Biosimilar insulin and insulin prices: What does this mean for Kyrgyzstan

Policy Brief

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1 | Background

Despite having been discovered over 100 years ago access to insulin remains problematic in many countries. This limited access can be due to a lack of adequate quantities of insulin in the country leading to problems of availability. In parallel insulin prices remain high for health systems and individuals raising issues of affordability. In terms of affordability of insulin, a variety of factors can influence this, including differential pricing initiatives of companies, purchasing practices, use of human versus more costly analogue insulin, purchasing of originator versus biosimilar insulin, purchasing insulin in vials versus pen devices, etc.

2 | What are biosimilars?

The European Medicines Agency (EMA) defines a biosimilar as "a biological medicine highly similar to another biological medicine already approved in the EU [European Union] (called "reference medicine") in terms of structure, biological activity and efficacy, safety and immunogenicity profile (the intrinsic ability of proteins and other biological medicines to cause an immune response)."[1]

2.1 Insulin biosimilars

For insulin different biosimilar products have been approved by the EMA, United States Food & Drug Administration (USFDA), and other Stringent Regulatory Authorities (or under the new World Health Organization (WHO) classification WHO Listed Authorities). The table below details the different products this includes. (Table 1)

Table 1 – List of biosimilar insulins approved by different regulatory authorities[2]

Active ingredient	Originator brand	Originator manufacturer	Biosimilar brand	Biosimilar manufacturer	Regulatory authorities approving product
Glargine	Lantus®	Sanofi	Rezvoglar® / Basaglar®	Eli Lilly	USFDA
			Semglee®	Mylan	USFDA/EMA
			Absalgar®	Eli Lilly	EMA
Aspart	Novolog®	Novo Nordisk	Merilog®	Sanofi	USFDA
			Insulin Aspart Sanofi	Sanofi	EMA
			Kirsty	Biocon/Viatris (formerly Mylan)	EMA
Lispro	Humalog®	Eli Lilly	Insulin Lispro Sanofi	Sanofi	EMA

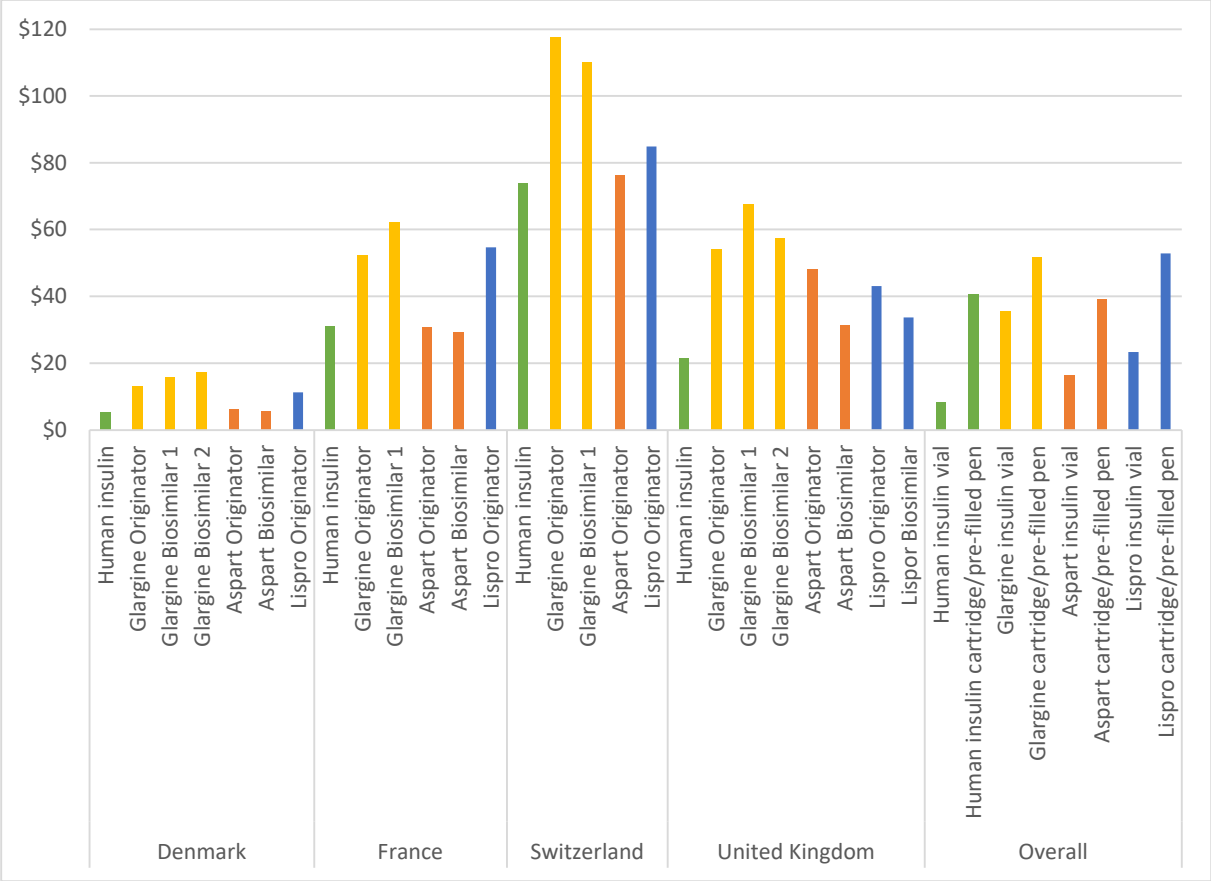
[1] https://www.ema.europa.eu/en/human-regulatory-overview/biosimilar-medicines-overview#:~:text=A%20biosimilar%20is%20a%20biological,apply%20to%20all%20biological%20medicines.
[2] Data obtained from USFDA and EMA websites as well as https://www.gabionline.net/biosimilars/general/biosimilars-approved-in-europe

The biosimilar insulins mentioned in the table above are thus seen as equivalent to the originator brand by the USFDA and EMA. In some countries Insulin Aspart Sanofi is branded as Trurapi® and Insulin Aspart Sanofi as Admelog®.

2.2 Country examples

The data provided below shows the products and prices of approved insulins used in different European countries. All prices are standardized to the equivalent of a 10ml 100IU vial. It should be noted that these prices cannot necessarily be compared as they represent different prices in different health systems from different sources.

Figure 1 – Prices in US$ (standardized to 10ml 100IU) of different types of insulin (formulations and presentations) in selected European countries[3]



 # - for the purpose of comparison Actrapid® (human insulin) is used
** - Denmark, France and Switzerland Retail prices which might include Value Added Tax and other fees (e.g. dispensation fees); where more than one price was available for the same product the average price is used; the average annual exchange rate for 2024 was used to convert from local currencies to US dollars.*

From the graph above the following should be noted:

- Wide range of prices across all insulins with for example the largest difference in price being human insulin which is 13.5 times more expensive in Switzerland than in Denmark
- Analogue insulin (Glargine, Aspart and Lispro) are more expensive than human insulin

[3] Data sources: Denmark (https://www.medicinpriser.dk); France (https://base-donnees-publique.medicaments.gouv.fr/index.php#result); Switzerland (https://www.spezialitätenliste.ch/); United Kingdom (https://formulary.nhssomerset.nhs.uk/?page_id=767)

- That the impact of biosmiliars on prices is unclear with in some cases the originator being less expensive than the biosmilar and in other cases the biosimilar is less expensive
- The price of vials for the same presentation are on average 2.7 times less expensive than pre-filled pens or cartridges

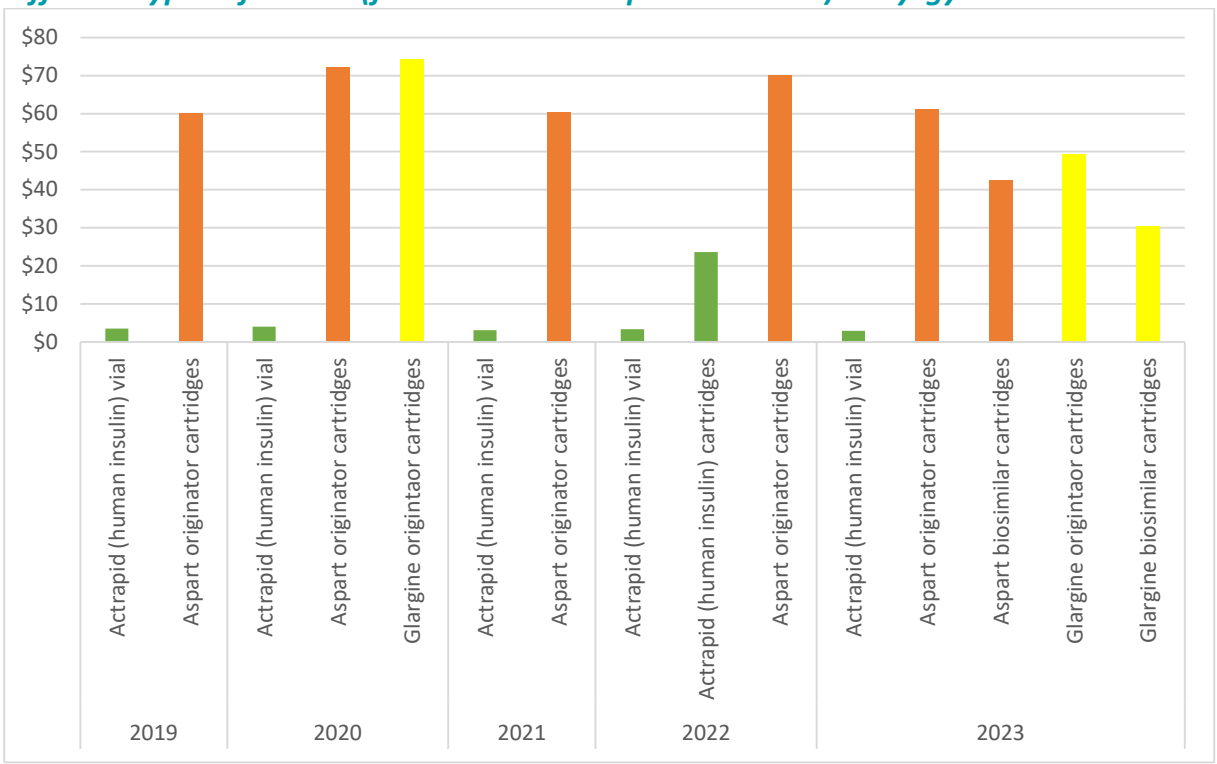
2.3 Impact of biosimilars on the price of insulin

A recent published study in BMJ Open investigated the impact of the introduction of biosimilar versions of insulin glargine on its price across 28 European countries over a period of 10 years.[4] What the study found was that overall, the introduction of biosimilar versions of glargine resulted in a median decrease of 21.6% of prices over the period. Whereas in some countries the introduction of biosimilar insulin glargine led to immediate and sustained price reductions of the originator product, in other countries a price increase following biosimilar entry was seen. One of the main potential policy implications of this study is that promoting biosimilar competition could be a key strategy for improving insulin affordability.

2.4 Data from Kyrgyzstan

Data on government procurement prices of insulin from 2019 to 2023 in Kyrgyzstan as part of the Addressing the Challenge and Constraints of Insulin Sources and Supply (ACCISS) Study was collected by the Health Policy Analysis Center. This data shows that for the insulin formulations included in Figure 1, for human insulin Kyrgyzstan is getting a lower price compared to the countries. In contrast the prices for analogue insulins are similar to those found in France and the United Kingdom and higher than prices for Denmark. As in other settings and studies, in Kyrgyzstan the price of biosimilars (Aspart and Glargine) are lower than the originator products.

Figure 2 – Government procurement prices in US$ (standardized to 10ml 1000IU) of different types of insulin (formulations and presentations) in Kyrgyzstan



[4] https://bmjopen.bmj.com/content/15/1/e090484

3 What does this mean for Kyrgyzstan?

Many biosimilars as noted above have been approved by regulatory authorities such as the USFDA and EMA and are used in many European countries. Biosimilar insulins have been found to be less expensive than originator products. For insulin, human versus analogue and insulin and vial versus pre-filled pens or cartridges are less expensive options. For Kyrgyzstan the price of analogue insulin remains high in comparison to other European countries, whereas the price for human insulin is lower than these settings. Some options for Kyrgyzstan include:

- Use of different initiatives available to ensure access to low prices of insulin. This is already the case for human insulin. These initiatives can be found at: https://ncdpolicylab.org/resources/factsheets/sources-of-insulin-oral-medicines-and-medical-devices-for-diabetes-for-low-and-middle-income-countries
- Assess need and use for analogue versus human insulin, prioritizing the use of analogue insulin for people with type 1 diabetes
- Strengthen regulatory processes for the assessment of biological products within the regulatory authority
- Promote the use of biosimilars through information and education to prescribers and people with type 1 diabetes

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