

## **A.20 - Long-acting insulin analogues**

MSF welcomes the ongoing focus on insulin at the WHO Model List of Essential Medicines (EML) Expert Committee. From experience in low resource settings (LRS) and humanitarian emergencies, MSF knows the importance of this focus to raise awareness of the gaps in access to treatment, and to recognize its urgency especially for those living with type 1 diabetes.

MSF would like to acknowledge the crucial importance for the Expert Committee to listen to the voices of people living with diabetes in this discussion of inclusion of long acting insulin analogues on the EML.

MSF agrees with the submission's authors that the evidence of clinical efficacy and safety advantages for analogues over human insulin is not critically significant, while observing the ongoing gap in knowledge in humanitarian emergencies and LRS (which was also acknowledged two years ago). Indeed, the evidence presented mostly emanates from food-secure, high income settings. In much of the relatively resource-rich contexts, analogues have already established themselves as a *de facto* standard of care, in particular for type 1 diabetes. MSF also notes the inclusion of insulin analogues as a recommendation in the 2018 WHO "Guidelines on second-and third-line medicines and type of insulin for the control of blood glucose levels in non-pregnant adults with diabetes mellitus", for use in those people who experience episodes of hypoglycaemia with human insulin (weak recommendation, moderate quality evidence for severe hypoglycaemia).

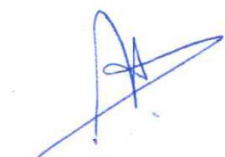
Clinical data notwithstanding, MSF invites the committee to consider the question of analogues in a broader access realm: through the lenses of (a) the potential for significant price decreases from market volumes, pooled procurement opportunities, and the availability of quality assured biosimilars, (b) overcoming regulatory challenges for biosimilars, (c) the research and development pipeline, what opportunities it holds to improve and simplify diabetes treatment, and how any development must be done with access in mind for those most in need, and finally (d) the qualitative advantages of potentially using a once per day (and in the future, even less frequent) analogue regimen versus multiple daily injections which could have significant advantages in LRS and challenging humanitarian settings.

Inclusion of insulin analogues on the EML may facilitate biosimilar insulin development, and work should be done with manufacturers to ensure the appropriate mix of insulins continues to be available. WHO should also provide clear guidance to governments - as outlined in the submission - when considering the use of insulin analogues in national programs (availability of biosimilar products to be included in national tenders, acceptable price differentials between analogues and human insulins, etc)

MSF supports the inclusion on the EML of multiple insulin formulations from vials, cartridges and pens. Based on the cost of production data from 2018<sup>1</sup> – which MSF suggests should be updated to reflect current API and manufacturing costs – the prices of both human and insulin analogues can fall significantly, especially when biosimilar sources are available to increase competition.

While considering the potential addition of analogues, it is equally important to ensure the retention of human insulins on the EML and to better ensure that global supply for all insulins is sufficient to meet the growing needs, through diversifying suppliers and supporting regulatory approval of biosimilar products. Increasing access to insulin requires a multi-factorial approach. To date, having human insulins on the EML has not enabled biosimilar manufacturers to significantly impact insulin availability and price. This status quo needs to change as today, still only half of those who require insulin have secure access to it.

For Médecins Sans Frontières

A handwritten signature in blue ink, appearing to be 'M. Henkens', with a stylized flourish at the end.

Myriam Henkens, MD, MPH  
International Medical Coordinator

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<sup>1</sup> <https://gh.bmj.com/content/bmjgh/3/5/e000850.full.pdf>