



The Hon Mark Butler MP
Minister for Health and Aged Care

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Ms Susan Templeman MP
Chair
Standing Committee on Petitions
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Dear Chair

Thank you for your correspondence of 12 August 2024 regarding petition number EN6367 relating to the legislative change to remove medicines containing glucagon-like peptide-1 receptor agonists (GLP-1 RAs) from the pharmacist compounding exemption. I understand that the petition requests compounded GLP-1 RA products to be supplied to patients through a special accreditation pathway, facilitated by the Therapeutic Goods Administration (TGA), as part of the Department of Health and Aged Care.

The Australian Government has secured new regulation amendments to remove GLP-1 RAs from the pharmacy compounding exemption from 1 October 2024. The concern regarding the compounding of GLP-1 RAs is that of public safety, primarily due to the potential impact of commercial-scale manufacturing of unregulated products. The practice of large-scale manufacturing is beyond the current exemptions applied to compounded medicines.

Pharmacy compounding is intended only for small quantities, for an individual patient who has a prescription, where a commercially manufactured medicine is either not suitable or not clinically appropriate. Compounded medicines are not listed or registered, and no assessment of quality, stability or efficacy of the final medicinal product is required prior to the supply to the patient. That is, compounded medicines are not regulated in the same way that large-scale manufactured prescription medicines are. The large-scale manufacturing of medicines through compounding means that these products are being provided in large quantities, without the regulation and evaluation that such volumes should undergo. The TGA has a role to evaluate and facilitate access to appropriate treatments. However, when the risks outweigh the benefit of access, it recommends the appropriate regulatory actions to be taken.

The TGA has concerns that the proposed accreditation system outlined in the petition will not address the risks and concerns relating to public safety in the large-scale manufacturing and dispensing of compounded GLP1-RAs. Specifically, the proposed accreditation scheme is not in line with the current legislative exemptions for compounding medicines (i.e. small volumes of drug specifically compounded for an individual patient need) and does not align with the TGA's current Good Manufacturing Practice licensing processes for manufacturers of registered products, including both new medicines and generic branded medicines.

While it is recognised that shortages cause significant anxiety for patients, alternative treatments accessed during these situations must still be safe and of good quality. The TGA is working hard to improve the shortage situation of Ozempic (semaglutide) and Mounjaro (tirzepatide) as quickly and effectively as possible. As part of this, the TGA has been regularly liaising with the sponsors of Ozempic and Mounjaro, Novo Nordisk and Eli Lilly respectively. Recently, the TGA has been advised by Novo Nordisk that new semaglutide product, Wegovy has now become available in the Australian market. While Wegovy and Ozempic contain the same active ingredient, the approved indications (circumstances for use) are different. Further information is available at www.tga.gov.au/safety/shortages/medicine-shortage-alerts/new-semaglutide-product-becomes-available. The TGA will continue to monitor the supply of GLP-1 RAs in coming months and update the advice on their webpages as required.

It is important to note that compounded GLP-1 RA products supplied through compounding pharmacies are not identical to the TGA-approved products Ozempic or Mounjaro. For a medicine, such as Ozempic®, to be registered in the Australian Register of Therapeutic Goods, the sponsor must lodge an application to the TGA supported by the necessary evidence to establish the quality, safety and efficacy of the medicine for the requested use. This information, submitted to the TGA by the sponsor, would typically include data from well-conducted clinical trials in addition to other information such as information on manufacturing processes, toxicology and chemistry data. Once registered, medicines are also subject to rigorous post-market monitoring, including for adverse events experienced by patients. These regulatory controls are crucial to provide the community and health professionals with confidence of the safety of medicines they access or prescribe. This process provides the public with assurances that their medicines meet the expected standards.

The legislative change to commence from 1 October 2024 is intended to provide assurance to the public that there are measures in place to ensure medicines containing GLP-1 RA products prescribed to Australian patients are of appropriate quality, safety and efficacy.

Thank you for writing on this matter.

Yours sincerely 

Mark Butler

 29/09/2024