JPSIM Journal of Pakistan Society of Internal Medicine

Editorial

The Urgent Need and Expanding Scope of Semaglutide Biosimilars in Pakistan

Prof. Aziz-ur-Rehman

How to cite this:
Rehman AU. The Urgent Need and Expanding Scope of Semaglutide Biosimilars in Pakistan. J Pak Soc Intern Med. 2025;6(2): 104-105

Corresponding Author: Prof. Aziz-ur-Rehman **Email:** profazizurrehman@gmail.com

Received: 20-04-2025 **Revised:** 02-05-2025 **Accepted:** 18-05-2025

DOI: https://doi.org/10.70302/jpsim.v6i2.2520

Pakistan is grappling with a burgeoning diabetes crisis. With the highest prevalence of diabetes globally, an alarming 8.9 million individuals remain undiagnosed, and nearly half of those diagnosed struggle with effective management. This escalating health emergency underscores the critical need for innovative and accessible treatment options.

Semaglutide: A Game-Changer in Diabetes Management

Semaglutide, a glucagon-like peptide-1 receptor agonist (GLP-1 RA), has emerged as a transformative therapy for type 2 diabetes mellitus (T2DM). Approved by the U.S. FDA in 2017, semaglutide not only improves glycemic control but also promotes significant weight loss and offers cardiovascular benefits. Its availability in both subcutaneous and oral formulations enhances patient compliance and broadens its therapeutic appeal.[1]

Clinical trials, such as SUSTAIN and PIONEER, have demonstrated semaglutide's superiority over other antidiabetic agents, including insulin glargine and sitagliptin, in reducing HbA1c levels and body weight. Moreover, studies like SELECT and SOUL are exploring its potential in improving cardiovascular outcomes, further solidifying its role in comprehensive diabetes care.[1]

The Pakistani Landscape: Challenges and Opportunities

Despite its proven efficacy, semaglutide's accessibility in Pakistan has been limited. Until recently, Ozempic, manufactured by Novo Nordisk, was the sole semaglutide product registered by the Drug Regulatory Authority of Pakistan (DRAP). This limited availability, coupled with high costs, has restricted its use to a small segment of the population.[2] The scarcity has also led to the proliferation of falsified GLP-1 RA products in the market, posing significant health risks. DRAP has issued alerts regarding the circulation of counterfeit semaglutide, emphasizing the need for stringent regulatory oversight and increased availability of authentic products.[3]

Emergence of Biosimilars: A Beacon of Hope

Biosimilar drugs are biological products that are manufactured by pharma companies other than the originator or innovator. To be qualified as a biosimilar the company must demonstrate same efficacy, safety, immunogenicity, and clinical effects in large scale phase 3 clinical trials. The introduction of semaglutide biosimilars in Pakistan marks a pivotal development in addressing these challenges. Companies like Macter International and Ferozsons BF Biosciences have launched locally manufactured semaglutide biosimilars, such as Seglutide and Sematide, respectively. These companies have not reported any large-scale phase 3 trial to demonstrate their similarity to the originators. However, the latest addition of Sem-P, by Getz have completed phase 3 trials awaiting publication. Ideally these trials should be conducted locally to make sure that the biosimilars have same effects in the local communities as there may be different response due to different genomics and metabolomics. No company including the innovators (Novo Nordisk) have done any trials

locally. These products aim to provide cost-effective alternatives without compromising on quality, thereby enhancing accessibility for a broader patient population.

The local production of biosimilars not only reduces dependency on imports but also fosters the growth of Pakistan's pharmaceutical industry. It encourages self-reliance and can lead to more sustainable healthcare solutions in the long term.

Expanding Therapeutic Horizons

Beyond glycemic control, semaglutide has shown promise in managing obesity-related heart failure with preserved ejection fraction (HFpEF). Clinical studies indicate that semaglutide can significantly reduce symptoms and improve exercise capacity in patients with obesity-related HFpEF. Given the high prevalence of obesity and cardiovascular diseases in Pakistan, semaglutide's multifaceted benefits could have far-reaching implications for public health.[4]

Call to Action: Collaborative Efforts for a Healthier Future

To fully harness the potential of semaglutide biosimilars, concerted efforts are required from all stakeholders:

1. *Regulatory Bodies:* DRAP must expedite the approval processes for biosimilars while ensuring rigorous quality control to prevent the circulation of counterfeit products.
2. *Healthcare Professionals:* Continuous medical education programs should be implemented to familiarize clinicians with the benefits and administration of semaglutide biosimilars.
3. *Pharmaceutical Industry:* Investment in research and development is crucial to produce high-quality biosimilars that meet international standards.
4. *Public Awareness:* Educational campaigns can inform patients about the availability and advantages of biosimilars, promoting informed decision-making.

The advent of semaglutide biosimilars in Pakistan represents a significant stride towards combating the diabetes epidemic.[5] By improving accessibility and affordability, these biosimilars have the potential to transform diabetes management and enhance patient outcomes. However, realizing this potential necessitates a collaborative approach involving regulatory authorities, healthcare providers, the pharmaceutical industry, and the public. Together, we can pave the way for a healthier Pakistan.

References

1. Memon A, Tehrim M, Kumari B. Semaglutide: new dawn for diabetics. J Pak Med Assoc. 2023;73(3):721.
2. Drug Regulatory Authority of Pakistan. Rapid Alert: Drug Product; Suspected increase in the availability of falsified versions of Glucagon-like Peptide-1 Receptor Agonist (GLP-1-RA) in the markets. [updated July 14, 2023 Cited March 15 2025] Available from: [https://www.dra.gov.pk-/safety_info/product_recalls/recall_alerts/rapid-alert-drug-product-suspected-increase-in-the-availability-of-falsified-versions-of-glucagon-like-peptide-1-receptor-agonist-glp-1-ra-in-the-markets/].
3. BF Biosciences expands production, launches diabetes treatment, secures listing approval. Profit by Pakistan Today. [updated Sept 09, 2024 Cited March 15 2025] Available from: [https://profit.pakistan-today.com.pk/2024/09/09/bf-biosciences-expands-production-launches-diabetes-treatment-secures-listing-approval/].
4. Khaskheli SA, Rajpar NA. Semaglutide: An emerging treatment option for patients with obesity related HFpEF. J Pak Med Assoc. 2024;74(9):1743.
5. Baig MU, Farooq MA. Awareness Of Use Of GLP-1 Agonists In The Treatment Of Diabetes Mellitus In Pakistan. J Pak Med Assoc. 2023;73(8):1769.