EML Open Session - CHAI Statement

June 21st, 2-5pm CET / 8-11am EST

We / the Clinton Health Access Initiative would like to share our thoughts on the inclusion of SGLT2 inhibitors and long-acting analog insulins into the WHO EML.

SGLT2 inhibitors

- 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 that have an impact on cardiovascular disease and kidney disease outcomes.
- SGLT2 inhibitors, in addition to being effective blood glucose-lowering drugs, have shown to have a significant impact on reducing the complications of type 2 diabetes mellitus, including cardiovascular disease and chronic kidney disease.
- CHAI agrees with the International Diabetes Federation that the introduction of SGLT2 inhibitors for patients most at risk of developing complications could greatly reduce morbidity and mortality and could generate significant health system savings.
- Early research suggests that target prices to achieve common thresholds for cost-effectiveness could be achievable with modest price reductions to products within the SGLT2 inhibitor drug class.
- CHAI has historically worked with innovator and generic companies to develop, commercialize, and introduce quality treatment regimens at the most sustainable and affordable price 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 working with partners on reducing market risk through volume guarantees and other financial instruments.
- We are keen to work in partnership with industry, governments, and other global health organizations to pursue similar initiatives in the field of diabetes, and help shape the development and introduction of these much-needed therapeutics in low- and middle-income countries.

Long-Acting Analog Insulin

With regard to long-acting analog insulin, we would like to share the following:

- While we acknowledge that the available data points to limited clinical superiority of long-acting analog insulin versus NPH, we also see that the de-facto standard of care in high-income countries are long-acting analogs, particularly for people living with Type 1 diabetes.
- The statements of people living with diabetes on their experiences using long-acting analog insulin, that T1International included in their letter of support, are an important testament and explanation for why these products are considered the standard of care, which underscores the importance of pursuing equity in diabetes care.
- In addition, the evidence highlighting limited clinical benefits of long-acting analog insulin is mostly generated in high- or upper-middle income countries. These settings are very different

from low-resource and humanitarian settings, where we know people living with diabetes frequently struggle to achieve glycemic control, as they may suffer from food insecurity and will often have limited or irregular access to additional diabetes commodities such as self-blood glucose monitoring.

- In these specific circumstances, having access to a regimen that requires fewer doses, offers more dosing flexibility and predictability and potentially improved quality of life and treatment adherence, *may* lead to improved glycemic control.
- Therefore, we would like to underscore the critical importance of generating specific evidence on comparative clinical outcomes between long-acting analog insulin and NPH or regular human insulin, which is lacking to date.
- With the entrance of biosimilar analog insulins, and the willingness of established insulin manufacturers to support efforts to improve access, we believe there is momentum now to explore price reductions for long-acting analog insulins and for other diabetes commodities.
- With the Global Diabetes Compact this year, it is important to seize on this opportunity to collaborate across stakeholders to improve equity in access to diabetes care. We are looking forward to working together in partnership towards that goal.