Australian Government
Department of Health
Therapeutic Goods Administration

# Extemporaneous Compounding of Emergency Medicines

## Proposal to improve patient access to critical medicines in acute-care settings

Version 1.0, November 2021

TGA Health Safety Regulation

**Confidentiality**
All submissions received will be placed on the TGA's Internet site, unless marked confidential. Any confidential material contained within your submission should be provided under a separate cover and clearly marked "IN CONFIDENCE". Reasons for a claim to confidentiality must be included in the space provided on the TGA submission form. For submission made by individuals, all personal details, other than your name, will be removed from your submission before it is published on the TGA's Internet site. In addition, a list of parties making submissions will be published. If you do not wish to be identified with your submission you must specifically request this in the space provided on the submission form.

# Contents

# Consultation Overview

The Therapeutic Goods Administration (TGA) is seeking feedback on a proposal to help facilitate patient access to critical medicines.

Timely access to critical medicines is essential for medical professionals and their patients, particularly in acute-care settings. We are seeking your feedback on proposed regulatory reforms to support hospital pharmacists to extemporaneously compound certain medicines in advance of a patient being identified, so they can be available for immediate use in an emergency.

## Background

Normally, medicines used in Australia have been assessed and approved by the TGA prior to supply. These are listed or registered on the Australian Register of Therapeutic Goods (ARTG) and identified with an AUST L or AUST R number on the label.

In some circumstances, where a commercial product isn't available, hospital pharmacies can 'extemporaneously compound' - they will make a medicine for a particular patient who would otherwise not have a medicine suitable for them. However, there are situations where the delay while the pharmacist makes the medicine puts the patient at risk or there is an 'out of hours' emergency and no pharmacist is available. In these emergency situations, patient needs can only be met if the medicines are made in advance.

There are other mechanisms in our existing therapeutic goods legislative framework to allow medical practitioners access to medicines that are not on the ARTG. Under the Authorised Prescriber and Special Access Scheme, the TGA approves the use of a nominated treatment by a practitioner for their patients. Neither of these approval pathways allow timely access to extemporaneously compounded medicines in all emergency situations.

## Why are we consulting?

The current regulatory framework does not permit hospital pharmacists to extemporaneously compound medicines before a specific patient is identified. In particular emergency situations, this puts patients at risk.

After preliminary discussions with hospital pharmacists, we believe there are situations where certain critical medicines can be prepared in advance of receiving a prescription. Existing hospital Drug and Therapeutics Committees [1] (or equivalent systems) provide adequate clinical oversight and could identify these situations and approve compounding in advance. The primary consideration is that untimely treatment, delay to treatment or absence of treatment is reasonably likely to cause premature death, disability, significant loss of function or significant and permanent decrease in quality of life. The medicines involved are only required in low volumes and have very short shelf-lives, often making them difficult to transport and not commercially viable. Hospitals would only compound them in the smallest quantities, sufficient to meet a defined need, using standardised formulations and processes to ensure quality.

We now seek your feedback on a proposal to amend existing regulations to allow this type of extemporaneous compounding, particularly to identify any concerns or unforeseen risks.

[1] Council of Australian Therapeutic Advisory Groups, www.catag.org.au/wp-content/uploads/2012/08/OKA9964-CATAG-Achieving-Effective-Medicines-Governance-final1.pdf

# Consultation scope

The scope of this consultation is limited to the proposal to provide a specific exemption for pharmacists within hospitals to extemporaneously compound before a specific patient is identified, under certain limited circumstances. We are not seeking feedback regarding any other exemptions included in the existing regulatory framework.

# How to respond

We have posed questions within this paper and on our consultation hub to help guide your feedback. You can also give us any additional comment and attach a separate response document if you wish.

You do not have to answer all the questions, none are compulsory.

Please submit your views by clicking the link below – this will take you to our consultation hub, step you through our questions and give instructions for how to provide your response.

**https://consultations.tga.gov.au/tga/proposal-to-improve-patient-access-to-critical-med**

# Proposed Action

## Proposal

We propose to amend the *Therapeutic Goods Regulations 1990* to include a new exemption that would permit hospital pharmacists to extemporaneously compound certain medicines, prior to identification of a patient and without the requirement for the medicine to be included on the ARTG.

This exemption would only apply in certain circumstances. These are described below:

| Proposal | Explanation |
|---|---|
| The medicines can only be extemporaneously compounded by pharmacists employed by a public or private hospital. | Ensure that the medicines are made by appropriately qualified pharmacists supplying medicines in acute-care settings. |
| The medicine can only be prepared following approval by the hospital's Drugs and Therapeutic Committee, or equivalent. | Drug and Therapeutics Committees (DTCs) provide appropriate clinical oversight of extemporaneous compounding, ensuring it is based on clinical need and in accordance with relevant quality requirements. |
| 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 | This would ensure that the medicines are only compounded and used where there are no other options for treatment. |

| Proposal | Explanation |
| --- | --- |
| The medicines are prepared in quantities determined by established demand. | Hospital DTCs can determine and anticipate the quantities required, ensuring only sufficient amounts are made. |

Questions

Q1. Do you think that proposed change, to allow pharmacists to extemporaneously compound certain medicines without a named patient, is necessary?

Q2. Do you believe the suggested approach is fit-for-purpose?

Q3. Do you think proposed amendment will achieve desired patient outcomes?

Q4. Are there any unforeseen risks associated with the proposed approach?

# Version history

| Version | Description of change | Author | Effective date |
|---|---|---|---|
| V1.0 | Original publication | Manufacturing Quality Branch | 02/12/2021 |

**Therapeutic Goods Administration**

PO Box 100 Woden ACT 2606 Australia
Email: info@tga.gov.au  Phone: 1800 020 653  Fax: 02 6203 1605
**https://www.tga.gov.au**

Reference/Publication #