Update on the glucagon-like peptide-1 receptor agonists (GLP-1 RAs) pharmacy compounding changes

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Acknowledgement of Country

In the spirit of reconciliation, the Department of Health and Aged Care acknowledges the Traditional Custodians of country throughout Australia and their connections to land, sea and community.

We pay our respect to their Elders past and present and extend that respect to all Aboriginal and Torres Strait Islander peoples present today.

Welcome

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Today’s session

- The role of the Therapeutic Goods Administration (TGA)
- The regulatory framework for medicine approval vs pharmacy compounding
- The ‘why’- public health risks in large-scale compounding
- The ‘how’- the consultation process
- The ‘when’- the timeframe for change
- Medicine shortages and TGA strategy
- Information for prescribers, pharmacists and consumers
- The way forward

The role of the TGA

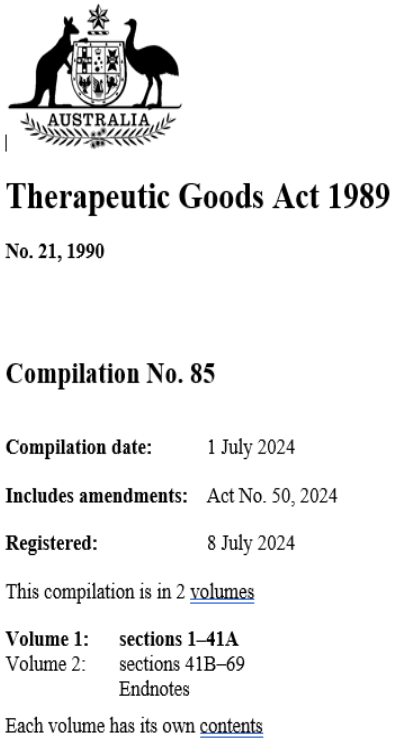
Established to “safeguard and enhance the health of the Australian community through effective and timely regulation of **therapeutic goods”.**

- **Regulates therapeutic goods** including prescription, over-the-counter and complementary medicines, medical devices, biologicals, blood and blood products
- **Evaluates therapeutic goods** before they are marketed and monitors products once they are on the market
- Assesses suitability of medicines and devices for **export**
- Focuses on **safety, efficacy and quality**
- **Works closely** with consumers, health professionals, industry and international counterparts

The Therapeutic Goods Act 1989

- **Provides a national framework** for regulating therapeutic products in Australia to ensure the quality, safety, efficacy and performance of medicines and medical devices.

- Sets requirements for entry of products in the **Australian Register of Therapeutic Goods (ARTG)**
  - all therapeutic products **must be entered on the ARTG** before they can be supplied or exported
  - there are some special circumstances where individuals can request access to **an unregistered product** through their healthcare practitioner via certain exemptions.



AUSTRALIA

Therapeutic Goods Act 1989

No. 21, 1990

Compilation No. 85

Compilation date: 1 July 2024

Includes amendments: Act No. 50, 2024

Registered: 8 July 2024

This compilation is in 2 volumes

Volume 1: **sections 1–41A**
Volume 2: sections 41B–69
Endnotes

Each volume has its own contents

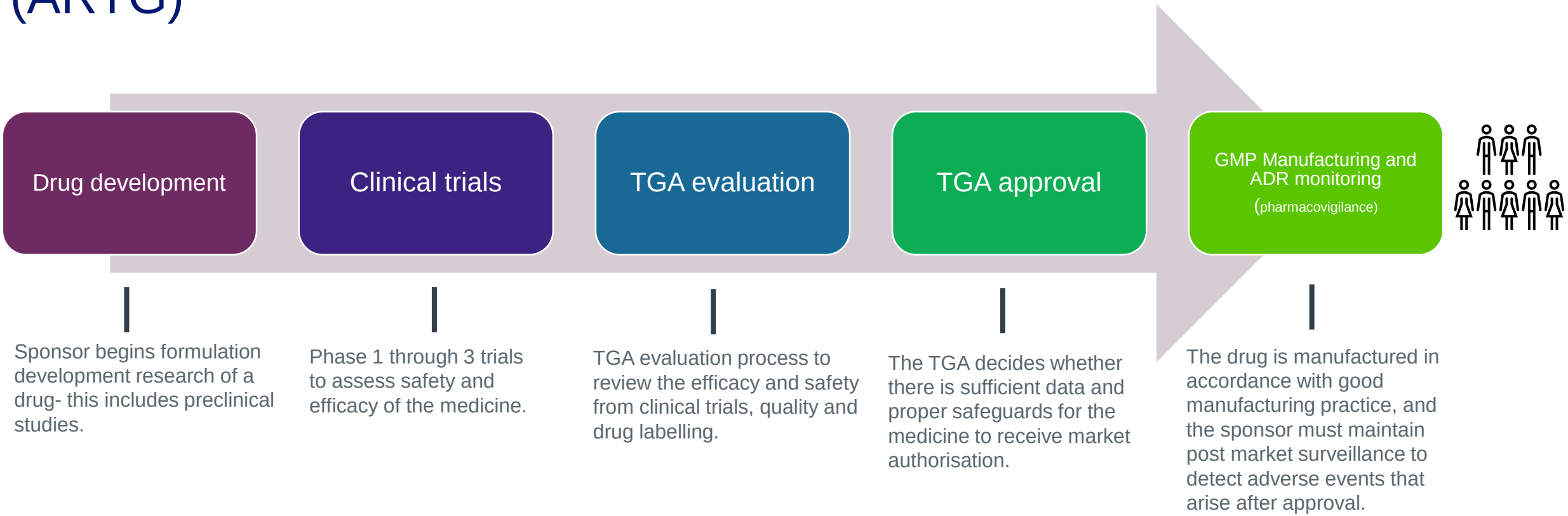
Risk management

- All therapeutic goods have **some level of risk.**
- Our role is to determine whether the benefits outweigh known risks.
- Management of uncertainty is a greater challenge – and an area where we will seek stakeholder and expert input.

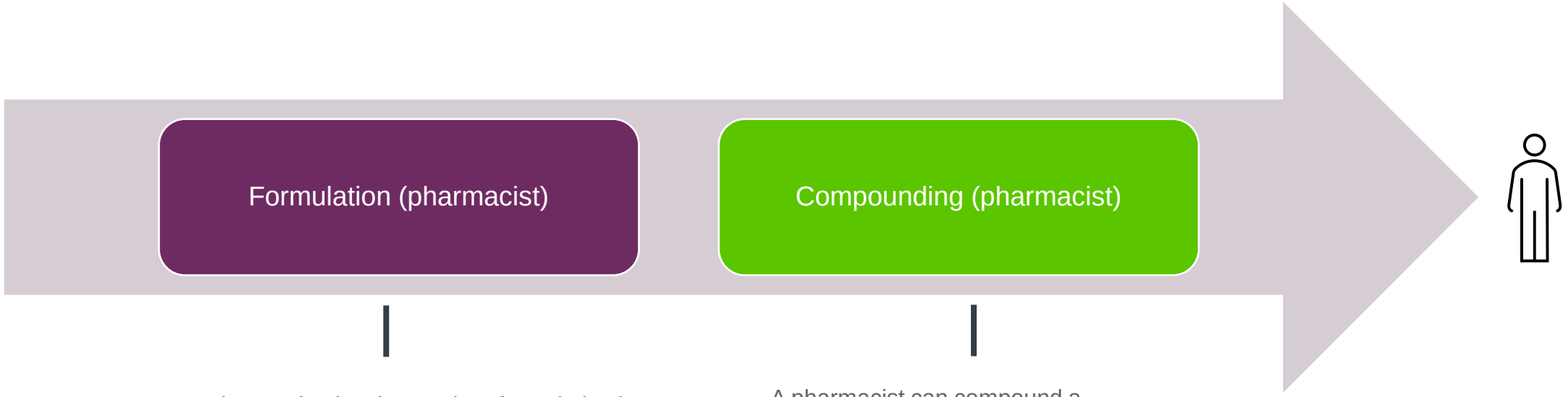
TGA's approach to risk management involves:

- identifying, assessing and evaluating the risks posed by therapeutic products.
- applying any measures necessary for treating the risks posed.
- monitoring and reviewing risks over time.

The regulatory framework for a prescription medicine to be included in the Australian Register of Therapeutic Goods (ARTG)



The regulatory framework for a medicine to be compounded for an individual patient



A pharmacist develops a drug formulation in consultation with the prescriber, formulation resources (i.e Australian Pharmaceutical Formulary) and professional judgment.

A pharmacist can compound a medicine for a specific patient on a prescription in the pharmacy accordance with relevant Commonwealth and state/territory legislation and relevant practice guidelines and standards.

The ‘why’- public health risks

Risk identified:

- the unknown nature and safety of the raw ingredients imported and used in manufacture,
- the absence of regulatory evaluation for safety and quality,
- compounding practices that are outside of the current exemptions that specify manufacture only on an individual patient basis and only after receipt of a valid prescription, and
- the lack of reporting of adverse events related to the quality and safety of compounded drugs.

The ‘why’- public health risks identified

FDA alerts health care providers, compounders and patients of dosing errors associated with compounded injectable semaglutide products

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JAMA Network Open

Research Letter | Nutrition, Obesity, and Exercise

Safety and Risk Assessment of No-Prescription Online Semaglutide Purchases

Amir Reza Ashraf, PharmD; Tim K. Mackey, MAS, PhD; János Schmidt, MA; Győző Kulcsár, MSc, PhD; Róbert György Vida, PharmD, PhD; Jiawei Li, MS; András Fittler, PharmD, PhD

Introduction

The popularity of branded semaglutide is surging, with widespread media coverage, viral social media exposure, and celebrity endorsements.[1] Although Wegovy (Novo Nordisk) is approved for long-term weight management, Ozempic (Novo Nordisk) (only approved for type 2 diabetes) is often

+ Supplemental content

Author affiliations and article information are listed at the end of this article.

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Compounding safety information: semaglutide-like products

Published: 15 December 2023

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Press release

MHRA warns of unsafe fake weight loss pens

The ‘how’- consultation process

- We undertook targeted consultation with peak representative bodies for health professionals, industry and consumers.
- Prior to the consultation process, in January 2024, the TGA hosted a roundtable discussion with health regulators.
- We met with a number of individual stakeholders to discuss matters relating to the compounding of GLP-1 RAs.

The ‘how’- consultation process

- The majority of stakeholders who responded supported the proposed change, citing safety and clinical concerns in relation to the scale and complexity of the manufacture of the GLP-1 RAs through pharmacy compounding.

- Responses also highlighted that the existing Pharmacy Board and state/territory notification and compliance processes for compounding are not adequate to address safety and efficacy concerns unique to the large-scale compounding of GLP-1 RAs.

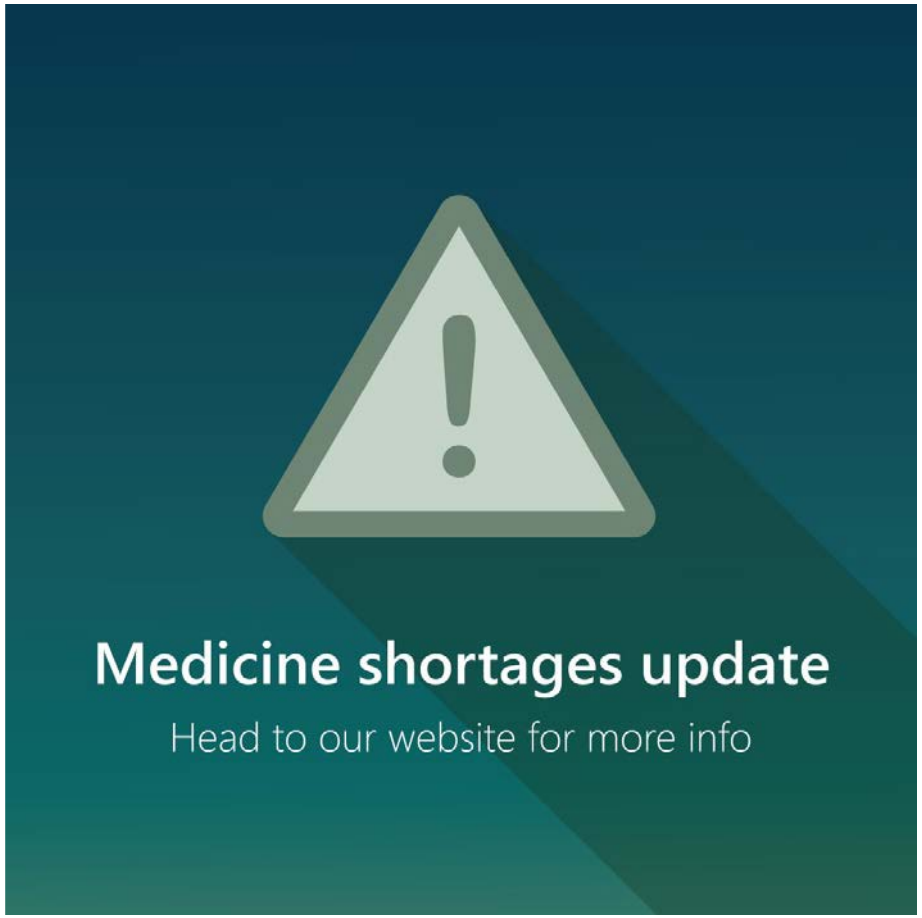
- Several stakeholders indicated that the current regulatory exemptions have not kept pace with compounding practices. The TGA is active in this space.

The ‘when’- timeframe for change

* Therapeutic Goods Regulations 1990

Medicine shortages and TGA strategy

- Shortages occur for many reasons and sometimes they cannot be avoided.
- We take shortages very seriously and work with pharmaceutical companies to help minimise the effects on consumers and healthcare practitioners.
- While we recognise shortages cause concern for patients, it is important that the alternative treatments accessed during shortages are safe and of good quality.
- Medicine shortage report database is available on the TGA website



Medicine shortages and TGA strategy

- The TGA will continue to actively monitor the supply of Ozempic, Wegovy, Mounjaro and Trulicity and liaise with sponsors of GLP-1 RAs regarding supply status and

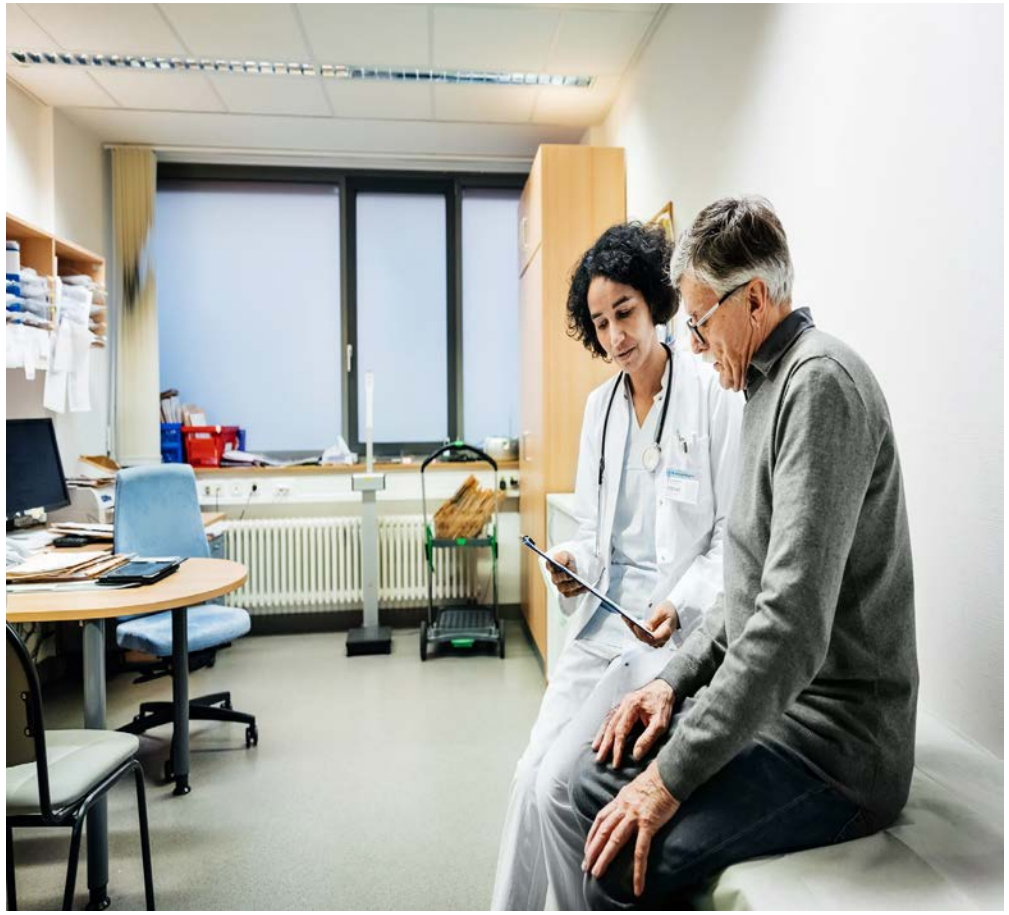
- **Up-to-date information about the shortages of GLP-1 RA medicines is available on the TGA website.**

Key points for consumers

- Compounded GLP-1 RAs are not identical to TGA- approved medicines.
- Speak to your doctor regarding your individual situation.
- Beware of online scams offering injectable weight loss products.
- Report adverse effects.

Key points for HCPs

- Compounded medicines containing GLP-1 RAs **cannot be** prescribed and compounded after 1 October 2024.
- Consult with your patient/s on alternative healthcare plans.
- Keep up to date with TGA GLP-1 RA product supply updates and S19A information via the TGA website.
- Report adverse effects.



The way forward

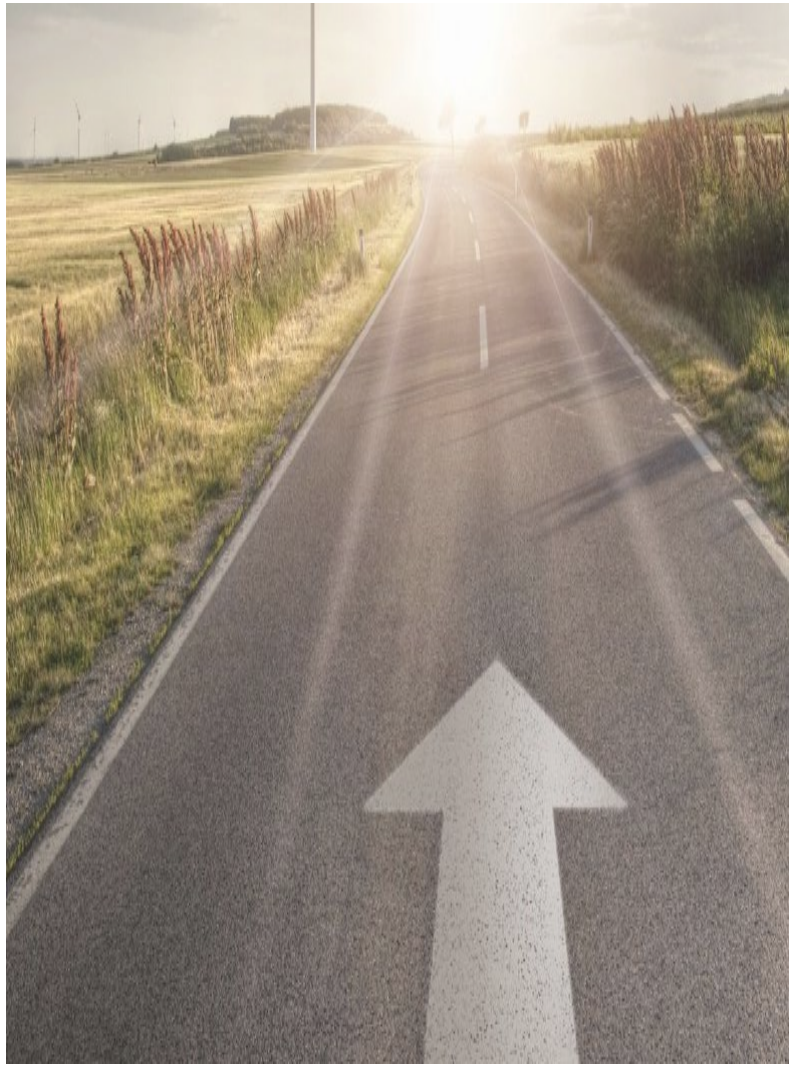
Enforcement and Compliance

- **Civil and criminal penalties may apply to anyone who is found to have unlawfully manufactured and supplied compounded products containing GLP-1 RAs from 1 October 2024.**
- Consumer advertising of compounded products is also unlawful.
- The TGA is working in partnership with law enforcement, other health regulators and state and territory colleagues to address non-compliance.
- The TGA is dedicating significant resources to investigate these matters and take appropriate enforcement action against anyone found to have breached the law.
- The professional conduct of medical practitioners and pharmacists is regulated by the Australian Health Practitioner Regulation Agency (Ahpra).

The way forward

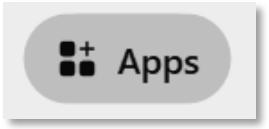
Next steps

- The TGA will work with key medical, pharmacy and consumer stakeholders, and other health system regulators, to provide guidance in navigating the impact of these changes.
- Feedback from stakeholders noted a need for regulatory reform of the compounding framework.



How did we go?

Take a moment to complete our survey



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Frequently asked questions

1. Is this change a reflection on the pharmacy profession?

2. What is the consequence for pharmacists found compounding after 1 Oct?

3. Is stockpiling of compounded GLP-1 RAs permitted before 1 Oct?

4. Can I import GLP-1 RA products through the Personal Importation Scheme (PIS)?

5. How does the TGA intend to provide access to this medication which is still in shortage?

Frequently asked questions

6. Are there concerns about the longer-term health implications of GLP-1 RAs and what research is being done to understand their impact?

7. Is there a possibility of reversal of this change in the future?

8. Do you anticipate further changes to the way compounded medicines are regulated?

Information and resources

Compounding safety alerts relating to GLP-1 RAs	
Substandard semaglutide vials	https://www.tga.gov.au/news/safety-alerts/substandard-semaglutide-vials
Compounding safety information: semaglutide-like products	https://www.tga.gov.au/news/safety-alerts/compounding-safety-information-semaglutide-products
What you need to know about compounded weight-loss medicines.	https://www.tga.gov.au/news/blog/what-you-need-know-about-compounded-weight-loss-medicines
Medicine shortage information	
About the Ozempic (semaglutide) shortage 2022 - 2024 | Therapeutic Goods Administration (TGA)	https://www.tga.gov.au/safety/shortages/information-about-major-medicine-shortages/about-ozempic-semaglutide-shortage-2022-and-2023
About the Trulicity (dulaglutide) shortage 2022 - 2024 | Therapeutic Goods Administration (TGA)	https://www.tga.gov.au/safety/shortages/information-about-major-medicine-shortages/about-trulicity-dulaglutide-shortage-2022-and-2023
Shortage of Mounjaro (tirzepatide) injections | Therapeutic Goods Administration (TGA)	https://www.tga.gov.au/safety/shortages/medicine-shortage-alerts/shortage-mounjaro-tirzepatide-injections

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