pharmacist to prepare and supply the medication. In normal business hours, compounding a specific item would take away from the clinical duties of hospital pharmacists, further impacting patient care. The proposed amendment would allow for hospital pharmacists to dedicate more time to clinical duties, ultimately improving patient outcomes.

4. **Are there any unforeseen risks associated with the proposed approach?**

Anticipated needs of critical medicines will vary across different hospitals depending on their hospital size, their clinical services and specialties, and patient profile of their hospital catchment area. Hospital pharmacy departments, in conjunction with DTCs should be responsible for determining and adjusting the anticipated required quantities of prepared medicines according to regular use patterns. Regular auditing is recommended of prepared medication against actual usage to reduce wastage and ensure that only sufficient quantities are compounded to treat anticipated patient cohorts.

To discuss this submission further, please contact Jerry Yik, Head of Policy and Advocacy at jyik@shpa.org.au.