PHARMACEUTICAL MONOPOLY UNDER THE CDSCO REGULATORY FRAMEWORK

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ABSTRACT

Glucagon-like peptide-1 (GLP-1) receptor agonists have recently emerged as a significant advancement in the treatment of metabolic disorders, particularly Type 2 Diabetes and Obesity**.** Medicines such as Ozempic and Wegovy have gained global prominence due to their effectiveness in improving glycaemic control and facilitating weight management. However, the rapid rise in demand for these drugs has also raised critical concerns relating to pharmaceutical monopoly, drug pricing, and regulatory oversight. The patent protection and market exclusivity enjoyed by manufacturers, particularly Novo Nordisk, have resulted in limited competition, thereby enabling significant control over pricing and market supply.

In India, the regulation and approval of pharmaceutical products are governed by the Central Drugs Standard Control Organization (CDSCO) under the framework of the Drugs and Cosmetics Act, 1940. While CDSCO plays a crucial role in ensuring the safety, efficacy, and quality of medicines through drug approval processes, clinical trial supervision, and post-marketing surveillance, the growing prominence of GLP-1 medicines presents new regulatory challenges. These include concerns regarding off-label use for weight loss, increasing market concentration, and the broader implications of patent-driven monopoly in the pharmaceutical sector.

This paper examines the regulatory framework governing GLP-1 medicines in India and analyses the extent to which existing mechanisms effectively address issues arising from market dominance and limited competition. Through doctrinal analysis of statutory provisions, regulatory guidelines, and policy frameworks, the study identifies gaps in regulatory coordination and oversight that may allow pharmaceutical monopolies to influence access and affordability of these drugs. The research argues that a stronger and more coordinated regulatory approach is necessary to balance pharmaceutical innovation with public health interests. By exploring the intersection of drug regulation and monopoly power in the context of GLP-1 medicines, the paper contributes to ongoing discussions on strengthening India's pharmaceutical regulatory system to ensure equitable access to emerging therapeutic treatments.

I. INTRODUCTION

The pharmaceutical industry has a unique position as an industry at the crossroads of commerce and healthcare. Drug development innovation is crucial for addressing new health issues, but commercializing such advances frequently raises questions about accessibility, price, and fair distribution. Glucagon-like peptide-1 also commonly known as GLP-1receptor agonists have become a major advancement in the treatment of metabolic diseases, especially obesity and Type-2 Diabetes Mellitus.[1] Endocrinology therapy techniques have changes as a result of the widespread identification of medications like Ozempic and Wegovy for their dual efficacy in glycaemic control and weight management.[2]

The structural problems of the pharmaceutical sector, including those relating to monopolization, patents, and regulations, have come to the fore due to the sudden surge in the demand for such drugs. it should be noted that only a few companies dominate the field of drug manufacturing, such as Novo Nordisk. The contradiction lies in the fact that while stimulating innovation, the ability of citizens to receive life-saving medicines is equally critical.

In India, the Drugs and Cosmetics Act, 1940 grants the CDSCO control over the regulation of pharmaceuticals. The CDSCO performs an important function in making sure that the drug is safe and effective by facilitating clinical trials, licensing, and post-marketing surveillance. However, the introduction of highly sought-after, patent-protected medications such as GLP-1 receptor agonists creates new regulatory issues that put the effectiveness of current framework to the test.

With an emphasis on the effects of pharmaceutical monopoly, this research aims to investigate the regulatory environment controlling GLP-1 medications in India. It assesses how well the existing legal and regulatory frameworks handle problems with pricing control, market dominance, and access to medications. The report finds oversight deficiencies and suggests ways to improve India's pharmaceutical regulatory system through a doctrinal analysis of statutory provisions, policy frameworks, and regulatory practices.

[1] Paul Z. Magliano et al., Diabetes: a 21st century challenge, 2 THE LANCET 56, 58-60 (2014).
[2] Gurdeep Singh et al., Wegovy (Semaglutide): A New Weight Loss Drug for Chronic Weight Management, 70 JIM 5, 7-11 (2022).

II. UNDERSTANDING GLP-1 REGULATOR AGONISTS

One recent advancement in current medicine is that of the use of the GLP-1 receptor agonists, particularly for managing metabolic disorders. This class of drugs acts to imitate the effect of GLP-1, an endogenous incretin hormone responsible for regulating glucose levels. These drugs offer a complete strategy for managing hyperglycemia and helping with weight loss by glucose-dependent insulin secretion, suppressing glucagon release, postponing stomach emptying, and boosting feelings of satiety.

Given the rising prevalence of Type 2 diabetes and obesity worldwide, the clinical significance of GLP-1 receptor agonists is particularly noteworthy.[3] The prevalence of these two illnesses is rising quickly, especially in developing nations like India, and they are intimately related. Clinical research has shown that medications like Semaglutide, which is sold under brand names including Ozempic and Wegovy, are remarkably effective.[4] Along with helping to significantly reduce weight and cardiovascular risk factors like dyslipidemia and hypertension, they also enhance glycaemic management. They are very useful in comprehensive metabolic care because of these two advantages.

However, a number of obstacles prevent their widespread accessibility and equal use, notwithstanding their therapeutic potential. The high cost of these medications, which is mostly caused by patent protection and the ensuring market exclusivity enjoyed by pharmaceutical firms, is one of the main issues. A significant portion of the population, particularly in low-middle income nations, cannot afford these therapies because of the monopolistic control that prevents generic alternatives from entering the market.

Furthermore, limited availability has been caused by supply issues and rising worldwide demand, which occasionally even affects individuals who need these drugs for valid medical reasons. The growing trend of off-label use, especially among non-diabetic people looking to lose weight quickly, isanother significant emerging problem. In addition to creating ethical and legal issues, this worsens the lack of patients with actual clinical needs.

All things considered, GLP-1 receptor agonists have enormous potential to change the way

[3] Bontha V. Babu et al., Prevalence of Type 2 Diabetes among Tribal Population of India: A Multi-Centric Cross-Sectional Study, 116 J. NATL. MED. ASSC. 153, 155-157 (2024).
[4] Mads F. Rasmussen, The development of oral semaglutide, an oral GLP-1 analog, for the treatment of type 2 diabetes, 11 DIABETOL. INT. 76, 79-82 (2020).

metabolic illnesses are treated, but their advantages are currently limited by problems with accessibility, cost, and regulatory control.[5] To guarantee that the benefits of these cutting-edge treatments are dispersed more fairly, it will be crucial to address these issues.

III. PHARMACEUTICAL MONOPOLY: CONCEPT AND IMPLICATIONS

A pharmaceutical monopoly typically arises when a company holds exclusive rights over the production and sale of a drug, often through patent protection and sale of a drug, often through regulatory exclusivity and patent protection. By enabling businesses to recoup research and development (R&D) expenses, these monopolies are permitted by law to encourage innovation. However, they also have a significant impact on access, competition, and drug pricing.

3.1 Patent Protection and Market Exclusivity

Patents are essential to the pharmaceutical sector because they give businesses the only right to produce, use, and market a medication for a predetermines amount of time, usually 20 years from the date of filing. By enabling businesses to recoup the significant expenses related to research and development, this method aims to encourage innovation. Pharmaceutical companies frequently profit form governmental safeguards like data exclusivity and market exclusivity in addition to patents. These rights keep generic manufacturers from using the originator's clinical trial data for a predetermines amount of time, which further delays competition.

Companies such as Novo Nordisk have amassed substantial patent portfolios related to GLP-1 receptor agonists. These patents cover formulations, administration techniques, and drug delivery systems in addition to the active pharmaceutical ingredient. Such comprehensive protection significantly delays generic manufacturers entry into the market by creating substantial obstacles. As a result, the patent holder is able to regulate supply, establish a dominating position, and maintain high prices for an extended period of time.

3.2 Pricing and Accessibility

Pharmaceutical corporations can set prices without being constrained by competition thanks to monopolistic control. As a result of this, GLP-1 medications continue to be costly and largely

[5] Eugenia Piragine et al., Adherence to oral antidiabetic drugs in patients with type 2 diabetes: systematic review and meta-analysis, 12 JCM, (1981).

unavailable to a huge segment of the population, especially in developing nations like India.

Exorbitant costs harm public healthcare systems in addition to restricting individual access. Essential medications run the risk of turning into luxury items in the absence of price control measures, jeopardizing the right to health.

3.3 Supply Constraints and Market Control

Monopolistic control can have a substantial impact on pharmaceutical product availability and distribution in addition to pricing. The increase in demand for GLP-1 medications worldwide, which is fueled by both off-label and medical need, has resulted in significant supply shortages.

Distribution in high-income markets may be given priority by pharmaceutical corporations operating under profit-maximizing incentives. This frequently leads to an uneven distribution of resources, which disadvantages low and middle-income nations. Even patients who depend on the drugs for necessary therapy may experience shortage as a result of such supply instabilities.

IV. The CDSCO Regulatory Framework

The central authority responsible for regulating pharmaceutical regulation in India is the Central Drugs Standard Control Organization (CDSCO). The Drugs and Cosmetics Act, 1940 and the Drugs and Cosmetics Rules, 1945 provide it authority, and it functions under the Ministry and Health and Family Welfare. The framework's main goal is to safeguard public health by ensuring that medications brought to the Indian market adhere to safety, efficacy, and quality requirements.

4.1 Drug Approval Process

The CDSCO uses a methodical, scientific approval procedure. Pre-clinical research is the first step in which medications are evaluated for pharmacological action and toxicity in lab and animal settings. Human clinical trials are then carried out in several stages to assess safety, dose, and therapeutic efficacy.

Regulatory specialists evaluate the data following successful studies and evaluate the drug's risk-benefit profile before approving it. CDSCO may permit bridge studies, which combine

restricted local trials with local data to expedite access, in situations where a medicine has already received approval in other countries.

For instance, these assessments led to the approval of GLP-1 receptor agonists like semaglutide in India. However, the approval process remains focused on clinical outcomes and does not consider factors like drug pricing, affordability, or market competition, which can significantly affect access.

4.2 Clinical Trial Regulation

India has stringent ethical and procedural regulations governing clinical studies. By mandating informed consent, openness, and appropriate documentation, the CDSCO guarantees adherence to Good Clinical Practice (GCP) guidelines. In order to protect participant rights, ethics committees are essential.

Regulations also require compensation for deaths or injuries sustained during a trial, indicating a strong focus on participant protection. Additionally, the CDSCO keeps an eye on ongoing trial and has the authority to halt them for noncompliance.

The framework is mostly limited to guaranteeing ethical and scientific validity throughout the trial phase, despite these protections. It ignores problems like delayed generic entry, selective patenting, and other actions that could result in monopolistic market control.

4.3 Post Marketing Surveillance

Post-marketing surveillance systems ae used to continuously monitor a drug's safety after it has been approved. The Pharmacovigilance Programme of India (PvPI) gathers and examines patient and healthcare provider data on adverse medication reactions.

Regulators can use this approach to find previously undiscovered adverse effects and take appropriate corrective action, such as changing labels, issuing warning, or, if needed, stopping the use of medications.

However, post-marketing surveillance is restricted to safety monitoring. It excludes market concentration, supply limitations and pricing practice oversight, all of which are crucial in combating pharmaceutical monopolies. As a result, even effective and safe drugs may remain

inaccessible due to high costs or limited competition.

V. REGULATORY CHALLENGES IN THE CONTEXT OF GLP-1 DRUGS

The rapid rise of GLP-1 medicines has exposed several gaps within India's pharmaceutical regulatory framework, particularly affecting the role of the CDSCO and related authorities.

5.1 Off-Label Use

The growing off-label usage of GLP-1 medications for weight loss is a major concern. These medications are commonly used to manage obesity, including by people without diabetes, even though their primary approved use is for the treatment of Type 2 diabetes.[6]

Inappropriate prescribing, possible health hazards, and uneven access for people who actually require the medication for approved uses are just a few of the ethical and legal concerns brought up by this practice.[7] There are now gaps in oversight and enforcement since CDSCO lacks a specific method to monitor or limit off-label use.

5.2 Lack of Price Regulation

The CDSCO does not control pricing; its authority is restricted to medicine approval and safety. The National Pharmaceutical Pricing Authority (NPPA) is responsible for this task. However, there is a regulatory gap as a result of CDSCO and NPPA's poor collaboration. There is no comprehensive framework in place to guarantee that a medication stays inexpensive even after it has been approved. Because there are currently no stringent price control measures in place, many GLP-1 medications are supplied at exorbitant prices, which limits accessibility for a sizable portion of the population.

5.3 Limited Generic Competition

Strong patent laws under the Patents Act 1970 protect GLP-1 medications, delaying the introduction of generic copies. Even though Indian law offers protections like mandatory licensing to enhance access in the public interest, these clauses are rarely applied in real-world situations.

[6] Christopher J. Brewer & Adam Balen, The adverse effects of obesity on conception and implantation, 140 REPRODUCTION 347, 357-358 (2010).
[7] Alejandra S. Rodriguez et al., Investigating the Impact of GLP-1 Receptor Agonist-Induced Fat Loss on Collagen Synthesis and Skin Elasticity, 18 JBiSE, (2025).

A few manufacturers are able to control the market because of the extended market exclusivity caused by the delayed arrival of generics. Limited supply and persistently high pricing are caused by this lack of competition.

5.4 Regulatory Fragmentation

As noted by Colin Scott, "regulatory power is frequently fragmented across various organizations with different capacities". This applies to the Indian pharma industry, where different organizations like CDSCO (responsible for drugs), NPPA (price regulation), and Controller General of Patents regulate different aspects of the industry.

This fragmentation leads to weak coordination, making it difficult to address complex issues like pharmaceutical monopolies in a holistic manner. Despite strict safety regulations, there are gaps where pricing, competitiveness, and access issues are not sufficiently addressed due to the lack of uniform regulatory strategy.

VI. LEGAL FRAMEWORK ADDRESSING MONOPOLY IN PHARMACEUTUCALS

The issue of monopoly in the pharmaceutical sector is addressed in India through a combination of competition law, patent law, and price control mechanisms. However, the effectiveness of these legal tools in regulating high-value drugs like GLP-1 medicines remains limited.

6.1 Competition Law

The Competition Act, 2002 aims to stop behaviours that negatively impact market competition, misuse of dominant positions, and anti-competitive agreements. The Competition Commission of India (CCI) has the authority to look into matters like market manipulation, cartelization, and exorbitant prices.

Theoretically, monopolistic activities in the pharmaceutical industry can be contested using this approach. Its practical relevance to drug pricing is, nevertheless, restricted. It is challenging for the CCI to prove abuse of dominance based only on price since pharmaceutical companies tout innovation, R&D expenses, and patent protection as justification for high prices.

6.2 Patent Law and Compulsory Licensing

Besides providing inventors with strong protection, the Patents Act, 1970 provides for the mandatory licensing provision. In case the specific criteria have been met, including

affordability, inadequate supply, and health considerations, the government is at liberty to authorize other entities to produce a particular patented medicine without the authorization of the patentee.

This clause could increase access to necessary medications and dismantle monopolies. However, mandatory licensing has been applied extremely infrequently in India, which reduces its usefulness. Because of this, GLP-1 medications and other proprietary medications frequently maintain their extended market exclusivity.

6.3 Price Control Mechanisms

The Drug Price Control Order (DPCO), issued by the National Pharmaceutical Pricing Authority (NPPA), regulates the pricing of drugs in India. In cases of essential medicines available on the National List of Essential Medicines (NLEM), there will be price limits under the DPCO.

This results in patients not being able to access such advanced but expensive medicines. Improving affordability and availability could be greatly aided by extending the reach of price regulation or implementing alternative pricing techniques.

VII. GLOBAL REGULATORY APPROACHES AND LESSONS FOR INDIA

United States of America

The U.S. Food and Drug Administration (FDA) claims that unapproved and compounded forms of GLP-1 receptor, like tirzepatide and semaglutide, pose serious safety risks since they are not subjected to the agency's evaluation for quality, safety, and efficacy before being marketed.[8] Compounded medications are not assessed by the FDA, which raises the possibility of degraded quality. However, they may be used in specific circumstances, such as when a patient's unique medical demands cannot be satisfied by an FDA-approved medication or when the approved medication is unavailable. The FDA has also discovered problems that can negatively impact injectable medications efficacy and safety, such as incorrect storage during transportation,

[8] FDA's Concerns with Unapproved GLP-1 Drugs Used for Weight Loss, FOOD AND DRUG ADMINISTRATION (Feb. 04, 2026), https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/fdas-concerns-unapproved-glp-1-drugs-used-weight-loss#reporting

especially when the necessary refrigeration isn't maintained.[9]

The FDA also issues a warning over the increasing number of fake and fraudulent GLP-1 medications on the market. These items may be mislabeled with pharmacies that don't exist or are misrepresented, and they may contain hazardous, inadequate, or wrong ingredients. Furthermore, dosage problems with compounded semaglutide and tirzepatide have been extensively documented. These errors result from inappropriate prescribing methods or inaccurate self-administration, which can cause side effects such as nausea, vomiting and gastrointestinal issues.[10] The use of semaglutide salt forms, which lack proof of safety and equivalency, and the illicit use of prohibited chemicals like **retratrutide** and **cagrilintide** in compounding have also drawn criticism from the agency.

The FDA has responded with enforcement actions, including as warning letters against illicit distributors and import warnings to stop inferior raw materials from entering the supply chain. Additionally, it recommends consumers to exercise caution by only getting prescriptions from authorized medical professionals, buying medications from state-licensed pharmacies, and thoroughly confirming the legitimacy of products.[11] In general, the FDA highlights that in order to reduce the grave health hazards connected to unapproved and compounded GLP-1 medicines, reliance on licensed treatments and expert medical advice is crucial.

United Kingdom

The Medicines and Healthcare products Regulatory Agency (MHRA) states that using GLP-1 receptor agonists and dual GLP-1 and glucose dependent insulinotropic polypeptide receptor agonists carry a slight but significant risk of severe acute pancreatitis.[12] Even though acute pancreatitis is a known but uncommon adverse effect, it can occasionally worsen and result in major consequences. It is recommended that patients and medical professionals stay vigilant for early signs, such as severe and persistent stomach discomfort that may radiate to the back and may be accompanied by nausea and vomiting, and to seek prompt medical attention if such symptoms manifest.

[9] *Ibid.*
[10] *Ibid.*
[11] Ashour, M. M., Mabrouk, M., Aboelnasr, M.A., Beherei, H. H., Tohamy, K.M., & Das, D.B. (2023). Anti-Obesity Drug Delivery Systems: Recent Progress and Challenges. *Pharmaceutics,* 15(11), 2635.
[12] MHRA updates guidance for GLP-1 prescribers and patients (01.29.2026). *Medicines and Healthcare products Regulatory Agency.*

The MHRA stresses that certain GLP-1 medications are not risk-free, even though they are typically regarded as safe and effective for their authorized applications. The organization tells patients that there is extremely little chance of serious side effects, but patient safety depends on awareness and prompt action. Healthcare providers are urged to keep a close eye on patients and advise them on possible warning indicators.

In order to better understand if generic variables may influence an individual's risk of developing pancreatitis from these drugs, the MHRA also emphasizes ongoing research activities, such as partnership with Genomics England through the Yellow Card Biobank initiative. The goals of this research are to increase medication safety and provide more individualized care.[13] The Yellow Card program encourages patients to report any potential adverse effects, highlighting the significance of ongoing pharmacovigilance.

How can India learn from USA and UK in regulating GLP-1 Drugs

Asian patients had the lowest rates of GLP-1 use and more than 40% lower odds of GLP-1 prescription. Barriers to accessing care, less patient-centered interactions by practitioners, and biases in care delivery have been well-documented among Asian patients and likely play a role in the inequitable use of GLP-1 in this population. However, especially in a developing nation like India, the growing dominance of a small number of pharmaceutical corporations in this market has sparked grave worries about monopoly power, exorbitant prices, and restricted access.[14] India may draw important lessons from the FDA and MHRA about improving public awareness, safety monitoring, and regulation of GLP-1 medications. Stricter regulation of unapproved and compounded medications is one important area. In the United States, the FDA regularly monitors counterfeit goods, controls compounding procedures, and issues import alerts to stop dangerous or low-quality substances from entering the supply chain. Similar proactive surveillance measures can be implemented in India through the CDSCO, especially to stop illicit internet sales, abuse for weight reduction, and the distribution of inferior or fake GLP-1 medications.

The MHRAs emphasis on reliable pharmacovigilance systems and real-time safety communication is another crucial lesson. Reporting is achieved through systematic methods

[13] *Ibid.*
[14] Lauren A. Eberly et al., Racial, ethnic, and socioeconomic inequities in glucagon-like peptide-1 receptor agonist use among patients with diabetes in the US, 2 JAMA 1, 8-9 (2021).

such as the use of the Yellow Card Scheme for India, along with alerting patients and professionals regarding the risk of conditions such as acute pancreatitis. In strengthening adverse event reporting, involving patients and making information on emerging risks available to the public in a timely manner, India can improve its system of pharmacovigilance. Additionally, India can adopt the use of evidence-based and personalized medicine systems to ensure medication safety, as illustrated by the incorporation of research activities in the case of the UK and its collaborations with genomics organizations.

Finally, India can further develop patient education and responsible prescribing practices that are common concerns in both the US and the UK. Misuse and harm from medications can be avoided through dosing instructions, prescription use only, and knowledge of side effects. Public initiatives like the MHRAs safety alerts and the FDA's safe online pharmacy programs could enable Indian patients to make knowledgeable decisions. India can guarantee that the increasing use of GLP-1 medications stays safe, efficient, and well-regulated by combining tighter enforcement, more robust pharmacovigilance, and increased public knowledge.

VIII. CONCLUSION

GLP-1 receptor agonists represent a major improvement in the treatment of type 2 diabetes and obesity with their strong therapeutic benefits. Although the CDSCO is essential in guaranteeing the safety and effectiveness of drugs, its existing regulatory framework is insufficient to handle the wider commercial and economic effects of pharmaceutical monopolies.

However, there should be a change in the existing system towards a better regulatory system involving drug approval, price control, and competition laws to ensure equal access to these medicines. India can effectively resolve issues associated with monopolies in the pharma sector through institutional collaboration, competition for generics, price controls, and better pharmacovigilance. In the end, a patient-centric regulatory strategy that puts public health ahead of business interests is necessary to guarantee that everyone in society may benefit from innovation.