Analogue Insulin on WHO Model List of Essential Medicines

Statement | 01 October 2021 | Download PDF

AMSTERDAM— Following the decision by the World Health Organization (WHO) Expert Committee on Selection and Use of Essential Medicines to add long-acting analogue insulin to the <u>Model List of Essential Medicines</u> (EML), the Addressing the Challenge and Constraints of Insulin Sources and Supply (<u>ACCISS) Study</u>, made the following statement:

Available evidence fails to prove that the benefits of analogue insulins justify a six-fold higher price over human insulin. Despite this, the WHO Expert Committee has decided to list long-acting analogue insulins on the EML.

For this decision to make any real impact in improving access to insulin, and to avoid any deleterious effect, such as added pressures on individuals and health systems in lower income settings, urgent action is required. WHO must act to ensure access to quality-assured affordable insulin remains a top priority, and coordinated actions must be taken with governments, insulin manufacturers and civil society. This includes:

- Ensuring human insulins remain on the market as they are more affordable than analogues.
- Addressing current regulatory barriers for biosimilar insulins.
- Including insulin and diabetes-related supplies in Universal Health Coverage.
- Strengthening health systems and policy frameworks to ensure clinical guidelines, health professional education and insulin user training includes information about *all* insulins.
- Development of a comprehensive approach to address high insulin prices. Such approaches should include:
 - A ceiling price for analogue insulin in low- and middle-income countries (LMICs) commensurate with the \$3 ceiling price for human insulin[1], which is reasonable given the similar cost of production of analogues and human insulins.
 - $\circ\,$ Guidance to governments on good procurement practices for insulin.
 - \circ A pooled procurement mechanism.
 - Implementing a global price reporting mechanism for net prices of all insulins (human and analogue) purchased by governments to assist procurers in determining reasonable prices.
 - $\circ\,$ Regular country monitoring of the availability, patient price and affordability of all insulins.
 - $\circ\,$ Support for countries on pricing policies.

It is crucial that the impact of the Committee's decision is monitored and evaluated, especially in lower-income countries, and reported at the next Committee meeting in 2023.

We strongly endorse the establishment of an EML Working Group to support and provide advice on how to make high priced medicines on the EML more affordable and accessible, as recommended in the current report.

[1]

<u>https://www.novonordisk.com/sustainable-business/access-and-affordability/access-to-diabet</u> <u>es-care-position.html</u>

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