THE UNIVERSITY OF SYDNEY

May 21, 2021

The Benedikt Huttner
Secretary
Expert Committee on the Selection and Use of Essential Medicines
Medicines Selection, IP and Affordability (MIA)
Department of Health Products Policy and Standards (HPS)
20 Avenue Appia
CH-1211 Geneva 27

Dear Huttner

RE: Application to add (ultra-) long-acting insulin analogues to the WHO Model List of Essential Medicines

I am writing to express concern about the prospect of adding (ultra-) long-insulin analogues to the WHO Model List of Essential Medicines.

There are several reasons why I believe this proposal should not be supported at this time.

1. Efficacy:
While analogue insulins are promoted as a technological advance in insulins, this has not translated into improved clinical outcomes. While the application suggests an evidence-base in support of analogue insulins, careful analysis of the submission indicates little new data to support the view that these insulins have a demonstrable clinical benefit compared with human NPH insulin, especially for people with type 2 diabetes, who are numerically the predominant users of insulin. While some studies report a small benefit in relation to severe hypoglycaemia, this is not consistent across the various analogue insulins. Furthermore, the relevance to people with type 2 diabetes is questionable given their overall low rates of severe hypoglycaemia.

2. Cost:
Cost is a major concern with analogue insulins as they are more expensive compared with human insulin as has been widely documented. In the context of questionable clinical benefits, cost-effectiveness has not been satisfactorily demonstrated. A costlier insulin will have the most impact in LMICs and will impact pharmaceutical budgets of health systems and personal costs to consumers. The impact on the health budgets of LMICs of purchasing more expensive insulin with questionable clinical benefit will be significant. Although there is the promise of cheaper biosimilar (analogue) insulins, this is not yet a reality and is unlikely to be for the foreseeable future. Even then they are likely to continue to be more expensive than human insulin.

3. Impact on global insulin availability:
This centenary year of the development of therapeutic insulin has highlighted the ongoing challenge of lack of access to affordable insulin in many parts of the world results in preventable death of children and adolescents with type 1 diabetes. Tens of thousands of people with type 1 diabetes who need insulin to survive and more than 30 million people with type 2 diabetes who need require insulin do not have access to a reliable and affordable supply. This is an extraordinary situation considering that the insulin patent from the University of Toronto was sold for $1 on the understanding that cheap insulin would be available for those who needed it.

The addition of analogue insulins to the EML will not improve access to affordable insulin and is like to exacerbate the current situation and increase access inequity.

In summary, the addition of analogue insulin is not support by clinical benefits and it is more costly than available human insulins. While cost may reduce in the future, it would seem premature to approve analogue insulins for the EML at this time.

Yours sincerely

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