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A.18 Rapid-Acting Insulin Analogues

MSF supports the proposal by T1International to include rapid-acting insulin analogues (insulin lispro, insulin aspart, insulin glulisine) in both the WHO Model List of Essential Medicines (EML) and the WHO Model List of Essential Medicines for Children (EMLc), for the treatment of adults and children living with type 1 and type 2 diabetes mellitus and for the treatment of gestational diabetes.

MSF acknowledges the primary role that insulin analogues play in diabetes care for people in high-income countries (HICs), and their growing role for patient care in low- and middle-income countries (LMICs). Even though the evidence from multiple systematic reviews show that rapid-acting insulin analogues provide only modest improvements in hemoglobin A1C (HbA1c) and do not consistently reduce severe hypoglycemic events compared to regular human insulin, inclusion in the EMLs is important given the recent global strain on the supply of human insulin in pen devices.

It is well noted that most of the clinical data for the use of analogues has arisen from HIC settings and may not reflect the realities of all LMIC settings; as such, MSF has previously called for more data, trials and implementation in LMICs. The past debates on the "risks" and benefits of increasing access to analogues have generally been put to rest as more data (1), use, and input from people living with diabetes have arisen. More documentation of their implementation in LMIC settings can only strengthen ongoing advocacy efforts towards equitable access. Inclusion in the EMLs is another step to help facilitate this.

MSF remains alarmed by recent announcements from two of the three dominant insulin manufacturers – Novo Nordisk and Sanofi – regarding discontinuation of human insulin altogether or specifically in pen devices, especially in LMIC markets (2,3). In South Africa, the withdrawal of human insulin pens forced patients to change to vial and syringes for administering their insulin (4). This supply situation - that is likely to increase the double standard between insulin products available to those in need in high- and low-resource settings – underscores the urgent need for WHO and Member States to challenge the increasing industry- and profit- driven decisions that directly affect patient lives. WHO has a role in helping to ensure such decisions do not worsen already significant global inequities in access.

MSF rejects the global double standard that grants HIC patients access to pen devices, while people living with diabetes in LMICs are more often offered insulin in vials through procurement, supply and pricing initiatives. Thus, MSF strongly supports the inclusion of insulin pens for all in the Model EML, to promote equitable access to selected insulin types, knowing that rapid- and long-acting products are needed for most people to achieve their clinical diabetes targets. We wish to highlight that the estimated cost of production for insulin pens is around $1 per pen ($0.94 - $1.40), depending on the insulin, and that pens may even be more cost-effective than vial-and-syringe delivery for basal bolus regimens for people with T1D when the costs of pen needles and insulin syringes are factored in (5).

Rapid-acting insulin analogues remain significantly more expensive than human insulin, despite their estimated cost of production outlined above and availability of (and thus competition from) biosimilars. The reasons behind the price discrepancies remain unclear: the insulin market remains dominated by three companies, and insulin price transparency is still lacking.

MSF has requested WHO to urgently publish updated, simplified, and harmonized guidance on insulin use, delivery formats, and procurement strategies. This guidance is necessary to support countries in selecting preferred insulins and devices based on clinical evidence, affordability, and supply security – factors not currently balanced in the global access to insulin context.

MSF urges the Expert Committee on the Selection and Use of Essential Medicines to include rapid-acting insulin analogues (insulin lispro, insulin aspart, insulin glulisine) in both the WHO Model List of Essential Medicines and the WHO Model List of Essential Medicines for Children and to consider:

- Explicitly supporting the inclusion of rapid-acting analogues in pen devices.
- Emphasizing the need for fair prices, price transparency, and biosimilar competition.
- Urging WHO to update its diabetes treatment and procurement guidance, including advice on delivery devices and reflection of patient preferences, to help Member States navigate insulin selection in a context of insecure supply.

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