From: noreply@pws.gov.au
To: LAWLER, Tony
Subject: MS24-000320 : PDMS Notification - Record Assigned [SEC=OFFICIAL]
Date: Tuesday, 26 March 2024 1:53:23 PM

SEC=OFFICIAL

s22 has assigned MS24-000320 to **Tony LAWLER**.
Click on the above link to open the record in Microsoft Edge.

Record details*	
Subject	APPROVAL TO REMOVE GLUCAGON-LIKE-PEPTIDE-1 (GLP-1) RECEPTOR AGONIST ANALOGUES FROM THE PHARMACY COMPOUNDING EXEMPTION
Type	Minister
Processing Instructions	Hi Tony, this is the revised GLP1 min sub a cleared by Robyn. I've reviewed and made a couple of edits in tracked. For your review and clearance by COB tomorrow, WEDNESDAY 27 MARCH please. Cheers,s22
Milestones	Due for Clearance: 27/03/2024 12:00:00 PM Due to Parliamentary: 27/03/2024 5:00:00 PM Due to Ministers Office: 28/03/2024 5:00:00 PM Critical Date: 8/04/2024 5:00:00 PM
Responsible Area	|Health Products Regulation| Medicines Regulation
Status	Awaiting Clearance

**Please note if any fields are empty, the associated field has not been populated in PDMS.*

Have a question or would like to organise some training?
Contact the Ministerial and Parliamentary Services Branch on s22 You can also visit the MPS Intranet page for the latest information, news, and events.
Thank you
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Document 2

Australian Government

Department of Health and Aged Care

Information Brief
MB24-000319
Version (1)
Date sent to MO: 13/02/2024

To: Minister Butler

Subject: EXTEMPORANEOUS COMPOUNDING OF GLUCAGON-LIKE- PEPTIDE-1 (GLP-1) RECEPTOR AGONISTS- PROPOSAL TO UNDERTAKE TARGETED CONSULTATION REGARDING REGULATORY REFORM

Comments: Noted with approval 15/2			
Contact Officer:	s22 [redacted]	s22 [redacted] Health Products Regulation Group	Ph: s22 [redacted] Mobile: s22 [redacted]
Clearance Officer:	Professor Robyn Langham	Chief Medical Adviser, Health Products Regulation Group	Ph: (02) 6289 4210 Mobile: s22 [redacted]

Key Issues:

1. There is a need to consider changes to the Therapeutic Goods Administration's (TGA) regulatory framework for extemporaneous pharmacy compounding following widespread safety concerns locally and internationally in relation to the scale and complexity of the products that are now being prepared through pharmacy compounding.

2. Compounded products are not subject to evaluation for safety, quality and efficacy by the TGA. Poor compounding practices can result in serious patient harm. There are a number of examples of large-scale patient harm with compounding, such as in the United States where more than sixty people died in 2012-2013 from contaminated steroid injections prepared by a compounding pharmacy. There are additional concerns of compounders adding in undeclared ingredients, with no concern for drug interaction, or the additional possibility of drug interactions and toxicity.

3. A specific driver to consider regulatory reforms is the emerging trend for telehealth providers and integrated community pharmacies to offer compounded Glucagon-Like Peptide -1 (GLP-1) receptor agonists to patients for weight loss management on a commercial-like scale. One of these providers, Eucalyptus, has met the TGA regarding their business model of online prescribing, compounding operations and drug delivery as a means of increasing access to off-label compounded medications to Australian consumers. The TGA is increasingly concerned about the volume of compounded products being prescribed in the community, as well as reported production for export purposes.

The compounding of GLP-1 receptor agonists has been identified by the TGA and state and territory health departments as a significant public health concern due to the complexity of manufacture of these injectable medicines and the large population base exposed to these unregulated and untested compounded products. There are legal concerns regarding this activity, which is difficult to monitor and regulate, in addition to safety concerns.

4. The TGA has no regulatory oversight of the number of compounding operations as the majority of compounded medicines are not supplied through the Pharmaceutical Benefits Scheme (PBS). There is no single database on the number and range of private prescriptions, including compounded medicines, supplied in Australia.

5. In 2021, the extemporaneous compounding exemption was amended to carve out medicinal cannabis products to ensure greater regulatory oversight of compounding operations due to the high-risk nature of these medicines. Similarly, the TGA is proposing immediate changes to the Therapeutic Goods Regulations 1990 (the Regulations) to remove all medicines containing GLP-1 receptor agonists from the compounding exemption, precluding the compounding of these medicines by compounding pharmacists.

6. We will conduct targeted consultation on the proposed amendments in February 2024, consulting with peak representative bodies for health professionals, industry and consumers. Outcomes of the consultation will further inform any policy or regulatory changes, all of which will be provided to you for further approval.

7. The TGA plans to progress broader reforms to the Regulations to amend the regulatory framework for extemporaneous pharmacy compounding, following further widespread consultation in mid- 2024.

Background:

- The *Therapeutic Goods Act 1989* (the Act) currently provides certain exemptions to allow the manufacture of individual prescribed medicines by registered pharmacists practicing in community pharmacies. The exemptions permit the manufacture of medicines to supply individual patients in order to meet the individual patient's clinical needs, where a commercially manufactured medicine isn't suitable. This practice is known as extemporaneous compounding. Additional exemptions apply to hospital pharmacists and, at present, these are outside the scope of our concerns.
- The current Regulations exempt compounded medicines from being included in the Australian Register of Therapeutic Goods (ARTG) and exempt the compounding pharmacist from requiring a TGA Good Manufacturing Practice (GMP) licence. These arrangements recognise the role of professionally trained pharmacists in preparing medicines which are not otherwise commercially available for an individual patient. Such medicines are most often simple preparations such as a preservative-free form of a topical cream or a children's syrup without particular flavourings or colourings.
- However, these legislated exemptions have not kept pace with developments in online prescribing models or pharmacy compounding practices, leaving large numbers of patients exposed to potentially unsafe medicines. The TGA has concerns that there are organisations that are producing compounded medicines for local supply and even export on a scale and of a complexity

that would make them equivalent to a manufacturer that would otherwise require them to be controlled under the Act and be required to hold a GMP licence from the TGA.

- As compounded medications have not been evaluated by the TGA for quality, safety, or efficacy, there is a serious possibility of unforeseen or less well-understood adverse events in patients who use them.
- The recent uptick of large-scale compounding of medicines containing GLP-1 receptor agonists for weight loss management is of pressing public health concern.
- Specific risks identified in the compounding of GLP-1 receptor agonist medicines include:
  - **little or no safety oversight** - the lack of visibility regarding the number of prescriptions dispensed complicates efforts to assess the prevalence of inappropriate prescribing and potential adverse events associated with compounded medications.
  - **unable to enforce product quality standards** - while, at law, quality standards apply to compounded medicines, it is impossible to enforce these requirements as the TGA has no visibility of compounding operations. This is of particular concern to the states and territories. There is a potential for significant quality issues with the product due to poor compounding practices, e.g., bacterial and fungal contamination.
  - **compliance** – while extemporaneous compounding is only legally permitted for individual named patients, the TGA has been advised of potential cases of bulk manufacture. The compounding exemptions in the Regulations do not apply if a pharmacist is compounding products for bulk supply in anticipation of patient needs. Compounding medicines on a commercial-like scale has the potential to adversely affect many patients, as they are not subject to rigorous testing for safety and quality.
- Internationally, the FDA has released a statement warning consumers of the safety risks associated with the use of compounded products containing a different salt formulation of semaglutide, including semaglutide sodium and semaglutide acetate. This follows an increase in adverse event reports after patients have been administered compounded semaglutide-like products. The FDA's warning is clear that these salted semaglutide compounds are not the same as the semaglutide that has been tested and approved for use in the US.
- In December 2023, the TGA published a statement regarding the compounding of semaglutide-like medicines, available at www.tga.gov.au/news/safety-alerts/compounding-safety-information-semaglutide-products.
- The proposed reforms to compounding of GLP-1 receptor agonists would remove medicines containing GLP-1 receptor agonists from the extemporaneous compounding exemption. This would overcome the need for regulatory oversight of these medicines and potential for patient harm.

Budget/Financial Implications:

There are no anticipated budget or financial implications of the consultation or any anticipated regulatory changes.

Sensitivities:

The exclusion of a specific class of medicines from the compounding exemption may be contentious and considered a barrier to the access of GLP-1 receptor agonists in Australia. The proposed amendment is intended to provide public assurance that there are measures in place to ensure medicines containing GLP-1 receptor agonist products prescribed to Australian patients are of appropriate quality, safety and efficacy.

Consultation:

To accurately identify the scale of the problem, the TGA met with State and Territory Chief Health Officers, Chief Pharmacists, and the Australian Health Practitioner Regulation Agency (Ahpra) in January 2024. There was unanimous concern that current regulatory arrangements do not provide adequate public protection regarding compounded medicines and support for a national approach to restrict access of medicines containing GLP-1 receptor agonists.

Further targeted stakeholder feedback will be conducted to assist in determining whether the proposed action will achieve the intended benefits.

Regulatory Burden Implications and/or Deregulation Opportunities:

Once it is agreed whether the proposal will go ahead, details will be discussed with the Office of Best Practice Regulation to confirm regulatory burden implications.

Communication/Media Activities:

Communication opportunities for consumers and health providers related to announcement of the outcomes of this consultation process will be discussed with you prior to any decisions being finalised.

Australian Government

Department of Health and Aged Care

Ministerial Submission – Standard
MS24-000320
Version (2)
Date sent to MO: 2 April 2024

To: **Minister Butler**

Subject: **APPROVAL TO REMOVE GLUCAGON-LIKE-PEPTIDE-1 RECEPTOR AGONIST ANALOGUES FROM THE PHARMACY COMPOUNDING EXEMPTION**

Critical date: 15 April 2024 to allow the amendments to the Therapeutic Goods Regulations 1990 (the Regulations) to be drafted by the Office of Parliamentary Counsel (OPC) in time for the May Federal Executive Council meeting.

Recommendation/s:

1. Agree to progress amendments to the Therapeutic Goods Regulations 1990 to remove glucagon-like-peptide-1 receptor agonist analogues, such as semaglutide-like products, from the pharmacy compounding exemption.	**1. Agreed/Not agreed/Please discuss**
2. Agree to the measure commencing on 1 August 2024 to allow for a transitional period of 2 months.	**2. Agreed/Not agreed/Please discuss**
3. Note the summary of the Therapeutic Goods Administration's (TGA) targeted consultation on the proposed amendments at Attachment A.	**3. Noted**

Signature ..... Date: / /
Comments:

Contact Officer:	*Professor Robyn Langham*	*Chief Medical Adviser, Health Products Regulation Group*	Ph: (02) 6289 4210 Mobile: s22 [redacted]
Clearance Officer:	*Professor Anthony Lawler*	*Deputy Secretary, Health Products Regulation Group*	Ph: (02) 6289 4200 Mobile: s22 [redacted]

Issues:

1. There are significant public health risks in the large-scale manufacture of copies of TGA-approved glucagon-like-peptide-1 receptor agonist analogues (GLP-1 Ras), like Ozempic® (semaglutide), under the provisions of pharmacy compounding.
2. The Therapeutic Goods Regulations 1990 currently provide certain exemptions to pharmacists practising in community pharmacy and in hospitals to compound medicines to supply to individual patients to meet the clinical needs of the patient. This practice is intended only for the preparation of small quantities of medicines, at the request of a medical practitioner, for an individual patient with an individual prescription. Unlike TGA-approved products, pharmacy-compounded products are not clinically evaluated for safety, quality or efficacy.
3. The specific risks relating to the large-scale manufacture and dispensing of GLP-1 Ras include:
    a) **the unknown nature and safety of the raw ingredients imported and used in manufacture,**
    b) **the absence of regulatory evaluation of the compounded medicines for safety and quality**,
    c) **the scale of the practice being magnified by ease of access to prescribers and pharmacists through online telehealth and closed-loop programs,**
    d) **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**
    e) **the lack of reporting of adverse events related to the quality and safety of compounded drugs.**
4. The rapid growth in closed-loop prescribing models of medical care, such as online prescribing models or pharmacy compounding practices, is of significant concern due to the escalating patient-driven demand for GLP-1 Ras for weight loss management. These online businesses have seized upon a business opportunity to expand their activities beyond the boundaries and intent of the current pharmacy compounding exemption.
5. As an example, the TGA is aware of at least 10 individual pharmacies and 3 large telehealth providers supplying compounded GLP-1 Ras to patients across Australia. One telehealth provider, Eucalyptus, has claimed a patient base of over 20,000 patients. Furthermore, in February 2024, the TGA executed a search warrant on a pharmacy in Melbourne and seized over 145 vials of compounded semaglutide-like products.
6. The significant increase in the compounding of these products has also been driven by the official shortages in the approved products, such as Ozempic (semaglutide) and Mounjaro (tirzepatide). These shortages, which have impacted significantly on those with diabetes who require these medicines for their approved indications, have also been used publicly as an argument against any amendments.
7. The TGA currently has a range of management actions that can be implemented to help reduce the impact of medicine shortages on Australian patients. These include temporarily approving the use of overseas registered medicines, allowing pharmacy-level substitution to occur for specified medicines and working with sponsors and pharmaceutical wholesalers to manage equitable supply.
8. To address these concerns, it is proposed to exclude GLP-1 RAs from the compounding exemptions. In effect, this would mean that these products can no longer legally be compounded.

9. The TGA will continue to engage with key health professional and pharmacy stakeholders to develop communication and media materials to support medical practitioners and their patients in navigating the change and implementing alternative treatment plans prior to the legislative change.
10. The TGA has conducted a targeted consultation on the proposed amendments. 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.
11. Responses also highlighted that the existing Pharmacy Board and state/territory notification and compliance processes for compounding are not adequate enough to address safety and efficacy concerns.
12. Future consideration should be given to wider regulatory reform of the existing Commonwealth legislative provisions for compounding of medicines. This is supported in the responses from the consultation with several stakeholders indicating that the current regulatory exemptions have not kept pace with compounding practices. The TGA is active in this space.
13. Your approval is required to progress amendments to the regulations.

Timing:

- The TGA is proposing for the amendment to commence on 1 August 2024. This will allow a transitional provision of 2 months following the legislative change. The transitional provision will enable the TGA to work with stakeholders to manage current stock levels and provide sufficient time for healthcare practitioners to discuss and implement alternative treatment plans for their patients.

Consultation:

- Targeted consultation on the proposed amendments was undertaken with peak representative bodies for health professionals, industry and consumers from 28 February to 15 March 2024 (MB24-000319 refers). A summary of the consultation responses is included at **Attachment A.**
- Of particular note in the responses, the Royal Australian College of General Practitioners (RACGP), the Australian Medical Association (AMA), Diabetes Australia, the Pharmaceutical Society of Australia (PSA) as well as state and territory health departments were supportive of the proposal, noting the change is urgently needed to mitigate clinical and public health risks.
- The Eating Disorders Alliance of Australia has since also publicly supported the proposed amendments in a media release on 4 March 2024 (edfa.org.au/news-media/eating-disorder-alliance-eda-welcomes-potential-ban-of-compounded-weight-loss-dr/).
- The Pharmacy Guild of Australia (PGA) and the Australian Society of Compounding Pharmacists (ASCP) did not support the proposal noting that compounding of GLP-1 RAs is required to enable continuous supply of these products for patients and the TGA should consider other measures, such as greater enforcement, to mitigate the safety concerns around large-scale compounding. The PGA and the ASCP represent independent pharmacy compounding businesses in Australia.

Background:

- Compounding is the manufacture of a medicine by a pharmacist where the medicine is required for a particular patient, to meet the individual's clinical needs, where a commercially manufactured medicine is either not suitable or not clinically appropriate. Unlike with commercial medicines, the pharmacist does not require prior TGA approval for the medicine, and the pharmacist is not required to hold a manufacturing licence from the TGA.
- The practice of compounding relies on the professional training of the pharmacist and compliance with professional practice standards and guidelines set by the Pharmacy Board of Australia, with the practice outside the remit of TGA oversight.
- The risk-benefit ratio of using compounded medicines is favourable for patients who require specialised medications that are not commercially available, as they would otherwise not have access to suitable treatment.
- A specific driver to consider regulatory reforms is the emerging trend for telehealth providers and integrated community pharmacies to offer compounded GLP-1 RAs to patients for weight loss management on a commercial-like scale. The TGA is increasingly concerned about the volume of compounded products being prescribed in the community, as well as reported production for export purposes.
- In January 2024, the TGA met with state and territory Chief Health Officers and Chief Pharmacists and the Australian Health Practitioner Regulation Agency (AHPRA) to discuss the scale of the issue. There was unanimous agreement that current regulatory arrangements regarding compounded medicines should be strengthened to provide improved public protection, with broad support expressed for a national approach to restrict compounding of medicines containing GLP-1 RAs.
- Internationally, the FDA has released a statement warning consumers of the safety risks associated with the use of compounded products containing a different salt formulation of semaglutide, including semaglutide sodium and semaglutide acetate. This follows an increase in adverse event reports after patients have been administered compounded semaglutide-like products. The FDA's warning is clear that these salted semaglutide compounds are not the same as the semaglutide that has been tested and approved for use in the US.
- In 2021, the extemporaneous compounding exemption was amended to remove some medicinal cannabis products to ensure greater regulatory oversight of compounding operations due to the high-risk nature of these medicines.

Sensitivities:

- The exclusion of a specific class of medicines from the compounding exemption has been contentious amongst pharmacy business owners and telehealth providers, specifically those offering weight loss management options, and those for whom reliance on these practices is key to a rapidly expanding business model.
- These stakeholders consider the proposal a barrier to the ongoing access to GLP-1 RAs in Australia. The proposed amendment is intended to provide public assurance that there are measures in place to ensure medicines containing GLP-1 RA products prescribed to Australian patients are of appropriate quality, safety and efficacy.
- We anticipate you will receive correspondence from patients who may have benefited from GLP1-RA products for weight loss, including through telehealth services. The volume of enquiries is of significant concern to the TGA as it highlights the high-throughput nature of the single-issue online business models and the large patient population that are being prescribed medicines outside the rigorous evaluation process undertaken by the TGA that assures the quality, safety and efficacy of medicines supplied to Australian patients.

Regulatory Burden Implications:
The Office of Impact Analysis (OIA) considers that the proposed amendment is unlikely to present more than minor regulatory impact (OIA24-06619).

Communication/Media Activities:
The TGA plans to undertake a widespread communication campaign to ensure pharmacists, health professionals and consumers will be informed of the changes via appropriate channels. We will coordinate all communication and media activities with your office. A draft media release has been prepared for dissemination following legislative amendment at **Attachment B.**

Attachments:
A: Summary of the targeted consultation responses
B: Draft media release for publication following legislative amendment

Minister	**Minister Butler**
PDR Number	**MS24-000320**
Subject	APPROVAL TO REMOVE GLUCAGON-LIKE-PEPTIDE-1 RECEPTOR AGONIST ANALOGUES FROM THE PHARMACY COMPOUNDING EXEMPTION
Critical Date	**Monday, 15 April 2024**
Contact Officer	s22 [redacted]
Clearance Officer	Professor Robyn Langham AM Chief Medical Adviser
Division/Branch	|Health Products Regulation| Medicines Regulation
Has Budget Branch been consulted if there are financial implications?	Not Applicable

Adviser/DLO comments:	Returned to Dept for: REDRAFT ☐ NFA ☐

Please complete	
Quality Assurance Check (completed by line area)	s22 [redacted]

s22

Document 3

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Document 3

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Document 3

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MARK BUTLER MP
MINISTER FOR HEALTH AND AGED CARE

DRAFT MEDIA RELEASE

TGA TO BAN PHARMACY COMPOUNDING OF REPLICA WEIGHT LOSS PRODUCTS

The Therapeutic Goods Administration (TGA) is taking steps to better protect consumers by announcing changes to compounding pharmacy legislation.

New regulations will remove glucagon-like peptide-1 receptor agonists (GLP-1 RAs), such as semaglutide-like products, from the pharmacy compounding exemption. This change will take effect from <insert date>.

In Australia, around 20,000 patients are accessing compounded GLP-1 RAs, the majority for weight loss management.

However, unlike TGA-approved products, pharmacy-compounded products are not clinically evaluated by the independent regulator for safety, quality or efficacy.

There is increasing concern both in Australia and internationally about the commercial-like scale and practice standards of compounded GLP-1RA products being prescribed in the community. This is particularly the case as there is no regulatory control over what is in the compounded products, whether the products work, or if the products are safe.

It is important to note that compounded GLP-1RA products supplied through the compounding pharmacies are **not** identical to the TGA approved products Ozempic® (semaglutide) or Mounjaro® (tirazapetide)

Affected patients are encouraged to discuss alternative treatments with their medical practitioner.

Quotes attributable to Minister Butler:

“Australia is seeing a growing number of patients being exposed to medicines outside the rigorous evaluation process undertaken by the TGA.

“Compounding of sterile injectable medicines can pose significant risks to the public if standards are not strictly adhered to throughout the compounding and supply process.

“This action taken by the TGA will prevent harm and save lives.”

Quotes attributable to XXX, position, TGA:

“A growing number of patients are being exposed to medicines outside the exacting assessment processes of the TGA.

“The compounding of medicines on a commercial-like scale changes the risk profile of these medicines and the potential to harm patients is too great.

“The TGA will work with key medical and pharmacy stakeholders to support patients and their practitioners to navigate the change and find alternative and safe treatment plans that best works for them.”

WEDNESDAY, 1 MAY 2024

MEDIA CONTACT:

s22 [redacted]