

Statement from the ACCISS Study regarding the WHO announcement of the first-ever insulin prequalification programme

Health Action International (HAI)'s ACCISS Study commends World Health Organization (WHO) on the launch of their insulin prequalification programme. ACCISS has long-advocated for human insulin, which is listed in the WHO Model List of Essential Medicines, be included in WHO's Prequalification of Medicines Programme.

It is essential that insulin products, whether originator brands or biosimilars, are quality-assured. Being a biologic, assessing insulin quality is challenging for regulatory authorities. Currently, no biosimilar human insulin products have marketing authorisation from a stringent Regulatory Authority.

This is why the decision by WHO to include human insulin in their PQ programme is a crucial development. "We fully support today's announcement by WHO that human insulin will be included in their PQ programme" says Dr. Margaret Ewen, Senior Projects Manager, Medicines Prices at HAI and co-lead investigator of the ACCISS Study.

Molly Lepaska (ACCISS Study) added, "People who use insulin must be confident that the products they receive are quality assured. This is an important step for improving access to insulin".

Dr. David Beran, University of Geneva and co-lead investigator of the ACCISS Study expressed his hope that WHO's decision will impact the insulin market, which is currently determined by limited competition: "This initiative should ultimately lead to greater competition and hopefully lower prices, thus improving affordability for people and health systems."

Over the last four years, HAI's ACCISS Study has looked at access to insulin issues from multiple perspectives to gain a comprehensive understanding of the insulin landscape and factors impacting access. Our objective has always been to continue to work toward increased access to affordable, quality-assured insulin for everyone in need.

[Read more the WHO announcement and their prequalification programme](#)