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23 September 2024

To: David Ricks, Chief Executive Officer, Eli Lilly

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

Dear Mr Ricks,

I write to you on behalf of Medecins Sans Frontieres (MSF) to highlight our concerns on the consequences of Eli Lilly'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 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 as highlighted in a survey conducted by MSF and T1International, 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 significantly 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 major insulin manufacturers.

For instance, South Africa recently predicted a nationwide stockout of insulin pens due to the decision of key pharmaceutical corporations who control 90% of the market to deprioritise and not respond to the tender for supply of human insulin pens to the country's Department of Health. This reinforces the double standard that has long existed against people living with diabetes in South Africa and other LMICs. Eli Lilly's agreement with Eva Pharma is yet to address this double standard. In December 2022, Eli Lilly entered into an agreement with EVA Pharma to supply its active pharmaceutical ingredient (API) for insulin at a reduced price and provide a pro bono technology transfer to enable EVA Pharma to formulate, fill and finish human and analogue insulin in vials and cartridges used to refill pens, and to start distributing insulin products within 18 months (by July 2024) in LMICs. However, we are unable to find any publicly available information on the registration, pricing and availability of any of these products.

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. The analysis covered insulins in all presentations (vials, cartridges and pre-filled pens), including those from Eli Lilly. It estimated that human insulin in pre-filled pens could be sold profitably at US$0.94/pen, rapid-acting lispro pre-filled pen at $1.4/pen and glargine at $1.30/pen

compared to the much higher current market price range of $1.99-90.69, $5.34 -$30.54 and $2.98-$28.41 respectively. The high prices set by your and other corporations for human insulin in pre-filled pens, rapid-acting lispro and glargine pose a significant barrier to scaling up their availability in health systems in resource-poor settings.

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 just as they do in high-income settings.

Indeed, GLP-1 RAs are now included in treatment algorithms for type 2 diabetes in all high-income countries. In 2023, MSF reviewed our own treatment guidelines to include GLP-1 RAs. However, there is a significant 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 formulations are simply not available.

There are patent barriers in LMICs to the entry of more affordable generic GLP-1 RAs. Eli Lilly's primary patent on dulaglutide expires in 2024 but there are secondary patents until 2028, including in South Africa. The primary patent on tirzepatide will expire in 2036. The 2023 cost-based sustainable price analysis noted above includes GLP-1 RAs. This analysis estimated that injectable dulaglutide could be sold profitably for $7.05 per month at WHO-recommended daily doses, compared to the current market price range of $22.20-227.25 per month, which is simply unaffordable for treatment providers and health systems.

The introduction of generics could ease the supply constraint and provide a more affordable option, an essential consideration for their inclusion in public health systems in LMICs. Non-assert declarations and voluntary licensing through the Medicines Patent Pool have been crucial to scaling up supply of generic versions of other new medicines under patents.

To address the above concerns on the double standard of care for people with diabetes and a sustainable supply of diabetes medicines, we request Eli Lilly to take the following actions:

Insulin pens

1. Make transparently available the agreement conditions and timelines with EVA Pharma to formulate, fill and finish, and distribute human and analogue insulin in pre-filled pens and cartridges (used to refill pens) in LMICs. Ensure there are no restrictions on supply or pricing and provide support on regulatory filings.
2. If supply from EVA Pharma is delayed, urgently start supplying your own insulin pens in adequate quantities to South Africa's Department of Health and beyond.
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.

Injectable dulaglutide and tirzepatide

4. Provide a price for injectable dulaglutide and tirzepatide for LMICs and humanitarian agencies like MSF reflecting their cost of production.

5. Refrain from asserting patents on the medicines or their delivery devices in LMICs and/or engage with the Medicines Patent Pool for licensing to facilitate generic competition and supply for LMICs.

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 Eli Lilly 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