From:	s22	
То:	Minister Butler	
Cc:	s22	
Subject:	Potential impact of compounded Semaglutide on patient safety	
Date:	Friday, 1 March 2024 2:54:48 PM	
Attachments:	image001.png	
	Letter to Minister Butler.pdf	

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Dear Minister Butler,

Please find attached a copy of our letter regarding the potential impact of compounded Semaglutide on patient safety.

We fully acknowledge and commend the Department of Health and Aging and the Therapeutic Goods Administrator for the work it has undertaken to ensure Australian patients continue to access medicines which are safe.

We welcome the opportunity to discuss the contents of this letter with you.

Kind regards,				
s22				
Oceania (Australia & NZ)				
s22	(direct)			
s22 @novonorc	<u>lisk.com</u>			

Novo Nordisk Pharmaceuticals Pty. Ltd. | Level 10 | 118 Mount Street | North Sydney NSW 2060 | +61 2 8858 3600 (switchboard) | <u>novonordisk.com.au</u> | <u>Facebook</u> | <u>Linkedin</u> | <u>Instagram</u> | <u>X (Twitter</u>) | <u>YouTube</u> | <u>TikTok</u>



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1 March 2024

By Email: <u>Minister.Butler@health.gov.au</u>

The Hon Mark Butler, MP Minister for Health & Aged Care Parliament House CANBERRA ACT 2600

Confidential

Dear Minister Butler

Potential impact of compounded semaglutide on patient safety

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.

Since 2022, Novo Nordisk has experienced intermittent supply shortages of Ozempic[®], and during some of that time, Ozempic[®] was out of stock altogether.

Novo Nordisk continues to receive regular stock delivery of Ozempic[®] in 2024; however, stock remains constrained given significant market demand. We have collaborated with key external stakeholders including TGA, RACGP, AMA, PSA, Diabetes Australia, and others to minimise the impact on Australian patients. A public guidance has also been issued by the TGA on the matter.

I would like to take this opportunity to express our appreciation for the constructive approach the TGA has taken and the work it has done to date. Novo Nordisk looks forward to continuing to work closely with the TGA in 2024.

As a result of the continued rise in demand for Ozempic[®], and ongoing limited supply, the availability of compounded semaglutide has risen in the market. A number of serious patient safety concerns have also increased in connection with the availability of compounded semaglutide. We understand that this significant safety matter is a priority for the TGA.

On 28 February 2024, we received correspondence from the TGA Health Products Regulatory Group advising us of its intention to undertake proposed 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 your and the TGAs attention to this matter and the effort and work it has undertaken to engage with the relevant stakeholders to develop the Proposed Changes.

Novo Nordisk fully supports the Proposed Changes.

For your convenience, we attached a copy of our correspondence regarding Novo Nordisk's position with respect to the Proposed Changes.

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

For your information, I attach correspondence from Novo Nordisk to the Australian Health Practitioner Regulation Agency (AHPRA) and National Boards outlining Novo Nordisk's specific concerns. To date, we have not received a response to our correspondence from AHPRA.

You will see that our specific concerns are related to patient safety. Accordingly, we seek your assistance to ensure there is sufficient resources and knowledge to investigate and address the issues relating to compounding, advertising, and importation of therapeutic goods as they are in direct breach of the *Therapeutic Goods Act 1989* (Cth) and the *Therapeutic Goods Regulations 1990* (Cth), and the many iterations of the *Therapeutic Goods Advertising Code*.

With their primary role being 'to protect the public', we ask that you direct 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 by some of their members.

We have also raised our concerns with the TGA. Attached is the correspondence from Novo Nordisk to the TGA. In late December 2023, representatives from two units; the Advertising and Product Investigations, and Import, Manufacturer, and Supply reached out to Novo Nordisk to discuss the issues relating to compounding, advertising, and importation of therapeutic goods.

We also request you write to State Health and Territory Ministers asking that they do all that is in their power to consider the significant patient safety concerns and to take appropriate action.

We believe the vast majority of community pharmacies support and comply with the AHPRA compounding guidelines. It seems a few opportunistic operators with commercial drivers, with scant regard for patient safety are compounding what they assert is semaglutide under false pretences.

We welcome the TGA's proposals in this space, and we ask for your continued support to see through the TGA's proposed changes. We also ask for your support to ensure AHPRA and its members comply with their own compounding guidelines to protect patient safety.

I appreciate your attention to this matter and look forward to working with you to resolve this matter.



If you require any further information, please contact me on <u>\$22</u> <u>@novonordisk.com</u> or my colleague, <u>\$22</u> on <u>\$22</u> <u>@novonordisk.com</u>.

Yours sincerely







1 March 2024

By Email: S22

<u>@health.gov.au</u>

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;
- 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 <u>\$22 @novonordisk.com</u>.

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

Yours sincerely





16 March 2023

Confidential

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

Dear S22

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:



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 **novo nordisk** 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 <u>\$22 @novonordisk.com</u> or mobile <u>\$22 @novonordisk.com</u> I also welcome the opportunity to discuss our concerns with you.

I look forward to hearing from you.





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.

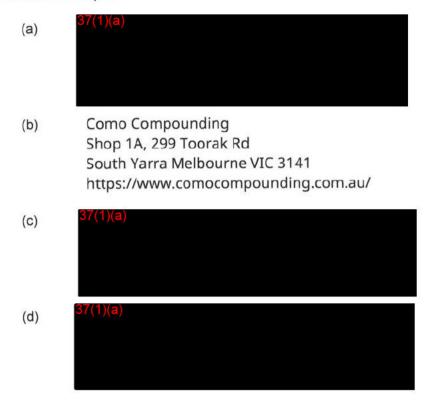
It is unclear to Novo Nordisk what raw materials are being used and how the product is being compounded, having regard to the fact that Novo Nordisk is the patent holder of the active ingredient, Novo Nordisk is not supplying semaglutide to these pharmacies for compounding or re-supply and supply of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



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) Never Give Up Team
 35-39 Bourke Road
 Alexandria NSW 2015
 http://nevergiveupteam.com/blog/ozempic/



- (b) Ozempic Australia 87C Little Malop Street Geelong VIC 3220 http://buyozempiconlineaustralia.com
- Australia Weight Loss
 87C Little Malop Street
 Geelong VIC 3220
 http://australiaweightloss.com/ozempic-online/
- (d) Ozempic 87C Little Malop Street Geelong VIC 3220 http://ozempicaustralia.org

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) Ozempic Australia claims "you can Ozempic Semaglutide for Weight Loss in Australia without prescription."

https://buyozempiconlineaustralia.com/

 (b) Australia Weight loss 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."

https://australiaweightloss.com/ozempic-online/

 Ozempic claims "you can buy Ozempic online for weight loss at Ozempicaustralia.org and have your order delivered to you. Delivery time 8 to 10 days"

https://ozempicaustralia.org/

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 @novonordisk.com or mobile \$22 II also welcome the opportunity to discuss our concerns with you.





21 November 2023

By email: Nicole.McLay@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)	37(1)(a)
(b)	Cambooya Community Discount Pharmacy 53 Eton St Cambooya QLD 4358
(c)	37(1)(a)

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, Total Compounding Pharmaceuticals which advertises 'Semaglutide for Weight Loss' at <u>https://www.totalcompoundingpharmaceuticals.com/semaglutide1</u>. 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** <u>@novonordisk.com</u> or mobile **s22**. I also welcome the opportunity to discuss our concerns with you.

I look forward to hearing from you.

Yours sincerely

s22		
s22		

Novo Nordisk Pharmaceuticals Pty Ltd