
FACT SHEET **Insulin Market Profile**

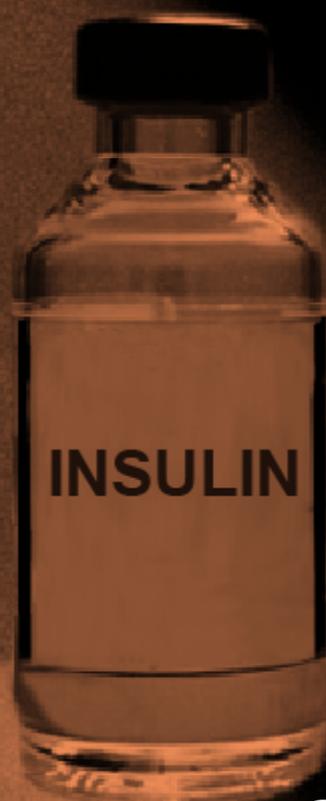
The *Insulin Market Profile*, published in April 2016, contributes to a better understanding of insulin supply and demand, and is based on an extensive review of market intelligence information, including an analysis of national medicines regulatory authority websites and national essential medicines lists, and literature reviews on the latest evidence on the clinical efficacy of human versus analogue insulin and insulin consumption in people living with type 2 diabetes. This fact sheet provides an overview of the key findings of this research and is the result of the mapping work completed in phase one of the Addressing the Challenge and Constraints of Insulin Sources and Supply (ACCISS) Study and

is one of several profiles on the global insulin market to be published.

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All profiles and fact sheets can be accessed on the ACCISS Study section of HAI's website: <http://haiweb.org/what-we-do/acciss/>

Access to Insulin in the Spotlight



Please note, all references in this fact sheet come directly from the *Insulin Market Profile*.

The Global Insulin Market and Manufacturers

- As of 2012, the global insulin market was valued at US\$20.8 billion.
- The big three insulin manufacturers, Novo Nordisk, Sanofi and Eli Lilly, hold 88.7 percent value share of the global insulin market. They are the only insulin manufacturers with products registered and/or sold in 55 percent of the 121 countries reviewed in this profile.
- In many low- and middle-income countries, particularly those in sub-Saharan Africa, insulin is exclusively supplied by one or two of the big three manufacturers. Similarly, they are the sole providers of insulin products in most high-income countries in Western Europe.
- Of the smaller 39 insulin manufacturers identified and thought to be independent, 23 only sell insulin in one country (usually in the country where the manufacturer is located). Only Bioton, Wockhardt, Biocon, and Julphar have products registered and/or sold in 10 or more countries.
- Most insulin manufacturers have headquarters in South East Asia, the Middle East, and high-income countries.
- Although the prevalence of diabetes is increasing globally and access to insulin is a problem, it does not appear that there is a lack of supply. A global surplus of 67.6 million vials was reported in 2014.

Inclusion of Insulin in National Essential Medicine Lists (NEMs)

- Based on an analysis of 100 NEMs from low- and middle-income countries, nearly all countries list both intermediate-acting and short-acting human insulin (as recommended by WHO). Therefore barriers to accessing insulin are not due to exclusion from NEMs.
- Sixteen percent of countries included analogues in their NEMs. Those in the WHO EMRO region have the highest number.

Insulin Product Registration

- Of the 1,988 insulin products registered in 75 middle- and high-income countries, 56 percent were human insulins.
- Of these 1,988 registered insulin products, Novo Nordisk accounted for 36 percent, followed by

- 24 percent for Eli Lilly and 18 percent for Sanofi.
- There were large variations in the number of registered insulin products even for countries in the same income level bracket. For example, South Africa and China had eight and 79 registered insulin products, respectively.
- Europe had the highest number of insulin products registered and the highest ratio of analogue versus human insulin. Africa had the lowest.

Efficacy and Safety of Analogue and Human Insulin

- Analyses in the last five years of studies on the comparative efficacy and safety of analogue versus human insulin showed that although analogue insulin did protect from severe and nocturnal hypoglycaemic events, it was not clinically significant.

Consumption of Insulin in People Living with Type 2 Diabetes

- The rate of insulin consumption for those living with type 2 diabetes is generally between 10 – 25 percent. This includes those using insulin as primary treatment or in combination with oral medication.

There is a general lack of transparency on insulin market data and a need for more public health-focused market research. This was especially the case in market volume information including that of smaller insulin manufacturers, and data in low-income countries. Further, clarity is needed on the 'independent' status of smaller insulin manufacturers.

In terms of insulin product registration, there were large gaps in information particularly in low-income countries. When data on registered insulin products is unavailable, incomplete, or out-of-date, it can result in patient harm.