ACCISS Study Report | Access to Insulin: Current Challenges and Constraints

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Executive Summary

The Addressing the Challenge and Constraints of Insulin Sources and Supply (ACCISS) Study has completed its first phase of work, which aimed to gain an overall understanding of the insulin market through different profiles. These included profiles on the insulin market, intellectual property, insulin trade, prices, and taxes and tariffs. The main lessons from this work are presented in this report. The full profiles are referenced and available on the Health Action International website.

From the insulin market profile 40 independent insulin manufacturers were identified in 17 countries, however following additional discussions and reviews it would seem that there are probably only 10 independent insulin manufacturers globally. A total of 55 countries had 1,985 insulin products registered. Of these, 58 percent were human insulin, 38 percent were analogue insulin, three percent were animal insulin, and one percent was unknown. Novo Nordisk had the highest number of registered products (719) followed by Eli Lilly and Company (470) and Sanofi (369). Together, these companies represent 88 percent of total product registrations globally. Only two countries did not list any insulin on their National Essential Medicines List. In looking at insulin use in people with type 2 diabetes, the literature showed a range from 2.4 percent in Taiwan to 23.5 percent in the United States.

Regarding intellectual property, no patents were found for human insulin. For analogue insulins, 61 patents were found in the United States Food and Drug Administration’s Orange Book and eight patents were listed in the Canadian Online Drug Product Database Online Query and its Patent Register. For products already marketed in the United States and Canada, Eli Lilly and Company, Novo Nordisk, and Pfizer will have their patents expire by 2023. Sanofi has an additional 10 years of protection for these products.

The trade profile gives a unique insight into the overall insulin market. In looking at exports between 2003 and 2013, 10 countries made up 98 percent to 99 percent of the global value of retail insulin exports. Over this period, Denmark, France, and Germany collectively exported between 85 percent to 96 percent of global retail insulin by value. Fifty percent of global imports were to the United States, United

Kingdom, Germany, and Japan. Around 60 countries (mostly low- and middle income countries with no local insulin manufacturing) imported insulin from only one country for at least one year, making then vulnerable to disruptions in supply.

Data from different sources were used to develop an overall understanding of the varying price of insulin. Data from Management Sciences for Health for 1996 to 2013 shows that median supplier and buyer prices for human insulin were, on average, US$5.30 and US$4.31, respectively, for 10ml 100IU/ml of human insulin. A difference between the price of insulin versus other non-communicable disease medicines was seen when looking at the overall range of prices for defined daily doses. Insulin had the smallest range over the period of analysis. Over the time period, all antiretrovirals and simvastatin were at one point higher priced than insulin. At the end of the analysis only zidovudine remained higher priced than insulin. Looking at government procurement prices for 10ml 100IU/ml insulin, human insulin was more often procured and were lower priced (median US$5.99) than analogue insulin (US$34.20). Procurement prices varied across countries e.g. regular/isophane (premixed) 30/70 insulin ranged from US$2.24 in Pakistan to US$32.00 in the Kyrgyzstan. Presentation of insulin also had an impact on price. Across the five insulin types with the most price points (aspart, glargine, isophane, regular, and premixed 30/70), vials (US$5.84) were lower priced than cartridges (US$17.93) and pens (US$27.31).

For insulin users, the median price in the public sector was US$7.64 for human insulin and US$45.03 for analogue. A similar picture was seen in the private sector with analogue insulin higher priced (US$39.35) than human insulin (US$16.65). Overall, insulins were unaffordable for those on low incomes. Mean affordability in the public sector was 2.5 days’ wages for human insulin, and 7.5 day’s wages for analogue insulin. In the private sector, it was 3.5 and 9.5 days’ wages for human and analogues insulin, respectively. Reimbursement price for human and analogue insulin was also high at US$19.14 and US$27.90, respectively.

Different mark-ups along the supply chain, including tariffs and taxes, impact the final price of insulin to individuals. The proportion of countries without tariffs on insulin has increased since 2004 from 52 percent to 77 percent. Global weighted average import tariffs have decreased from slightly less than 3.5 percent (2004) to about 1.9 percent (2013). Value added tax on insulin ranged from 0-24 percent.

The profiles and other data within this report provide a unique addition to the information presented previously by the ACCISS Study. Although this data needs to be complemented by on-going work, it already highlights some areas of possible intervention. It also confirms from different data perspectives the dominance of Eli Lilly and Company, Novo Nordisk, and Sanofi with regards to the global insulin market. Although other insulin manufacturers have been identified based on data available, their size and market penetration seems to be low. Another factor that has again been highlighted by this work is the high price of insulin–both for governments when purchasing insulin and for insulin users when forced to pay out-

of-pocket. The price of human insulin based on Management Sciences for Health data has remained stable over time in comparison to other non-communicable disease medicines and those used in the treatment of HIV/AIDS. Insulin affordability is poor in both the public and private sectors in many countries. Unlike for many other medicines, intellectual property is not an issue for insulin itself.

With the completion of this phase of its work, the ACCISS Study has further contributed to a better understanding of the insulin market. And as it progresses into its final year, the information collected to date, as well as additional research, will assist in developing interventions to address the challenge of access to insulin.

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