



Boston, May 21<sup>st</sup> 2021

**To:** The 23rd WHO Expert Committee on the Selection and Use of Essential Medicines

**Subject:** Support for including novel products for managing type 2 diabetes into the WHO EML

The Clinton Health Access Initiative (CHAI) welcomes the opportunity to provide comments on the application of the inclusion of SGLT2 inhibitors for the 2021 update of the World Health Organization (WHO) Model List of Essential Medicines (EML).

As the prevalence of type 2 diabetes mellitus increases in low- and middle-income countries, a critical question is whether – and how to – enhance access to newer pharmacological therapies. Current WHO guidelines for the pharmacological treatment of diabetes are focused on reducing microvascular complications (nephropathy, retinopathy, and neuropathy) through the use of metformin, sulfonylureas, and subsequently human insulins to lower fasting blood glucose or hemoglobin A1c levels. These recommendations are based on historical evidence that glycemic control is a critical determinant of microvascular outcomes, in particular. The WHO guidelines focus on reducing the risk of macrovascular complications primarily through the use of blood pressure and statin medicines.

Evidence on the benefits of newer pharmacological therapies for diabetes suggests that some may address the risks of both microvascular and macrovascular complications. This evidence and prior work suggest that it is reasonable to consider inclusion of SGLT-2 inhibitors in the WHO EML and country formularies, and that target prices to achieve common thresholds for cost-effectiveness would be achievable with only modest price reductions to products within the SGLT2 inhibitor drug class.

CHAI has worked with innovator and generic companies to develop, commercialize, and introduce quality treatment regimens at the lowest cost of goods sold (COGS) possible for many of the diseases that impact people living in resource limited settings. This is done through licensing and product development agreements as well as volume guarantees and other financial instruments. Such initiatives, in partnership with governments and other global health organizations would be pursued in the field of diabetes to help shape the development and introduction of these new and much needed therapeutics.

In closing, the pairing of new clinical evidence and health economic analysis with the market shaping work performed by groups like CHAI will result in introducing new medicines that provide cost-effective high-quality care for people from resource limited settings that are living with diabetes.

Thank you for your consideration,

Sincerely,

A handwritten signature in black ink that reads "Paul L. Domanico".

Paul L. Domanico, Ph.D.  
Senior Director, Global Health Sciences  
Clinton Health Access Initiative