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Inclusion of human insulin in the scope of products covered by WHO Prequalification Programme

Dear Ms Cooke,

Access to insulin remains a global challenge, despite its being on the market for close to a century and having been part of the WHO Model List of Essential Medicines since 1985.

Although essential to treat diabetes, insulin is reported as generally available in only a minority of low-income countries; in middle-income and high-income countries, affordability remains in question. People with diabetes, including an estimated 1.1 million children with type 1 diabetes, depend on affordable, quality-assured insulin.

It is therefore important that the WHO Prequalification Programme is now announcing a pilot on the prequalification of human insulin. Expanding the WHO Prequalification Programme will play a pivotal role in improving market conditions for human insulin. UNICEF recognises the important contribution the WHO Prequalification Programme has already made to various products and markets, such as direct-acting antivirals, antiretrovirals, antimalarials and antituberculosis medicines, resulting in improved access to several quality-assured essential medicines. The current market situation of human insulin requires urgent action that will alleviate market challenges and facilitate access to affordable treatment for diabetes.

Yours sincerely,

Etleva Kadilli
Director, UNICEF Supply Division