From: s22
To: s22
Cc: s22 @endocrinesociety.org.au
Subject: Re: [SEC=OFFICIAL] ESA- Consultation letter from the TGA Chief Medical Adviser re compounding of glucagon-like-peptide-1 (GLP-1) receptor agonists
Date: Monday, 4 March 2024 3:02:17 PM
Attachments: image001.png

Dear s22

Members of ESA Council have been provided with a copy of the consultation letter from Prof Robyn Langham. We believe this is a good step to amend the compounding exemption to remove GLP-1 RAs and believe it will mitigate concerns around public safety from such compounded products. We can't forsee any unintended consequences.

Kind regards

s22

s22

s22

s22

s22

s22 Endocrine Society of Australia

signature_1914983672

From: s22 @health.gov.au>
Date: Friday, 1 March 2024 at 9:51 am
To: s22 @endocrinesociety.org.au" s22 @endocrinesociety.org.au>, s22 s22
Cc: "LANGHAM, Robyn" s22 @Health.gov.au>
Subject: [SEC=OFFICIAL] ESA- Consultation letter from the TGA Chief Medical Adviser re compounding of glucagon-like-peptide-1 (GLP-1) receptor agonists

Dear s22 ,

Please find attached a consultation letter from Professor Robyn Langham AM, Chief Medical Adviser, Health Products Regulation Group regarding compounding of glucagon-like-peptide-1 (GLP-1) receptor agonist analogues for your attention.

Kind regards,

s22 [redacted]

Health Products Regulation Group
T: s22 [redacted] E: s22 [redacted]@health.gov.au
Location: 27 Scherger Drive, Level 2
PO Box 100, Canberra ACT 2601, Australia

The Department of Health and Aged Care acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

1 March 2024

By Email: s22 [redacted] @health.gov.au

Professor Robyn Langham AM
Chief Medical Adviser
Health Products Regulatory Group
Minister for the Department of Health and Aged Care
Parliament House
CANBERRA ACT 2600

Confidential

Dear Professor Langham

Consultation to remove glucagon-like peptide-1 (GLP-1) receptor agonist analogues from the pharmacist extemporaneous compounding exemption

Thank you for your letter dated 28 February 2024 regarding the above consultation

We understand from your correspondence that the Therapeutic Goods Administration (TGA) is proposing to undertake changes to the *Therapeutic Good Regulations 1990* (Cth) to remove all medicines containing GLP-1 receptor agonist (GLP-1 RA) analogues from the pharmacy extemporaneous compounding exemption (the Proposed Changes).

We appreciate the TGA's attention to this matter and the effort and work it has undertaken to engage with the relevant stakeholders to develop the Proposed Changes.

We take this opportunity to thank you and the TGA for the actions it has taken to enforce the provisions of the Therapeutic Goods Advertising Code since the changes with respect to the advertising of schedule 4 therapeutic goods came into force on 1 January 2022.

Background and TGA Collaboration to Date

As you are aware, Novo Nordisk Pharmaceuticals Pty Ltd (Novo Nordisk) is the sponsor of two schedule 4 therapeutic goods:

1. Ozempic® (semaglutide), indicated for the treatment of insufficiently controlled type 2 diabetes which is currently marketed and supplied in Australia; and
2. Wegovy® (semaglutide 2.4mg), indicated for the treatment of obesity and overweight.

As a result of increased global demand for semaglutide including via social media and other channels, there has been intermittent stock shortages over the past two years.

We have collaborated with the TGA Medicines Shortage Unit and the Medicines Shortages Advisory Group to minimise the impact on Australian patients.

Compounding and Patient Safety

We appreciate the TGA's priority is patient safety, and we agree patient safety is paramount.

We understand compounding is permitted in Australia in accordance with the Pharmacy Board of Australia Guidelines for Compounding of Medicines (the Compounding Guidelines). However, in certain circumstances, we have grave concerns that some operators may not be following the Compounding Guidelines and taking advantage of patients for their commercial benefit.

On 4 April and 21 November 2023, we wrote to the TGA conveying our concerns regarding the unorthodox practices of compounding by some pharmacies. For your convenience, I attach a copy of both letters.

In December 2023, we notified the TGA Advertising and Product Investigations Unit, and the Import, Manufacturer, and Supply Unit of potential telehealth providers offering, via third-party pharmacies, commercial volumes of compounded semaglutide. These offerings appear to be "off-label", relying on clinical evidence linked to an ARTG approved therapeutic good. This is misleading and deceiving to patients. This, you will agree, poses a significant safety risk and even possible health consequences.

Attached for your convenience is correspondence from Novo Nordisk to the Australian Health Practitioner Regulation Agency (AHPRA) and National Boards. In that correspondence we urged AHPRA and the Pharmacy Board to investigate the compounding of semaglutide and the very serious risks to patients exposed by these products. To date, we have not received a response from AHPRA.

Risk Evaluation of Compounded Semaglutide

We agree with the risks you have identified in the compounding of GLP-1 RA analogues. We draw your attention to other risks which include:

a. misleading and deceiving patients as to the quality, safety, efficacy of compounded semaglutide;
b. misleading representations by telehealth prescribers of compounded semaglutide and breaching of their duty of care to patients and quality use of medicines.

Novo Nordisk Position with respect to the Proposed Changes

Novo Nordisk agrees with, and is fully supportive of, the Proposed Changes suggested by the Health Products Regulation Group.

We believe the Proposed Changes will mitigate the risk of those who are compounding for a commercial gain and not in accordance with the spirit of the Compounding Guidelines, as well as ensuring that patients access medicines of assured high quality, safety, and efficacy.

Novo Nordisk agrees that given this is a matter of public safety, the Proposed Changes should come into force immediately and no grace period be granted.

Potential Unintended Consequences

We consider the following potential unintended consequences resulting from the implementation of the Proposed Changes:

a. given the demand for semaglutide, there is a possibility that those patients who have accessed compounded semaglutide or other GLP-1 RA analogues will not appreciate the implementation of the Proposed Changes and believe that access to medicine irrespective of safety or quality is the priority;

b. telehealth operators may view the introduction of the Proposed Changes a limitation to healthy competition in a market where there is high demand for GLP-1 RA analogues, especially following the release of the Telehealth Post-Implementation Review released in September 2023;

c. legitimate pharmacy compounders might view the changes, in addition to the changes impacting pharmacy 60-day dispensing and others changes over the last few years, a further restriction on pharmacists to operate a business in a market already with small profit margins; and

d. Increase in black-market or illegal compounding channels.

In addition to implementation of the Proposed Changes, the TGA may want to consider how it will enforce, whether independently or in collaboration with AHPRA and the National and State Pharmacy Boards, these changes.

Next Steps or Further Questions

We appreciate your attention to this matter.

If you require any further information or would like to discuss the contents of this letter, please contact me on s22 @novonordisk.com.

We look forward to working with you to ensure that patient and public safety is a top priority.

Yours sincerely

s22

4 April 2023

Confidential

Nicola McLay
Regulatory Compliance Branch
Australian Government Department of Health and Aged Care
Therapeutic Goods Administration
TGA, PO Box 100
Woden Act 2606

Dear Nicola

Compounding and dispensing of Ozempic (semaglutide)

Novo Nordisk Pharmaceuticals Pty Ltd (Novo Nordisk) is the sponsor of Ozempic (semaglutide) which is a Prescription Only (Schedule 4) Medicine indicated for the treatment of insufficiently controlled type 2 diabetes mellitus.

It has recently come to our attention that certain pharmacies across Australia are advertising the supply of "semaglutide" or "Ozempic", which has not been sourced from Novo Nordisk, for purchase in-store and online. Many such pharmacies are advertising compounding services in relation to the supply of semaglutide.

It is unclear to Novo Nordisk what raw materials are being used and how the product is being compounded, having regard to the fact that Novo Nordisk is the patent holder of the active ingredient, Novo Nordisk is not supplying semaglutide to these pharmacies for compounding or re-supply and supply of semaglutide has faced serious supply shortages since November 2022.

While Novo Nordisk has no information about the source of the raw materials used by the compounding pharmacies to product semaglutide, given the lack of available supply in Australia, it is concerned that these pharmacies may be importing the active ingredient (or something which purports to be the active ingredient) in a form which does not satisfy the requirements for an exemption from ARTG registration pursuant to Schedule 5, item 9 of the Therapeutic Goods Regulations 1990.

Novo Nordisk is also concerned that the promotion by the compounding pharmacies of specified dose forms of semaglutide means that the compounded medicines do not meet the requirements for an exemption from ARTG registration pursuant to Schedule 5, item 6 of the Therapeutic Goods Regulations 1990.

We have also been made aware of the following pharmacies who advertise and sell compounded Ozempic:

(a) s22 [redacted]

(b) s22 [redacted]

(c) s22 [redacted]

(d) s22 [redacted]

It is likely that there are other pharmacies who offer compounded Ozempic in addition to the ones listed above.

Counterfeit websites

Additionally, Novo Nordisk has had a number of medical professionals seek advice with respect to potential counterfeit websites.

We understand that the TGA have been investigating scam websites and pharmacies claiming to be selling products claiming to contain semaglutide, for the treatment of type 2 diabetes and off-label for weight loss.

We have been made aware of the following websites through customer enquiries reported directly to Novo Nordisk in Australia and New Zealand:

(a) s22 [redacted]

(b) s22 [redacted]

(c) s22 [redacted]

(d) s22 [redacted]

The above sites promote Ozempic for use outside of its approved indication, describe the mechanise of how it works for weight loss, and promoting to the general public:

(a) s22 [redacted] claims "you can Ozempic Semaglutide for Weight Loss in Australia without prescription."

s22 [redacted]

(b) s22 [redacted] advertises "Ozempic is a new injectable drug for people with excess body fat. Only 4 doses of this medication (1 dose per week) are enough to make you feel less hungry for 1 month."

s22 [redacted]

(c) s22 [redacted] claims "you can buy Ozempic online for weight loss at s22 [redacted] and have your order delivered to you. Delivery time 8 to 10 days"

s22 [redacted]

Novo Nordisk suspects that there may be other pharmacies making similar offers.

Action to be taken

In light of the concerns we have expressed, Novo Nordisk urges the TGA to investigate the compounding of Ozempic and its advertising on these websites.

It is imperative whether the "semaglutide" being used for compounding or being promoted for sale over the web and the compounded products themselves pose a risk to Australian patients.

If you require any further information, please do not hesitate to reach out to me directly via email s22 @novonordisk.com or mobile s22 I also welcome the opportunity to discuss our concerns with you.

I look forward to hearing from you.

s22

Yours sincerely

s22 s22

Novo Nordisk Pharmaceuticals Pty Ltd

21 November 2023

By email: s22 [redacted]@health.gov.au

Confidential

Nicola McLay
Assistant Secretary – Regulatory Compliance
Regulatory Compliance Branch
Australian Government Department of Health and Aged Care
Therapeutic Goods Administration
TGA, PO Box 100
Woden ACT 2606

Dear Ms McLay

Compounding and dispensing of Ozempic® (semaglutide) by Pharmacies

We refer to our letter dated 4 April 2023 (**enclosed**) and your email in response dated .

We write to re-iterate our concerns regarding certain pharmacies in Australia which are advertising to supply compound "semaglutide" or "Wegovy®" or "Ozempic®" for purchase in-store and online and to seek a response to our 4 April 2023 in relation to these issues.

In addition to corresponding with the TGA in early April 2023, we also wrote to the Australian Health Practitioner Regulation Agency. Unfortunately, AHPRA is yet to respond to our letter. We would be grateful if you could please provide the contact information of a direct contact at AHPRA who may be able to assist.

Since our previous letter, we have identified further pharmacies that may be in breach of the Therapeutic Goods Act 1989 (**TG Act**) in respect of advertising in respect of these medicines and the Therapeutic Goods Regulations 1990 (**TG Regulations**) in respect of exemptions for ARTG registration.

Background

As you are aware, Novo Nordisk has seen high local demand for Ozempic following an increase in the off-label prescribing and use of the medicine for weight loss, together with unlawful advertising in Australia of the prescription medicine to consumers. Ozempic has faced intermittent supply shortages. Supply has been managed in collaboration with the TGA and other key stakeholders.

Novo Nordisk related companies overseas are also deemed manufacturers of Wegovy which is approved by the Federal Drug Administration in the United States for chronic weight management in adults with obesity or overweight with at least one weight-related condition (such as high blood pressure, type 2 diabetes, or high cholesterol), for use in addition to a reduced calorie diet and increased physical activity. Wegovy. Wegovy has also been registered on the ARTG but is not yet available in Australia.

Concerns expressed by healthcare professionals

Since our last letter, Novo Nordisk has received further communications from healthcare professionals expressing their concern and enquiring about the legitimacy of pharmacies who are offering to provide compounded Ozempic and Wegovy. In addition to the concerns raised with respect to compounding, this also raises issues with respect to advertising. To this end as you are aware:

(a) The TG Act prohibits the advertising of prescription only medicine to the general public; and

(b) The publication of information about unauthorised medicines that amounts to an advertisement or promotion of the medicine including off-label information is prohibited.

Compounding Pharmacies

In addition to the pharmacies set out in our previous letter, we have been made aware of the following further pharmacies which advertise to sell compounded forms of semaglutide:

(a) s22 [redacted]

(b) s22 [redacted]

(c) s22 [redacted]

It has come to our attention that these pharmacies are actively reaching out to general practitioners to promote their compounding services.

We have major concerns that the above pharmacies are not only sourcing the Approved Pharmaceutical Ingredient (**API**) via unapproved channels but the use of such API poses a significant risk to patient health.

Novo Nordisk believes there are further pharmacies that are offering to supply compounded semaglutide.

We note that the TGA issued a media release on 1 March 2023 warning consumers of Ozempic scams which include offers to compound semaglutide in pharmacies and advertising offers being distributed to GPs for distribution to their patients. However, it appears that these practices are continuing.

We have also received notifications from health care professionals of a further online pharmacy, s22 [redacted] which advertises 'Semaglutide for Weight Loss' at s22 [redacted] We have concerns that this website is one of the scams noted by the TGA in its media release. We request the TGA investigate this and consider taking appropriate action pending the outcome of any investigation.

We also note the Federal Drug Administration in the United States is undertaking investigations into compounding pharmacies for producing versions of semaglutide, due to questions regarding the safety and efficacy of such versions.

Action requested

In our letter of 4 April 2023, Novo Nordisk requested the TGA to investigate the pharmacies who are compounding Ozempic and advertising its sale on their website. It is imperative in light of the risks posed to Australian patients.

Could you please urgently let us know if the TGA has considered and acted upon the request and their position in relation to the issues raised in our letter of 4 April 2023 and this letter. We also note that the TGA in its April 2023 correspondence informed us that it would share insights with AHPRA. We would appreciate any information you could provide in this regard.

If you require any further information, please do not hesitate to reach out to me directly via email s22 @novonordisk.com or mobile s22 I also welcome the opportunity to discuss our concerns with you.

I look forward to hearing from you.

Yours sincerely

s22

Novo Nordisk Pharmaceuticals Pty Ltd

16 March 2023

Confidential

s22 [redacted]

AHPRA & National Boards
Level 51
680 George Street
Sydney NSW 2000

Dear s22 [redacted]

Compounding and dispensing of Ozempic® (semaglutide) by Pharmacies

Novo Nordisk Pharmaceuticals Pty Ltd (**Novo Nordisk**) is the sponsor of Ozempic® (semaglutide) which is a Prescription Only (Schedule 4) Medicine indicated for the treatment of insufficiently controlled type 2 diabetes mellitus.

Novo Nordisk has recently seen high local demand for Ozempic following an increase in the off-label prescribing and use of the medicine for weight loss, together with prohibited advertising in Australia of the prescription medicine to consumers.

Ozempic has faced intermittent supply shortages throughout 2022 and has been out of stock since November 2022, which have been managed in collaboration with the Therapeutic Goods Administrator (**TGA**) and other key stakeholders. It is our understanding that the TGA has also attempted to manage supply challenges, in part, by supporting temporary supply of overseas-registered semaglutide products under section 19A of the *Therapeutic Goods Act 1989* (Cth).

It has recently come to our attention that certain pharmacies across Australia are advertising the supply of "semaglutide" or "Ozempic", which has not been sourced from Novo Nordisk, for purchase in-store and online. Many such pharmacies are advertising compounding services in relation to the supply of semaglutide.

Concerns relating to the compounded product

1. We have concerns over these compounded products, including about whether they comply with the relevant Pharmacy Board Compounding Guidelines (the **Compounding Guidelines**). It is unclear to Novo Nordisk what

raw materials are being used and how the product is being compounded, having regard to the fact that Novo Nordisk is the patent holder of the active ingredient, Novo Nordisk is not supplying semaglutide to these pharmacies for compounding or re-supply and supply of semaglutide has faced serious supply shortages throughout 2022.

2. Novo Nordisk accepts that pharmacists are permitted to compound medicines in certain circumstances, such as where an appropriate commercial product is unavailable. However, it is not appropriate for pharmacies to offer compounded semaglutide, for the reasons set out below.

3. Ozempic is a complex biological medicine which requires very advanced laboratory techniques in providing compounding services (clause 4 of the Compounding Guidelines). The Pharmacy Board recognises specific requirements of complex compounding, through publication of the Professional practice profile for pharmacists undertaking complex compounding and meeting continuing professional development registration standards. These requirements reflect the specific competencies, processes, advanced laboratory techniques and equipment needed to demonstrate sufficient competence to undertake this complex compounding.

4. Since Ozempic is a biological medicine, its formulation is complicated and not based in established precedent (clause 6.1 of the Compounding Guidelines). Particular care should be exercised by pharmacists who are requested to compound medicines for which there are no precedent, and patients must be advised that the compounding has taken place under these circumstances.

5. Compounding of sterile injectable medicines pose significant risks to the public if requirements are not strictly adhered to throughout the compounding and supply process (clause 6.2 of the Compounding Guidelines). Ozempic is a sterile injectable medicine which requires stringent conditions in its manufacturing process, which are not easy to replicate.

6. In order to address risks associated with compounded sterile injectable medicines, the Pharmacy Board recommends that pharmacists determine and assign a 'beyond use date' of no more than 24 hours (when stored under optimal storage conditions for the particular product) from the time of compounding the medicine (section 6.2 of the Compounding Guidelines). The pharmacies we have identified below advertise 2-3 days for delivery of the compounded semaglutide and suggest to customers that the compounded product can be stored in the fridge for a range of 30 days to 3 months.

7. Novo Nordisk have received online communications from a number of patients and medical professionals enquiring about the legitimacy of

compounding pharmacies, some of which have been rebranding compounded Ozempic as a weight loss injectable. In addition to the concerns raised above (which may raise a range of patient safety concerns), this constitutes off-label promotion of a Schedule 4 (Prescription Only) substance, and a breach of the AHPRA shared Code of Conduct (dated June 2022).

8. Principle 6 of the Code of Conduct states that practitioners have a responsibility to contribute to the effectiveness and efficiency of the healthcare system and use resources wisely. Off-label rebranding and marketing of compounded semaglutide as a weight loss drug is contributing to the ongoing shortage, in turn, affecting those patients suffering from type 2 diabetes (for which Ozempic is indicated).

Compounding Pharmacies

9. We have been made aware of the following pharmacies who advertise and sell compounded Ozempic:

(a) s22 [redacted]

(b) s22 [redacted]

(c) s22 [redacted]

(d) s22 [redacted]

10. Novo Nordisk suspects that there may be other pharmacies making similar offers.

Action requested

11. In light of the concerns we have expressed, Novo Nordisk urges AHPRA and the Pharmacy Board to investigate the compounding of semaglutide and the very serious risks to which patients may be exposed by these products.

12. Pharmacies who are engaging in this practice should be asked to cease doing so. Novo Nordisk requests AHPRA and the Pharmacy Board to consider a formal communication to all registered pharmacists to require the immediate cessation of this practice.

If you require any further information, please do not hesitate to reach out to me directly via email s22 @novonordisk.com or mobile s22 I also welcome the opportunity to discuss our concerns with you.

I look forward to hearing from you.

Yours sincerely

s22

Novo Nordisk Pharmaceuticals Pty Ltd

Contact officer: s22 [redacted]
Contact phone: s22 [redacted]

Level 27, 135 King Street
Sydney NSW 2000
GPO Box 3131
Canberra ACT 2601
tel: (02) 9230 9133
www.accc.gov.au

15 March 2024

Professor Robyn Langham AM
Chief Medical Advisor
Health Products Regulation Group

Sent via email to: s22 [redacted]@health.gov.au

Dear Professor Langham,

ACCC response to consultation to remove glucagon-like-peptide-1 (GLP-1) receptor agonist analogues from the pharmacist extemporaneous compounding exemption.

Thank you for your letter dated 28 February 2024 seeking the Australian Competition and Consumer Commission's (ACCC) views on the proposed amendment to the Therapeutic Goods Regulations (1990) to remove glucagon-like-peptide-1 (GLP-1) receptor agonist analogues from the pharmacist extemporaneous compounding exemption.

As this issue relates specifically to the regulation of therapeutic goods, we do not have a view on whether the proposed amendment to the compounding exemption will enhance public safety. However, in general, the ACCC supports introducing regulatory measures to mitigate public safety risks where there is evidence of consumer harm.

We understand you will be consulting with consumer representative groups on this initiative and we support this, as consumers currently accessing these compounded medicines may be adversely impacted in respect of both access and cost of the product if the proposed exemption is removed.

The ACCC's role and responsibilities

The ACCC is an independent Commonwealth statutory agency that promotes competition, fair trading and product safety for the benefit of consumers, businesses and the Australian community. The primary responsibilities of the ACCC are to enforce compliance with the competition, consumer protection, fair trading and product safety provisions of the Competition and Consumer Act 2010 (CCA) which includes the Australian Consumer Law (ACL), and to regulate national infrastructure and undertake market studies.

The ACL is economy-wide legislation that contains a limited suite of provisions for general product safety regulatory tools. The product safety provisions in the ACL do not contain sectoral-specific regulatory tools, such as those that are required for the effective and tailored regulation of specialist products, such as therapeutic goods.

Next steps

If you would like to discuss the ACCC's response, please contact s22 s22 , Consumer Product Safety Division on s22 or s22 @accc.gov.au

Yours sincerely

s22

s22
Consumer Product Safety Division

Document 4

From: s22
To: s22 Robyn
Cc: s22
Subject: RE: Position on compounded GLP-1 RAs
Date: Friday, 15 March 2024 8:33:39 AM
Attachments: image001.png
image002.jpg

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Hi Robyn,

We have a formal response from s to your letter which will hopefully come through today. In case it doesn't we are **supportive of the proposal but suggest it be time limited**. Happy to chat with someone from the team if needed.

Best,

s22

AUSTRALIAN MEDICAL ASSOCIATION
Level 1, 39 Brisbane Ave, Barton ACT 2600
P | s22 M | s22 | www.ama.com.au

The Australian Medical Association acknowledges the Traditional Owners of land and sea throughout Australia where we live and work, and pays respect to Elders past, present, and emerging.

AUSTRALIAN MEDICAL ASSOCIATION
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PO Box 6090 Kingston ACT 2604
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19 March 2024

A/Prof Robyn Langham
Chief Medical Officer

Dear A/Prof Langham,

Thank you for consulting with the AMA to remove glucagon-like-peptide-1 (GLP-1) receptor agonist analogues from the pharmacist extemporaneous compounding exemption. The AMA supports with reservation the TGA's proposal to amend the Therapeutic Goods Regulations 1990 (the Regulations) to remove all medicines containing GLP-1 receptor agonist analogues (GLP-1 RAs) from the pharmacy extemporaneous compounding exemption.

The AMA shares the TGA's concerns with the quality and safety of compounded GLP-1 RAs. The scale of some compounding operations has created mini factories to address the demands of what are essentially retail services. The AMA has been concerned by the exploitation of regulatory loopholes by these services more broadly. However, we acknowledge that this response will also limit access for patients, some of whom may have been using compounded GLP-1 RAs to manage their diabetes safely for some time.

Noting the impact on patients, the AMA suggests that this regulation be time limited to allow for the TGA to develop a permanent regulatory approach. It is possible similar scenarios will arise in the future. A proactive regulatory approach would be to prevent this would be preferable. Communication will to all stakeholders will be very important throughout this process.

The AMA would welcome an opportunity to discuss this and other matters with you and the TGA in the near future.

Kind regards,

s22 [redacted]

s22 [redacted]

NSW poisons Information Centre
the children's hospital at Westmead

s22 [redacted]
NSW Poisons Information Centre
www.poisonsinfo.nsw.gov.au

The Children's Hospital at Westmead
Locked Bag 4001
Westmead, NSW 2145
Sydney, Australia

t: s22 [redacted]
f: [redacted]
e: s22 [redacted]@health.nsw.gov.au

March 12, 2024

Professor Robyn Langham AM

Chief Medical Adviser
Health Products Regulation Group

Therapeutic Goods Administration

Re: Consultation to remove glucagon-like-peptide-1 (GLP-1) receptor agonist analogues from the pharmacist extemporaneous compounding exemption.

The NSW Poisons Information Centre (NSW PIC) provides a phone-based advice service on poisonings and suspected poisonings to the public and health professionals calling from NSW, TAS and ACT on a near full-time basis and a shared after-hours service to the remainder of Australia. This results in approximately half of Australia's poisons-related calls being received by our Centre.

We have reviewed calls made to the NSW PIC in 2023 regarding exposures to GLP-1 receptor agonist analogues. These included semaglutide, liraglutide, dulaglutide, exenatide and tirzepatide. In 2023 we received 196 calls regarding exposures to GLP-1 analogues, involving 176 individual exposures to these medications.

Information collected by the NSW PIC during the call is generally limited to that which is required to provide advice on immediate clinical care of acute poisonings. We do not routinely collect information on the substance's source, but callers occasionally provide extra information which may be included in clinical documentation. From this extra information we have determined there were at least s47F cases in which the product was compounded by a pharmacy in Australia. The clinical effects in these patients were not significantly different to those seen in other patients. There were also at least 15 cases in which the caller indicated the error or adverse event was associated with stock shortages. Most commonly people had ceased the GLP-1 analogue due to stock shortage issues and had made an error or developed adverse effects on recommencing the medication without re-titration. In 13 cases patients, including s47F children, admitted using semaglutide with the intent of weight loss which had not been prescribed for themselves, but a family member or friend. s47F

Of these 176 exposures 133 were therapeutic errors, cases in which the person prescribed the medication had made an error in dose, time, or route of exposure while using therapeutically. There was 13 adverse reactions, where the patient developed symptoms following correct usage of the medication. 107 of the 176 patients had symptoms at the time of the call, we are aware of at least another 12 who subsequently developed symptoms. 76 of the patients required medical assessment and 18 of those developed a more severe toxicity.

Symptoms seen in patients commonly included gastrointestinal effects including nausea, vomiting and diarrhoea. More significant symptoms included intractable vomiting, severe headaches and hypoglycemia.

Medication	**Exposures reported to NSW PIC in 2023**
Semaglutide	129
Liraglutide	35
Dulaglutide	s47F
Tirzepatide	6
Exenatide	s47F
TOTAL	**176**

Given the NSW PIC does not collect routine data on compounded products, it is unknown what proportion of GLP-1 analogue calls to the service are a result of compounded products, and if they are posing a greater public health risk. Therefore, we are unable to comment on the effectiveness of the proposed removal of GLP-1 agonist analogues from the pharmacist extemporaneous compounding exemption to sufficiently mitigate the risk to public safety.

Regards

s22

s22

Australian Society of Compounding Pharmacists

Therapeutic Goods Administration
PO Box 100
Woden ACT 2606
Australia
s22 [redacted]@health.gov.au

13 March 2024

Dear s22 [redacted],

Re: Consultation to remove glucagon-like-peptide-1 (GLP-1) receptor agonist analogues from the pharmacist extemporaneous compounding exemption.

This letter is in response to your letter dated 28/04/2024 regarding the proposed exclusion of Glucagon-Like-Peptide-1 (GLP-1) Receptor Agonist Analogues (GLP-1 RAs) from the pharmacist extemporaneous compounding exemption, as outlined in item 6 of Schedule 5 to the Regulations.

The Australian Society of Compounding Pharmacists (ASCP) is grateful for the opportunity extended to ASCP to provide feedback on this matter. The ASCP serves as a key stakeholder representing the pharmacy compounding industry in Australia. Our organisation is dedicated to upholding the standards of safety, efficacy and high quality in compounded medicines to ensure optimal patient care. The ASCP supports the compounding of medicines within the regulatory framework set by the Therapeutic Goods Administration (TGA) and the Pharmacy Board of Australia (PBA).

While the ASCP acknowledges the valid public health and safety considerations stemming from the growing complexity and scale of manufacturing extemporaneously prepared medicines, we would like to express our specific reservations regarding the proposed changes.

The exclusion of GLP-1 RAs in item 6 of Schedule 5 to the Regulations is proposed to:

1. remove the legislative exemptions that allow community pharmacists to compound GLP-1 RAs in the absence of a TGA Good Manufacturing Practice (GMP) licence; and

2. bring the compounding requirements for these medicines in line with other high-risk medicines such as medicinal cannabis products and gene therapies.

The enduring scarcity of commercial GLP-1s, persisting for over a year, is duly acknowledged on the official Therapeutic Goods Administration (TGA) website. The TGA's shortage database advises of the extended unavailability of commercial semaglutide until December 2024, and commercial terzepatide until the conclusion of August 2024. We contend that the proposed legislative amendments will undeniably disrupt the continuum of healthcare for Australian patients. The absence of compounded alternatives during these shortages not only compromises patient access to treatment but also contravenes the tenets of the National Medicines Policy. Currently GLP-1RAs are prescribed for glucose control in diabetic patients and as a weight loss agent in obesity treatment. GLP-1RAs address the critical health risks associated with excess weight, notably cardiovascular disease, type 2 diabetes, musculoskeletal conditions, and certain cancers. Acknowledging obesity as

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a pivotal health concern, the Australian government has embarked on a ten-year National Obesity Strategy since 2022. Given the instrumental role of GLP-1RAs in combating the obesity pandemic, their consistent and reliable accessibility is imperative for patients to realise their intended health outcomes, a reliance underscored by clinicians in their patient treatment protocols. The compounding exemptions in the Therapeutic Goods Reg (1990) are exactly fit for purpose, to fulfill supply during times of shortage (only).

The ASCP is of the view that there are currently risk mitigating measures already in place when it comes to the compounding of medicines, including high risk medications. The *Guidelines on compounding of medicines* by the Pharmacy Board of Australia, in addition to the *Australian Pharmaceutical Formulary and Handbook* provide guidance to pharmacists in relation to the compounding of medicines to ensure product quality, safety and efficacy. State, Territory and Commonwealth legislation provides requirements on the facilities, training, processes and testing in addition to the sourcing and use of active ingredients when compounding medications including sterile compounding. In addition, pharmacists have a professional obligation to undertake a risk assessment before compounding medications for a patient. In doing so, pharmacists must ensure that there is good clinical and pharmaceutical evidence to support the quality, stability (including appropriate expiry periods), safety, efficacy and rationality of any extemporaneous formulation. Currently these rules are enforced by State and Territory regulators, which often work alongside the TGA.

Sterile compounding requires pharmacists to comply with standards which provide greater assurances and risk reduction measures. The *Guidelines on the compounding of medicines* requires pharmacies engaged in sterile compounding to meet the standards of the USP <797> or PIC/S Guide to Good Manufacturing Practice for Medicinal Products. The revised USP Sterile chapter <797>, which came into effect on the 1st November 2023, provides a very detailed risk-based approach to sterile compounding. Compounded medicines are categorised according to risk into 3 categories. Each category has minimum mandated actions, checks & balances which include the following parameters:

- *Personnel competency, such as training, retraining and mandated 3 consecutive gloved-finger-thumb sterility tests prior to commencing compounding & at regular specified intervals thereafter.*
- *Facility design including air pressure differentials, minimum air exchanges per hour*
- *Facility certification and recertification of the facility, as per ISO classification*
- *Viable air sampling at certification and at regular specified intervals*
- *Total airborne particle sampling at certification and at regular specified intervals*
- *Sporicidal disinfectants, cleaning and disinfecting regimes*
- *Compounded Sterile Preparations (CSP) Master formulation record*
- *CSP Stability Study via stability-indicating assays (high standard, not simple potency-over-time testing)*
- *CSP Sterility Testing as per validated sterility testing methods, such as USP <71>*
- *CSP Endotoxin Testing*

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Upon careful consideration of the updated USP797, it is that the standard adopts a risk-based methodology, necessitating the implementation of risk mitigation policies and procedures with the overarching goal of ensuring patient safety. It represents a delicate equilibrium between facilitating access to medications and safeguarding patient well-being. The expiration date of the CSP is determined by the level of risk. The **ASCP advocates for the sustained enforcement of the current standards of regulations governing medicine compounding in Australia**, a which is a preferable alternative to the outright prohibition of specific classes of medicines – for those pharmacy practices which align with all relevant regulatory obligations.

The ASCP acknowledges the distinct risks outlined by the TGA in its correspondence to stakeholders pertaining to the compounding of GLP-1 RAs analogues. We provide commentary on each of the concerns articulated below.

Non-identical product- Concerns around the Active Pharmaceutical Ingredient (API) and excipients used in compounded products being of a different molecular nature with unassured quality is presently mitigated in regulations which prescribe the process under which a compounding pharmacy sources and uses an active ingredient in compounding. Finished products which have been compounded are able to be analysed and assessed to contain the same molecule as the commercial product. For the expiry date of injectable medicines to exceed 24 hours, evidence of stability is mandated.

Lack of ability to enforce product quality standards – As mentioned above, stringent regulations exist when a pharmacy compounds a medication including measures to prevent bacterial and fungal contamination of the finished compound. With reference to sterile compounding, this is additionally covered by further regulatory guidance through the likes of USP797 and PIC/S Guide to Good Manufacturing Practice for Medicinal Products. As such, quality standards are already in place and can be enforced by State and Territory regulators. It is the opinion of the ASCP that the regulators are already enforcing such standards and should the TGA be concerned that this is not the case, greater enforcement is a more appropriate alternative to the proposed regulatory changes.

Concerns of lack of compliance – The ASCP does not condone anticipatory compounding of any nature. Such practices are not in line with the current regulations and standards which govern the compounding of medicines. Should pharmacies be practicing outside of the regulatory framework, they should be dealt with through the appropriate processes. Compounding pharmacies making a conscious effort to uphold their regulatory obligations, should not be penalised. It is the understanding of the ASCP, that it is within the current scope of the TGA to exercise enforcement of the legislation which permits the compounding of medicines for individual named patients only after the receipt of a prescription (or request to compound the medication in the case of a non-prescription product) whereby all other regulations are met.

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No obligations to report adverse effects- The Pharmacy Board *Guidelines on the compounding of medicines* states that pharmacists should report all suspected adverse reactions to compounded medicines to the :

- TGA for suspected adverse reactions occurring in humans, and
- veterinary surgeon who issued instructions for the compounded medicine for suspected adverse reactions occurring in animals.

As such, ASCP disagrees with the notion that there is no obligation for the reporting of adverse effects associated with compounded medications. Irrespective of whether a medicine is compounded or not, pharmacists are required to make a report to the TGA in the same manner.

Large volumes of production- Extemporaneous compounding involves the preparation of a medicine for an individual named patient, in the absence of a suitable and/or available commercial product. As such these medicines are not required to be included in the Australian Register of Therapeutic Goods (ARTG) and exempt the compounding pharmacist from the requirement to obtain and maintain a TGA GMP licence. In certain circumstances, a pharmacist may be required to compound multiple units of issue of a particular product (i.e. a batch) for individual named patients. When doing so, a pharmacist must not only conduct a risk assessment for each patient they are preparing a compound for but also the risks associated with preparing a batch. A pharmacist must ensure that they have sufficient evidence that appropriate processes are in place and have been followed to effectively manage any additional risk associated with batch preparation. In the case of sterile compounding, USP <797> contains additional requirements when conducting batches of medication including sterility testing and other measures to ensure a quality end product and improve patient safety. USP <797> limits batch sizes to 250 units.

In responding to the proposed regulatory changes, the ASCP believes that there are numerous options available to the TGA before it prohibits the compounding of certain medicines. The ASCP lists several potential options for the TGAs consideration below:

1. **Provide clear standards on the compounding of GLP-1s:** The TGA has published information on its website with regards to the compounding of medicines and what constitutes appropriate compounding, referring specifically to the State and Territory requirements, including requirements under the Health Practitioner Regulations Law and the Pharmacy Board of Australia *Guidelines on compounding of medicines*. Similar information and standards, can be provided by the TGA to ensure that there are clear guidelines which sets out quality, testing and safety rules around compounded GLP-1s.

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2. **Improve enforcement of existing rules:** The ASCP contends that existing regulations adequately establish a framework for pharmacists to deliver high-quality compounded medications in situations where commercial products are unavailable or unsuitable. The proposed alterations by the TGA, however, would unduly impact the majority of compliant pharmacies, endangering the timely accessibility of vital medications for their patients. This proposed shift aims to rectify non-compliance among (what is likely to be a minority of) pharmacies but could inadvertently compromise the broader efficacy of pharmacies adhering to the regulations. Instead of implementing a blanket prohibition on the compounding of GLP-1s, a more effective approach would be to advocate for enhanced enforcement of regulations, ensuring stricter adherence and accountability across all pharmacies, thereby maintaining the necessary balance between regulatory compliance and patient access to critical medications.

3. **Utilise Authorised Prescriber and Special Access Scheme Pathways:** In contemplating regulatory adjustments for the compounding of GLP-1s, the Therapeutic Goods Administration (TGA) may consider adopting a framework akin to the authorised prescriber and special access scheme pathways, a successful approach already implemented for medicinal cannabis. By leveraging these pathways, prescribers could seek approval from the TGA to compound GLP-1s under specified conditions. This approach not only facilitates necessary patient access to compounded medications but also enables the TGA to systematically collect valuable data on prescription numbers, associated health conditions, and any potential adverse effects. Similar to the experience with medicinal cannabis, employing authorised prescribers and special access schemes could strike a balance between ensuring regulatory compliance and fostering data-driven oversight in the compounding of GLP-1s.

4. **Delay proposed changes:** The ASCP expresses considerable apprehension about the TGA's intent to promptly enforce the proposed changes. The immediate implementation of these measures raises significant concerns for the ASCP, as it will adversely affect the health outcomes of numerous patients by leaving them without essential treatment. The ASCP suggests that the TGA take additional time to explore alternative options, allowing for more thorough consideration of regulatory measures pertaining to the compounding of GLP-1s. This approach aims to ensure heightened oversight without compromising the accessibility of quality compounded medication for the majority of patients.

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In summary, the Australian Society of Compounding Pharmacists advocates for stringent regulations to enhance the quality of compounded medications, emphasising the importance of striking a delicate balance between regulatory measures and ensuring unfettered patient access to essential medicines. The ASCP contends that the current regulatory landscape already imposes numerous guidelines on compounding pharmacies, encompassing both sterile and non-sterile processes. Instead of an outright prohibition on the compounding of GLP-1 RAs, the ASCP suggests that additional measures, as outlined in our submission, can be adopted to further strengthen regulatory oversight without compromising patient accessibility to compounded medications.

Should you have any further questions or queries, please do not hesitate to contact me for further information. The ASCP appreciates the opportunity to provide input on this important matter and look forward to your response.

Yours Faithfully

s22 [redacted]

s22 [redacted]

s22 [redacted]

On behalf of ASCP Board

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Department of Health

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Tasmanian Government

Contact: Pharmaceutical Services Branch
Phone: (03) 6166 0400
E-mail: pharmserv@health.tas.gov.au

Professor Robyn Langham
Chief Medical Adviser
Health Products Regulation Group
Department of Health and Aged Care
s22 [redacted] @health.gov.au

Dear Professor Langham

Subject: Consultation to remove glucagon-like-peptide-1 receptor agonist analogues (GLP-1 RAs) from the pharmacist extemporaneous compounding exemption.

Thank you for your correspondence to s22 [redacted] of 28 February 2024 seeking a written response to the Therapeutic Goods Administration (TGA) proposed amendment to extemporaneous compounding exemptions to remove all medicines containing GLP-1 RAs, thereby precluding the compounding of these medicines by compounding pharmacists.

Tasmania has a small number of pharmacies who specialise in providing extemporaneously compounded medicines. Anecdotally, Tasmania has not seen the rise of commercial-scale manufacturing in pharmacies that has been observed in other jurisdictions. The Department is not aware of any local large-scale compounding with GLP-1 RAs.

The Tasmanian s22 [redacted] attended the January 2024 meeting and has briefed me on this issue. There are sound reasons for such an amendment which include both clinical and public health grounds. The Tasmanian Government is in caretaker mode due the State election on 23 March 2024, during caretaker mode it is not appropriate for me to provide a policy position on this matter.

There will likely be consequences in relation to ongoing stock unavailability of GLP-1 RAs in Australia, as those patients previously supplied with compounded products will likely seek supply of registered products. It will be critical that guidance and resources are provided by the TGA to medical practitioners, pharmacists, and consumers to navigate the consequences of this proposed amendment.

Thank you for seeking our input on this important issue.

Yours sincerely

s22 [redacted]

s22 [redacted]
Department of Health

13 March 2024

From: LANGHAM, Robyn
To: s22
Cc: s22
Subject: RE: Submission re: Compounded semaglutide - for your consideration [SEC=OFFICIAL]
Date: Wednesday, 13 March 2024 9:44:43 AM
Attachments: image001.png
image002.png
image003.gif
image004.png
image005.jpg
image006.png
image007.png
image008.png
image009.png

Dear s22

Thank you for your email,

We will consider your response along with others from the consultation process,

Regards,

Robyn Langham

Prof Robyn Langham AM
s22

Chief Medical Adviser

Health Products Regulation Group
Australian Government Department of Health
T: s22 | E: s22 @health.gov.au

PO Box 100, Woden ACT 2606, Australia

The Department of Health acknowledges the Traditional Custodians of Australia and their continued connection to land, sea and community. We pay our respects to all Elders past and present.

From: s22 @alevia.com.au>
Sent: Wednesday, March 13, 2024 8:31 AM
To: LANGHAM, Robyn s22 @Health.gov.au>
Subject: Submission re: Compounded semaglutide - for your consideration

s22 [redacted]

[redacted]

Alevia Medical Weight Loss

374 Mountain Hwy

Wantirna VIC 3152

s22 [redacted]

Prof Robyn Langham

Therapeutic Goods Administration

Dear Prof Langham,

I am writing to express my concerns regarding the proposed restrictions on compounded semaglutide, a GLP-1 agonist, and its potential impact on Australians living with obesity. As the director of Alevia Medical Weight Loss, a specialized obesity primary care service, I have witnessed firsthand the transformative effects of GLP-1 agonists like semaglutide and tirzepatide in managing obesity and improving the health outcomes of our patients.

Semaglutide has been a superior therapeutic option for individuals living with obesity, offering significant weight loss benefits and improvements in metabolic parameters. However, the proposed restrictions on compounded semaglutide raise serious concerns about access to this critical medication for patients. To withdraw this option for patients, without an equivalent medication being available is, in my view, unethical, and will result in weight rebound and all the complications of obesity that go with it. I have witnessed firsthand the heavy psychological burden this has had for patients, to have lost significant amount of weight, only to put it back on again without treatment for their condition.

Obesity shortens lifespan by 8-10 years and by withdrawing treatment, it will have a major impact on the health of our nation. By restricting the compounding of semaglutide, patients will be deprived of a valuable treatment option that could significantly improve their quality of life and reduce the burden of obesity-related comorbidities.

I know that the TGA is responsible fore ensuring the safety of medicines that are available to Australians. If safety is a concern, then I'd urge you to consider maintaining compounded GLP-1's but with regulation around sterility, toxins, and efficacy to protect the health of these patients. We have treated around 2000 patients with compounded semaglutide and have not had any issues relating to safety or any serious side effects, apart from those recognised in clinical trials ie. mild gastrointestinal side effects.

It is essential to recognize that obesity is a complex chronic disease that requires a multifaceted treatment approach encompassing lifestyle modifications, behavioural interventions, and pharmacotherapy. GLP-1 agonists like semaglutide have demonstrated efficacy in addressing the physiological drivers of obesity, making them valuable tools in the comprehensive management of this challenging condition.

In light of these considerations, I urge the Therapeutic Goods Administration to reconsider the proposed restrictions on compounded semaglutide and recognise the importance of preserving access to this medication for Australians living with obesity. By supporting the compounding of semaglutide, we can ensure that patients receive the individualised care they need to achieve sustainable weight loss and improve their overall health outcomes.

Thank you for your attention to this matter. I am hopeful that you will carefully consider the concerns raised and take appropriate action to safeguard the interests of patients affected by obesity.

Sincerely,

s22 [redacted] [redacted]

FC225C50

s22 [redacted]

[redacted]

Phone: s22 [redacted]

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Wantirna VIC 3152

https://alevia.com.au

Queensland Government

Queensland Health

Enquiries to: s22
Medicines Approvals and Regulation Unit
Telephone: s22
File Ref: C-ECTF-24/3557

Professor Robyn Langham
Chief Medical Advisor
Health Products Regulation Group
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

Email: s22 @health.gov.au

Dear Professor Langham

Thank you for your letter dated 28 February 2024, regarding the proposed immediate amendment to the Therapeutic Goods Regulation 1990 to remove all medicines containing GLP-1 receptor agonist analogues (GLP-1 RAs) from the pharmacy extemporaneous compounding exemption. We understand that this proposal seeks to enhance public safety regarding these substances. Your letter was addressed to s22 s22 and s22 who have referred the matter to Queensland Public Health and Scientific Services for my response.

We share your concerns regarding the utilisation of the extemporaneous compounding pathway to compound GLP-1 RAs analogues for individuals and **support the amendment** as described to further restrict the ability of pharmacists to extemporaneously compound these products. GLP-1 RAs analogues are relatively new, and access to the Active Pharmaceutical Ingredient is unreliable and therefore inherently risky for pharmacists. The quality controls that apply to the approved product cannot be assured in the compounded product, particularly as there is a worldwide shortage of the Active Pharmaceutical Ingredient.

On another, but related, matter, your letter states that the proposed controls would be the same as those applied to medicinal cannabis where either the Special Access Scheme Category B or Authorised Prescriber pathway is used to enable a prescriber to prescribe the extemporaneously compounded product. Queensland Health has noted a proliferation of extemporaneous compounding of medicinal cannabis products even though there are now over 500 medicinal cannabis products commercially available through various sponsors. According to the Pharmacy Board guidelines, extemporaneous compounding of a product should only be undertaken when there is no other commercially available product available. Queensland Health believes it is now timely to review the continued need for pharmacists to extemporaneously compound medicinal cannabis. It is difficult to identify a condition or situation where there is not a product already commercially available.

Thank you again for giving us the opportunity to provide feedback on this important initiative. Queensland Health supports the proposed amendment and encourages further review of medicinal cannabis extemporaneous compounding policy with a view to significantly curtailing this activity as well. If you require any further information in relation to this matter, please contact s22 Medicines Approvals and Regulation Unit, Department of Health, on telephone s22 or via email at s22 @health.qld.gov.au.

Yours sincerely

s22

s22
s22

Queensland Public Health and Scientific Services
Queensland Health
11 / 03 / 2024

diabetes australia

Friday, March 8, 2024

s22 [redacted]
s22 [redacted]
Therapeutic Goods Administration
PO Box 100
Woden ACT 2606
By email only: s22 [redacted]@health.gov.au

Dear s22 [redacted]

Removing GLP-1 receptor agonist analogues from the pharmacist extemporaneous compounding exemption

Thank you for inviting Diabetes Australia to respond to the Therapeutic Goods Administration (**TGA**) proposal to remove all medicines containing GLP-1 receptor agonist analogues (**GLP-1 RAs**) from the pharmacy extemporaneous compounding exemption.

Diabetes Australia and the Australian Diabetes Society support the proposed removal.

While addressing the shortage of diabetes medicines in Australia is critical, we do not think compounding is the answer. Given the risk to safety and efficacy, we support the removal of medicines with GLP-1 RAs from the pharmacy extemporaneous compounding exemption, and encourage the TGA to redouble efforts to increase and improve supply of diabetes medicines.

Diabetes medicines

As you know, GLP-1 RAs such as semaglutide are currently registered in Australia for the treatment of glucose control in Type 2 diabetes, and in some cases as weight loss agents for the management of obesity.

Shortages of diabetes medicines

Diabetes Australia and the Australian Diabetes Society – and the communities with whom we work – are concerned about the increasing frequency of shortages of diabetes-related medicines and products. In the past 18 months people living with diabetes have been impacted by shortages of Ozempic (semaglutide), Ryzodeg (insulin) and the GlucaGen HypoKit. In the case of both the HypoKit and Ozempic, there are no comparable products available in Australia. Shortages of diabetes medicines and products interrupt diabetes self-management and add to the mental health challenges associated with living with diabetes.

The three products outlined above are all produced by Novo Nordisk. It is not clear whether these are isolated cases or a systemic issue.

It is essential the Therapeutic Goods Administration thoroughly investigate the cause of these shortages and implement measures to ensure Australians can be confident that supply chains are sufficient to meet their needs.

Compounding is not the answer

While we are concerned about the impact of diabetes medical shortages, in our view, compounding is not a safe, efficacious or quality response.

It is not clear what safety and efficacy tests compounding pharmacies do to ensure no harm to people taking these compounds. We are also concerned about the lack of reporting of adverse events with compounded medicines, including suggestions that consumers may be less likely to report adverse events for compounded medicines (including where prescribed outside their ordinary healthcare setting).

We know that some people living with diabetes are accessing compounded medicines due to the medical shortages, and this has a significant financial impact (as the compounded substitutes are not subsidised by the Pharmaceutical Benefits Scheme). Again, we recommend increased and improved access to approved medicines as the preferred solution.

Conclusion

While we support the TGA proposal to remove all medicines containing GLP-1 from the pharmacy extemporaneous compounding exemption, we strongly encourage the TGA and other agencies to work with manufacturers to ensure adequate supply of life-saving medicines for Australians living with diabetes.

If you would like to discuss this response, please contact s22 Diabetes Australia's s22 , at s22 @diabetesaustralia.com.au.

Yours sincerely,

s22

s22

s22

Diabetes Australia

s22

Australian Diabetes Society

About Diabetes Australia and the Australian Diabetes Society

Diabetes Australia and the Australian Diabetes Society represent 1.5 million Australians living with known, diagnosed diabetes; approximately 500,000 Australians living with silent, undiagnosed type 2 diabetes; and around 2 million Australians living with prediabetes; as well as their families and carers, diabetes healthcare professionals and researchers.

We are dedicated to reducing the incidence and impact of diabetes on people, health systems and society. We work with people living with, or at risk of diabetes, their families and carers, health professionals, researchers, funders, other diabetes organisations and the community to positively change people's lives.

Find out more at www.diabetesaustralia.com.au and www.diabetessociety.com.au

Government of **Western Australia**
Department of **Health**

Our Ref: 24-277
Contact: s22 [redacted]

Professor Robyn Langham AM
Chief Medical Adviser
Health Products Regulation Group
Department of Health and Aged Care
PO Box 100
WODEN ACT 2606

Via email: s22 [redacted]@health.gov.au
s22 [redacted]@health.gov.au

Dear Professor Langham

CONSULTATION TO REMOVE GLUCAGON-LIKE-PEPTIDE-1 (GLP-1) RECEPTOR AGONIST ANALOGUES FROM THE PHARMACIST EXTEMPORANEOUS COMPOUNDING EXEMPTION

Thank you for your letter of 28 February 2024 regarding a proposal by the Therapeutic Goods Administration (TGA) to remove GLP-1 receptor agonists from the pharmacist extemporaneous compounding exemption.

In your letter, you have outlined concerns around use of the exemption to undertake commercial scale manufacturing of compounded products. Specifically, the risks identified by the TGA include differences in active ingredient and excipients of unassured quality, inability to apply quality standards, and bulk supply in anticipation of patient needs.

I acknowledge these risks and agree that they represent a real concern for larger scale manufacturing, when not conducted under Good Manufacturing Practice conditions and regulatory oversight. In respect to batch manufacturing by pharmacists, I firmly support the TGA, as the regulatory authority, taking all necessary compliance actions to ensure that the provisions of the legislation are being properly met.

Specifically, you have asked whether the proposal will mitigate public safety. The exact public health risk is difficult to quantify, and the Western Australian Department of Health (DOH) is unable to contribute any authoritative information on the amount of GLP-1 agonist manufacturing by pharmacists in Western Australia (WA), or on potential harms caused arising from this. A complete prohibition on manufacturing of these items will, in theory, mitigate all associated risks; however, noting that parts of the industry are already non-compliant, any prohibition may have limited effect unless accompanied by active enforcement and compliance measures.

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You have also asked about unforeseen consequences. As the prohibition would remove all access, irrespective of medical indication, consumer circumstances or need, this may well impact some patients with diabetes seeking supply through alternative means during a prolonged and difficult period of product shortage.

The WA DOH supports all medicines that are supplied to consumers in Australia as having met the highest achievable standards of quality in manufacture. This principle must be balanced against commercial constraints and other limits that could otherwise mean some critical medicines may not be available at all.

It is the viewpoint of the WA DOH that the pharmacist exemption has a small but valuable place, in specific circumstances. These may include where a suitable formulation does not exist, such as in children, in times of medicines shortages, or where products are not available, or withdrawn in the Australian market. This should be considered low-risk when employed appropriately on an individual patient basis. For these reasons, it is important that this facility be retained, irrespective of the current proposal.

You have noted that the current lawful exemption appears problematic with regard to developments in high throughput models of medicine. In recent years, schemes have emerged in Australia which provide or will provide large scale access to unregistered products, such as cannabis-based products and vapes.

Beyond the current proposal to prohibit a specific problematic type of medicine, it would be desirable to consider the need for wider regulatory reforms, so as to address and manage the broader issues raised across the pharmacy and medical sectors. The WA DOH also supports a coordinated approach between the TGA, State and Territory Health Departments, profession regulators, and professional bodies to work on enhanced education and improved industry standards for extemporaneous compounding.

Yours sincerely

s22 [redacted]

6 March 2024

Department of Health

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DX 210081

s22
Department of Health and Aged Care
s22 @health.gov.au

Dear s22

Thank you for your email of 28 February from the Chief Medical Adviser, Prof Robyn Langham, regarding the Therapeutic Goods Administration (TGA) proposal to undertake changes to the Therapeutic Goods Regulations 1990 (the Regulations) to remove all medicines containing GLP-1 receptor agonist analogues (GLP-1 RAs) from the pharmacy extemporaneous compounding exemption.

I understand that the TGA has concerns with the impact of commercial-scale manufacturing of compounded GLP-1 RA containing products and note the agreement during earlier consultation with the Chief Health Officers, that current regulatory arrangements regarding compounded medicines should be strengthened.

Victoria shares the concern of pharmacy compounding practices, potentially leaving large numbers of patients exposed to unregulated medicines, where the safety and quality of these provided medicines cannot be assured.

The Victorian Department of Health does not have concerns regarding the TGA's proposed amendment from a state medicine regulatory perspective.

We also recognise the importance of ensuring access to essential medicines for people with diabetes whilst balancing regulatory considerations.

We further acknowledge the global challenges impacting medicine GLP-1 agonist therapy availability.

I strongly encourage the TGA to communicate the amendment and its reasons clearly to the public when it is implemented and provide practical information/links to patients who may be affected by this change.

Yours sincerely

s22

15 /03 / 2024

VICTORIA State Government

CONSULTATION SUBMISSION TO THE TGA – PROPOSED REMOVAL OF GLUCAGON-LIKE-PEPTIDE-1 (GLP-1) RECEPTOR AGONIST ANALOGUES FROM THE PHARMACIST EXTEMPORANEOUS COMPOUNDING EXEMPTION

1. **TGA Proposal**

The TGA is proposing a ban on the compounding of GLP-RA medications.

The TGA's website states:

“The current proposal aims to mitigate safety risks that may be present in the compounding of GLP-1 RAs. These risks may include:
a. the unknown nature and safety of the ingredients used in manufacture;
b. compounding outside of the current exemptions that specify manufacture only on an individual patient basis and only after receipt of a valid prescription; and
c. the absence of evaluation of these medicines for safety and quality that is a feature of other drugs, that are evaluated by the TGA and entered onto the Australian Register of Therapeutic Goods (ARTG).
“The TGA met with state and territory Chief Health Officers and Chief Pharmacists and the Australian Health Practitioner Regulation Agency (Ahpra) in January 2024 to discuss this 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.”

2. s47F [redacted]

s47F [redacted]

Whilst we do not compound glucagon-like-peptide-1 (GLP-1) receptor agonist analogues (**GLP-RA medications**), as a participant in the compounding industry, with a strong regard for patient safety and standards, I feel it is important to contribute to the TGA’s consideration of the compounding of these medications.

I contribute to this discussion with a broad and practical view of the pharmacy industry, that part of the industry that engages actively in compounding, the medical profession (particularly general practitioners and specialists) and, most importantly, patients.

3. My submission

I oppose a ban which would prevent duly qualified pharmacists working in appropriately equipped and operated pharmacy facilities, from compounding GLP-RA medications.

Instead, I agree with the unanimous agreement reached between state and territory officials and the TGA (cited in the TGA’s website announcement) that "that current regulatory arrangements regarding compounded medicines" should be strengthened in respect to GLP-RA medications. In the current circumstances, there is merit to carefully formulated, appropriate regulation in the public interest that ensures the wide availability of in-demand medications that meet appropriate regulatory and safety requirements.

In our view, a ban on compounding of the GLP-RA medications would be contrary to the public interest. A ban applicable to all pharmacies would:

(a) deny an in-demand medication to Australian patients in circumstances where there is grossly inadequate current supply;

(b) fly in the face of evidence, now clear from widespread use of these medications, that they are safe and effective for the purposes for which they are prescribed; and

(c) likely cause severe and widespread negative health consequences for patients, limit the effectiveness of medical practitioners and pharmacists in treating obesity and other conditions, cause considerable distress in the community for those people who are either using this medication or wish to commence doing so, and will be denied the means to do so, and result in increased cost for the health system..

The approach of appropriately "regulating" compounding of these medications is preferred.

4. Supply issues in Australia of GLP-RAs

The current shortages of supply of GLP-RA medications is of concern to pharmacists Australia-wide. It is widely reported that these medications hold enormous promise for the treatment of obesity and other conditions, and hence, a reduction in the ailments and symptoms often associated with these conditions. In our pharmacy, we have witnessed the transformative impact of these medications for a large number of patients.

Whatever the origins of the current shortage of many of the GLP-RA medications, it is clear that these medications are now in chronically short supply. Pharmacy wholesalers, the usual channel for supply of medications to pharmacies, only occasionally have these medications available for general ordering by pharmacies. When they are available, they are only available in small quantities which do not come close to meeting the demand of the Australian public. The lack of availability of these medications represents a widespread denial of an important (even revolutionary) breakthrough for patients tackling obesity and other conditions.

The exemption which allows compounding of medications by pharmacies (including GLP-RA medications) is specifically designed to enable pharmacies to preserve patient health outcomes in the event of a medication shortage. Any ban on the making or supply of compounded GLP-RA medications by pharmacy undermines the very purpose of the exemption. .

5. Impact of a ban on patients

When the prospect of a ban on compounded SLP-RA medication is raised with them, patients currently using these medications are, without exception, upset by the prospect for a variety of reasons.

First, compounded GLP-RA medications have facilitated continuity of care in circumstances where the manufacturers of these medications have not been able to facilitate this continuity.

Prior to compounded GLP-RA medications being available, patients were forced by the shortage to cease using the GLP-RA medications that they were prescribed. This often resulted in them putting on weight or suffering the ill effects of their conditions.

If and when they were able to further source a limited supply of their prescribed GLP-RA medication, medical practitioners typically prescribe lower dosages of the medication than the patient previously had to minimise the prospect of side effects in the initial stages of their resumption of the medication. While commencing these medications at a lower dosage is recommended, the lower doses of the medication often lack efficacy. Consequently, not only are patients denied treatment for periods, but also expend significant monies to achieve substandard health results for the initial period they recommence on the medications.

Further, many patients have ended up in a cycle whereby they transfer between GLP-RA medications to maintain continuity of care. Appropriately, medical practitioners are actively involved in assisting patients to transfer between medications safely. However, where shortages exist, the choice of alternative medications is by the lack of availability of the medications rather than clinical need. Ideally, patients should continue on a course of medication that is proving fit for purpose without interruption. To make a change a patient's medication purely based on its unavailability is not consistent with high standards of care.

Secondly, compounded medications have been important to protect the mental health of patients prescribed GLP-RA medications. Medication shortages are stressful and potentially psychologically damaging for any patient, let alone those that are most vulnerable.

We are aware of a substantial number of patients who have been forced to stop their prescribed GLP-RA medications due to the lack of supply. Often the first time they are aware of a shortage is when they have used up most or all of their existing GLP-RA medication, and visit a pharmacy for prescription repeats. They are then forced into a continuous cycle of contacting multiple pharmacies to locate supply of the medications; in most cases, only to be told that there are none available, that there is no certainty about when the medications will be back in stock, and to put themselves on a waiting list for the medication for when it does become available within the pharmacy. The most determined of these patients live a compromised lifestyle characterised by constant communication with large numbers of pharmacies in a desperate bid to maintain supply of their medication. We are aware of the great distress these patients experience, particularly when their efforts fail, and they are forced to discontinue a treatment that had been achieving positive results for them.

What does the TGA expect these patients to do in the immediate foreseeable future if it bans compounded GLP-RA medications made by reputable compounding pharmacies with sterile facilities? In such circumstances, how can a ban be justified when supply could be maintained with appropriate levels of regulation.

6. Medical practitioner / health systems impact of proposal

A ban on pharmacies compounding GLP-RA medications will effectively deny medical practitioners one of the most effective and important tools available to them to manage patients who are pre-diabetic or suffering from obesity or other health conditions.

s47F is aware of numerous general practitioners and specialists who prescribe compounded GLP-RA medications due to their experience that the medications are efficacious, safe and consistently available.

GLP-RA medications obviously have the potential to dramatically reduce the demands on the general health system including hospitals for a significant cohort of the populations, whose illnesses and symptoms have their origins in obesity or being overweight. The removal of this medication from the exemption will do nothing to help alleviate the demand on our already overworked health system or reduce demands on public funding of health care institutions.

7. Pharmacist impact of proposal

Obviously, I am best placed to comment on the impact of the proposal on pharmacies and the pharmacy industry.

The proposal to remove the compounding exemption for GLP-RA medications directly and indirectly threatens a significant portion of the pharmacy industry which is engaged in compounding activities.

The proposal directly and immediately threatens compounding pharmacies that currently compound GLP-RA medications. In our experience (publicised exceptions aside), these pharmacies operate reputable sterile facilities, with high regard for all relevant safety standards. In some cases, their facilities would rival those with GMP certifications. Related to this, these compounding pharmacies operate with highly skilled pharmacists and pharmacy technicians, and have invested considerable time and expense making the GLP-RA medications to the highest possible standard.

For other compounding pharmacies s47F the removal of the exemption targeted at GLP-RA is an indirect threat. In essence, the logic behind the removal (namely, concerns around the lack of testing of the safety or efficacy of compounded medicines, as well as the scale on which the compounding is occurring) could be relied upon by the TGA to justify removing the compounding exemption altogether.

This is despite the fact that reputable compounding pharmacies engaged in complex compounding go to great lengths to ensure all medications are made in modern, well-equipped facilities by well trained and supervised professional staff. These pharmacies are supervised by the pharmacy authorities, and the pharmacists take their professional standing as compounding pharmacists seriously. Safety remains the foremost consideration when making the compounded medications, and these pharmacies subject their products to regular independent third-party testing.

If the TGA is willing to introduce a ban with no or minimal consultation with the sector, this will create a level of regulatory uncertainty in the industry. Establishing and operating compounding pharmacies requires a substantial investment of human and financial resources. The prospect that the TGA can and will remove specific medications from compounding exemption will undermine the business case for investment required to establish and operate compounding pharmacies. The ultimate losers from a lack of investment in compounding by pharmacies will be medical practitioners and patients, who are denied the tools and health benefits (respectively) under the current system.

s47F, I support regulation designed to ensure that medications dispensed for the public are safe and efficacious. Our motto is to do no harm.

However, while there is a clear imperative on regulators to maintain a vigilant watch over the safety of medications to safeguard the public health, a ban is an extreme measure to be applied only in the face of clear evidence that safety concerns exist and only when those concerns can only be adequately addressed by a ban. We believe the basis for a ban does not exist in the case of these medications, where other regulatory measures would be sufficient.

Compounded GLP-RA medications have now been available for more than 12 months. If these medications were neither safe nor efficacious, then demand for the medications from medical practitioners and patients would have all but dissipated. Instead, the opposite is true. Demand is probably greater than at any time in this period due to the fact that the shortage of these manufactured medications has become pervasive.

This sends a clear message to regulators that highly trained health professionals, who place patient health at the centre of their practices, understand that the compounded medications are both safe and efficacious.

While patients can and do experience side effects from compounded GLP-RA medications, these side effects are the same or similar to those which arise, on occasion, from the manufactured GLP-RA medications. These side effects are typically closely managed by the prescribing medical practitioners, and patient treatment is sometimes ceased if these side effects are serious or continue for any undue period.

In our experience, pharmacists are skilled and adept (particularly with these medications) at recommending that patients engage with their medical practitioner, and proactive in referring patients to a medical practitioner if and when adverse side effects for any medication are reported.

It appears that a major concern of the TGA relating to safety, is the scale at which the compounding of GLP-RA medications is occurring. Allied to this, the TGA appears concerned that compounding medications are not being made for individual patients, but instead are being "bulk manufactured" without a prescription.

The issue of scale and the requirement for prescriptions are separate and distinct issues. Neither issue should be conflated with safety concerns.

Prescriptions

In our experience, reputable pharmacies compound GLP-RA medications only if they have a prescription for the individual patient. This is not only a legal requirement which gives them the right to compound, but it is appropriate and necessary. If the TGA has concerns that particular pharmacies are not following this requirement, then this matter should be addressed with those outlier pharmacies. The TGA should not remove the compounding exemption for these GLP-RA medications from all pharmacies.

Scale of compounding

The issue of scale is different. It appears the TGA's concern about the scale of compounding of these medications is that, at certain volumes, the normal safeguards and protections relating to the making and supply of GLP-RA medications and the supervision of those medications by medical practitioners with sufficient knowledge about the patient, are may be compromised. That is, where the scale of compounding of a medication is increased, the

balance of risks shifts towards the need for public health intervention; in this case, a ban on making and supply of these GLP-RA medications.

While there is some attraction to this argument, it needs to be properly examined and scrutinised.

For instance, the converse is likely to be true in relation to pharmacy compounding. As a practical matter, the more regularly a pharmacy makes a medication, the more likely it is to have developed expertise and invested time and funds in its development and making.

Also, there are likely to be many compounded medications made by compounding pharmacies (under prescription) that are made in greater numbers than the compounded GLP-RA medications. The art and science of compounding is practiced widely throughout the pharmacy industry, across a range of different specialties. Collectively, the industry achieves a certain 'scale' in compounding.

The issue of the 'scale' of the compounding across the pharmacy industry has not thus far been the subject of any challenge by regulators. No ban has been considered for these medications compounded by pharmacies simply because compounding is a growing and increasingly important industry. Consequently, it seems that 'scale' alone would not appear to be a satisfactory motive, or a primary concern, sufficient to justify the TGA's proposed ban on GLP-RA medications.

Testing and safety

Finally, on its website the TGA states that there is an "absence of evaluation of these medicines for safety and quality".

It is important to distinguish between:

(a) a lack of safety and quality;
(b) a lack of testing of safety and quality of the medications; and
(c) a lack of testing of safety and quality (or oversight thereof) by the TGA.

The exemption for compounding of medications is founded on the requirement that pharmacies compound only quality medications that are safe and efficacious. It is inherent in the act of compounding that pharmacists self-regulate, and only proceed to compound when these conditions are satisfied.

To our knowledge, reputable compounding pharmacies that compound GLP-RA medications are not only principally concerned about safety and quality, but they submit themselves, *inter alia*, to:

(a) unscheduled inspection of their facilities by the pharmacy authorities;
(b) independent third-party testing of their facilities, including practices and procedures; and
(c) independent third-party testing of their compounded formulations both at the stage of development and during compounding.

The efficacy of the compounded medications is also assessed in real time by the medical practitioners who prescribe the medications and review patients using those medications. As mentioned earlier, given the widespread use of these medications, any genuine concerns

about the safety of the medications would by now be well known to medical practitioners, patients, compounding pharmacies and regulators.

In my submission, any identified safety concerns or concerns about the level of risk involved in the compounding of these medications, should be addressed by imposing mandatory requirements on the pharmacies that are compounding the GLP-RA medications. These requirements should:

(a) be formulated only after extensive and meaningful consultation with those pharmacies (not just through a regulatory process of submission and reporting), and

(b) balance the TGA's desire to reduce the public health and safety risks identified, against the ability of those compounding pharmacies to continue to assist patients with valued GLP-RA medications.

8. Marketing companies

As we have examined, it is clear from the TGA's public statements, that a substantial concern about these medications relates to the 'scale' on which they are being supplied on prescription to Australian patients.

A key concern about this 'scale' is that it appears to be driven by marketing companies (supported by aligned medical practitioners) that it is often said, may not offer the level of patient care required to adequately monitor patients using these medications.

In our submission, the monitoring and management of symptoms and outcomes is crucial to successful outcomes for patients on these medications. Any lack of care or supervision from a prescribing medical practitioner in respect a patients receiving GLP-RA medications (whether manufactured or compounded) would be a concern.

9. Impact on drug manufacturers

s47F [redacted] is concerned that large multinational pharmaceutical companies have been making representations to the TGA and other government officials to stop the compounding of GLP-RA medications.

These representations should be treated with great caution:

(a) These companies are attempting to create a monopoly over semaglutide in the Australian market in circumstances where they have no lawful monopoly. These companies are well aware that they lack these monopolistic rights. Any attempt by these manufacturers to create a de facto monopoly by restricting the operation of compound pharmacists should be resisted.

(b) For a government regulator to effectively grant these large multinational pharmaceutical companies monopolistic rights that they do not have in law on inconclusive safety concerns, is to act in a manner that is entirely inconsistent with decades of established public policy. It is entirely contrary to the policy underpinning the prohibitions against substantially lessening competition that are set out in the *Australian Consumer Law*. The representations of these companies is an attempt to eliminate competition for their own financial advantage.

(c) The conduct of these companies is entirely perverse because they are not in any way losing out from the conduct of compounding pharmacies. They are able to sell every unit of medication that they bring into the Australian market. The issue here is their persistent failure to satisfy the demand of Australian patients. The interests of the Australian public and Australian patients should prevail over the profit motive of these multinational corporations. Indeed, the conduct of these companies and their representations arguably warrant a full and proper investigation by the Australian Competition and Consumer Commission.

(d) Any claim that patients are unable to distinguish between these companies' product and compounded semaglutide is without foundation. In our experience, patients are clearly able to differentiate between manufactured and compounded GLP-RA medications. Compounded formulations are typically supplied in syringes rather than vials or pens, making the distinction between the two medications abundantly clear. Doctors regularly write prescriptions for the compounded rather than the manufactured form of the GLP-RA medications.

(e) There is no real prospect that compounded medications will erode the market share of any of the manufacturers of GLP-RA medications. The exemption allowing for compounding of medications, including GLP-RA medications, only applies where a suitable alternative medication is not available – in this case, by virtue of the shortage of supply by the manufacturers. By definition then, the making and supply of compounded semaglutide does not deny the drug manufacturers their revenues or profits. When adequate supply is eventually achieved, compounding will cease. In the interim, TGA should refrain from protecting the private property rights of multinational pharmaceutical companies making vast profits, and act in the interest of patients suffering from serious health conditions who need access to these medications.

s22 [redacted]
15 March 2024

The Pharmacy Guild of Australia

15 March 2024

Professor Robyn Langham
Chief Medical Adviser
Health Products Regulation Group
PO Box 100
Woden ACT 2606

Dear Professor Langham,

Re Compounding exemption for glucagon-like-peptide-1 receptor agonists (GLP-1 RA) medicines

The Pharmacy Guild of Australia (Guild) appreciates being consulted on the proposal to remove exemptions which allow pharmacists to compound GLP-1-RA medicines. The Guild has considered this proposal first from a patient care perspective and we do not support the proposal. The Guild believes the existing regulatory framework should be sufficient to address the problem. An overtly strong reactionary response to amend the regulations may compromise patient access and care.

Compounding can be useful for patients for a range of circumstances such as difficulty in administering or use of the medicine, sensitivities to non-therapeutic excipients or requirements for different strengths to what is commercially available. Compounding can also be useful to help patients manage supply disruptions for commercially available products. In the case of GLP-1 RA medicines, we note that the shortage for Ozempic® (semaglutide) is expected to continue until December 2024 and that supplies for other GLP-1 RA medicines like Mounjaro® (tirzepatide) and Trulicity® (dulaglutide) are also compromised – unavailable until 31 August 2024 and 31 December 2024 respectively[1]. Given the ongoing shortage of commercial GLP-1 RA medicines worldwide, compounded products may be the only solution for some patients in dire need.

With compounding, pharmacists must meet regulatory and professional requirements with strict controls in place for sterile injectable medicines regulated jointly by the Therapeutic Goods Administration (TGA) and Pharmacy Board of Australia (Pharmacy Board).

Current restrictions already cover:

- compounding only for individual patients according to a prescription
- restrictions on compounding prior to receipt of a prescription
- prohibition of batch compounding in anticipation of a prescription
- requirements for the compounding of sterile injectable medicines
- providing prescribers and patients with relevant information about the appropriateness and safety of the supply and compounding of a medicine

[1] Medicine shortage reports database | Therapeutic Goods Administration (TGA); accessed 12 Mar 2024

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Compounding prior to receiving a prescription or in batches is manufacturing, requiring the necessary licencing and approval from the TGA. Pharmacists, including employee compounding pharmacists and pharmacy owners, that breach these requirements can be prosecuted by the TGA and may also be subject to professional disciplinary action by the Pharmacy Board.

While we oppose the proposal to remove the compounding exemption for GLP-1 RA medicines for the reasons described above, we recognise the concerns of the TGA and other regulators at Commonwealth and state/territory levels. The Guild does not support non-compliance, deliberate or otherwise that does not put patient safety first.

With that in mind, we would consider supporting alternative arrangements, including:

- prohibiting online prescribing of GLP-1 RA compounded products (only allowing patients to attend a prescriber face-to-face)
- requiring pharmacies compounding GLP-1 RA products to provide monthly reports to the regulator on the quantity of prescriptions compounded and dispensed to assist the regulator to monitor and better identify any potential aberrant practice to investigate further
- requiring clinically significant adverse drug reactions to be reported to the regulator by prescribers and compounding pharmacies
- an awareness campaign for patients to be able to lodge complaints against practitioners in relation to any alleged improper practice

We would also support working with the TGA and other regulators to:

- work with the community pharmacy sector to continuously inform and educate community pharmacists on professional and compliant compounding practices
- provide pharmacists and prescribers with evidence-based information related to specific compounded products such as semaglutide

Should you wish to discuss our response further, please contact our s22 [redacted] s22 [redacted]@guild.org.au.

Yours sincerely

s22 [redacted]

s22 [redacted]
Pharmacy Guild of Australia

From: Regulatory Affairs, Sydney
To: s22
Cc: s22 ; s22
Subject: RE: Consultation letter from the TGA Chief Medical Adviser re compounding of glucagon-like-peptide-1 (GLP-1) receptor agonists [SEC=OFFICIAL]
Date: Friday, 15 March 2024 5:07:53 PM
Attachments: image001.png

Dear s22 ,

Thank you and Professor Langham for the opportunity to comment on the TGA proposed change to the Therapeutic Goods Regulations 1990 (the Regulations) to remove medicines containing GLP-1 receptor agonist analogues (GLP-1 RAs) from the pharmacy extemporaneous compounding exemption.

As a Sponsor of Therapeutic Goods in Australia, AstraZeneca's primary focus is on the Quality use of Medicines. Patients in Australia have the right to expect that they will receive medicines of the highest quality, tailored to their needs and based on the best treatment advice from their healthcare practitioner.

Although currently the Sponsor of a registered GLP-1RA in Australia (BYETTA 5mg and 10mg ARTG 123609 and ARTG 123610), our medicine is not reimbursed on the PBS and supply in Australia has recently been discontinued. For these reasons we are not sufficiently engaged in the intricacies of the supply challenges for GLP-1 RAs to be able to offer informed comment on the extent to which the proposed amendment to the compounding exemption will sufficiently mitigate public safety.

Recognising that patient care continues to be impacted by supply shortages of GLP-1RAs, and as a Sponsor of Therapeutic Goods for the treatment of Type II diabetes, AstraZeneca supports the RACGP advice for diabetes reviews by the patient's treating clinician, to ensure care is delivered in accordance with Australian Diabetes Society clinical guidelines and the various alternative diabetes treatment options can be considered.

Thank you once again for the opportunity to comment on the TGA proposals.

Yours Sincerely

s22

s22

AstraZeneca
66 Talavera Road, Macquarie Park, NSW 2113, Australia
T: s22 F: s22 M: s22
s22 @astrazeneca.com

From: s22 @health.gov.au>
Sent: Wednesday, February 28, 2024 5:52 PM
To: Regulatory Affairs, Sydney <Regulatory-Affairs-Sydney@astrazeneca.com>
Cc: s22 @astrazeneca.com>
Subject: Consultation letter from the TGA Chief Medical Adviser re compounding of glucagon-like-peptide-1 (GLP-1) receptor agonists [SEC=OFFICIAL]

Dear s22 ,

Please find attached a consultation letter from Professor Robyn Langham AM, Chief Medical Adviser, Health Products Regulation Group regarding compounding of glucagon-like-peptide-1 (GLP-1) receptor agonist analogues for your attention.

Kind regards,

s22

Health Products Regulation Group
T: s22 | E: s22 @health.gov.au
Location: 27 Scherger Drive, Level 2
PO Box 100, Canberra ACT 2601, Australia

The Department of Health and Aged Care acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

Document 17

15 March 2024

Professor Robyn Langham AM
Chief Medical Adviser
Health Products Regulation Group
Department of Health and aged Care

By email: s22 [redacted] @health.gov.au

Dear Professor Langham

Consultation to remove glucagon-like-peptide-1 (GLP-1) receptor agonist analogues from the pharmacist extemporaneous compounding exemption.

Thank you for the opportunity to respond to the Therapeutic Goods Administration (TGA) consultation to remove glucagon-like-peptide-1 (GLP-1) receptor agonist analogues from the pharmacist extemporaneous compounding exemptions set out in the Therapeutic Goods Regulations 1990 (the Regulations). We note that the proposed action would result in the removal of the legislative exemptions that currently allow community pharmacists to compound GLP-1 RA analogues.

National Boards and the Australian Health Practitioner Regulation Agency (Ahpra) note the significant increase in patient-driven demand for GLP-1 RA analogues for weight loss management involving online prescribing models while there are shortages of commercial medicines and the reports of commercial-scale manufacturing of compounded GLP-1 RA containing products to meet those demands. We also note concerns about large numbers of patients receiving unregulated injectable medicines provided in high volumes in Australia and understand that there are similar practices of equal concern occurring in other countries.

National Boards and Ahpra recognise the important role that compounded medicines play in meeting the unique needs of patients when available medicines, such as medicines on the Australian Register of Therapeutic Goods (ARTG), are not suitable or not available. We also recognise the important role of telehealth consultations in meeting community healthcare needs. National Boards to date have developed guidelines and other information for health practitioners which are relevant to these practices:

- the *Medical Board of Australia Guidelines: Telehealth consultations with patients, 2023*
- the Ahpra and National Board's *Telehealth guidance for practitioners*
- the *Pharmacy Board of Australia Guidelines on compounding of medicines*, *2015* which provide guidance to pharmacists on safe compounding which must comply with the requirements of therapeutic goods legislation and other relevant legislation, and
- *the Joint statement on compounded medicines – Pharmacy Board of Australia and Medical Board of Australia, 2017* which sets out good practice for medical practitioners prescribing and pharmacists compounding medicines required by patients.

We note that while the risks raised in your letter apply in all compounding situations, the impact of unmitigated risks is elevated for the compounding of sterile injectable medicines and can result in disastrous outcomes. Such was the case in the incident that occurred in 2012 in the United States when the compounding of a steroid injection resulted in fungal meningitis adversely affected more than 700 patients and resulted in the death of more than 100 people.

The evaluation of risk associated with compounding medicines is a crucial component of informing decisions to prescribe, compound and use these medicines. A primary consideration before prescribing and compounding GLP-1 RA containing products for use by patients is whether the active pharmaceutical ingredients (APIs) are safe and effective if used in compounded medicines. We understand that TGA is not required to make an assessment of the suitability of medicines unless an application is made for inclusion of a medicine in the ARTG.

If TGA has gathered information independently or in collaboration with regulators including overseas counterparts about the safety and quality of the APIs used in the compounding of GLP-1 RA analogues then it would assist stakeholders to provide feedback on proposals and options in addressing the current risks. If based on the assessment of available information, the APIs used to compound these medicines do not meet the thresholds for safety and quality, then dissemination of this determination should lead to an immediate halt of their prescribing and compounding in this country which could also be enforced by TGA's proposed action.

If available APIs meet the standard for human use and medicines of acceptable quality can be compounded safely and legally by pharmacists in community pharmacies, then the proposed immediate removal GLP-1 RA analogues from the exemptions in the Regulations may have impacts that warrant consideration, such as:

- the effect on the health of patients who cannot access these compounded medicines as part of an effective treatment plan provided by their prescriber when there is a shortage of a commercial product
- the effect on health service providers needing to respond to the changes and meet the arising needs of these patients both in the short and longer terms
- patients may be required to periodically change to different medicines and dose forms if there are periodic shortages of the commercial medicines in the future which may effect their treatment
- patients for whom the available commercial products are not suitable would not be able to access a similar compounded medicine, and
- patients in the community would be disadvantaged compared with patients in hospitals who may be able to access these compounded medicines (if compounding is supported by a risk assessment).

We share concerns that some compounding of medicines containing GLP-1 RA analogues may be anticipatory (before receipt of prescriptions for individual named patients) and occurring on a large-scale equivalent to a TGA-licensed manufacturer, which does not meet the exemptions set out in the Regulations. We support regulatory action by Commonwealth, state and territory regulators to stop such practices and the referral of health practitioners to National Boards and Ahpra and decision-making bodies in co-regulatory jurisdictions for any required action under the National Law.

While the lack of ability to enforce product quality standards is a risk and a concern in relation to current compounding of GLP-1 RA analogues, we acknowledge that this is relevant to all medicines including other sterile injectable medicines that are compounded in premises which are not licensed by TGA. Alignment of regulatory powers in all states and territories to monitor and enforce product quality standards which apply to compounded medicines would enable greater public protection.

Given that the risks associated with the large-scale compounding of unregulated sterile injectable medicines containing GLP-1 RA analogues and the capacity for high-risk practices to impact a large number of patients, National Boards and Ahpra note that the benefits of the proposed action may outweigh the impacts.

While the proposal would bring the compounding requirements for these medicines in line with other high-risk medicines such as medicinal cannabis products, it is unclear whether other regulatory pathways that enable the prescribing of compounded medicinal cannabis would also apply to GLP-1 RAs analogues.

While medication shortages may be resolved in time, the current regulation by the Commonwealth, states and territories may require review to address the risks associated with the compounding sterile injectable medicines as compounding operations are not monitored for compliance with quality standards in all jurisdictions. National Boards and Ahpra welcome the opportunity to collaborate further to explore options for addressing these risks.

If you would like more information, do not hesitate to contact me on s22 .

Yours sincerely

s22

s22

On behalf of Ahpra and National Boards

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via: s22 @health.gov.au

Dear Professor Langham

RE: CONSULTATION TO REMOVE GLUCAGON-LIKE-PEPTIDE-1 (GLP-1) RECEPTOR AGONIST ANALOGUES FROM THE PHARMACIST EXTEMPORANEOUS COMPOUNDING EXEMPTION.

Thank you for the correspondence and for organising the multijurisdictional and multi-departmental meeting on this topic. I am advised by our Chief Pharmacist that this was a productive session and many pragmatic approaches to regulation and governance were discussed.

The exemption from the Therapeutic Goods Regulations to enable pharmacist compounding exists to recognise that pharmacists have an accepted scope of practice in pharmaceutical compounding, particularly for bespoke formulations of low risk medicines where current products on the Australian market cannot meet s patient's individual dosing needs.

I recognise that this exemption also enables patients to access some medicines where there are temporary shortages in the Australian market such as reformulation of Lisdexamfetamine capsules to oral liquids to allow correct patient dosing from limited product strengths.

The large scale production of GLP-1 RA medicines such as Semaglutide does not align with the intent of this exemption. The compounding of injectable medicines without suitable quality controls or regulation is a significant public health risk.

As such I am supportive of the TGA's proposed amendments. Alternative regulatory models - such as licencing of pharmacies compounding injectable medicines, may be a more suitable approach but are not feasible to achieve in the timeframe needed to address this current concern.

Similarly. I have no concerns with the lack of a transition period as this regulation needs to come into effect as soon as possible to mitigate the current risk.

As the stock shortage of these medicines eases, I expect a decreased need for pharmacies to compound these to meet patient needs. Therefore, I would request the TGA consider reviewing this decision at a later stage to ensure the benefits of this regulation continue to outweigh the risks of reducing pharmacist scope of practice or is otherwise not required under an expanded regulatory framework in the future.

As with all states and territories, Obesity and Diabetes are significant causes of ill health in the NT and our Aboriginal and Torres Strait Islander peoples experience a disproportionate burden of these diseases. GLP-1 RA medicines are an important tool to reduce this however access to compounded products by this group in the NT is believed to be limited so I do not believe there will be any unintended impact in that area.

I recognise that global demand for these products has outstripped production which is not a risk easily mitigated for the Australian market. However, I would encourage the Department and the TGA to continue to enhance its ability to respond to stock shortages such as the one which is driving this compounding and which for other medicines has a significant impact to Territorians.

Thank you again for the quick response to this public health issue and for considering the impact to the NT. If you require any further support or information on the implementation of these reforms in the NT, please contact myself and s22 , Medicines and Poisons at any stage.

Yours sincerely

s22

s22

17 March 2024 @ 4.10pm

Pharmaceutical Society of Australia

PSA Committed to better health

19 March 2024

Professor Robyn Langham AM
Chief Medical Advisor
Health Products Regulation Group
Therapeutic Goods Administration

Dear Professor Langham,

Thank you for your letter to s22 [redacted] of the Pharmaceutical Society of Australia (PSA) inviting PSA to provide feedback on the Therapeutic Goods Administration (TGA) proposal to remove all medicines containing GLP-1 receptor agonist analogues (GLP-1 RAs) from the pharmacy extemporaneous compounding exemption in item 6 of Schedule 5 to the *Therapeutic Goods Regulations 1990*.

PSA response

PSA acknowledges that unique challenges have arisen and continue from the shortage of *Ozempic*. PSA accepts that the TGA has evidence and information relevant to the current unprecedented situation that PSA does not have access to. PSA also understands that the TGA is seeking a national regulatory approach that immediately mitigates potential risks to public safety.

However, PSA is firmly of the view that if the proposed amendment is made, it should be **temporary**, and further discussion be continued with key stakeholders, including state and territory regulatory authorities and compounding pharmacists. A temporary amendment could manage the current unique, unprecedented situation associated with GLP-1 RAs, while acknowledging that extemporaneous compounding within the existing regulatory and professional framework is appropriate to support individual patient access, needs and care.

For reasons outlined below, PSA suggests it is critical that TGA works to provide a pathway for removing or reversing the temporary amendment as soon as reputable evidence and information is available that GLP-1 RAs can be compounded according to the existing regulatory framework and professional guidelines and standards.

In this regard, PSA is committed to providing professional practice advice and support to pharmacists and to assisting the TGA to strengthen appropriate regulatory oversight in partnership with other regulatory bodies and stakeholders.

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Issues relevant to PSA's response

The circumstances and issues surrounding the current compounding of GLP-1 RAs is complex. PSA outlines its views below in the context of information at hand.

1. Extemporaneous compounding by pharmacists

PSA supports compounding of medicines by pharmacists according to the existing regulatory framework and professional standards and guidelines, to support individual patients' needs. PSA firmly believes that patient safety is the most important consideration when a pharmacist compounds any medicine.

The regulatory environment that supports safe and appropriate compounding of medicines by pharmacists is complex, with some functions supported by Commonwealth legislation and other functions supported by state or territory legislation. For example, compounded medicines must meet relevant quality standards as set out in the Commonwealth *Therapeutic Goods Act 1989*. In addition, state and territory legislation specifies requirements for the compounding environment that promotes quality assurance in compounding.

Pharmacists who compound medicines are also bound by professional standards and guidelines including the Pharmacy Board of Australia *Guidelines on Compounding of Medicines*, PSA's *Professional Practice Standards* and the *Australian Pharmaceutical Formulary and Handbook* (APF). These professional standards and guidelines outline how pharmacists can align their compounding practice with the principles of Good Manufacturing Practice.

In response to changes that have occurred over time in the compounding of medicines, PSA has recently published (in February 2024) a completely revised Compounding section of the APF, with improved clarity and guidance for compounding pharmacists. This revision comes after significant stakeholder consultation, including with the Therapeutic Goods Administration, the Pharmacy Board and state and territory regulatory authorities. The APF Compounding section includes detailed consensus guidance for pharmacists about assigning expiry dates and storage conditions to compounded medicines (including sterile medicines), clear explanation of the regulatory and quality assurance framework that applies to compounding and expanded guidance on compounding sterile medicines.

Some relevant excerpts of guidance on compounding from the APF are as follows:

> *Pharmacists must conduct and document a risk assessment for each request for a compounded medicine, and include clinical justification for compounding. Pharmacists must assess the potential risks (to pharmacy personnel, the patient, the public and the environment) associated with compounding a medicine, and have processes in place to mitigate the risks. Risk assessment and risk management processes must align with relevant standards, guidelines and regulatory requirements.*
>
> *Do not compound a medicine if there is a suitable commercial product that has a similar therapeutic effect and can be safely used for the intended purpose, and that can be accessed within a suitable timeframe. Consult with the patient and the prescriber when other supply pathways are more appropriate than compounding.*

Pharmacists who are requested to compound a medicine that has no formulation precedent in a reputable reference, and has inadequate published safety, stability, efficacy, pharmacokinetic and clinical data, should use professional judgement and risk assessment to determine if it is appropriate to compound the medicine. Pharmacists must document reputable evidence to support a decision to compound the medicine, and document discussions with the prescriber and the patient. In the absence of reputable evidence, pharmacists must not compound the medicine.

All ingredients used in compounding should be produced by manufacturers that have suitably approved quality assurance and quality control procedures in place. Acceptable Australian manufacturers will hold a Licence to Manufacture Therapeutic Goods issued by the TGA for manufacture of the relevant ingredients. Acceptable overseas manufacturers will hold a certificate of GMP compliance or equivalent accreditation from a regulatory or accrediting authority equivalent to the TGA.

All ingredients used in compounding should be of the pharmaceutical grade suitable for the compounded medicine. They should comply with the requirements of the relevant pharmacopoeial standards (e.g. BP, Ph. Eur., USP–NF), including microbiological quality, at the point of use. If there is no pharmacopoeial monograph for an ingredient, the pharmacist should conduct a risk assessment to determine whether to proceed with compounding.

All ingredients used for compounding injectable sterile medicines must be of a quality suitable for administration by injection.

2. Possible breach of compounding arrangements

Based on the information PSA currently has access to, it seems that the preparation of at least some semaglutide compounded medicines may not be consistent with the APF guidelines noted above.

Pharmacists who are operating outside of the regulatory and professional framework for compounding or who are not able to produce the necessary documentation to support their compounding activities should be dealt with under the Pharmacy Board and state or territory notification and compliance processes. PSA acknowledges, as outlined in the TGA letter, that existing processes might not be able to adequately address factors unique to the current unprecedented situation. We seek to understand what regulatory actions have already been undertaken to manage any breach in compounding activities.

From our experience, pharmacists are responsive to messages and guidance from regulators and PSA, especially when they are issued jointly or concurrently. PSA would welcome the opportunity to work in partnership with the TGA and/or state and territory officers in this regard. Depending on the nature of the issue, the Pharmaceutical Defence Limited may also be an important partner.

3. Semaglutide or a semaglutide salt as an active pharmaceutical ingredient

PSA has confirmed that a pharmacopoeial standard (acceptable in Australia) for semaglutide (or a semaglutide salt) as an active pharmaceutical ingredient (API) does not exist at present.

PSA seeks advice or guidance from the TGA on any information relating to semaglutide or a semaglutide salt as an API that may be available via other international regulatory agencies. Clearly, the availability or imminent publication of reputable evidence and information will inform and impact on pharmacist compounding activities.

4. Availability of ARTG-registered semaglutide products

PSA has been involved in the work of the TGA's Medicine Shortages section including the *Ozempic* Medicine Shortage Action Group convened in April 2022. It is unfortunate that the shortage has continued despite the sponsor's initial indications that production had been ramped up and stock availability was likely to return to a level where demand for its registered indication could be adequately met. The group has not met for some time now and it would be helpful to understand the current situation with respect to stock availability in Australia.

PSA is also aware that *Wegovy* is registered on the Australian Register of Therapeutic Goods but stock has not been available, and further, understands that recently it did not receive a positive recommendation from the Pharmaceutical Benefits Advisory Committee for PBS-listing. Given *Wegovy* has a different indication to *Ozempic*, any change in the shortage situation of *Ozempic* and/or PBS subsidy arrangement for *Wegovy* may have a significant downward impact on demand for compounded preparations of semaglutide.

5. Prescriptions for semaglutide products

The *Ozempic* Medicine Shortage Action Group held considerable discussions in 2022 and 2023 with the sponsor, patient groups and health professionals. As a result, advice was issued to pharmacists and prescribers to help manage the shortage in a safe, clinically appropriate and equitable manner. Specifically, prescribers were advised not to initiate new patients on *Ozempic* for the time being, unless there were no suitable alternatives or there was a compelling clinical reason to do so.

It may be timely for TGA to convene another meeting of the group to consider whether the guidance for patients and health professionals should be reviewed and updated, and messages around compounding of semaglutide preparations strengthened.

6. Possible unintended consequences of the proposed amendment

PSA believes that the TGA proposed amendment to item 6 of Schedule 5 to the *Therapeutic Goods Regulations 1990* may have the following unintended consequences:

- Patients may be denied access unnecessarily to an appropriately compounded GLP-1 RA (if there is a shortage of commercial product suitable for the patient and a pharmaceutical grade API and suitable formulation are available).
- Patients may personally import compounded GLP-1 RA preparations of uncertain quality and safety.
- Prescribers and patients may switch from semaglutide to another GLP-1 RA. Consequently, a supply shortage may occur with other GLP-1 RA commercial products.

Thank you for consulting with PSA and for your time in considering our response. We are happy to discuss this matter further. For any queries, please don't hesitate to make contact with myself directly, or the APF Team at *apf@psa.org.au*

Sincerely,

s22 [redacted]

s22 [redacted]

s22 [redacted]

Pharmaceutical Society of Australia

From: s22
To: s22
Subject: RE: Consultation letter from the TGA Chief Medical Adviser re compounding of glucagon-like-peptide-1 (GLP-1) receptor agonists [SEC=OFFICIAL]
Date: Friday, 5 April 2024 4:31:18 PM
Attachments: image001.png
image002.png
image003.png
image004.png

Hi s22

Thank you for Prof Langham's letter, we really appreciate being invited to consult on behalf of our Compounding Services Specialty Practice Group members. I understand we have missed the deadline and the changes have been made, but I do want to convey our support for the changes that have been implemented. We have had longstanding concerns about these practices and are grateful TGA has taken this course of action after consultation with relevant pharmacy stakeholders.

We look forward to being engaged again on any related matters going forward and I promise we will provide feedback within the timeframes requested.

Kind regards

s22 | s22
The Society of Hospital Pharmacists of Australia
shpa.org.au | PO Box 1774, Collingwood Victoria 3066
s22

From: s22 @health.gov.au>
Sent: Wednesday, February 28, 2024 2:44 PM
To: s22 @ths.tas.gov.au>

Cc: LANGHAM, Robyn s22 @Health.gov.au>; shpa@shpa.org.au
Subject: Consultation letter from the TGA Chief Medical Adviser re compounding of glucagon-like-peptide-1 (GLP-1) receptor agonists [SEC=OFFICIAL]

> You don't often get email from s22 @health.gov.au. Learn why this is important

Dear s22 ,

Please find attached a consultation letter from Professor Robyn Langham AM, Chief Medical Adviser, Health Products Regulation Group regarding compounding of glucagon-like-peptide-1 (GLP-1) receptor agonist analogues for your attention.

Kind regards,

s22

Health Products Regulation Group
T: s22 | E: s22 @health.gov.au
Location: 27 Scherger Drive, Level 2
PO Box 100, Canberra ACT 2601, Australia

The Department of Health and Aged Care acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

Eli Lilly Australia Pty Ltd

ABN 39 000 233 992

Level 9, 60 Margaret St

Sydney NSW 2000

Australia

CONFIDENTIAL

22 March 2024

Health Products Regulation Group
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

Via email

Dear Sir/Madam

Eli Lilly Australia Pty Ltd (Lilly Australia)
Submission in relation to TGA's Consultation to remove glucagon-like-peptide-1 (GLP-1) receptor agonist analogues from the pharmacist extemporaneous compounding exemption.

Eli Lilly and Company (**Lilly**) is a leading global healthcare company developing innovative pharmaceutical products in the fields of diabetes and metabolic disease, immunology, dermatology, neuroscience, oncology, and cardiovascular medicine. Lilly Australia, as local medicine sponsor, currently has multiple products that have an effect on GLP-1 (in some cases, amongst other targets) registered in Australia.

Lilly Australia welcomes the opportunity to provide feedback on the Therapeutic Goods Administration's (**TGA**) proposal for removing GLP-1 receptor agonist analogues (**GLP-1 RAs**) from the extemporaneous compounding exemption under the *Therapeutic Goods Act 1989* (the **Act**) and the *Therapeutic Goods Regulations 1990* (the **Regulations**).

We share the TGA's concerns that current 'compounding' practices from some entities is in breach of the Act, may amount to counterfeiting in some instances, and has potentially harmful consequences to the Australian public. We have considered the TGA's consultation letter in this light.

Lilly Australia strongly supports increased enforcement against entities in breach of the Act and its Regulations, and the improvements to patient safety that will flow from these actions. Increased enforcement should occur without delay while the TGA considers changes to the extemporaneous compounding exemption to address the current situation.

As to the proposed compounding exemption changes, Lilly Australia has concerns that the TGA's proposal comprises limited additional regulation and permits commercial manufacture if Good Manufacturing Practice (**GMP**) licensing requirements are met. This approach will not achieve its stated aim of addressing patient safety and may have unintended consequences, such as undermining public confidence in Australia's regulatory system via the widespread supply of unregistered products and disincentivisation of innovator companies.

Rather, Lilly Australia considers that the measures by the TGA must involve removal of the products from the compounding exemption *and* require that products meet the full requirements of the Act, as is required of any other therapeutic good. It will not be sufficient if GMP requirements only are applied.

Without full measures of the kind outlined, there will remain significant patient risk, and the potential for a lack of confidence in the medicines regulatory environment in relation to medications of this type.

If full enforcement and regulatory measures are adopted there would be improvement in patient safety, maintenance of public confidence, and a stable environment in which innovator manufacturers are able to bring to the Australian market products containing GLP1-RAs and other medications to assist patients.

Our response to the consultation letter's proposal is set out in detail in Attachment 1.

We thank the TGA for the opportunity to review and comment on the consultation. If you would like clarification of any aspect of this submission, we would be pleased to discuss with you, and we look forward to continuing to work with the TGA on these reforms.

Yours sincerely

s22 [redacted]

s22 [redacted]

s22 [redacted]
Eli Lilly Australia & New Zealand and North Asia Pacific Hub

Attachment 1

Does the TGA proposal sufficiently mitigate public safety?

1. As per the TGA correspondence, the TGA proposal is the following:

   "The exclusion of GLP-1 RAs in item 6 of Schedule 5 to the Regulations is proposed to:
   1. *remove the legislative exemptions that allow community pharmacists to compound GLP-1 RAs in the absence of a TGA Good Manufacturing Practice (GMP) licence; and*
   2. *bring the compounding requirements for these medicines in line with other high-risk medicines such as medicinal cannabis products and gene therapies."*

2. Lilly Australia understands that the TGA's primary objective of this proposal is to improve patient safety by introducing a level of manufacturing compliance to entities undertaking this 'compounding' that does not currently exist.

Lilly's general position in response

3. Lilly Australia is fully aligned with the TGA that the actions of these entities is a potential threat to public safety and measures should be taken to mitigate public safety risks.

4. While the basic mechanisms of the TGA's proposal as outlined in paragraph 1 are clear, it is less clear to Lilly Australia whether entities who seek a GMP licence to manufacture GLP-1 RAs must subsequently fully comply with the Act and seek registration of such goods on the Australian Register of Therapeutic Goods (**ARTG**).

5. Lilly Australia strongly believes that compliance with the remainder of the Act and an attempt to register any resulting product on the ARTG is critical:

   a. to patient safety; and

   b. for a consistent approach to the regulation and supply of safe and efficacious therapeutic goods.

6. For this reason, Lilly Australia is aligned with the TGA's proposal to require GMP, but does not believe this action alone goes far enough to adequately address the potential public safety risk of GLP1-RA unapproved supply, by what in truth is manufacturing on a commercial scale by businesses not pharmacists, under the guise of compounding. Lilly submits that any purported supply by such GMP licensees should be treated as the supply of any other therapeutic good by a commercial-scale manufacturer and subject to the full scope of the Act. In this aspect, if the TGA's proposal means to remove the products from the compounding exemption but to permit manufacture if there is GMP compliance, that approach would not sufficiently mitigate public safety in Lilly Australia's view.

7. Lilly Australia submits that for this proposal to address the potential public safety risks, enforcement of the current compounding exemption is required pending regulatory change, plus regulatory change to remove the products from the compounding exemption and apply full regulatory oversight, as outlined below. These measures are not currently articulated in the TGA's correspondence.

8. The below provides further background and explanation as to Lilly Australia's position.

Compounding of Pharmaceutical Products

9. Compounding of pharmaceutical products is the process of combining, "mixing, assembling, altering, packaging and labelling of a medicine, medicine-delivery device or device in accordance with a doctor's prescription, or initiative based on the doctor/patient/pharmacist/compounder relationship in the course of professional practice".[1]

10. As noted in a previous discussion paper on this issue[2], when the Act was enacted in 1989, exemptions to certain legislative provisions were given for extemporaneous compounding and dispensing. Extemporaneous compounding and dispensing is intended to be where a pharmacist prepares a medicine for an individual patient in response to an identified need of that patient. The medicine might be prepared in response to a diagnosis by the pharmacist or to a prescription by a medical practitioner. The exemptions recognised the one-off nature of such medicines and the professional training of the pharmacist to prepare a medicine extemporaneously.

11. Lilly submits that the actions described in the TGA's correspondence are inconsistent with, and should not be called, compounding as per this definition. Use of the 'compounding' terminology minimises and misrepresents the actions of these entities, which are in essence commercial-scale manufacturing in breach of the Act with medicines manufactured in large volumes and promoted and supplied including through the internet. This should be more appropriately addressed as unapproved supply or counterfeiting, as relevant to the specific circumstance of manufacture.

Current Compounding Exemption

12. The compounding exemption under the Act means that compounded medicines (other than medicines that are used for gene therapy or that are medicinal cannabis products) "*are not required to be entered on the ARTG before they can be supplied, provided they are extemporaneously compounded by a pharmacist for a particular person, for therapeutic application to that person*".[3] That is, on presentation of a prescription for an individual patient, a pharmacist may extemporaneously compound the prescribed medicine for that particular patient.

13. In addition, a pharmacist is exempt from the requirement to hold GMP manufacturing licences in certain circumstances.[4]

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[1] TGA, "Compounded medicines and good manufacturing practice (GMP)" (May 2017), page 4, available at link.

[2] National Coordinating Committee on Therapeutic Goods (NCCTG), "A Discussion paper on regulation of extemporaneously prepared medicines in non-hospital pharmacies" (10 April 2008), available at link.

[3] Pharmacy Board of Australia, "Background on the regulation of the supply and manufacture of medicines including medicines compounded by pharmacists" (March 2015, updated 2023), available at link or link. The relevant exemption is that "medicines that are dispensed, or extemporaneously compounded, for a particular person for therapeutic application to that person, other than medicines that are used for gene therapy or that are medicinal cannabis products …" are exempted from ARTG entry under Item 6, Schedule 5 of the Therapeutic Goods Regulations 1990 (Cth).

[4] Schedule 8, item 2, the Regulations. Pharmacists are exempt from the requirement to hold a manufacturing licence when therapeutic goods (other than biologicals) are (i) produced by the pharmacist in a pharmacy where the pharmacist practices and the pharmacy is open to the public, and (ii) the goods are supplied (other than by wholesale) on or from those premises.

14. The Pharmacy Board of Australia Guidelines on Compounding of Medicines provide additional details that batch preparation should not occur for compounding unless prescriptions have been received for each patient[5] (this position is consistent with the legislative exemption and its reference to extemporaneous). In addition, the TGA's Guide to the interpretation of the PIC/S Guide to GMP for compounded medicinal products [6] states that "as there is no Marketing Authorisation, as such, the product formulation must be in line with the order supplied."

15. Products that are compounded in this very narrow and specific framework are not required to be included in the ARTG by the supplier, and thus not assessed by the TGA (nor any global regulatory agency) for safety, quality, or efficacy.[7] Importantly, nor are pharmacists required to monitor and report any adverse events from compounded medicines.[8]

16. In contrast to the lack of regulation of such products, therapeutic goods registered on the ARTG undergo rigorous evaluation for safety, efficacy, and quality prior to supply. This evaluation follows a considered clinical trial process to provide evidence for such evaluation.

17. In addition, after drug registration, sponsors are obliged to have pharmacovigilance monitoring in place for adverse event reporting. The totality of this system is to provide patients with certainty that the products they are taking are safe and manufactured to high standards.

18. Failure to abide by the limits of this compounding exemption essentially means that a pharmacist is supplying a therapeutic good that is not otherwise approved or exempted for supply and is therefore in breach of the Act. More particularly, the commercial supply described by the TGA in its correspondence is not compounding as that definition is understood.

19. As most recently shown by the TGA's raid on Como Compounding Pharmacy in Melbourne[9], the TGA already has demonstrated its statutory authority to take enforcement action against compounding pharmacy advertising or supplying therapeutic goods to persons in Australia in breach of the Act.[10] Lilly Australia strongly supports such increased enforcement by the TGA and believes that this should be the TGA's initial focus to address the current concerns.

20. An advantage of enhanced enforcement is that it does not require the TGA to account for advances in pharmaceutical innovation by ongoing updates of products that should be removed from the exemption. For example, while the TGA's correspondence refers to "all medicines containing GLP-1 receptor agonist analogues (GLP-1 RAs)", it will need to clearly

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[5] Pharmacy Board of Australia, "Guidelines on Compounding of Medicines" (August 2017), p9, available at link.
[6] TGA, "Compounded medicines and good manufacturing practice (GMP): Guide to the interpretation of the PIC/S Guide to GMP for compounded medicinal products" (May 2017), p6, available at link.
[7] Pharmacy Board of Australia and Medical Board of Australia, "Joint Statement on Compounded Medicines" (24 November 2017), available at link.
[8] Pharmacy Board of Australia, "Guidelines on Compounding" (August 2017), available at link, provide only that pharmacists *should* report adverse events. In contrast, sponsors must maintain a mandatory pharmacovigilance system to monitor, collect and report any adverse events in relation to their products.
[9] *Elise Worthington*, Australian Broadcasting Corporation, "Melbourne compounding pharmacy raided as part of probe into alleged copycat Ozempic manufacturing" (1 March 2024), available at link.
[10] See generally, Therapeutic Goods Act 1989 (Cth), Chapter 5A – Enforcement and Chapter 6, Pts 6-1A – Information gathering powers, 6-2 – Entry, searches and warrants. See also, TGA, Enforceable Undertaking: Net Pharmacy Ptd Ltd (8 December 2020) available at link.

define the scope. Lilly Australia submits that the TGA should define the scope to include current medicines as well as other drug candidates in development acting against other receptors in addition to GLP1.

GMP Licence Proposal

21. Lilly Australia understands that, via this proposal, the TGA would require any companies wishing to supply products containing GLP1-RAs to obtain a GMP licence. What is not clear is if this is the limit of compliance expected of these entities by the TGA.

22. Products manufactured under such a GMP licence are commercial in nature and should therefore be subject to the full oversight of the TGA and the Act. It is not enough that only GMP requirements directed to quality apply.

23. Indeed, Lilly Australia submits that the TGA itself recognizes that these organizations are commercial manufacturers in the below passage of its correspondence [*emphasis added*]:

> *"The TGA has concerns with the impact of **commercial-scale manufacturing** of compounded GLP-1 RA containing products. The large volumes of production for local supply and export involves a **degree of complexity equivalent to that of a manufacturer that is required to comply with the Act** and to be required to hold a GMP licence from the TGA".*

24. Lilly Australia submits that the emphasised sections from the TGA's correspondence are key. Our position is that if an organisation is sufficiently sophisticated to manufacture pharmaceutical products in commercial volumes, that organisation should also be sufficiently sophisticated to comply with the remainder of the Act, namely the Act's requirements for the registration of therapeutic goods.[11]

25. It is not clear from the TGA's proposal if such products would be required to register in the usual manner under the Act. If it is not a requirement, this proposal will encourage what Lilly submits is inappropriate supply with the only obvious compliance requirement being the holding of a GMP licence.

26. Lilly's position is that TGA should not create another approval mechanism for supply and should instead require the usual product registration pathways be followed.

27. Most importantly for public safety, this would require such organizations to undergo the same steps as other sponsors of prescription products and submit evidence for evaluation to demonstrate the safety, efficacy, and quality of their products as well as implement pharmacovigilance programs. Without such an obligation for a GMP licence holder to demonstrate efficacy and safety via a robust clinical trial process, and improved quality and production standards, there is little likelihood that the TGA's proposal will positively impact the safety of the Australian public.

28. Moreover, it is unclear why entities that have consciously and wilfully breached the Act and the broader regulation of pharmaceutical compounding should be rewarded by being able to

[11] For example, Regulation 12(1) of the Regulations provides that therapeutic goods in the classes of goods mentioned in Sch 5 are exempt from the operation of Part 3-2 ("Registration and Listing of therapeutic goods") of the Act with some exceptions and Div 4 Part 3-2A of the Act.

benefit from minimal compliance measures, yet produce at commercial volumes. This would be a very unfortunate precedent.

29. To date, some of these self-proclaimed manufacturers have stated that they believe in the efficacy of their product, but have not been required to submit any evidence of such.[12] It is a risk to the Australian public that such unregulated and unapproved products would be widely available (or at all) in the market. This is particularly the case when the products in question are injectable, sterile products and patient safety and treatment efficacy should not be undermined by the supply of unregulated products.[13]

Patent Notification

30. While Lilly is aligned with the TGA that the greatest concern from the ongoing unapproved supply of products containing GLP1-RAs is patient safety, it would be remiss not to note the significant concerns about patent protection that are raised by the proposal.

31. There is no indication in the TGA's correspondence that it will require a patent certification in similar terms to that required of all product registrations under section 26B.[14]

32. It is not in the TGA's or the public's interest for the TGA to register (or otherwise exempt from registration) products in Australia where they involve likely or blatant patent infringement and may immediately result in highly contentious legal proceedings, which would place considerable costs on innovator companies.

33. In addition, the TGA puts itself at risk of being seen to authorise patent infringement and does so on behalf of entities that have shown a willingness to disregard regulation. This risk to the TGA is heightened if the approach of medicinal cannabis regulation is adopted and Special Access Scheme (**SAS**) or Authorised Prescriber (**AP**) approvals are required for each patient.

34. Without applying the usual considerations of patent certification to pharmaceutical products, the TGA may imply to entities who obtain the proposed GMP licences that the Australian government is not concerned with recognizing pharmaceutical patent rights, as required under various international agreements.[15]

Additional Unintended Consequences

Medicinal Cannabis Regulation

35. Lilly Australia notes that the TGA's correspondence refers to medicinal cannabis as an example of removal from the extemporaneous compounding exemption.

[12] Nick Bonyhady, The Australian, "Start-up to sell 'unapproved' replica Ozempic, upending market" (13 December 2023), available at link.
[13] European Confederation of Pharmaceutical Entrepreneurs, "Position Paper: Compounding Drugs to Lower Costs Puts Patients at Risk" (2016), available at link.
[14] *Therapeutic Goods Act 1989* (Cth), s26B.
[15] World Trade Organisation, "Pharmaceutical patents and the TRIPS Agreement" (21 September 2006), available at link.

36. In contrast to the proposal at hand, a prescription for medicinal cannabis requires an SAS/AP approval[16] and also requires the manufacturer to comply with Therapeutic Goods Order 93 (**TGO 93**).[17]

37. The SAS/AP pathway imposes on HCPs some requirements for the reporting of AEs, which does not appear to be contemplated by this proposal. In addition, TGO 93 applies a level of consistency to the compounded medicinal cannabis that does not appear achievable in relation to GLP1-RAs.

38. It is not clear to Lilly Australia if the TGA anticipates requiring SAS/AP approval for each individual GLP1-RA patient. As can be imagined, this would represent a huge administrative burden to the TGA and any reporting supplier. It also is not clear how this can be reconciled with a standard prescription for commercially available products containing GLP1-RAs that do not require such an approval.

39. Further, Lilly is only aware of two medicinal cannabis products registered by the TGA on the ARTG as a prescription medicine[18], with only one of these products available in limited circumstances via the PBS.[19] That is, there are not otherwise commercially available medicinal cannabis products (in their final form) for supply in Australia.[20]

40. Accordingly, medicinal cannabis products must be accessed in practice through special pathways available for unapproved medicines[21], and approval or authorization (i.e. doctor obtaining approval as an AP or applying on the patient's behalf through SAS) is granted on a case-by-case basis only. These controls have not, however, constrained businesses from promoting these unapproved medicinal cannabis medicines to the public, contrary to the Act, as evidenced by the multiple infringement notices issued by the TGA.

41. Lilly Australia observes that, given the rapid growth of digital healthcare, it is very easy for consumers to obtain a prescription online from a doctor in a digital healthcare clinic (such as Juniper, see link), and then have the script fulfilled by a partner pharmacy, with the medication being promptly dispensed and delivered to the patient's home all at the touch of a button (see link).

42. Based on these issues, it does not appear that the mechanisms used for regulation of medicinal cannabis products would be a viable option for GLP1-RA products. Lilly Australia is of the view that creating a *sui generis* mechanism for GLP1-RAs is not an advisable approach.

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[l] If a medicinal cannabis product is unapproved, a medical practitioner would need to organize access for his/her patient through TGA pathways for unapproved medicines, such as by notifying/applying on the patient's behalf for approval to import and supply these products through the TGA's Special Access Scheme (SAS), or else the doctor may apply to the TGA to become an Authorised Prescriber (AP), TGA, "Guidance for the use of medicinal cannabis in Australia: Patient information" (December 2017), available at link.

[17] TGA, "Medical cannabis: Information for sponsors" (11 January 2024), available at link.

[18] See NSW Health 'Cannabis Medicines' (22 December 2022), available at link.

[19] Department of Health and Aged Care, Pharmaceutical Benefits Scheme for CANNABIDIOL Available brand: Epidyolex, available at link.

[20] A number of medicinal cannabis products are listed on the ARTG for export only and are not considered approved products for supply in Australia. See TGA, "Medicinal cannabis products by active ingredients" (7 September 2023), available at link.

43. In addition, given global public health concerns relating to obesity, an easing of therapeutic goods regulatory framework for GLP1-RAs may give rise to a perception that in Australia such medications are treated in the same way as low risk listed medicines where sponsors may supply products such as dietary supplements to consumers without pre-market assessment of efficacy, quality and safety by the TGA (rather than a prescription only medicine containing pharmaceutical ingredients included on the Poisons Standard). Lilly Australia considers that this would be undesirable and not in the public interest.

Disincentivisation of Innovator Companies

44. While TGA may seek to implement this proposal as an interim solution to supply constraints, it may have the inadvertent effect of disincentivizing valuable research and development, manufacture, and supply by innovator companies.

45. If the TGA implements its proposal and consequently implicitly authorises widespread use of products under GMP licence only, innovator companies "*will be less ready to undergo the costly and time-consuming research and development process needed to bring a safe, efficacious, and approved drugs to market*".[22]

46. This potential disincentivisation may be augmented by the possible view that innovator patent rights are not recognised or respected in this process and ensure that Australia is seen as a less desirable market to supply.

47. Companies are disincentivised from allocating valuable resources to supplying a country where that country's regulator has provided an almost *sui generis* system that encourages the supply of products that have not been assessed for safety, quality, and are available in market with fewer regulatory burdens than those observed by the innovator.

Reduced International Harmonisation

48. An additional factor in Lilly's position is that the TGA's proposal is less likely to achieve harmonisation between Australia's regulatory regime and comparable international practice. These issues of unapproved supply currently appear to be a global issue, but the adoption of this proposal (without the additional steps suggested by Lilly Australia) may mean that Australia is alone in providing a mechanism that may inadvertently encourage 'compounding' by introducing a relatively minor regulatory burden to supply.

Conclusion

49. Lilly Australia is pleased to see the TGA and the various other regulators take positive steps to rein in the unapproved supply of prescription products by pharmacists claiming to rely on the extemporaneous compounding exemption.

50. However, Lilly Australia respectfully expresses its concern that the current TGA proposal will not sufficiently address the issues raised by these activities. Lilly Australia submits that the following may be more appropriate measures for the TGA to consider:

[22] European Confederation of Pharmaceutical Entrepreneurs, "Position Paper: Compounding Drugs to Lower Costs Puts Patients at Risk" (2016), available at link.

a. immediate enhanced enforcement by the TGA of the current extemporaneous compounding exemption (without the removal of GLP1-RAs from this exemption) while the TGA considers and implements a change to the regulatory environment;

b. rather than a limited hybrid approach, if GLP1-RAs are removed from the exemption and permitted for commercial scale activities with only GMP licensing, full compliance with the Act should be required of licensees and products submitted for evaluation and needing to demonstrate quality, safety and efficacy just like any other products, and complying with advertising regulation. There is no value to the Australian public's safety in having prescription drugs on the market that have not undergone appropriate regulatory review for all such requirements, namely safety and efficacy, in addition to relevant GMP and quality requirements.

51. Lilly Australia is in full agreement with the TGA that unapproved supply of GLP1-RAs in Australia must be addressed immediately. Australian patients should have trust and confidence in the regulatory system and that prescription products are subject to appropriate oversight, particularly when produced by commercial manufacturers. Thank you for the opportunity to review and comment on this issue, and we look forward to continuing to work with the TGA on these reforms.

Australian Patients Association Limited
ABN 25 146 474 688
Level 22, 114 William Street
Melbourne, VIC. 3000
Phone: 03 92740788

Date: 15 March 2024

Att: s22 [redacted]@health.gov.au

Submission to the Therapeutic Goods Administration

Subject: Consultation to remove glucagon-like-peptide-1 (GLP-1) receptor agonist analogues from the pharmacist extemporaneous compounding exemption.

Submission by: The Australian Patients Association.

Introduction

We thank the TGA for providing the opportunity to contribute to its review of this issue.

The Australian Patients Association (APA) draws its consumer voice from a mixture of sources including:

- Feedback from members;
- Feedback from people who utilise our support and case management services; and
- Higher level and extensive surveys conducted 6 monthly, (the *Australian Health index* and *The Patient View* with respondent numbers between 10,000-20,000 for each survey.

Our board and Executive regularly review issues and based on the feedback from our various patient sources, from policy positions on those issues.

Our interest in this issue

The availability of the drug Ozempic has been on our radar since it was first announced that there were shortages of the drug, and we have been aware that analogues have been compounded for approximately the last12 months.

We recognise that the drug is one of a number available to people with Diabetes, and significantly, and as the TGA is aware has also been found to be effective as a treatment for obesity. A recent study in the new England Journal of Medicine for example, has found an increase in life expectancy for people using the drug as an obesity treatment.

The high demand for this drug, coupled with its relative shortages and attempts to mitigate shortages, have brought this to the fore as a patient issue.

The TGA Proposal

The TGA has proposed to remove the legislative exemptions that allow community pharmacists to compound GLP-1 RAs in the absence of a TGA Good Manufacturing Practice (GMP) licence; and to bring the compounding requirements for these medicines in line with other high-risk medicines such as medicinal cannabis products and gene therapies.

In describing this proposed approach it has outlined concerns about weakness in legislation which is "not responsive to developments in high throughput models of medical care, such as online prescribing models or pharmacy compounding practices, leaving large numbers of patients exposed to unregulated medicines provided in high volume, where the safety and quality of these provided medicines cannot be assured."

Secondly, that there are concerns "with the impact of commercial-scale manufacturing of compounded GLP-1 RA containing products. The large volumes of production for local supply and export involves a degree of complexity equivalent to that of a manufacturer that is required to comply with the Act and to be required to hold a GMP licence from the TGA."

The Australian Patients Association view

- ***Concerns about pre-emptive compounding, or larger scale manufacturing with the concern about possible export.***

We recognise these concerns, and note that under available rules, any such behaviours can and should be identified and prevented. Compounding chemists are regulated, and this behaviour, if and where it exists, should be stamped out. While it may be true in the view of the TGA that legislation and regulation relating to compounding chemists is no longer fit for purpose, this issue has evolved over significant time. We would support an immediate review of the role and function of compounding chemists, however we would not pre-empt the outcome of that review, which this proposal appears in part to do. For example, it may be that a review would find that there is a potentially expanded role of compounding chemists, but in a more strongly regulated environment, bridging the divide between manufacturing regulation and compounding regulation.

- ***Limiting the use of the available supply to only those with Diabetes?***

While we are advised that this issue is not directly related to the immediate decision of the TGA and is outside its remit, however the TGA can make recommendations. We are strongly of the view that during any shortage there should be no move to limit the use of those drugs that are available to only people with Diabetes. As we understand it, there are a number of drugs currently not experiencing shortages, with similar efficacy in the treatment of Diabetes, however there are not any drugs currently available and not in short supply, for the treatment of Obesity. We are concerned that the importance of this drug as a treatment for obesity, and the current large number of Australians under prescription, is being considered a second order issue and concern.

- ***Safety concerns***

We recognise two critical areas of safety concern:

1. The compounding process, on which the TGA has focused its safety concerns; and
2. The possible impact of immediate removal of availability of the current prescribed compounded drugs from tens of thousands of Australians, carrying with it, continuity of Care issues and possible side-effects.

On the basis of discussions and the available material, at this stage we do not believe that adequate weight is being applied to the second of these safety considerations.

We do not accept on face value that the shortage of data on the safety of the compounded drug equates to confirmation that the drug is therefore unsafe. However, we acknowledge the uncertainty and share that concern, We also note that:

- only very scarce information exists relating to adverse events;
- the limited testing which has occurred, has shown no adverse effects or manufacturing issues; and
- the analogues have been widely prescribed already for the past 12 months.

The TGA proposal, to remove the legislative exemptions that allow community pharmacists to compound GLP-1 RAs in the absence of a TGA Good Manufacturing Practice (GMP) licence; and bringing compounding requirements for these medicines in line with other high-risk medicines such as medicinal cannabis products and gene therapies.

Based on our discussion with the TGA it seems clear that the taking of these actions, in the face of the weight of number so people currently prescribed the analogues, is effectively a ban on the compounding of the analogues. Under the existing rules, only under significant exceptions would the TGA approve a prescription for compounding of an analogue. In our view, this proposal overall is too extreme when considering the wellbeing of people already on prescriptions.

These types of drugs are compounded already by compounding chemists and have been for decades, under their own regulation. While they are not manufacturers they are approved for compounding, and regulated in relation to them. The main issues in this case have arisen about *possible practices and concerns* linked to larger scale production and the risks that brings, in the face of the compounding chemists not being licensed as a manufacturer. However, there are clear rules which limit and control compounding chemists in this area, and any practice against any form of existing regulation can be properly identified and the regulation properly enforced, without the widespread banning of the practice.

We are not clear of the criteria being applied to consider this a 'high-risk' medicine or whether this is simply the best available instrument to allow greater control in the circumstances. However, we were advised that TGA exceptions under these rules would only be applied in extraordinary circumstances, and so this approach would again, equate to the effective banning of compounding these analogues.

Proposed way forward

We believe that the ideal outcome, if achievable, is that compounding be able to continue through the period of shortage, with a number of controls placed on the process to reduce concerns about safety, and any other improper practices.

We are concerned about safety issues raised but not convinced that these represent enough data. As a result, we propose that:

- Conditions should be put in place to enable the TGA to properly monitor adverse events, and in the event that there are issues, these should be immediately identified and action taken.

- Only properly regulated and qualified compounding chemists should be able to compound the analogies.
- We suggest that the TGA, in concert with state regulators for compounding chemists, produce an immediate and clear set of guidelines should be created and released which underlines both existing regulations, and any additional requirements.

The concerns about pre-emptive manufacturing or manufacturing for export and outside of existing rules and controls and should be monitored and the rules applied as firmly as possible.

This approach would ensure continuity of care for the tens of thousands of people already prescribed these drugs.

If there are, upon monitoring, an unacceptable level of adverse events, this process can be immediately reviewed.

We again thank you for the opportunity to comment and acknowledge the great ongoing work of the TGA.

Yours sincerely

s22 [redacted]

s22 [redacted]

RACGP
Royal Australian College
of General Practitioners

Healthy Profession.
Healthy Australia.

15 March 2024

Professor Robyn Langham AM
Chief Medical Adviser
Health Products Regulation Group
Department of Health and Aged Care

Via email: s22 [redacted] @health.gov.au

Dear Professor Langham,

Re: Consultation to remove glucagon-like-peptide-1 (GLP-1) receptor agonist analogues from the pharmacist extemporaneous compounding exemption.

Thank you for your letter regarding the proposal by the Therapeutic Goods Administration (TGA) to undertake changes to the Therapeutic Goods Regulations 1990 (the Regulations) to remove all medicines containing GLP-1 receptor agonist analogues (GLP-1 RAs), including semaglutide-like medicines, from the pharmacy extemporaneous compounding exemption.

The RACGP understands the difficulties of monitoring the quality and nature of compounded medications and that compounding at scale can become a defacto manufacturing activity operating with fewer regulations, compliance and process checks than typically required. We are supportive of measures to protect patients from harmful compounded medications.

Worldwide, semaglutide remains under post-marketing surveillance, raising concerns that early issues regarding safety of the compounded version might be missed due to potential underreporting.

As such, the RACGP supports the TGA's proposal to exclude GLP-1 RAs in item 6 of Schedule 5 and the immediate removal of exemptions permitting pharmacists to compound GLP-1 receptor agonists.

We propose mitigating unintended consequences of this decision could involve:

- increased efforts to secure a reliable supply of GLP-1 receptor agonists and creating the legislative environment that would eventually ensure safe and reliable onshore production.
- implementing a nationally coordinated distribution of GLP-1 receptor agonists (and other medicines subject to supply interruptions) to minimise disruptions to patients' medication regimes.
- formulating management strategies for patients prescribed a particular GLP-1 receptor agonist, such as switching to an alternative GLP-1 receptor agonist or class of medication. The prescribing clinician should oversee these strategies.

It is also important the TGA ensures the potential increase in demand on already limited supplies of semaglutide can be met when the regulations are in place.

Additionally, the RACGP recommends the TGA should exclude any GLP-1RA and Glucose-dependent insulinotropic polypeptide (GIP) combinations medications from being compounded to replace Tirzepatide if there is a shortage of this medication and that oral semaglutide be included in the review.

RACGP
Royal Australian College of General Practitioners

Healthy Profession.
Healthy Australia.

Thank you again for the opportunity to provide feedback. For any enquiries regarding this letter, please contact s22 on s22 or s22 @racgp.org.au.

Yours sincerely

s22

s22
RACGP s22

GLP1-RA	Compounding	Compounded	Total
Semaglutide	107	166	273
Liraglutide	0	1	1
Dulaglutide	0	0	0
Tirzepatide	2	1	3
Exenatide	0	0	0
Total	109	168	277

Semaglutide

Record Number	Title	Date Created
D23-5023010	(referral from TGA Info) Alleged breach of Act or questionable practices by compounding pharmacies re semaglutide - Email 06-01-2023 13:22:43 (0) TGA Info	06/01/2023 at 1:22 PM
D23-5023498	(response to TGA Info) Alleged breach of Act or questionable practices by compounding pharmacies re semaglutide - Email 10-01-2023 16:08:00 (0) Advertising Enquiries	10/01/2023 at 4:08 PM
D23-5023594	(referral to CAMS) Alleged breach of Act or questionable practices by compounding pharmacies re semaglutide - Email 10-01-2023 16:12:09 (1) Advertising Enquiries	10/01/2023 at 4:12 PM
D23-5039847	(response from CAMS) Alleged breach of Act or questionable practices by compounding pharmacies re semaglutide - Email 16-01-2023 10:32:01 (0) TGA Advertising	16/01/2023 at 10:32 AM
E23-516134	THERAPEUTIC GOODS REGULATION - Investigations - Advertising - AC-000000014903 - s22 [redacted] - Semaglutide - 24/02/2023	07/03/2023 at 11:52 AM
D23-5213642	RE_ s22 [redacted] -Semaglutide CCEMS_01400000600 _SEC_OFFICIAL_.msg	15/03/2023 at 1:38 AM
D23-5213658	FW_ s22 [redacted] -Semaglutide _SEC_OFFICIAL_ CCEMS_01400000600.msg	15/03/2023 at 1:38 AM
E23-522034	THERAPEUTIC GOODS REGULATION - Investigations - Advertising - AC-000000015251 - MAR23 - s22 [redacted] - Semaglutide - Advertising - 26/03/2023	27/03/2023 at 5:12 PM
D23-5259665	FW: Compounding of semaglutide [SEC=OFFICIAL] - Email 29-03-2023 15:50:22 (1) s22 [redacted]	29/03/2023 at 3:50 PM
D23-5259671	FW: Compounding of semaglutide [SEC=OFFICIAL] - Email 30-03-2023 15:43:18 (1) GMP Compliance	30/03/2023 at 3:43 PM
D23-5340685	(referral to CAMS) Alleged breach of Act or questionable practices by compounding pharmacies re semaglutide _SEC_OFFICIAL_.msg	01/05/2023 at 5:15 AM
D23-5340687	RE_ (referral to CAMS) Alleged breach of Act or questionable practices by compounding pharmacies re semaglutide _SEC_OFFICIAL_.msg	01/05/2023 at 5:15 AM
E23-530217	THERAPEUTIC GOODS REGULATION - Investigations - Advertising - AC-000000012666 - s22 [redacted] - Semaglutide - 09/01/2023	01/05/2023 at 2:56 PM
E23-530216	THERAPEUTIC GOODS REGULATION - Investigations - Advertising - AC-000000012666 - s22 [redacted] - Semaglutide - 09/01/2023	01/05/2023 at 2:56 PM
D23-2177461	[Query - compounding pharmacies and semaglutide] TGA Website | Form submission | Get in touch [SEC=OFFICIAL] CCEMS:01820001507	26/06/2023 at 1:13 PM
D23-2177493	[TGA response to query - compounding pharmacies and semaglutide] TGA Website | Form submission | Get in touch [SEC=OFFICIAL] CCEMS:01820001507	29/06/2023 at 4:06 PM
D23-2179089	s22 [redacted] semaglutide s22 [redacted] .pdf	10/07/2023 at 1:47 AM
E23-185547	THERAPEUTIC GOODS REGULATION - Investigations - Advertising - AC-000000015596 - MAY23 - s22 [redacted] - Semaglutide - Advertising - 22/04/2023	10/07/2023 at 1:19 PM
D23-3928220	Response to ACT Health re semaglutide compounding - October MAWG meeting	31/10/2023 at 12:43 PM
D23-4063883	Snagit - s22 [redacted] - Semaglutide for Weight Loss - 31-10-2023.pdf	09/11/2023 at 8:53 AM
E23-352428	THERAPEUTIC GOODS REGULATION - Investigations - Advertising - AC-000000025072 - OCT23 - s22 [redacted] - Semaglutide - 08/10/2023	09/11/2023 at 4:18 PM
D24-1283755	FW: Compounding of Semaglutide	21/11/2023 at 9:17 AM
E23-369585	THERAPEUTIC GOODS REGULATION - Investigations - Advertising - AC-000000015610 - APR23 - s22 [redacted] - Semaglutide - 26/04/2023	22/11/2023 at 3:09 PM
E23-369594	THERAPEUTIC GOODS REGULATION - Investigations - Advertising - AC-000000015610 - s22 [redacted] - Semaglutide - Evidence	22/11/2023 at 3:15 PM
E23-369595	THERAPEUTIC GOODS REGULATION - Investigations - Advertising - AC-000000015610 - s22 [redacted] - Semaglutide - Internal correspondence	22/11/2023 at 3:15 PM
E23-369603	THERAPEUTIC GOODS REGULATION - Investigations - Advertising - AC-000000015610 - s22 [redacted] - Semaglutide - External correspondence	22/11/2023 at 3:18 PM
E23-369604	THERAPEUTIC GOODS REGULATION - Investigations - Advertising - AC-000000015610 - s22 [redacted] - Semaglutide - Working documents	22/11/2023 at 3:18 PM
D24-1307036	RE: Compounding of Semaglutide	22/11/2023 at 10:06 PM
E23-372621	THERAPEUTIC GOODS REGULATION - Complaints handling - Advertising - AC-000000025072 - s22 [redacted] - Semaglutide - Evidence	24/11/2023 at 12:57 PM
E23-372625	THERAPEUTIC GOODS REGULATION - Complaints handling - Advertising - AC-000000025072 - s22 [redacted] - Semaglutide - Internal correspondence	24/11/2023 at 12:58 PM
E23-372627	THERAPEUTIC GOODS REGULATION - Complaints handling - Advertising - AC-000000025072 - s22 [redacted] - Semaglutide - External correspondence	24/11/2023 at 12:58 PM
E23-372630	THERAPEUTIC GOODS REGULATION - Complaints handling - Advertising - AC-000000025072 - s22 [redacted] - Semaglutide - Working documents	24/11/2023 at 12:58 PM
D23-4425610	Investigation plan - s22 [redacted] - Semaglutide - AC-000000025072	05/12/2023 at 5:01 PM
D24-1307017	FW: Compounding of Semaglutide [SEC=OFFICIAL]	07/12/2023 at 9:56 AM
D23-4555398	DEP SEC APPROVED Statement on extemporaneous compounding- semaglutide	13/12/2023 at 3:33 PM
D25-312284	For clearance by 2pm today- Compounding safety information: semaglutide-like products [SEC=OFFICIAL] - Email 15-12-2023 13:44:16 (1) s22 [redacted]	15/12/2023 at 1:44 PM
D23-4592338	HPRGCorro - CMA Office - For clearance by 2pm today- Compounding safety information: semaglutide-like products [SEC=OFFICIAL] - Email 15-12-2023 13:44:16 (1) s22 [redacted]	15/12/2023 at 1:44 PM
D23-4578427	Social for Compounding safety information - semaglutide-like products	15/12/2023 at 1:52 PM
D25-312276	RE: For clearance by 2pm today- Compounding safety information: semaglutide-like products [SEC=OFFICIAL] - Email 15-12-2023 14:49:12 (1) LAWLER, Tony	15/12/2023 at 2:49 PM
D23-4592416	RE: For clearance by 2pm today- Compounding safety information: semaglutide-like products [SEC=OFFICIAL] - Email 15-12-2023 14:49:12 (1) LAWLER, Tony - Cleared by Dep Sec WITH EDITS - 15 Dec 2023	15/12/2023 at 2:49 PM
D25-312266	RE: For clearance by 2pm today- Compounding safety information: semaglutide-like products [SEC=OFFICIAL] - Email 15-12-2023 15:58:18 (0) s22 [redacted]	15/12/2023 at 3:58 PM
E23-402913	THERAPEUTIC GOODS REGULATION - Investigations - AC-000000025096/ RC-027741- s22 [redacted] - Semaglutide & Sarms November 2023	18/12/2023 at 9:34 AM
D24-1283509	Meeting with s22 [redacted] - Compounding of Semaglutide [SEC=OFFICIAL]	21/12/2023 at 5:16 PM

D24-31201	[redirecting an enquiry about semaglutide compounding] RE: TGA Website | Form submission | Get in touch CCEMS:03790000565 [SEC=OFFICIAL] - Email 03-01-2024 12:06:32 (0) Medicine Shortages	03/01/2024 at 12:06 PM
D24-601062	Semaglutide - Compounding [SEC=OFFICIAL] - Email 05-01-2024 12:33:18 (0) s22	05/01/2024 at 12:33 PM
D24-601056	RE: Semaglutide - Compounding [SEC=OFFICIAL] - Email 05-01-2024 12:39:52 (0) s22	05/01/2024 at 12:39 PM
D24-601049	RE: Semaglutide - Compounding [SEC=OFFICIAL] - Email 05-01-2024 12:48:38 (0) s22	05/01/2024 at 12:48 PM
D24-601044	RE: Semaglutide - Compounding [SEC=OFFICIAL] - Email 05-01-2024 12:56:08 (0) s22	05/01/2024 at 12:56 PM
D24-598012	Re: URGENT MEDIA FOR CLEARANCE: Due 3pm TODAY (13/2) - Medical Republic - compounding of semaglutide [SEC=OFFICIAL]	13/02/2024 at 3:06 PM
D24-668281	FW_ Compounding of Semaglutide _SEC_OFFICIAL_.msg	20/02/2024 at 6:41 AM
D24-809374	AC000000025096 Request for Labs analysis - s22 Warrant semaglutide AOD9604 BPC157. docx(7) - Project 2835	01/03/2024 at 8:36 AM
D24-841646	Corro re semaglutide compounding - Email 04-03-2024 09:47:29 (2) s22	04/03/2024 at 10:47 AM
E24-103832	THERAPEUTIC GOODS REGULATION - Liaison - FOI 5017 - Semaglutide Compounding	13/03/2024 at 1:19 PM
D24-1328165	IMG_3522 CMI-Semaglutide/L Carnitine produced by s22 connecting compounding pharmacies and facilities	27/03/2024 at 11:55 AM
D24-1328215	IMG_3558 Dispensary label Semaglutide 2.64mg/ml, L-carnitine 100mg/ml, B12 0.5mg/ml Solution for SC injection 3 s22	27/03/2024 at 12:44 PM
D24-1328210	IMG_3555 Dispensary Label for Semaglutide 2.64mg/ml,L-carnitine 100mg/ml B12 0.5mg/ml solution for SC inejection 3 dispensed to s22 batch OZ784FE. s22 s22 . s22	27/03/2024 at 12:53 PM
D24-1283730	20230404 - Compounding and dispensing of Ozempic (semaglutide)	08/04/2024 at 2:59 PM
D24-1438938	Internal email - New case AC-000000027275 entered for s22 - Semaglutide - 16/04/2024	16/04/2024 at 12:39 PM
D24-1975205	20230404 - Compounding and dispensing of Ozempic (semaglutide).pdf	21/05/2024 at 7:29 AM
D24-1975213	FW_ Compounding of Semaglutide _SEC_OFFICIAL_.msg	21/05/2024 at 7:29 AM
D24-1975342	FW_ Compounding of Semaglutide _SEC_OFFICIAL_.msg	21/05/2024 at 7:36 AM
D24-1975353	FW_ Compounding of Semaglutide _SEC_OFFICIAL_.msg	21/05/2024 at 7:37 AM
D24-1975367	20230404 - Compounding and dispensing of Ozempic (semaglutide).pdf	21/05/2024 at 7:38 AM
D24-1975427	FW_ Compounding of Semaglutide _SEC_OFFICIAL_.msg	21/05/2024 at 7:42 AM
D24-1975442	20230404 - Compounding and dispensing of Ozempic (semaglutide).pdf	21/05/2024 at 7:43 AM
D24-1975447	FW_ Compounding of Semaglutide _SEC_OFFICIAL_.msg	21/05/2024 at 7:43 AM
D24-1975468	20230404 - Compounding and dispensing of Ozempic (semaglutide).pdf	21/05/2024 at 7:45 AM
D24-1975473	FW_ Compounding of Semaglutide _SEC_OFFICIAL_.msg	21/05/2024 at 7:45 AM
E24-208428	THERAPEUTIC GOODS REGULATION - Investigations - Advertising - AC-000000025438 - NOV23 s22 - Semaglutide compounding-Advertising - 05/04/2023	21/05/2024 at 3:55 PM
E24-208427	THERAPEUTIC GOODS REGULATION - Investigations - Advertising - AC-000000025438 - NOV23 s22 - Semaglutide compounding-Advertising - 05/04/2023	21/05/2024 at 3:55 PM
D24-1985120	Email from s22 to s22 re Semaglutide Injection - 2023-5-29..pdf	22/05/2024 at 1:13 AM
E24-210054	THERAPEUTIC GOODS REGULATION - Investigations - Advertising - AC-000000015996 - MAY23 - s22 - Advertising - Semaglutide Products - 30/05/2023	22/05/2024 at 10:37 AM
D24-2312421	CLEARED MEDIA - 10 News - Compounding Semaglutide [SEC=OFFICIAL]	22/05/2024 at 1:52 PM
E24-230214	THERAPEUTIC GOODS REGULATION - Investigations - Advertising - AC-000000028099 - MAY24 s22 - SMS /Email requests for Orders-Semaglutide - 28/05/2024	03/06/2024 at 1:58 PM
E24-232107	THERAPEUTIC GOODS REGULATION - Investigations - Advertising - AC-000000028141 - MAY24 s22 - SMS /Email requests for Orders-Semaglutide - 29/05/2024	03/06/2024 at 8:38 PM
E24-232106	THERAPEUTIC GOODS REGULATION - Investigations - Advertising - AC-000000028141 - MAY24 s22 - SMS /Email requests for Orders-Semaglutide - 29/05/2024	03/06/2024 at 8:38 PM
E24-283510	THERAPEUTIC GOODS REGULATION - Investigations - s22 - Supply of compounded semaglutide	02/07/2024 at 10:31 AM
E24-324128	THERAPEUTIC GOODS REGULATION - Investigations - Advertising - AC-000000024940 - OCT23 - s22 - Advertising - Semaglutide - 08/10/2023	24/07/2024 at 4:55 PM
E24-360389	THERAPEUTIC GOODS REGULATION - Investigations - Advertising - AC-000000024837 - OCT23 - s22 - Semaglutide - 08/10/2023	15/08/2024 at 10:44 AM
E24-360388	THERAPEUTIC GOODS REGULATION - Investigations - Advertising - AC-000000024837 - OCT23 - s22 - Semaglutide - 08/10/2023	15/08/2024 at 10:44 AM

E24-360401	THERAPEUTIC GOODS REGULATION - Investigations - Advertising - AC-000000024842 - OCT23 - s22 [redacted] - Advertising - Semaglutide Products - 10/10/2023	15/08/2024 at 10:46 AM
E24-360501	THERAPEUTIC GOODS REGULATION - Investigations - Advertising - AC-000000025053 - OCT23 - s22 [redacted] - Ozempic - Semaglutide - 24/10/2023	15/08/2024 at 11:04 AM
E24-360500	THERAPEUTIC GOODS REGULATION - Investigations - Advertising - AC-000000025053 - OCT23 - s22 [redacted] - Ozempic - Semaglutide - 24/10/2023	15/08/2024 at 11:04 AM
E24-360550	THERAPEUTIC GOODS REGULATION - Investigations - Advertising - AC-000000025152 - NOV23 s22 [redacted] - Semaglutide for Weight loss- Advertising - 30/10/2023	15/08/2024 at 11:15 AM
D24-3663174	Internal corro - information from industry contact - updated Compounding Guidelines and request for clarity on Item 6 Schedule 5 to the Reg - medicinal cannabis and semaglutide - Email 21-08-2024 07:31:06 (1) s22 [redacted]	21/08/2024 at 7:31 AM
D24-3712207	RE: Testing of Semaglutide Samples for Compounding Investigation Section [SEC=OFFICIAL] - Email 27-08-2024 16:42:30 (0) s22 [redacted]	27/08/2024 at 4:42 PM
D24-3711799	RE: Testing of Semaglutide Samples for Compounding Investigation Section [SEC=OFFICIAL] - Email 27-08-2024 17:57:15 (0) s22 [redacted]	27/08/2024 at 5:57 PM
D24-3746335	RE: Testing of Semaglutide Samples for Compounding Investigation Section [SEC=OFFICIAL] - Email 29-08-2024 17:32:10 (0) s22 [redacted]	29/08/2024 at 5:32 PM
D24-3746327	RE: Testing of Semaglutide Samples for Compounding Investigation Section [SEC=OFFICIAL] - Email 29-08-2024 17:56:17 (0) s22 [redacted]	29/08/2024 at 5:56 PM
D24-3806902	20230404 - Compounding and dispensing of Ozempic (semaglutide).pdf	03/09/2024 at 11:19 AM
D24-3806904	s22 [redacted] - Semaglutide-order form.pdf	03/09/2024 at 11:20 AM
D24-3806907	FW_ Compounding of Semaglutide _SEC_OFFICIAL_.msg	03/09/2024 at 11:20 AM
D24-3807139	FW_ Compounding of Semaglutide _SEC_OFFICIAL_.msg	03/09/2024 at 12:14 PM
D24-3807141	20230404 - Compounding and dispensing of Ozempic (semaglutide).pdf	03/09/2024 at 12:14 PM
D24-3807142	FW_ Compounding of Semaglutide _SEC_OFFICIAL_.msg	03/09/2024 at 12:14 PM
E24-393004	THERAPEUTIC GOODS REGULATION - Investigations - Advertising - AC-000000025437 - NOV23 s22 [redacted] - Semaglutide compounding - Advertising - 05/11/2023	03/09/2024 at 4:32 PM
E24-393082	THERAPEUTIC GOODS REGULATION - Investigations - Advertising - AC-000000025406 - NOV23 s22 [redacted] -(Ozempic) Semaglutide - Other Injectables- Advertising - 19/11/2023	03/09/2024 at 4:44 PM
E24-393097	THERAPEUTIC GOODS REGULATION - Investigations - Advertising - AC-000000025394 - NOV23 s22 [redacted] - Semaglutide - Other Injectables- Advertising - 21/11/2023	03/09/2024 at 4:47 PM
E24-393121	THERAPEUTIC GOODS REGULATION - Investigations - Advertising - AC-000000025467 - NOV23 - s22 [redacted] - Semaglutide Compounding - Advertising - 23/11/2023	03/09/2024 at 4:50 PM
E24-393315	THERAPEUTIC GOODS REGULATION - Investigations - Advertising - AC-000000025543 - DEC23 - s22 [redacted] - Semaglutide solution & Ultra Lipotropic Injection - 30/11/2023	03/09/2024 at 4:55 PM
E24-393313	THERAPEUTIC GOODS REGULATION - Investigations - Advertising - AC-000000025543 - DEC23 - s22 [redacted] - Semaglutide solution & Ultra Lipotropic Injection - 30/11/2023	03/09/2024 at 4:55 PM
E24-443735	THERAPEUTIC GOODS REGULATION - Investigations - Advertising - AC-000000026403 - DEC23 - s22 [redacted] - Compounded Semaglutide - 28/12/2023	01/10/2024 at 3:46 PM
E24-443766	THERAPEUTIC GOODS REGULATION - Investigations - Advertising - AC-000000025890 - JAN24 s22 [redacted] - Semaglutide Products- Advertising - 04/01/2024	01/10/2024 at 3:51 PM
E24-443765	THERAPEUTIC GOODS REGULATION - Investigations - Advertising - AC-000000025890 - JAN24 s22 [redacted] - Semaglutide Products- Advertising - 04/01/2024	01/10/2024 at 3:51 PM
E24-444190	THERAPEUTIC GOODS REGULATION - Investigations - Advertising - AC-000000026025 - JAN24 s22 [redacted] - Semaglutide - 18/01/2024	01/10/2024 at 4:05 PM
E24-444189	THERAPEUTIC GOODS REGULATION - Investigations - Advertising - AC-000000026025 - JAN24 s22 [redacted] - Semaglutide - 18/01/2024	01/10/2024 at 4:05 PM
E24-444211	THERAPEUTIC GOODS REGULATION - Investigations - Advertising - AC-000000026059 - JAN24 - s22 [redacted] - Semaglutide - 23/01/2024	01/10/2024 at 4:09 PM

Liraglutide

No documents found

Dulaglutide

No documents found

Tirzepatide

Record Number	Title	Date Created
D24-1291008	Email from s22 [redacted] to s22 [redacted] re Tirzepatide order - prescription attached	09/04/2024 at 4:41 AM

D24-1290946 Correspondence between [redacted] and [redacted] - Tirzepatide refund or replacement 09/04/2024 at 4:43 AM

Exenatide

No documents found

Semaglutide

Record Number	Title	Date Created
D23-5246775	PB CM - Reg. Compliance query with AEMDS response RE: Compounded Semaglutide/Cyanocobalamin. [SEC=OFFICIAL] - Email 27-03-2023 13:53:30 (0) ADR Reports	27/03/2023 at 1:53 PM
D23-3725362	FW: RE: Compounded Semaglutide CCEMS:06230004187 [SEC=OFFICIAL] - Email 10-10-2023 09:58:01 (0) TGA Info	10/10/2023 at 9:58 AM
D23-3725377	FW: RE: Compounded Semaglutide CCEMS:06230004187 [SEC=OFFICIAL] - Email 10-10-2023 10:08:29 (0) ECT	10/10/2023 at 10:08 AM
E23-317964	INFORMATION MANAGEMENT - Enquiries - Advertising - AC-000000024844 - Guidance on advertising compounded Semaglutide - 09/10/2023	13/10/2023 at 2:02 PM
D23-4415758	Email - From reporter to the TGA - s22 compounded semaglutide advertising to pharmacies - AC-000000025000 - 17/10/2023	17/10/2023 at 3:37 PM
D23-4407555	Internal email - Query re compounded semaglutide - manufacturing concerns - 4/12/2023	04/12/2023 at 5:14 PM
D25-312287	RE: compounded semaglutide [SEC=OFFICIAL] - Email 15-12-2023 10:29:34 (0) HENDERSON, Nick	15/12/2023 at 10:29 AM
D23-4572811	Semaglutide compounded product tradename - Email 15-12-2023 11:41:18 (0) s22	15/12/2023 at 11:41 AM
D23-4573538	Semaglutide compounded product tradename - Email 15-12-2023 11:53:10 (0) s22	15/12/2023 at 11:53 AM
D25-312274	TGA to release statement on compounded semaglutide [SEC=OFFICIAL] - Email 15-12-2023 15:03:13 (1) HENDERSON, Nick	15/12/2023 at 3:03 PM
D25-312271	RE: TGA to release statement on compounded semaglutide [SEC=OFFICIAL] - Email 15-12-2023 15:53:16 (0) s22	15/12/2023 at 3:53 PM
D25-312260	RE: TGA to release statement on compounded semaglutide [SEC=OFFICIAL] - Email 15-12-2023 16:00:18 (0) LAWLER, Tony	15/12/2023 at 4:00 PM
D23-4668892	Compounded semaglutide - Letter to jurisdictions - December 2023	21/12/2023 at 9:38 AM
D23-4668975	RE: Compounded semaglutide - letter to jurisdictions [SEC=OFFICIAL] - Email 21-12-2023 09:51:00 (0) s22	21/12/2023 at 9:51 AM
D23-4670004	ACTION - ADVICE and/ or REVIEW/ SIGNATURE - FW: Compounded semaglutide - letter to jurisdictions [SEC=OFFICIAL] - Email 21-12-2023 10:14:15 (0) s22	21/12/2023 at 10:14 AM
D25-312257	ACTION - ADVICE and/ or REVIEW/ SIGNATURE - FW: Compounded semaglutide - letter to jurisdictions [SEC=OFFICIAL] - Email 21-12-2023 10:14:17 (0) s22	21/12/2023 at 10:14 AM
D25-312253	RE: ACTION - ADVICE and/ or REVIEW/ SIGNATURE - FW: Compounded semaglutide - letter to jurisdictions [SEC=OFFICIAL] - Email 21-12-2023 12:21:12 (0) LAWLER, Tony	21/12/2023 at 12:21 PM
D23-4676269	Ltr to Medical Board of Australia re compounded semaglutide - 21 Dec 2023	21/12/2023 at 1:09 PM
D23-4676284	Ltr to Pharmacy Board of Australia re compounded semaglutide - 21 Dec 2023	21/12/2023 at 1:11 PM
D23-4676306	Ltr to ahpra re compounded semaglutide - 21 Dec 2023	21/12/2023 at 1:11 PM
D23-4676319	Ltr to s22 , WA re compounded semaglutide - L21 Dec 2023	21/12/2023 at 1:12 PM
D23-4676328	Ltr to s22 , Vic re compounded semaglutide - 21 Dec 2023	21/12/2023 at 1:13 PM
D23-4676340	Ltr to s22 , ACT re compounded semaglutide - 21 Dec 2023	21/12/2023 at 1:14 PM
D23-4676360	Ltr to s22 , Tas re compounded semaglutide - 21 Dec 2023	21/12/2023 at 1:15 PM
D23-4676385	Ltr to s22 , NSW re compounded semaglutide - 21 Dec 2023	21/12/2023 at 1:16 PM
D23-4676391	Ltr to s22 , NT re compounded semaglutide - 21 Dec 2023	21/12/2023 at 1:16 PM
D23-4676401	Ltr to s22 , Qld re compounded semaglutide - 21 Dec 2023	21/12/2023 at 1:17 PM
D23-4676409	Ltr to s22 , SA re compounded semaglutide - 21 Dec 2023	21/12/2023 at 1:18 PM
D23-4690509	Eml to s22 , Medical Board of Australia - Letter from the Chief Medical Adviser re compounded semaglutide [SEC=OFFICIAL] - Email 21-12-2023 13:50:06 (1) s22	21/12/2023 at 1:50 PM
D23-4690442	Eml to s22 , NSW - Letter from the Chief Medical Adviser re compounded semaglutide [SEC=OFFICIAL] - Email 21-12-2023 13:50:27 (1) s22	21/12/2023 at 1:50 PM
D23-4690413	Eml to s22 , Pharmacy Board of Australia - Letter from the Chief Medical Adviser re compounded semaglutide [SEC=OFFICIAL] - Email 21-12-2023 13:50:50 (1) s22	21/12/2023 at 1:50 PM
D23-4690385	Eml to s22 , ahpra - Letter from the Chief Medical Adviser re compounded semaglutide [SEC=OFFICIAL] - Email 21-12-2023 13:51:15 (1) s22	21/12/2023 at 1:51 PM
D23-4690357	Eml to s22 , WA - Letter from the Chief Medical Adviser re compounded semaglutide [SEC=OFFICIAL] - Email 21-12-2023 13:51:38 (1) s22	21/12/2023 at 1:51 PM
D23-4690321	Eml to s22 , Vic- Letter from the Chief Medical Adviser re compounded semaglutide [SEC=OFFICIAL] - Email 21-12-2023 13:52:09 (1) s22	21/12/2023 at 1:52 PM
D23-4690292	Eml to s22 , ACT - Letter from the Chief Medical Adviser re compounded semaglutide [SEC=OFFICIAL] - Email 21-12-2023 13:52:37 (1) s22	21/12/2023 at 1:52 PM
D23-4690263	Eml to s22 , Tas - Letter from the Chief Medical Adviser re compounded semaglutide [SEC=OFFICIAL] - Email 21-12-2023 13:52:58 (1) s22	21/12/2023 at 1:52 PM
D23-4690245	Eml to s22 , NT - Letter from the Chief Medical Adviser re compounded semaglutide [SEC=OFFICIAL] - Email 21-12-2023 13:53:24 (1) s22	21/12/2023 at 1:53 PM
D23-4690223	Eml to s22 , Qld - Letter from the Chief Medical Adviser re compounded semaglutide [SEC=OFFICIAL] - Email 21-12-2023 13:54:13 (1) s22	21/12/2023 at 1:54 PM
D23-4690142	Eml to s22 , SA - Letter from the Chief Medical Adviser re compounded semaglutide [SEC=OFFICIAL] - Email 21-12-2023 13:54:38 (1) s22	21/12/2023 at 1:54 PM
D23-4691280	FOI 4885 - For electronic signature - Notice of Decision - s22 - Compounded semaglutide - Email 22-12-2023 10:39:54 (0) TGA FOI	22/12/2023 at 10:39 AM
D23-4695105	RE: FOI 4885 - For electronic signature - Notice of Decision - s22 - Compounded semaglutide [SEC=OFFICIAL] - Email 22-12-2023 12:45:03 (0) KAY, Elspeth	22/12/2023 at 12:45 PM
D24-68600	RE: MEDIA FOR CLEARANCE: Due 4pm TODAY (5/1) - SMH/Age - Compounded Semaglutide [SEC=OFFICIAL]	05/01/2024 at 2:53 PM
D24-301802	Internal email - RCB - Update: s22 compounded semaglutide - 23/01/2024	23/01/2024 at 1:56 PM

D24-601033	RE: Compounded semaglutide testing (RC-027515) [SEC=OFFICIAL] - Email 24-01-2024 09:43:25 (0) s22	24/01/2024 at 9:43 AM
D24-393816	Laboratories Branch - Request for analysis form - RC-027515 s22 Compounded semaglutide - Project 2827	31/01/2024 at 4:16 PM
D24-519686	Summary report - Project 2827 - RC-027515 - LIMS 2402000424 2402000425 2402000428 - s22	09/02/2024 at 11:05 AM
D24-598490	RE: MEDIA FOR CLEARANCE: Due 12pm THURSDAY (15/2) - Aus Doc - Compounded semaglutide [SEC=OFFICIAL]	15/02/2024 at 9:50 AM
D24-680728	RE: MEDIA FOR CLEARANCE - COB Today 19/02 TGA: compounded semaglutide [SEC=OFFICIAL]	20/02/2024 at 10:37 AM
D24-963310	CLEARED RESPONSE - TGA: compounded semaglutide [SEC=OFFICIAL]	20/02/2024 at 10:45 AM
D24-898100	RE: Query re: Contact from WA GP re Compounded semaglutide [SEC=OFFICIAL] - Email 06-03-2024 17:27:57 (0) s22	06/03/2024 at 5:27 PM
FOI5018-2324	INFORMATION MANAGEMENT - Cases - FOI 5018 - Minister for Health & Aged Care Mark Butler - s22) - Health MO correspondence with s22 regarding compounded semaglutide	08/03/2024 at 12:26 PM
E24-98146	INFORMATION MANAGEMENT - Cases - FOI 5018 - Email correspondence - Minister for Health & Aged Care Mark Butler - s22 - Health MO correspondence with s22 regarding compounded semaglutide	08/03/2024 at 12:26 PM
D24-922305	FOI 5018 - New FOI received from s22 - Health Minister correspondence with s22 regarding compounded semaglutide - Email 08-03-2024 13:38:58 (0) TGA FOI	08/03/2024 at 1:38 PM
D24-922363	RE: FOI 5018 - New FOI received from s22) - Health Minister correspondence with s22 regarding compounded semaglutide [SEC=OFFICIAL] - Email 08-03-2024 13:53:15 (0) Minister Butler DLO	08/03/2024 at 1:53 PM
E24-98415	INFORMATION MANAGEMENT - Cases - FOI 5018 - Master documents - Minister for Health & Aged Care Mark Butler - s22 - Health MO correspondence with s22 regarding compounded semaglutide	08/03/2024 at 2:38 PM
D24-923625	FOI 5018 - Search and Retrieval - s22 - Health Minister correspondence with s22 regarding compounded semaglutide - (Minister Butler s Office) - Due COB Thursday 14 March 2024 - Email 08-03-2024 15:39:37 (2) TGA FOI	08/03/2024 at 3:39 PM
D24-923969	FOI Request Received - FOI 5018 - s22 - TGA - Health Minister correspondence with s22 regarding compounded semaglutide - Email 08-03-2024 15:50:55 (0) TGA FOI	08/03/2024 at 3:50 PM
D24-947324	FOI 5017 - New FOI received from s22 - TGA correspondence between s22 regarding compounded semaglutide [SEC=OFFICIAL] - Email 12-03-2024 13:19:01 (0) TGA FOI	12/03/2024 at 1:19 PM
D24-947319	RE: FOI 5017 - New FOI received from s22 - TGA correspondence between s22 regarding compounded semaglutide [SEC=OFFICIAL] - Email 12-03-2024 13:32:58 (0) s22	12/03/2024 at 1:32 PM
E24-101097	INFORMATION MANAGEMENT - Cases - FOI 5017 - Email correspondence - s22 - TGA correspondence between s22 regarding compounded semaglutide	12/03/2024 at 2:32 PM
FOI5017-2324	INFORMATION MANAGEMENT - Cases - FOI 5017 - s22 - TGA correspondence between s22 regarding compounded semaglutide	12/03/2024 at 2:33 PM
E24-101114	INFORMATION MANAGEMENT - Cases - FOI 5017 - Master documents - s22 - TGA correspondence between s22 regarding compounded semaglutide	12/03/2024 at 2:38 PM
D24-947315	FOI 5017 - New FOI received from s22 - TGA correspondence between s22 regarding compounded semaglutide [SEC=OFFICIAL] - Email 12-03-2024 15:21:02 (0) TGA FOI	12/03/2024 at 3:21 PM
D24-947312	RE: FOI 5017 - New FOI received from s22 - TGA correspondence between s22 regarding compounded semaglutide [SEC=OFFICIAL] - Email 12-03-2024 15:22:25 (0) s22	12/03/2024 at 3:22 PM
D24-947309	FOI 5017 - New FOI received from s22 - TGA correspondence between s22 regarding compounded semaglutide [SEC=OFFICIAL] - Email 12-03-2024 15:35:24 (0) TGA FOI	12/03/2024 at 3:35 PM
D24-947379	RE: FOI 5017 - New FOI received from s22 - TGA correspondence between s22 regarding compounded semaglutide [SEC=OFFICIAL] - Email 12-03-2024 15:37:59 (0) s22	12/03/2024 at 3:37 PM
D24-1419569	FOI 5017 - Search and Retrieval - s22 - TGA correspondence between s22 regarding compounded semaglutide - (HPRG Exec, MRD Exec) - Due COB Friday 15 March 2024 [SEC=OFFICIAL] - Email 12-03-2024 16:51:11 (2) TGA FOI	12/03/2024 at 4:51 PM
D24-1419555	FOI 5017 - Search and Retrieval - s22 - TGA correspondence between s22 regarding compounded semaglutide - (PB, PMAB, REB) - Due COB Friday 15 March 2024 [SEC=OFFICIAL] - Email 12-03-2024 16:56:22 (2) TGA FOI	12/03/2024 at 4:56 PM
D24-1065217	FOI 5017 - Search and Retrieval - s22 - TGA correspondence between s22 regarding compounded semaglutide - (PB, PMAB, REB) - Due COB Friday 15 March 2024 [SEC=OFFICIAL]	12/03/2024 at 4:56 PM
D24-1065205	FOI 5017 - Search and Retrieval - s22 - TGA correspondence between s22 regarding compounded semaglutide - (PB, PMAB, REB) - Due COB Friday 15 March 2024 [SEC=OFFICIAL]	12/03/2024 at 4:56 PM
D24-1419536	FOI Request Received - FOI 5017 - s22 - TGA correspondence between s22 regarding compounded Semaglutide [SEC=OFFICIAL] - Email 12-03-2024 17:02:55 (0) TGA FOI	12/03/2024 at 5:02 PM

	RE: FOI 5017 - Search and Retrieval - s22 - TGA correspondence between s22 regarding compounded semaglutide - (HPRG Exec, MRD Exec) - Due COB Friday 15 March 2024	
D24-964468	[SEC=OFFICIAL] - Email 12-03-2024 17:08:01 (0) s22	12/03/2024 at 5:08 PM
	RE: FOI 5017 - Search and Retrieval - s22 - TGA correspondence between s22 regarding compounded semaglutide - (HPRG Exec, MRD Exec) - Due COB Friday 15 March 2024	
D24-2194984	[SEC=OFFICIAL]	12/03/2024 at 5:14 PM
	RE: FOI 5017 - Search and Retrieval - s22 - TGA correspondence between s22 regarding compounded semaglutide - (HPRG Exec, MRD Exec) - Due COB Friday 15 March 2024	
D24-964478	[SEC=OFFICIAL] - Email 12-03-2024 17:14:41 (3) s22	12/03/2024 at 5:14 PM
	RE: FOI 5017 - Search and Retrieval - s22 - TGA correspondence between s22 regarding compounded semaglutide - (PB, PMAB, REB) - Due COB Friday 15 March 2024	
D24-1065197	[SEC=OFFICIAL]	12/03/2024 at 10:09 PM
	RE: FOI 5017 - Search and Retrieval - s22 - TGA correspondence between s22 regarding compounded semaglutide - (PB, PMAB, REB) - Due COB Friday 15 March 2024	
D24-957134	[SEC=OFFICIAL] - Email 12-03-2024 22:09:05 (0) s22	12/03/2024 at 10:09 PM
	Re: FW: FOI 5017 - Search and Retrieval - s22 - TGA correspondence between s22 regarding compounded semaglutide - (PB, PMAB, REB) - Due COB Friday 15 March 2024	
D24-1065185	[SEC=OFFICIAL]	13/03/2024 at 8:49 AM
	FW: FOI 5017 - Search and Retrieval - s22 - TGA correspondence between s22 regarding compounded semaglutide - (HPRG Exec, MRD Exec) - Due COB Friday 15 March 2024	
D24-964456	[SEC=OFFIC - Email 13-03-2024 09:08:59 (0) s22	13/03/2024 at 9:08 AM
D24-1002770	s22 response- RE: Submission re: Compounded semaglutide - for your consideration [SEC=OFFICIAL]	13/03/2024 at 9:44 AM
D24-1065173	Request for input - FOI 5017 - Search and Retrieval - s22 - TGA correspondence between s22 regarding compounded semaglutide - (PB, PMAB, REB) [SEC=OFFICIAL]	13/03/2024 at 10:17 AM
D24-1065164	RE: Request for input - FOI 5017 - Search and Retrieval - s22 - TGA correspondence between s22 regarding compounded semaglutide - (PB, PMAB, REB) [SEC=OFFICIAL]	13/03/2024 at 10:49 AM
D24-1065112	FW: Request for input - FOI 5017 - Search and Retrieval - s22 - TGA correspondence between s22 regarding compounded semaglutide - (PB, PMAB, REB) [SEC=OFFICIAL]	13/03/2024 at 11:14 AM
D24-960987	FW: Request for input - FOI 5017 - Search and Retrieval - s22 - TGA correspondence between s22 regarding compounded semaglutide - (PB, PMAB, REB) [SEC=OFFICIAL] - Email 13-03-2024 11:14:54 (2) s22	13/03/2024 at 11:14 AM
	RE: Stream 5 - Request for input - FOI 5017 - Search and Retrieval - s22 - TGA correspondence between s22 regarding compounded semaglutide - (PB, PMAB, REB)	
D24-1065104	[SEC=OFFICIAL]	13/03/2024 at 11:19 AM
	FOI 5017 - Search and Retrieval - s22 - TGA correspondence between s22 regarding compounded semaglutide - (HPRG Exec, MRD Exec) - Due COB Friday 15 March 2024	
D24-964450	[SEC=OFFICIAL] - Email 13-03-2024 11:58:07 (1) s22	13/03/2024 at 11:58 AM
	FOI 5017 - Search and Retrieval - s22 - TGA correspondence between s22 regarding compounded semaglutide - (PB, PMAB, REB) - Due COB Friday 15 March 2024	
D24-973782	[SEC=OFFICIAL] - Email 13-03-2024 12:08:15 (2) s22	13/03/2024 at 12:08 PM
	[nil CM input] - Request for input - FOI 5017 - Search and Retrieval - s22 - TGA correspondence between s22 regarding compounded semaglutide - (PB, PMAB, REB) - Email 13-	
D24-961004	03-2024 12:09:51 (2) s22	13/03/2024 at 12:09 PM
D24-1065094	FW: Request for input - FOI 5017 - Search and Retrieval - s22 - TGA correspondence between s22 regarding compounded semaglutide - (PB, PMAB, REB) [SEC=OFFICIAL]	13/03/2024 at 12:09 PM
	FOI 5017 - Search and Retrieval - s22 - TGA correspondence between s22 regarding compounded semaglutide - (PB, PMAB, REB) - Due COB Thursday 14 March 2024	
D24-962738	[SEC=OFFICIAL] - Email 13-03-2024 13:12:14 (1) TGA FOI	13/03/2024 at 1:12 PM
	RE: FOI 5017 - Search and Retrieval - s22 - TGA correspondence between s22 regarding compounded semaglutide - (PB, PMAB, REB) - Due COB Thursday 14 March 2024	
D24-964130	[SEC=OFFICIAL] - Email 13-03-2024 13:16:00 (1) s22	13/03/2024 at 1:16 PM
D24-968022	Enquiry - Using compounded Semaglutide in a clinical trial - s22 - CTN approval - 13/03/2024 - Email 13-03-2024 16:05:58 (0) Clinical Trials	13/03/2024 at 4:05 PM
	Re: FOI 5017 - Search and Retrieval - s22 - TGA correspondence between s22 regarding compounded semaglutide - (HPRG Exec, MRD Exec) - Due COB Friday 15 March 2024	
D24-975910	[SEC=OFFICIAL] - Email 13-03-2024 17:20:04 (0) TGA FOI	13/03/2024 at 5:20 PM
D24-977050	Attachment from s22 - Compounded Semaglutide Advertisment Document	14/03/2024 at 10:35 AM
	RE: FOI 5017 - Search and Retrieval - s22 - TGA correspondence between s22 regarding compounded semaglutide - (PB, PMAB, REB) - Due COB Friday 15 March 2024	
D24-988298	[SEC=OFFICIAL] - Email 14-03-2024 15:36:40 (0) s22	14/03/2024 at 3:36 PM
	FOI 5017 - Search and Retrieval - s22 - TGA correspondence between s22 regarding compounded Semaglutide - Due COB Tuesday 19 March 2024 - Email 14-03-2024	
D24-989080	16:04:17 (0) TGA FOI	14/03/2024 at 4:04 PM
	RE: FOI 5017 - Search and Retrieval - s22 - TGA correspondence between s22 regarding compounded semaglutide - (HPRG Exec, MRD Exec) - Due COB Friday 15 March 2024	
D24-1002087	[SEC=OFFIC - Email 15-03-2024 09:24:21 (0) s22	15/03/2024 at 9:24 AM

D24-998890	To EK: FOI 5017 - Search and Retrieval - s22 - TGA correspondence between s22 regarding compounded semaglutide - (PB, PMAB, REB) - Due COB Friday 15 March 2024 [SEC=OFFICIAL]	15/03/2024 at 10:28 AM
D24-998937	FOI 5018 - Search and Retrieval - s22 - Health Minister correspondence with s22 regarding compounded semaglutide - (Minister Butler s Office) - Due COB Thursday 14 March 2024 - Email 15-03-2024 10:32:06 (0) TGA FOI	15/03/2024 at 10:32 AM
D24-1002177	FW: FOI 5017 - Search and Retrieval - s22 - TGA correspondence between s22 regarding compounded semaglutide - (PB, PMAB, REB) - Due COB Friday 15 March 2024 [SEC=OFFICIAL] - Email 15-03-2024 10:37:13 (0) KAY, Elspeth	15/03/2024 at 10:37 AM
D24-1034211	RE: FOI 5017 - Search and Retrieval - s22 - TGA correspondence between s22 regarding compounded Semaglutide - Due COB Tuesday 19 March 2024 [SEC=OFFICIAL] - Email 18-03-2024 13:51:38 (0) Systems Interrogations	18/03/2024 at 1:51 PM
D24-1065087	FOLLOW-UP: FOI 5017 - Search and Retrieval - s22 - TGA correspondence between s22 regarding compounded semaglutide - (PB, PMAB, REB) - Due COB Friday 15 March 2024 [SEC=OFFICIAL]	18/03/2024 at 3:49 PM
D24-1034677	FOLLOW-UP: FOI 5017 - Search and Retrieval - s22 - TGA correspondence between s22 regarding compounded semaglutide - (PB, PMAB, REB) - Due COB Friday 15 March 2024 [SEC=OFFICIAL] - Email 18-03-2024 15:49:37 (0) TGA FOI	18/03/2024 at 3:49 PM
D24-1065078	FOLLOW-UP: FOI 5017 - Search and Retrieval - s22 - TGA correspondence between s22 regarding compounded semaglutide - (PB, PMAB, REB) - Due COB Friday 15 March 2024 [SEC=OFFICIAL]	18/03/2024 at 5:32 PM
D24-1065071	RE: FOLLOW-UP: FOI 5017 - Search and Retrieval - s22 - TGA correspondence between s22 regarding compounded semaglutide - (PB, PMAB, REB) - Due COB Friday 15 March 2024 [SEC=OFFICIAL]	18/03/2024 at 6:04 PM
D24-1065061	RE: FOLLOW-UP: FOI 5017 - Search and Retrieval - s22 - TGA correspondence between s22 regarding compounded semaglutide - (PB, PMAB, REB) - Due COB Friday 15 March 2024 [SEC=OFFICIAL]	19/03/2024 at 8:32 AM
D24-3020756	RE: FOI 5018 - Search and Retrieval - s22 - Health Minister correspondence with s22 regarding compounded semaglutide - (Minister Butler s Office) - Due COB Thursday - Email 19-03-2024 09:19:15 (2) Minister Butler DLO	19/03/2024 at 9:19 AM
D24-1419454	RE: FOI 5018 - Search and Retrieval - s22 - Health Minister correspondence with s22 regarding compounded semaglutide - (Minister Butler s Office) - Due COB Thursday - Email 19-03-2024 09:19:15 (2) Minister Butler DLO	19/03/2024 at 9:19 AM
D24-1043404	RE: FOI 5018 - Search and Retrieval - s22 - Health Minister correspondence with s22 regarding compounded semaglutide - (Minister Butler s Office) - Due COB Thursday - Email 19-03-2024 09:19:15 (2) Minister Butler DLO	19/03/2024 at 9:19 AM
D24-1065053	RE: FOLLOW-UP: FOI 5017 - Search and Retrieval - s22 - TGA correspondence between s22 regarding compounded semaglutide - (PB, PMAB, REB) - Due COB Friday 15 March 2024 [SEC=OFFICIAL]	19/03/2024 at 9:54 AM
D24-1065045	Re: FW: FOLLOW-UP: FOI 5017 - Search and Retrieval - s22 - TGA correspondence between s22 regarding compounded semaglutide - (PB, PMAB, REB) - Due COB Friday 15 March 2024 [SEC=OFFICIAL]	19/03/2024 at 1:01 PM
D24-1084671	PMAB FOI to TGA FOI - nil input - RE: FOLLOW-UP: FOI 5017 - Search and Retrieval - s22 - TGA correspondence between s22 regarding compounded semaglutide - (PB, PMAB, REB) - Due COB Friday 15 March 2024 [SEC=OFFICIAL]	19/03/2024 at 1:03 PM
D24-1053782	RE: FOLLOW-UP: FOI 5017 - Search and Retrieval - s22 - TGA correspondence between s22 regarding compounded semaglutide - (PB, PMAB, REB) - Due COB Friday 15 March 2024 [SEC=OF - Email 19-03-2024 13:03:21 (0) s22	19/03/2024 at 1:03 PM
D24-1064815	TGA FOI to PMAB FOI - FOI 5017 - Search and Retrieval - s22 - TGA correspondence between s22 regarding compounded semaglutide - Due COB today 20 March 2024 [SEC=OFFICIAL]	20/03/2024 at 10:01 AM
D24-1063452	FOI 5017 - Search and Retrieval - s22 - TGA correspondence between s22 regarding compounded semaglutide - Due COB today 20 March 2024 [SEC=OFFICIAL] - Email 20-03-2024 10:01:16 (1) TGA FOI	20/03/2024 at 10:01 AM
E24-113895	THERAPEUTIC GOODS REGULATION - Advice - FOI 5017 - s22 - TGA correspondence between s22 regarding compounded semaglutide	20/03/2024 at 10:38 AM
D24-1087109	AAM time input - RE: FOI 5017 - Search and Retrieval - s22 - TGA correspondence between s22 regarding compounded semaglutide - Due COB today 20 March 2024 [SEC=OFFICIAL]	20/03/2024 at 10:58 AM
D24-1087127	PMAB Exec time input - RE: FOI 5017 - Search and Retrieval - s22 - TGA correspondence between s22 regarding compounded semaglutide - Due COB today 20 March 2024 [SEC=OFFICIAL]	20/03/2024 at 11:24 AM
D24-1067004	Advice on sensitivities and third parties: FOI 5018 - Search and Retrieval - s22 - Health Minister correspondence with s22 regarding compounded semaglutide - (Minister Butler s - Email 20-03-2024 11:36:45 (3) TGA FOI	20/03/2024 at 11:36 AM
D24-1087098	CESA time input - RE: FOI 5017 - Search and Retrieval - s22 - TGA correspondence between s22 regarding compounded semaglutide - Due COB today 20 March 2024 [SEC=OFFICIAL]	21/03/2024 at 11:32 AM
D24-1086451	FOLLOW-UP: FOI 5017 - Search and Retrieval - s22 - TGA correspondence between s22 regarding compounded semaglutide - Due COB today 20 March 2024 [SEC=OFFICIAL] - Email 21-03-2024 11:58:50 (1) TGA FOI	21/03/2024 at 11:58 AM

D24-1089262	RE: FOLLOW-UP: FOI 5017 - Search and Retrieval - s22 - TGA correspondence between s22 regarding compounded semaglutide - Due COB today 20 March 2024 [SEC=OFFICIAL] - Email 21-03-2024 12:09:19 (0) s22	21/03/2024 at 12:09 PM
D24-1102558	FW: Request for signature: FOI 5017 - Search and Retrieval - s22 - TGA correspondence between s22 regarding compounded semaglutide - Due COB today 20 March 2024 [SEC=OFFICIAL] - Email 21-03-2024 17:22:37 (1) s22	21/03/2024 at 5:22 PM
D24-1153191	RE: Request for signature: FOI 5017 - Search and Retrieval - s22 - TGA correspondence between s22 regarding compounded semaglutide - Due COB today 20 March 2024 [SEC=OFFICIAL]	22/03/2024 at 11:28 AM
D24-1102552	RE: Request for signature: FOI 5017 - Search and Retrieval - s22 - TGA correspondence between s22 regarding compounded semaglutide - Due COB today 20 March 2024 [SEC=OFFICIAL] - Email 22-03-2024 11:28:48 (0) TGA FOI	22/03/2024 at 11:28 AM
D24-1419441	RE: Advice on sensitivities and third parties: FOI 5018 - Search and Retrieval - s22 - Health Minister correspondence with s22 regarding compounded semaglutide - (Mi - Email 25-03-2024 14:10:40 (0) Minister Butler DLO	25/03/2024 at 2:10 PM
D24-1419416	Advice on imposing charges: FOI 5018 - s22 - Health Minister correspondence with s22 regarding compounded semaglutide - (Minister Butler s Office) - Due Wednesday 3 April 2024 - Email 28-03-2024 14:12:13 (1) TGA FOI	28/03/2024 at 2:12 PM
D24-3020855	Request for advice: FOI 5017 - New FOI received from s22 - TGA correspondence between s22 regarding compounded Semaglutide - Thursday 4 April 2024 [SEC=OFFICIAL] - Email 02-04-2024 16:25:27 (3) TGA FOI	02/04/2024 at 4:25 PM
D24-1419483	Request for advice: FOI 5017 - New FOI received from s22 - TGA correspondence between s22 regarding compounded Semaglutide - Thursday 4 April 2024 [SEC=OFFICIAL] - Email 02-04-2024 16:25:27 (3) TGA FOI	02/04/2024 at 4:25 PM
D24-1220657	RE: Request for advice: FOI 5017 - New FOI received from s22 - TGA correspondence between s22 regarding compounded Semaglutide - Thursday 4 April 2024 [SEC=OFFICIAL] - Email 02-04-2024 17:51:23 (0) LUTTON, Tracey	02/04/2024 at 5:51 PM
D24-1306597	FW: Request for advice: FOI 5017 - New FOI received from s22 - TGA correspondence between s22 regarding compounded Semaglutide - Thursday 4 April 2024 [SEC=OFFICIAL]	03/04/2024 at 9:16 AM
D24-3020885	FOI 5017 - Search and Retrieval - s22 - TGA correspondence between s22 regarding compounded semaglutide - (RCB) - Due COB Monday 8 April 2024 [SEC=OFFICIAL] - Email 03-04-2024 14:08:57 (3) TGA FOI	03/04/2024 at 2:08 PM
D24-1220676	FOI 5017 - Search and Retrieval - s22 - TGA correspondence between s22 regarding compounded semaglutide - (RCB) - Due COB Monday 8 April 2024 [SEC=OFFICIAL] - Email 03-04-2024 14:08:57 (3) TGA FOI	03/04/2024 at 2:08 PM
D24-1232329	Follow-up: Advice on imposing charges: FOI 5018 - s22 - Health Minister correspondence with s22 regarding compounded semaglutide - (Minister Butler s Office) - Due Wednesday 3 A - Email 04-04-2024 11:44:55 (0) TGA FOI	04/04/2024 at 11:44 AM
D24-1248297	RE: Follow-up: Advice on imposing charges: FOI 5018 - s22 - Health Minister correspondence with s22 regarding compounded semaglutide - (Minister Butler s Office) - D - Email 04-04-2024 11:56:57 (0) Minister Butler DLO	04/04/2024 at 11:56 AM
D24-1244370	Social for Media release – Search warrant executed on Sydney residence in relation to substandard compounded semaglutide	05/04/2024 at 7:52 AM
D24-1340441	Compounded semaglutide matter (RC-029947) [SEC=OFFICIAL]	05/04/2024 at 11:42 AM
D24-1340422	RE: Relevant complaint - purchase of compounded semaglutide (RC-026121) [SEC=OFFICIAL]	05/04/2024 at 1:11 PM
D24-1284947	RE: FOI 5017 - Search and Retrieval - s22 - TGA correspondence between s22 regarding compounded semaglutide - (RCB) - Due COB Monday 8 April 2024 [SEC=OFFICIAL] - Email 08-04-2024 14:14:51 (0) s22	08/04/2024 at 2:14 PM
D24-1284942	RE: FOI 5017 - Search and Retrieval - s22 - TGA correspondence between s22 regarding compounded semaglutide - (RCB) - Due COB Monday 8 April 2024 [SEC=OFFICIAL] - Email 08-04-2024 15:33:35 (0) TGA FOI	08/04/2024 at 3:33 PM
D24-1285244	RE: FOI 5017 - Search and Retrieval - s22 - TGA correspondence between s22 regarding compounded semaglutide - (RCB) - Due COB Monday 8 April 2024 [SEC=OFFICIAL] - Email 08-04-2024 15:36:09 (0) s22	08/04/2024 at 3:36 PM
D24-1307603	Letter received 6April2023 from s22 re advertising and supply of compounded semaglutide [SEC=OFFICIAL]	09/04/2024 at 5:31 PM
D24-3020919	RE: FOI 5017 - Search and Retrieval - s22 - TGA correspondence between s22 regarding compounded semaglutide - (RCB) - Due COB Tuesday 9 April 2024 [SEC=OFFICIAL] - Email 09-04-2024 17:40:38 (6) s22	09/04/2024 at 5:40 PM
D24-1325273	RE: FOI 5017 - Search and Retrieval - s22 - TGA correspondence between s22 regarding compounded semaglutide - (RCB) - Due COB Tuesday 9 April 2024 [SEC=OFFICIAL] - Email 09-04-2024 17:40:38 (6) s22	09/04/2024 at 5:40 PM
D24-1344196	RE: FOI 5017 - Search and Retrieval - s22 - TGA correspondence between s22 regarding compounded semaglutide - (RCB) - Due COB Tuesday 9 April 2024 [SEC=OFFICIAL] - Email 10-04-2024 16:29:51 (6) s22	10/04/2024 at 4:29 PM
D24-1340657	Request for advice on sensitivities: FOI 5017 - New FOI received from s22 - TGA correspondence between s22 regarding compounded Semaglutide - Monday 15 April 2024 - Email 11-04-2024 14:31:43 (5) TGA FOI	11/04/2024 at 2:31 PM
D24-1407153	FW: Request for advice on sensitivities: FOI 5017 - New FOI received from s22 - TGA correspondence between s22 regarding compounded Semaglutide - Monday 15 April 2024 [SEC=OFFICIAL - Email 15-04-2024 17:07:09 (5) s22	15/04/2024 at 5:07 PM

D24-1388962	Forwarded to DBT - s22 - compounded semaglutide [SEC=OFFICIAL] CCEMS:01820003444 - Email 16-04-2024 08:33:29 (0) ADR Reports	16/04/2024 at 8:33 AM
D24-1407139	FOI 5017 - Estimate of Charges and approach to third party consultation - s22 - TGA correspondence between s22 regarding compounded Semaglutide - Due Wednesday 17 April 2024 - Email 16-04-2024 14:27:43 (0) TGA FOI	16/04/2024 at 2:27 PM
D24-1406382	FOI 5017 - Estimate of Charges and approach to third party consultation - s22 - TGA correspondence between s22 regarding compounded Semaglutide - Due Wednesday 17 April 2024 - Email 16-04-2024 14:27:43 (0) TGA FOI	16/04/2024 at 2:27 PM
D24-1406394	Automatic reply: FOI 5017 - Estimate of Charges and approach to third party consultation - s22 - TGA correspondence between s22 regarding compounded Semaglutide - Due Wednes - Email 16-04-2024 14:27:46 (0) s22	16/04/2024 at 2:27 PM
D24-1424946	Semaglutide compounded - AU-TGA-0000807225 - unapproved medicine (questionable supply pathway) - for info only	17/04/2024 at 10:31 AM
D24-1427041	RE: FOI 5017 - Estimate of Charges and approach to third party consultation - s22 - TGA correspondence between s22 regarding compounded Semaglutide - Due Wednesday 17 April - Email 17-04-2024 12:09:52 (0) s22	17/04/2024 at 12:09 PM
D24-1728914	FOI 5017 - Deputy Secretary Briefing - s22 - Correspondence between TGA and s22 regarding compounded semaglutide [SEC=OFFICIAL] - Email 17-04-2024 16:57:02 (2) TGA FOI	17/04/2024 at 4:57 PM
D24-1446234	RE: FOI 5017 - Estimate of Charges and approach to third party consultation - s22 - TGA correspondence between s22 regarding compounded Semaglutide - Due Wednesday 17 April 2024 [SEC=OFF - Email 18-04-2024 11:22:47 (0) TGA FOI	18/04/2024 at 11:22 AM
D24-1604608	RE: FOI 5017 - Estimate of Charges and approach to third party consultation - s22 - TGA correspondence between s22 regarding compounded Semaglutide - Due Wednesday 17 April - Email 18-04-2024 12:31:39 (0) s22	18/04/2024 at 12:31 PM
D24-1456128	RE: FOI 5017 - Estimate of Charges and approach to third party consultation - s22 - TGA correspondence between s22 regarding compounded Semaglutide - Due Wednesday 17 April - Email 18-04-2024 12:31:39 (0) s22	18/04/2024 at 12:31 PM
D24-1470602	RE: FOI 5017 - Deputy Secretary Briefing - s22 - Correspondence between TGA and s22 regarding compounded semaglutide [SEC=OFFICIAL] - Email 19-04-2024 13:00:38 (0) LAWLER, Tony	19/04/2024 at 1:00 PM
D24-1531471	CLL for Compounded Semaglutide for the period of 16 to 23 April 2024	24/04/2024 at 8:02 AM
D24-1729971	FOI 5018 - Deputy Secretary Briefing - s22 - Health MO correspondence with s22 regarding compounded semaglutide - Email 07-05-2024 11:37:19 (2) TGA FOI	07/05/2024 at 11:37 AM
D24-1729979	RE: FOI 5018 - Deputy Secretary Briefing - s22 - Health MO correspondence with s22 regarding compounded semaglutide [SEC=UNOFFICIAL] - Email 07-05-2024 11:39:35 (0) LAWLER, Tony	07/05/2024 at 11:39 AM
D24-1742677	Notification of withdrawal: FOI 5017 - s22 - TGA correspondence between s22 regarding compounded Semaglutide - Email 07-05-2024 17:09:42 (1) TGA FOI	07/05/2024 at 5:09 PM
D24-2002420	FAS Brief (FEB) - Compliance - compounded replicas of semaglutide	22/05/2024 at 9:14 AM
D24-2011517	Email to AS for CLEARANCE: Budget Estimates (FAS) brief - Compliance - compounded replica Semaglutide	23/05/2024 at 1:33 PM
D25-311998	FW: MO update- compounded semaglutide [SEC=OFFICIAL] - Email 29-05-2024 11:47:58 (0) s22	29/05/2024 at 11:47 AM
D24-2131163	Notification of Decision - FOI 5018 - s22 - TGA - Health Minister correspondence with s22 regarding compounded semaglutide - Email 31-05-2024 09:28:31 (1) TGA FOI	31/05/2024 at 9:28 AM
E24-232353	PHARMACEUTICAL BENEFITS & ACCESS - Reviewing - Ozempic (Semaglutide) - claiming for compounded replica versions	04/06/2024 at 8:50 AM

Liraglutide

Record Number	Title	Date Created
D24-1203672	IMG_0085 s22, Liraglutide pen, 5 unlabelled red liquid vials, 1x labelled Compounded Tirzepatide vial for s22	27/03/2024 at 2:34 PM

Dulaglutide

No documents found

Tirzepatide

Record Number	Title	Date Created
D24-1203672	IMG_0085 s22, Liraglutide pen, 5 unlabelled red liquid vials, 1x labelled Compounded Tirzepatide vial for s22	27/03/2024 at 2:34 PM

Exenatide

No documents found