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The Secretary
WHO Expert Committee on Selection and Use of Essential Medicines
Department of Health Products Policy and Standards
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Written by:
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Re: Updated Support for Application A.18 – Inclusion of Short-Acting Insulin Analogues on the WHO Model List of Essential Medicines

Dear Members of the WHO Expert Committee,

I am writing to reaffirm and strengthen my support for the inclusion of rapid-acting insulin analogues (insulin lispro, insulin aspart, and insulin glulisine) on the WHO Model List of Essential Medicines (EML), in light of recent comments submitted by the WHO Department of Non-communicable Diseases.

As a pediatrician, diabetologist, medical informatician, and a person living with type 1 diabetes, I bring both clinical and lived experience to this conversation. I understand the concerns raised regarding the evidence base and affordability. However, I urge the Committee to consider the broader clinical context, health equity implications, and the transformative potential of EML inclusion.

1. Clinical relevance beyond average HbA1c:

While average differences in HbA1c between analogue and human insulin may be modest, population-level data obscure significant individual benefits. For children, adolescents, people with recurrent hypoglycemia, and during pregnancy, analogue insulins enable safer, more flexible, and more physiologically appropriate treatment. These benefits often translate into increased self-efficacy and quality of life—outcomes that are frequently overlooked and not sufficiently captured in traditional trial endpoints.

2. Hypoglycemia and treatment burden:

The WHO's comments highlight the lack of statistically significant reductions in severe hypoglycemia. Yet even a perceived reduction in risk can meaningfully reduce diabetes distress, fear of hypoglycemia, and improve

mental health. Rigid dosing schedules required by regular human insulin increase treatment burden and limit full participation in school, work, physical activity, and religious fasting. This is particularly relevant for adolescents, women of childbearing age, and both working and underserved populations.

3. Bridging access gaps through policy leverage:

Including rapid-acting analogues in the EML is a strategic lever to influence procurement practices, promote biosimilar market entry, and encourage global price negotiations. The inclusion of long-acting insulin analogues in 2021 was an essential milestone—but without access to matching bolus insulins, people with diabetes cannot fully benefit from modern treatment approaches. The EML is a tool to enable access, not to restrict it.

4. Real-world use in low-resource settings:

Contrary to assumptions, analogue insulins are already in use in some low- and middle-income countries through NGO support, biosimilar manufacturers, and local procurement initiatives. Many countries have made notable progress in sourcing affordable analogues. EML inclusion can accelerate these efforts, guide national formularies, and support equitable pricing.

5. Reducing the digital divide

Rapid-acting insulin analogues are foundational to the safe and effective use of technologies such as insulin pumps, automated insulin delivery systems, and digital decision support tools for insulin injections. These technologies are expanding globally—and analogues are essential to their function. Denying access based on outdated metrics hinders innovation, prevents equitable participation, and perpetuates systemic disparities.

Rapid-acting insulin analogues are not luxury products—they are essential for safe, effective, and equitable diabetes care. As a clinician and as a person living with diabetes, I witness their transformative impact daily. Excluding them from the EML sends a message that safety, flexibility, quality of life, and technology-enabled solutions are privileges reserved for people in high-income settings.

I respectfully urge the Committee to reconsider the evidence in light of clinical realities and health system goals. Including these insulins in the WHO Model List will help advance global health equity, empower local health systems, and save lives.

Sincerely,

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