PROPOSAL FOR THE ADDITION OF VIALS FOR ANALOGUE INSULINS TO THE WHO MODEL LIST OF ESSENTIAL MEDICINES FOR THE TREATMENT OF DIABETES

Applicant:

ACCISS Study (Addressing the Challenge and Constraints of Insulin Sources and Supply)
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Section 1: Summary Statement

It is estimated that more than 420 million people are living with diabetes globally, and that 80% of them live in low- and middle-income countries (LMICs).[1] An estimated 9 million people are living with type 1 diabetes (all need insulin), and 60 million people living with type 2 diabetes use insulin.[2] It is essential that people can access the insulin they need, the delivery device and blood glucose self-monitoring devices.

In 2023, the World Health Organization (WHO) included long-acting analogue insulins to the Model List of Essential Medicines and the Model List of Essential Medicines for Children. The insulins are glargine, detemir and degludec. The presentations for these injectable insulins are listed as 100 IU/mL in 3 mL cartridge or pre-filled pen. This submission proposes the addition of long-acting analogues in 10mL vials.

Human insulins (soluble and intermediate-acting NPH) are listed in the two Model Lists with presentations in 10mL vials and 100 IU/mL in 3 mL cartridges or pre-filled pens. We seek uniformity for all insulins on the two Model Lists in terms of presentation.

Long-acting analogues are manufactured in vials. This proposal allows people living with diabetes, who use long-acting analogues, to have maximum choice of presentation/delivery device.

Glargine in vials has been shown to be lower priced, and hence more affordable for people forced to pay out-of-pocket, than when supplied in prefilled pens.

Ensuring options in presentation/delivery devices is important particularly in these uncertain times with regards to insulin supply. In 2024 there were disruptions in the supply of both prefilled pens and vials in a variety of locations around the world.

Governments have the responsibility of ensuring the availability and affordability of whatever delivery device is needed to inject insulin, including vials containing analogue insulin.

Section 2: Consultation with WHO technical departments

The secretariat of the WHO Expert Committee on Selection and Use of Essential Medicines was informed, in early 2024, of our intention to submit this proposal.

There was no consultation with WHO's NCD department, Access to Medicines and Health Products department or any other department. Nor were we advised to contact any WHO technical department.

Section 3: Other organization(s) consulted and/or supporting the submission

We informally discussed our intention to submit this proposal with several NGOs also working to improve access to insulin. They were supportive.

The submission was drafted entirely by HAI. David Beran, Assistant Professor at the Faculty of Medicine, University of Geneva and Geneva University Hospitals and co-leader of HAI's ACCISS Study, reviewed the proposal. We did not seek support from other organizations for the submission.

Section 4: Key information summary for the proposed medicine(s)

INN	i. Insulin detemir ii. Insulin degludec iii. Insulin glargine		
ATC Code	i. A10AE05 ii. A10AE06 iii. A10AE04		
ICD Classification	5A10 type 1 diabetes mellitus 5A11 type 2 diabetes mellitus		
Indication	Treatment of patients with type 1 or type 2 diabetes mellitus who are at high risk of experiencing hypoglycaemia with human insulin		
Dosage form	Strength	EML	EMLc
Injection	100 IU/mL in 10 mL vial	Yes	Yes

Section 5: Listing as an individual medicine or representative of a pharmacological class/therapeutic group

Medicine(s) are not the subject of this proposal.

Note: If the 25th Expert Committee receives a proposal to add rapid-acting analogue insulins (aspart, lispro, glulisine) to the Model List(s), we propose that the presentations be listed as 100 IU/mL vials, pre-filled pens or cartridges. This provides optimal choice in delivery for people who use these insulins, and would be consistent with human insulins and long-acting analogues.

Section 6: Information supporting the public health relevance

New medicines and/or indications are not the subject of this proposal

Section 7: Treatment details

Dosage regimens, duration of treatment and requirements to ensure appropriate use of the medicine are not the subject of this proposal

Section 8: Review of evidence for benefits and harms

New medicines and/or indications are not the subject of this proposal

Section 9: Summary of recommendations in current clinical guidelines

New medicines and/or indications are not the subject of this proposal

Section 10: Summary of available data on comparative cost and cost-effectiveness

There is limited data on price differences between long-acting analogues in vials, pre-filled pens and cartridges in LMICs, as vials are not commonly found in facilities. However, in private pharmacies in Peru (2022), the median price of 1000IU of Lantus® (glargine) in vials was $US 47.72 whereas in pre-filled pens it was $US 70.39 (an increase of 48%).[3] Similar findings were found in 2023. In Vietnam in 2022, the median price of 1000IU of Lantus in vials was $US 22.30 whereas in pre-filled pens it was nearly double the price at $US 42.51.[4]

Section 11: Regulatory status, market availability and pharmacopoeial standards

New medicines and/or indications are not the subject of this proposal.
Regulatory authorities have granted marketing authorisation to brands of long-acting analogue insulin produced in vials.

Section 12: Reference list

1. Roglic G, Norris S. Medicines for Treatment Intensification in Type 2 Diabetes and Type of Insulin in Type 1 and Type 2 Diabetes in Low-Resource Settings: Synopsis of the World Health Organization Guidelines on Second- and Third-Line Medicines and Type of Insulin for the Control of Blood Glucose Levels in Nonpregnant Adults With Diabetes Mellitus. *Ann Inter Med* 2018 Sep 18;169(6):394-397.
2. Basu S et al. Estimation of global insulin use for type 2 diabetes, 2018–30: a microsimulation analysis. *Lancet Diabetes Endocrinol* 2018; 7**:** 25–33
3. Data from monitoring prices in Peru using ACCISS's MAIn tool
4. Ewen M et al. Availability, prices and affordability of devices for self-monitoring blood glucose levels in low- and middle-income countries (in publication)