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Anti-Obesity Pharmacotherapy: Closing the Access Gap Through Local Manufacturing

Mojtaba Farjam[1], Babak Pezeshki[1,2], Narges Fereydouni[1,3]

1. Noncommunicable Diseases Research Center, Fasa University of Medical Sciences, Fasa, Iran
2. Department of Internal Medicine, School of Medicine, Fasa University of Medical Sciences, Fasa, Iran
3. Clinical Research Development Unit, Valiasr Hospital, Fasa University of Medical Sciences, Fasa, Iran

The global obesity epidemic, affecting approximately 890 million adults, has catalyzed substantial advances in pharmacological management. Contemporary anti-obesity medications, including GLP-1 receptor agonists, dual GLP-1/GIP agonists, lipase inhibitors, and combination neurochemical modulators, can achieve weight reductions ranging from 5% to 22%, thereby approaching outcomes that were previously attainable only through bariatric surgery. Notwithstanding these therapeutic gains, a pronounced gap persists between clinical capability and real-world accessibility, as many of these novel agents remain prohibitively expensive or unavailable across large regions.

Within this context, Iran's pharmaceutical sector has demonstrated notable progress in the domestic production of several anti-obesity medications, including orlistat, marketed under more than 15 local brands, as well as metformin, liraglutide (Melitide, Maciza, Vikitide), tirzepatide (Spartina), and naltrexone/bupropion combinations (Lipoxon, Fandex). These developments have substantially enhanced treatment accessibility despite import restrictions and persistent cost barriers. However, rigorous head-to-head clinical trials comparing domestically manufactured products with their reference counterparts, alongside systematic post-marketing surveillance, remain indispensable for establishing long-term safety and therapeutic equivalence. In this regard, Iran's experience delineates a viable model for expanding global access to obesity pharmacotherapy through localized manufacturing, with significant implications for health equity.

Advances in Anti-Obesity Pharmacotherapy

The obesity crisis has transitioned from a clinical concern to a defining global health challenge, with prevalence rates having tripled since 1975. Although lifestyle modification remains the cornerstone of management, its limited durability, evidenced by the fact that approximately 80% of individuals regain lost weight within one to five years, has rendered pharmacotherapy an essential component of comprehensive care. Increasing recognition of obesity as a chronic disease characterized by dysregulated neurobiological, metabolic, and hormonal pathways has fundamentally reshaped therapeutic paradigms over the past decade.

Among recent developments, incretin-based therapies represent the most transformative advance. GLP-1 receptor agonists, such as

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Corresponding Author: **Narges Fereydouni,** Noncommunicable Diseases Research Center, Fasa University of Medical Sciences, Fasa, Iran.
Email: narges.fereydouni2020@gmail.com

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liraglutide, which yields 5% to 8% weight loss, and semaglutide, associated with 15% to 17% reductions, achieve outcomes that previously required surgical intervention. The dual GLP-1/GIP agonist tirzepatide produces weight loss in the range of 20% to 22% and has demonstrated superiority over semaglutide in direct comparative studies; it has also recently received approval for the treatment of obstructive sleep apnea. Gastrointestinal adverse effects occur in approximately 40% to 50% of patients but are generally transient, whereas rare but serious risks include pancreatitis, occurring in 0.1% to 0.2% of cases, and gallbladder disease.

Additional pharmacological classes include phentermine/topiramate, associated with 9% to 11% weight loss; naltrexone/bupropion, yielding 5% to 9%; and orlistat, which produces 5% to 10% weight reduction through inhibition of fat absorption. Precision therapies, such as setmelanotide, are indicated for specific genetic obesity syndromes. Furthermore, off-label use of metformin and SGLT2 inhibitors provides modest weight reduction, typically in the range of 1 to 3 kilograms, with well-established safety profiles.

The Challenge of Equitable Access

The principal challenge in obesity pharmacotherapy lies not in efficacy but in equitable access. In the United States, novel GLP-1/GIP agonists are priced between $900 and $1,400 per month, and many insurance plans exclude coverage for obesity medications; moreover, supply shortages continue to constrain availability. These factors give rise to substantial inequities, whereby individuals with adequate financial resources can access therapies capable of producing approximately 20% weight loss, while others remain limited to older, less effective treatments or receive no pharmacological intervention at all.

Iran's Domestic Production Capacity

Iran's domestic manufacturing capacity illustrates a viable alternative pathway. At least 15 locally produced orlistat brands are currently available, fostering price competition and enabling over-the-counter access. In 2023, metformin production exceeded 1.224 billion tablets. SinaGen Pharmaceutical manufactures liraglutide formulations (Melitide, Maciza, Vikitide) as bioequivalent prefilled pens approved by the Iran Food and Drug Administration. Most notably, the company introduced Spartina, a domestically produced tirzepatide, in early 2024, positioning Iran among the first countries outside the United States and Japan to achieve commercial production of this molecule.

To contextualize affordability, Iran's statutory monthly minimum wage in 2024 was approximately 7 to 8 million tomans. Consequently, the monthly cost of Spartina, estimated at 10 to 12 million tomans, corresponds to roughly 1.3 to 1.5 times the minimum monthly wage. Although this represents a considerable financial burden for many patients, it remains substantially lower than the $900 to $1,400 monthly cost of the originator product in the United States. In parallel, Danesh Pajoohan Arya Daro produces bioequivalent naltrexone/bupropion combinations (Lipoxon, Fandex), comparable to Contrave.

Collectively, these advances have significantly improved both availability and affordability in the face of import constraints. Nevertheless, the full clinical value of domestically produced anti-obesity medications can only be established through rigorously designed head-to-head randomized controlled trials against originator products, complemented by structured post-marketing surveillance systems to assess long-term safety and sustained therapeutic equivalence. To date, no such comparative trials appear to be registered or underway in Iran. The establishment of a national pharmacovigilance framework, supported by registry-based surveillance, would therefore constitute a critical and achievable step toward generating high-quality evidence necessary for guideline

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integration and widespread clinical adoption.

Implications for Global Health Equity and Future Directions

This model carries important implications for global health equity. Regional collaboration could facilitate the consolidation of pharmaceutical production in countries with established manufacturing infrastructure, thereby serving multiple neighboring populations. Mechanisms such as technology transfer, voluntary licensing, biosimilar development, and differential pricing, all of which have proven effective in the context of HIV/AIDS treatment, could further accelerate the expansion of access.

Looking ahead, the therapeutic pipeline remains robust. Emerging agents include triple incretin agonists, such as retatrutide, which has demonstrated approximately 24% weight loss in Phase 2 trials; oral small-molecule GLP-1 receptor agonists, including orforglipron, which may reduce production costs; long-acting monthly injectables; and next-generation MC4R agonists. However, the translation of these pharmacological innovations into meaningful population-level health outcomes will depend critically on overcoming the structural barriers that currently limit access and real-world effectiveness.

In conclusion, contemporary obesity pharmacotherapy offers unprecedented therapeutic potential. Iran's expansion of domestic pharmaceutical manufacturing provides a compelling model for addressing global disparities in access through localized production and technology transfer. Realizing this potential, however, will require parallel investment in rigorous comparative clinical trials and sustained post-marketing surveillance, as well as coordinated, systematic efforts to ensure equitable access for all patients, irrespective of geographic or economic constraints.

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