Supplementary file 1. Summary of national pharmaceutical policy relevant to insulin

Brazil

Under the national pharmaceutical pricing policy the Medicines Market Regulatory Chamber (Câmara de Regulação do Mercado de Medicamentos—CMED) regulates factory prices (Preço Fábrica ou Preço Fabricante—PF); maximum consumer prices (Preço Máximo ao Consumidor—PMC); and public sector prices (Preço Máximo de Venda ao Governo—PMVG). Sanofi and Eli Lilly produce insulin products locally and a public sector factory (Farmanguinhos) is likely to start local biosimilar production in the future. Brazil has a national essential medicines list (Relação Nacional de Medicamentos Essenciais; RENAME) that is used for public procurement and includes regular human insulin and isophane (NPH) insulin. Some analogue insulins may be bought by public authorities due to popular legal action. Public supply of insulin falls under the main primary health component of the public health system with regular and isophane human insulins provided free-of-charge.

China – Hubei Province

About 80% of medicine supply is provided through the public sector. There is a central provincial tendering system with selection of insulin based on quality and price, but this represents a small proportion of total insulin public procurement. Private pharmaceutical agents can sell to public facilities, as well as to private facilities, through regional wholesalers. While there are maximum procurement prices and mark-up regulations in public outlets, there is little price regulation in the private sector since the repeal of pharmaceutical policy regulations in 2015. The Provincial Medicine Tender and Procurement Office (MTPO) maintains a list of medicines for public procurement (and sale) and sets a maximum procurement price based on the lowest procurement price in all provinces in China in the past 3 years. The procurement list gives the types of insulin as well as the manufacturer, thus limiting brand procurement. The maximum public sector mark-up is 15% although a zero mark-ups policy (published in 2012) is being rolled out in which medicines are sold at their procurement price. This policy had not yet been implemented in Wuhan city public hospital at the time of the study. Health insurance has been implemented but the amount patients have to pay for insulin varies depending on the type of insurance and level of facility. China is a manufacturer of biosimilar insulins with registration information at the China Food and Drug Administration (CFDA) indicating the main providers of insulin as Wanbang, Lianbang, Gan & Lee, and Dongbao for locally-produced insulin, and Novo Nordisk, Eli Lilly and Sanofi for imported insulins.

China – Shaanxi Province

The basic information is similar to that for Hubei Province although there will be some differences between how the provinces implement their public health services. Details of procurement policy and maximum mark-ups are not available. However, the zero mark-up policy of 2012 is a national policy but was not being applied in the public facilities that were

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visited. The manufacturing site of the Big Three[1] insulins was unclear since the multinational companies have established local companies in China where they at least package their products. Records at the China Food and Drug Administration (CFDA) indicate that most products are imported, but some Novo Nordisk products (Novolin® 30R cartridge and NovoRapid® cartridge) may have local production[2].

Ghana

All insulin products are imported into Ghana but there are very few importers, most of whom double as wholesalers. There is no pharmaceutical price regulation in Ghana although the public sector price is determined by the National Health Insurance Authority (NHIA) and private sector mark-ups and prices for Big Three products tend to be 'guided' by the manufacturer in consultation with their selected importer/wholesaler. All insulin and other pharmaceutical products have been recently exempted from 10% import duty although this may not be reflected in the current retail prices of insulin in some facilities. In addition, insulin importers are exempt from the payment of 17.5 % VAT if they apply to the VAT office through the Diabetes Association of Ghana although they may not do so due to what is seen as a cumbersome procedure. Public procurement is through government tenders by the Regional Medical Stores (RMS) with the public sector retail price determined by the NHIA.

India – Haryana State

India is one of the countries with multiple producers of biosimilar insulin products (including Biocon and Wockhardt). Insulin is available in 40 IU/ml and 100 IU/ml strengths with about 85% of consumption involving vials. Both public and private supplies pass through the manufacturer's appointed Carriage & Forwarding (C&F) agent. From there stockists (wholesalers) supply either the public sector (through the state's central warehouse or via private suppliers) or the private sector facilities. All essential medicines, including insulin, are provided free in the public sector in Haryana State. Insulin is included in national and state essential medicine lists. As a scheduled medicine, the maximum retail price of insulin is regulated by the National Pharmaceutical Pricing Authority (NPPA) under the Drug Price Control Order (DPCO 2013). Mark-ups for locally manufactured insulin include 16% for retailers under DCPO (2013). For imported products, 50% of the landed cost is allowed as margins. Three terms are commonly used in pricing; PTS (Price to Stockist/wholesaler), PTR (Price to Retailer) and MRP (Maximum Retail Price), with the latter required to be printed on the label or packaging.

Indonesia

Indonesia introduced Universal Health Coverage (UHC) – called "Jaminan Kesehatan Nasional" (JKN) – for all Indonesian citizens in 2014, operated by the Health Care and Social Security Agency ("Badan Penyelengara Jaminan Sosial Kesehatan"; BPJS). Coverage is about 60-70%. The Ministry of Health has launched two policy reforms to the National Medicine System through the National Formulary (FORNAS) and e-catalogue policy. FORNAS is a list of

[1] 'Big Three' refers to the main insulin producing companies - Eli Lilly, Novo Nordisk, or Sanofi
[2] For this paper, all 'Big Three' products in China are considered as 'imported'.

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medicines that should be used by JKN providers giving health care services, while the e-catalogue is an electronic procurement system managed by the Government Procurement Agency. Medicine prices in the e-catalogue are set by national tender and/or a price negotiation process by the Ministry of Health. Medicine procurement through FORNAS and the e-catalogue are mandatory for public health care facilities and private facilities affiliated with BPJS. Under FORNAS, insulin can only be prescribed to patients at secondary level care (hospitals). Insulin can be obtained from pharmacies in public or private hospitals, or from private pharmacies that are contracted by BPJS. Insulin is essentially free (fully reimbursed) for patients who are members of JKN while the private sector patient price has a regulated mark-up that should not exceed 25%. Private facilities may serve both JKN and non-JKN patients. All insulins are imported products.

Uganda

In Uganda, the private sector is subdivided into private not-for-profit (PNFP) and private for-profit (PFP). The public health care facilities provide free health care to the population, and the PNFP sector also receives some government support. Insulin supply follows the same supply chains as other essential medicines. Public health services are delivered at the health centre (HC) IIs at parish level, HC IIIs at sub-county level, and referral levels: HC IVs at county level, general hospitals at district level, Regional Referral Hospitals and National Referral Hospitals. Insulin is classified by the Ministry of Health as a 'Vital' medicine to be available at Health Centre IV and above i.e. referral levels at which a doctor should be present. As with other essential medicines, insulin is provided free in the public sector and is procured and supplied by the National Medical Stores. In the private sector, import tax (10%) on medicines was abolished in 2005. However, the National Drug Authority charges 2% of the CIF cost as verification fees for imported essential medicines. There is no price regulation in the private sector. All insulins are imported products.

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