Changing the Therapeutic Goods Regulations 1990 to support hospital compounding practices and timely patient care

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Background

- SHPA convenes a Compounding Services Specialty Practice Group with over 550 members. It is led by a seven-member Leadership Committee, currently co-chaired by Branko Radojkovic and previously inaugurally chaired by Priti Prasad.
- In late 2017, the Pharmacy Board of Australia (PBA) released an updated version of the *Guidelines on Compounding of Medicines* and a Frequently Asked Questions resource which inferred preparation of compounded medicines without a prescription, in anticipation of need, was not consistent with the *Guidelines on Compounding of Medicines.*
- This was inconsistent with longstanding compounding practices in hospitals, who required to prepare compounded medicines in advance and keep them as stock for emergency use and special populations where no commercial products are available, supporting timely access to critical and lifesaving medicines.
- Example medicines are frusemide oral liquid, hydrochlorothiazide oral liquid, spironolactone oral liquids, all used to treat cardiac conditions in neonates and paediatrics, and cefazolin eye drops and gentamicin eyedrops to treat bacterial keratitis .

Timeline of events

Late 2017

SHPA raises concerns with the PBA that guidance provided on the updated *Guidelines on Compounding of Medicines* challenged longstanding and safe compounding practices to support timely access to critical medicines in hospitals where commercial products are unavailable.

2018

PBA confirms with SHPA after discussing with the Therapeutic Goods Administration (TGA), that the *Guidelines on Compounding of Medicines* and its associated FAQ resource correctly reflected the exemptions for pharmacists to compound as stated in *Therapeutic Goods Regulation 1990.*
SHPA is advised by members that hospital compounding practices have changed to conform with *Guidelines on Compounding of Medicines* and associated guidance from PBA regarding batch compounding and the necessity to have a prescription in advance of compounding a medicine.

Early 2020

Amidst the COVID-19 pandemic, clinicians anticipate increased demand in compounded medicines in the event of a COVID-19 wave, whilst expecting reduced healthcare worker capacity due to COVID-19 infection. SHPA members once again raise the need to be able to compound medicines in anticipation of need in order to support safe and timely access, particularly in clinically urgent situations.

September 2020

SHPA's Compounding Services Leadership Committee and Chief Executive write to the TGA to discuss the clinical need to be able to compound medicines in advance of receiving a prescription in the hospital setting. SHPA also raises the numerous inefficient workarounds pharmacists and nurses had undertaken to support safe and timely access to compounded medicines while attempting to adhere to PBA guidelines.

The TGA writes back the same month acknowledging understanding of this specific issues, and refers it to work with the TGA to explore regulatory options to rectify the situation.

March 2021

SHPA writes to the PBA advising of TGA's response and offering to collaborate in seeking changes to *Therapeutic Goods Regulations 1990.*

September 2021

At TGA's request, SHPA provides TGA a detailed Problem Statement paper with preferred options for change.

October 2021

SHPA and TGA hold a workshop alongside PBA and jurisdictional pharmacy authority representatives to discuss various regulatory options and possible changes to support safe and timely access to compounded medicines in hospitals.

SHPA contends making these changes specifically for hospitals only, would be appropriate as they are accredited by an independent regulator against Commonwealth standards, and also have strong governance functions such as Drugs and Therapeutics Committees (DTC) which would be key to supporting safe compounding practices in hospitals.

The TGA are unfamiliar with DTCs and the SHPA writes a paper for the TGA titled *The Role and Function of Drugs and Therapeutics Committees in Australian Public Hospitals.*

The TGA advises any changes to *Therapeutic Goods Regulations 1990* requires a public consultation process.

February 2022

TGA releases the consultation paper *Extemporaneous Compounding of Emergency Medicines – Proposal to improve patient access to critical medicines in acute-care settings.*

The proposed changes, which are identical to the changes SHPA had requested during its discussions with TGA, will allow pharmacists to compound medicines in anticipation of need under the following conditions:

- The medicines can only be extemporaneously compounded by pharmacists employed by a public or private hospital
- The medicine can only be prepared following approval by the hospital's Drugs and Therapeutic Committee, or equivalent.
- The medicines are needed in an acute-care setting, in circumstances where delayed treatment is reasonably likely to cause premature death, disability, significant loss of function, or significant and permanent decrease in quality of life
- The medicines are prepared in quantities determined by established demand.

SHPA provides a written submission in support of the proposed changes.

July 2022

TGA advises SHPA there was strong support for the proposed changes from the public consultation process, and that they have decided to amend the *Therapeutic Goods Regulation 1990* to effect these changes in due course.

January 2023

***Schedule 5—Therapeutic goods exempt from the operation of Parts 3-2 and 3-2A of the Act* of the *Therapeutic Goods Regulations 1990* is updated to now allow for hospitals to compound medicines in anticipation of receiving a prescription.**

For the first time, Drug and Therapeutics Committees as a medicines governance bodies are mentioned and recognised by Commonwealth regulations.

AUSTRALIA

Therapeutic Goods Regulations 1990

Statutory Rules No. 394, 1990

made under the

Therapeutic Goods Act 1989

Compilation No. 111

Compilation date:	20 December 2022
Includes amendments up to:	F2022L01687
Registered:	4 January 2023

Schedule 5—Therapeutic goods exempt from the operation of Parts 3-2 and 3-2A of the Act

6A	medicines (other than medicines that are used for gene therapy or that are medicinal cannabis products) that are: (a) compounded in a hospital by: (i) in the case of a private hospital—a hospital pharmacist who is engaged in the manufacture of therapeutic goods (other than biologicals) on the premises of the private hospital; or (ii) in the case of a public hospital—a pharmacist who is employed by the public hospital and is engaged in the manufacture of therapeutic goods (other than biologicals); and (b) compounded in anticipation of being needed for therapeutic application to patients of the hospital; and (c) considered by the hospital's drug and therapeutic committee (however called) to be appropriate for compounding in anticipation of being needed to treat a patient at the hospital

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