Global Barriers to Accessing Insulin

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The **Addressing the Challenge and Constraints of Insulin Sources and Supply (ACCISS) Study** commenced in 2015, with the goal of improving the life-expectancy and quality of life for people with diabetes requiring insulin by addressing inequities and inefficiencies in the global insulin market. In 2015/16 the global insulin market was landscaped to identify factors influencing insulin access. Key findings are given below. Reports and factsheets on the findings are available at: <http://haiweb.org/what-we-do/acciss>.

ACCISS Findings

Global Market and Manufacturers

Eli Lilly and Company, Novo Nordisk and Sanofi have 99% value share and 96% volume share of the global market, and 78% of insulin product registration in 55 countries. There are an estimated 10 independent biosimilar insulin manufacturers globally, and only 4 of these have insulin products registered in 10 or more countries.

National Essential Medicines Lists

Of 100 lists from low- and middle-income countries (LMICs), only 2 did not include any insulin

Patents

No patents on any human insulins. Patents on analogues already marketed in the US & Canada have expired or will soon expire. Patents on some delivery devices.

Affordability

Median number of days' wages needed by the lowest paid unskilled govt. worker to buy 10ml 100IU/ml insulin:

	Public Sector	Private Sector
Analogue insulin	7.5 days	9.5 days
Human insulin	2.5 days	3.5 days

Trade

Between 2004 and 2013, Denmark, France and Germany exported 85-96% of global retail insulin by value. 50% of imports were to US, UK, Germany and Japan. Approx. 60 countries imported insulin from only one country.

Barriers to market expansions for biosimilar manufacturers

Investment levels, ownership of full manufacturing process, competing on price, marketing practices of the multinationals, and acceptance of biosimilars (doctors and users)

Biosimilar regulations

Not all countries have regulatory procedures for approving biosimilars. Of those that do, the requirements can be inconsistent. Main issue is satisfying the requirements of similarity to the reference insulin product.

Median prices of insulin (10 ml 100IU/ml)

	Human insulin	Analogue insulin
Government procurement prices (25 countries)	\$US5.99	US\$34.20
Patient prices, public sector (43 countries)	\$US7.64	US\$45.03
Patient prices, private sector (43 countries)	\$US16.65	US\$39.35

Tariffs and taxes

- Majority of countries have no import tariffs on retail insulin.
- The global weighted average import tariffs was 1.9% in 2013
- VAT on insulin 0-24%
- Average VAT 7% in LMICs.

In early 2018, the ACCISS Study will be launching an online toolbox of resources to improve access to insulin. The tools are based on our findings. They address many of the barriers to insulin access, providing practical recommendations for national and international health policy makers, health care funders, and others interested in improving access to insulin as part of universal access to diabetes care and treatment for those in need.