

Dear Mr Chairman,

My name is Hans Hogerzeil and I would like to make the following statement on behalf of Health Action International, with regard to the application to include long-acting analogue insulin in the next WHO Model List of Essential Medicines.

I will provide five arguments why the application needs to be rejected.

- 1) **There is no independent evidence that long-acting analogues are more cost-effective than human insulin.** The three cost-effectiveness studies quoted in the application are all from high-income countries and are all funded by the pharmaceutical industry. In 2018 HAI published the findings of a systematic study of 11 cost-effectiveness studies comparing long-acting analogues with human insulin. All studies were conducted in High-Income Countries and all but one were funded by insulin manufacturers. That one independent study, from Canada, found that long-acting analogues were not cost-effective. We conclude that at current prices there are no independent studies from Low-and Middle-Income countries to prove that long-acting analogues are a cost-effective alternative to human insulin.
- 2) **New evidence shows that long-acting analogues are a financial burden for health systems.** HAI conducted 15 price surveys in 13 Low- and Middle-Income countries. The governments in the studies were paying around US\$5 for the three types of human insulin, and US\$ 42-55 for two types of analogues – that is 8-11 times more.
- 3) **New evidence shows that long-acting analogues are a financial burden for individuals.** In the same survey, the median public sector prices for two human insulins were US\$ 9-10, while median prices for glargine and detemir were US\$ 72-81. Private sector prices showed a similar pattern. The price difference between human insulin and long-acting analogues is between 2-4 days and 2 weeks of minimum wage.
- 4) **New evidence proves that the price of biosimilar analogues is hardly any lower than originator products.** In another HAI survey biosimilars in four Low- and Middle-Income countries, France and Italy were only 17-28% cheaper than the originator analogues. In the UK they were of the same price as the originator, but 87% higher at the US Dept of Veterans Affairs.
- 5) **WHO endorsement of long-acting analogues will not lead to reduced insulin prices due to the lack of biosimilars in the market.** The insulin market is very imperfect, with three major companies supplying 96% of all insulin in the world and heavily pushing countries to switch from human insulin to analogues. There are very few biosimilar producers, and major regulatory barriers to biosimilar insulins. The low number of biosimilars in the market does not allow for any meaningful competition.

In summary, listing long-acting analogues as essential would strongly signal to governments to give in to the strong pressure by originator companies, to include them in national lists of essential medicines, and then to purchase or reimburse them at a much higher price than human insulin. Without a significant increase in public funding (which is highly unlikely in resource-constraint settings) this will result in lower insulin availability for other patients in the public sector. Where long-acting analogues have to be paid out-of-pocket, people with low incomes face catastrophic expenditure of two-weeks minimum wage per month of treatment. The ability of countries to provide long-acting analogues at affordable prices is extremely limited because of the lack of competition.

We agree that more competition is needed to reduce the price of insulin; but accepting this application is not the way. Instead, we make the following four recommendations to WHO:

1. Establish an independent working group, including various WHO clusters and key partners including people living with diabetes, to develop a comprehensive approach to improving the affordability of insulin;
2. Address the current regulatory barriers for biosimilar insulins;
3. Include human insulin and its biosimilars in the WHO Prequalification Programme;
4. Undertake a rigorous evaluation on the use of long-acting analogues, and define the price at which analogues would represent value for money when compared to human insulin.