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23 September 2024

To: Lars Fruergaard Jørgensen, President and Chief Executive Officer (CEO), Novo Nordisk Mads Krogsgaard Thomsen, CEO, Novo Nordisk Foundation

Cc: Madisyn Lu, Global Access Lead Nicolai Haugaard, Vice President and Global Head of Access to Care Carissa Vados, Head of Diabetes Health Equity Manisha Sekharan, Associate Global Project Director Niels Lund, Vice President, Climate Change & Health

Re: Access to diabetes medicines for people living with diabetes in humanitarian and resource-poor settings

Dear Dr Thomsen and Mr Jørgensen,

I write to you on behalf of Medecins Sans Frontieres (MSF) to highlight the harmful consequences of Novo Nordisk's current approach to the supply and pricing of its diabetes medicines, and to urge action for greater access to these medicines for people with diabetes in our care and beyond.

MSF is an international, independent, medical humanitarian organisation that works in humanitarian crises and with neglected and excluded populations. As part of this work, we strive to provide quality and evidence-based diabetes care in our programmes and advocate for better access to medical tools for people with diabetes in low- and middle-income countries (LMICs). Over the last few years, we have witnessed the lack of access to insulin pens and newer diabetes medicines due to high prices and supply constraints.

## Barriers to improving the availability of insulin pens in resource-poor settings

Through our experience of implementing diabetes programmes, and <u>as highlighted in a survey conducted by MSF and T1International</u>, it is evident that insulin in pen devices is preferred by people over insulin injected from vials. Due to accuracy and ease of dosing and reduced stigma, pens have improved the quality of life for people with diabetes and are now included in the World Health Organization (WHO) Model List of Essential Medicines. While pens and analogue insulins are the norm for diabetes care in high-income settings, they are not as widely available in LMICs and humanitarian settings due mainly to the business decisions of insulin manufacturers like Novo Nordisk. Indeed, we were informed by your Global Equity team this month that Novo Nordisk will stop production of human insulin pens (among other products) in favour of continuing the production of human insulin in vials.

South Africa recently predicted a nationwide stockout of insulin pens due to Novo Nordisk's decision to deprioritise the manufacturing and supply of human insulin pens, which impacted supply under the tender to the country's Department of Health.

All of this reinforces the double standard that has long existed against people living with diabetes in South Africa and

other LMICs. This is further highlighted in the approach to regional manufacturing that Novo Nordisk has implemented for African countries. Novo Nordisk's contract manufacturing deal with Aspen in South Africa has been lauded as one that will provide insulin for the African continent, but it currently only includes human insulin in vials, not the preferred pens.

On pricing, MSF recently analysed the market prices and estimated cost-based sustainable prices—at which a product could be profitably sold—of selected diabetes medicines and devices and <u>published these findings in the Journal of the American Medical Association in March 2024</u>. The analysis covered insulins in all presentations (vials, cartridges and pre-filled pens), including those from Novo Nordisk. It estimated that human insulin in pre-filled pens could be sold profitably at US\$0.94/pen, rapid-acting aspart pre-filled pen at \$1.4/pen and degludec at \$1.47/pen compared to the much higher current market price range of \$1.99-\$90.69, \$5.10-\$53.64 and \$11.27-\$97.65 respectively.

The high prices for human insulin in pre-filled pens, rapid-acting aspart and degludec pose a significant barrier to scaling up their availability in health systems in resource-poor settings. Under our current procurement agreement with your corporation, we buy human insulin pre-filled pens and aspart pre-filled pens for \$3/pen and \$6/pen respectively. The analysis shows significant room for price reductions for major procurers like governments, as well as for MSF.

## Barriers to accessing GLP-1 receptor agonists for people living with diabetes in low- and middle-income settings

GLP-1 RAs, currently available as once-weekly injections, have been shown to provide significant cardiovascular benefits to people living with diabetes and could delay or spare the need for daily insulin injections. They can thus improve and simplify diabetes treatment in low-resource, rural and humanitarian settings.

GLP-1 RAs are now included in treatment algorithms for type 2 diabetes in all high-income countries, and in 2023, MSF reviewed our own treatment guidelines to include them. However, there is a supply constraint. In high-income countries, people living with diabetes are struggling to access GLP-1 RAs because much of the supply has been diverted for use in the management of obesity, and in many LMICs the injectable formulation is simply not available. Further, the surge in demand for Wegovy pens is creating a supply constraint for both the semaglutide pen and insulin pens needed by people living with diabetes.

The expiry of Novo Nordisk's primary patent on semaglutide in 2026 and the subsequent introduction of generics could ease the supply constraint, provided your corporation agrees not to assert its secondary patents. Non-assert declarations have been crucial to the scale up of supply of new TB drugs at affordable prices. A key example of this is the step taken by the pharmaceutical corporation Johnson & Johnson (J&J). In September 2023, after the expiry of the basic patent on the DR-TB drug bedaquiline, J&J announced it would not enforce its secondary patents in 134 LMICs, facilitating the entry of more affordable, generic versions of bedaquiline into the LMIC market.

MSF would like to explore procurement of injectable semaglutide but has not been offered a price by Novo Nordisk. The 2023 cost-based sustainable price analysis noted above includes GLP-1 RAs. This analysis estimated that the injectable semaglutide could be sold profitably for \$0.89 per month at WHO-recommended daily doses, compared to the current market price range of \$38.21-\$351.74 per month, which is simply unaffordable for treatment providers and health systems.

To address the above concerns on the double standard of care for people with diabetes and sustainable supply of diabetes medicines, we request Novo Nordisk and Novo Nordisk Foundation, the controlling shareholder in Novo Nordisk, to take the following actions:

## **Insulin pens**

1. Ensure supply of human insulin pens in adequate quantities to South Africa and beyond and if unable to sustainably supply them, offer analogue insulin pens (like Novomix) at \$1 to LMICs to ensure health ministries are able to procure them.

- 2. Address supply constraints and diversify manufacturing. Focus on local or regional manufacturing of human and analogue insulin and transfer capacity to not just manufacture insulin but also pens, including by licensing patents on any devices that can be used by manufacturers to deliver insulin pens, without restriction on supply or pricing.
- 3. Ensure that all available insulins (human and analogue) in all delivery devices (vials, cartridges and pre-filled pens) are offered at a transparent (publicly available) price to LMICs and humanitarian agencies, based on the cost-based price estimates published in the JAMA study. Governments, humanitarian agencies and other procurers can then decide what devices and types of insulin they wish to procure, founded on evidence-based clinical guidance, with consideration to the quality of life of people living with diabetes. Currently, the offer of human insulin in vials for a ceiling price of \$3 per vial appears to be the only option available from Novo Nordisk to LMICs and humanitarian agencies.

## Injectable semaglutide

- 4. Provide a substantially lower price for injectable semaglutide for LMICs and humanitarian agencies like MSF, reflecting their cost of production.
- 5. Refrain from asserting any secondary patents on the medicine or the delivery device to facilitate generic competition and supply for LMICs as soon as the basic patent expires in March 2026.

Diabetes is assuming epidemic proportions in many low- and middle-income settings, and urgent action is needed from corporations that dominate the supply and pricing of medicines for diabetes. We urge Novo Nordisk to step up in its role of ensuring adequate supply and to make a decisive effort to lower the prices and profits of its diabetes medicines.

We thank you for your consideration of our concerns and request a written response and further meetings to address these issues by 10 October 2024.

Sincerely,

Joan Tubau Executive Director

Médecins Sans Frontières Access Campaign