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# Scaling GLP-1 therapies in India

## Engineering the packaging ecosystem behind sustainable market success

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# Abbreviations

| Abbreviation | Full form |
|---|---|
| GLP-1 | Glucagon-like peptide-1 |
| IDF | International Diabetes Federation |
| EPR | Extended Producer Responsibility |
| PPWR | Packaging and Packaging Waste Regulation (EU) |
| ISO 11607 | Packaging for terminally sterilized medical devices |
| COP | Cyclic olefin polymer |
| COC | Cyclic olefin copolymer |
| E&L | Extractables and leachables |
| CCI | Container closure integrity |
| HVLD | High voltage leak detection |
| HFE | Human factors engineering |
| IFU | Instructions for use |
| EPS / VIP | Expanded polystyrene / vacuum insulated panel |
| PCM | Phase change material |
| USP 1207 / 661 | Container closure integrity / plastics and polymeric systems used in packaging |
| CDSCO | Central Drugs Standard Control Organization (India) |
| ICH | International Council for Harmonization |

# Introduction

The rapid approval and adoption of glucagon-like peptide-1 (GLP-1) receptor agonists have transformed the global management of type 2 diabetes and obesity. Semaglutide-based therapies are marketed under brands including Ozempic®, Wegovy® and Rybelsus® and increasingly Tirzepatide-based therapies include Mounjaro®. Together, these therapies have demonstrated significant improvements in glycaemic control, cardiovascular outcomes and sustained weight reduction. With key semaglutide patents lapsing in India in 2026, affordable generic access to injectable drug-device combination products is expected to create a large, and fast-moving addressable market [2].

India represents one of the world's largest opportunities for GLP-1 therapies. According to the International Diabetes Federation (IDF) Diabetes Atlas 11th Edition (2025), approximately 89.8 million Indian adults were living with diabetes in 2024. This figure is projected to reach 156.7 million by 2050, with nearly 43% of cases undiagnosed [1]. The World Obesity Federation estimates that roughly one in three Indian adults now has a high BMI, with the affected population projected to reach 404 million by 2030 [9]. Together, these figures underscore the scale of latent, largely untreated demand.

However, manufacturing scale alone will not determine success in this market. Sustainable adoption depends on a highly integrated ecosystem spanning primary packaging, delivery devices, cold-chain logistics, regulatory compliance, traceability, patient usability and healthcare infrastructure. This whitepaper examines the strategic role of packaging engineering and drug-device systems in enabling large-scale, patient-safe adoption of GLP-1 therapies in India. It also outlines how HCLTech works with pharmaceutical and MedTech manufacturers to engineer and scale this ecosystem.

| | | |
|---|---|---|
| **89.8M**<br>Indian adults living with diabetes, 2024 (IDF) [1] | **~1 in 3**<br>Indian adults with high BMI (World Obesity Federation, 2025) [9] | **43%**<br>Diabetes cases in India that are undiagnosed [1] |
| **$150.8M → $1B+**<br>India GLP-1 market, 2025 to 2033 (22.7% CAGR) [6] | **2026**<br>Year of semaglutide patent expiry in India [2] | **2–8°C**<br>Cold-chain range required for many injectable GLP-1 therapies [5] |

# India's GLP-1 opportunity: Large but complex

India's GLP-1 opportunity is substantial on paper: a vast, undertreated population of people with diabetes and obesity, rising urban incomes and an accelerating wave of domestic generic entrants following semaglutide's patent expiry in India in 2026. Analysts now estimate the domestic GLP-1 market at $150.8 million in 2025, growing approximately $240.5 million in 2026 and exceeding $1 billion by 2033 [6]. This represents a 22.7% CAGR that outpaces many other therapeutic categories in the country. Globally, the GLP-1 class is expected to be worth approximately $82 billion in 2026, with obesity indications alone projected to grow at more than 23% CAGR through 2035 [6,7].

Yet despite the size of the patient population, commercial execution remains challenging. Large patient populations alone do not create sustainable markets. Companies entering India are finding that:

- Physician behavior can be difficult to change quickly, particularly around early pharmacological intervention for obesity.
- Therapy affordability remains a significant barrier, with monthly costs of approximately ₹14,000–₹17,500 still out of reach for many households in a predominantly self-pay healthcare system [2,3]
- Long-term adherence remains challenging, driven by side effects , injection anxiety and cost fatigue
- Infrastructure limitations, cold-chain reliability, last-mile delivery and access across tier 2 and tier 3 pharmacies access affect product availability and safety
- Competition has intensified sharply beyond global originators, following domestic launches such as Dr. Reddy's semaglutide brand Obeda in March 2026 and Novo Nordisk's Emcure-partnered Poviztra in November 2025. [2,3]

## The first wave of market entry: What we are learning

### A crowded market emerged quickly

Following patent expiry, multiple Indian pharmaceutical manufacturers, including Cipla, Lupin, Dr. Reddy's and others, have launched or announced branded generic semaglutide products [2,3]. Competing versions now target both the diabetes and obesity segments. A similar pattern is emerging in China, Brazil, Canada and Turkey as their respective semaglutide patents lapse through 2026 and beyond.

### Price competition has started

Many stakeholders expected lower-priced GLP-1 therapies to drive rapid market expansion on their own. Early market dynamics suggest that affordability alone does not determine success. Patient awareness, physician confidence, long-term adherence, supply reliability and ecosystem trust also influence treatment uptake. Even with substantial reductions in therapy costs, long-term retention remains a concern in

India's predominantly self-pay healthcare system. Once US-style generic competition matures, prices for the class have historically fallen 60–90% within two to three years, a trajectory India's market is now entering.

> The first phase of competition focused on molecule availability. The next phase will focus on ecosystem differentiation.

As multiple companies launch semaglutide and other GLP-1 products, differentiation based solely on the drug molecule or price becomes increasingly difficult. Future success will depend on the strength of the overall treatment ecosystem, including device packaging, cold-chain reliability, patient support programs, digital engagement, physician confidence and supply-chain consistency. Together, these factors can influence adoption, adherence and long-term market share.

# System architecture of injectable GLP-1 delivery

At scale, injectable GLP-1 therapies need to be understood as an integrated, multilayer system rather than a standalone drug. Beyond the active ingredient, product performance also depends on the container, closure, delivery device, labeling, transport conditions and user interaction. These packaging and delivery interfaces directly affect product integrity and patient outcomes.

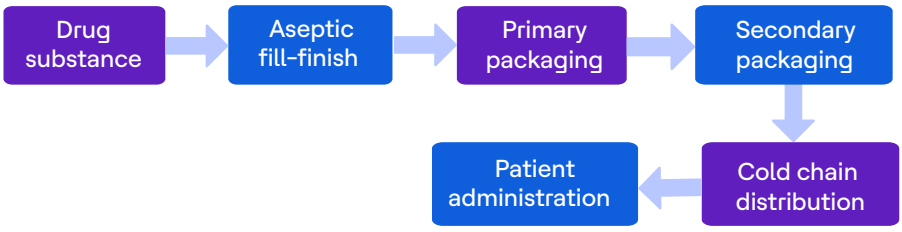


Figure 1: System architecture of the GLP-1 delivery chain, from drug substance to patient administration

Each interface in the delivery chain introduces potential risks, including product-container interactions, sterility breaches, temperature excursions and user error. As adoption of injectable GLP-1 therapies expands across India, these risks become even more consequential because delivery conditions vary widely across regions, providers and patient populations. A systems-engineering approach that integrates risk early across design, logistics and end-user use can be considered a suitable strategy help minimize downstream failures under highly variable real-world conditions.

# Primary packaging: Engineering for high-volume biologics

The transition to high-volume injectable GLP-1 delivery requires a reconfiguration of primary packaging strategies that prioritize scalability, compatibility and cost-efficiency.

## Material system selection

Type I borosilicate glass vs. polymer systems: cyclic olefin polymer (COP) and cyclic olefin copolymer (COC) present distinct trade-offs, summarized below.

| Material system | Key considerations |
|---|---|
| Type I borosilicate glass | A common industry standard with strong chemical resistance and a long history of use. However, it can carry a higher risk of delamination or breakage under certain handling and transport conditions. |
| Type I borosilicate glass | Can improve break resistance and handling safety, but require thorough evaluation of extractables and leachables (E&L), particularly for long-term stability and biologic compatibility. |

For India's scale and distribution challenges, COP and COC polymer systems may offer advantages by reducing breakage risk and improving handling safety during transport, provided E&L validation is rigorously managed.

## Closure systems

Bromobutyl vs. chlorobutyl closures: Closure selection affects moisture transmission, extractables profiles and long-term stability. For biologics distributed in hot and humid Indian conditions, the selected closure should balance permeability, compatibility and stability requirements.

## Critical engineering considerations

- E&L under real-time and accelerated conditions
- Silicone oil interactions in prefilled syringes, including protein aggregation and particulate concerns
- Container closure integrity (CCI) maintained until the point of use, with testing methods including:
  - Vacuum decay
  - High voltage leak detection (HVLD)

Combining deterministic CCI methods such as HVLD combined with real-time E&L studies can support consistent sterility assurance at scale.

# Secondary packaging: From containment to system interface

Secondary packaging is evolving into a critical interaction layer between the product and patient, particularly as self-administration increases. Human-centric packaging design, together with simplified IFUs and integrated kits can reduce user error in low-training environments and support adherence.

## System integration requirements

- Multi-component therapy kits: drug product, delivery device and ancillary components.
- Human factors engineering (HFE)-led IFU design for low-training environments, error minimization and dose accuracy.
- Labeling and traceability across multi-SKU dose configurations
- Digital traceability through QR-based serialization and authentication to help address counterfeit risk while supporting supply-chain visibility, patient adherence, usability and clinical outcomes.

# Cold chain engineering: The operational constraint

Many injectable GLP-1 therapies require strict temperature control of 2–8°C during storage and distribution, making the cold chain a critical determinant of product viability. Key challenges in India include infrastructure variability between tier-1 cities and tier 2 and tier 3 markets, last-mile delivery risks and cost constraints for thermal packaging.

## Engineering trade-offs

| Cooling solution | Trade-off summary |
|---|---|
| EPS (expanded polystyrene) | Lower cost and passive cooling, but weaker thermal reliability under extreme ambient swings. |
| VIP (vacuum insulated panel) | Superior thermal performance, but higher cost and greater fragility during handling. |
| Ice packs (passive cooling) | Cost-effective for shorter lanes but less predictable across variable transit times. |
| PCM (phase change material) | Reliable temperature control across longer, more variable routes, but higher upfront investment. |

A hybrid EPS + VIP configuration, validated through defined hold-time lane qualification and stress-tested under worst-case scenarios, can offer a practical balance between cost and thermal reliability for India's variable transit profile. Temperature excursion mitigation strategies should be built into lane qualification protocols rather than treated as a post-launch fix.

# Regulatory and compliance considerations

Scaling injectable GLP-1 delivery systems requires alignment with global and Indian regulatory frameworks, including:

- ISO 15378 — Primary packaging materials for medical products
- USP 1207 — Container closure integrity testing
- USP 661 — Requirements for COP, COC or other plastics used in contact with the drug product.
- CDSCO — Combination product classification and approval pathways in India
- ICH Stability Guidelines (Zone IVb) — High-temperature and high-humidity climate zone applicable to Indian distribution

Regulatory compliance is a design constraint that should be embedded in the system architecture from the start. Addressing requirements early in the design phase can reduce approval delays and rework costs.

# Conclusion: Packaging as healthcare infrastructure

The expansion of injectable GLP-1 therapies in India represents more than increased access. It signals a shift toward increasingly system-dependent healthcare delivery. Sustained success will depend on maintaining sterility assurance across high-volume manufacturing environments, protecting product stability across infrastructure-variable distribution networks and enabling consistent usability across diverse, self-administering patient populations.

An integrated packaging strategy that combines polymer-based primary packaging, human-centric secondary design and cost-optimized cold-chain systems offers a practical approach for India by balancing safety, scalability and affordability across a highly diverse healthcare infrastructure. Packaging is no longer just a supporting function in diabetes and obesity care in India; it is a core determinant of whether large-scale GLP-1 adoption can be sustained safely and consistently.

# What it takes to scale GLP-1 delivery

Pharmaceutical and medical device companies are competing for market share in India's fast-growing GLP-1 market. Sustainable success depends on integrating packaging engineering, device compliance, validation, human factors and supply-chain resilience into a unified development strategy. As organizations move from pilot programs to large-scale deployment, building readiness across the GLP-1 value chain will be critical to achieving sustainable growth.

| Service area | How we help |
|---|---|
| Primary packaging assessment | Material system selection across glass and COP/COC, E&L strategy design, CCI method selection and validation planning. |
| Human factors and secondary packaging | IFU simplification, kit configuration and usability testing for low-training environments. |
| Cold chain qualification | Lane qualification, thermal packaging trade-off analysis and worst-case stress testing. |
| Regulatory strategy | CDSCO combination product pathway navigation, ICH Zone IVb stability program design, multijurisdiction EPR alignment. |
| Digital traceability | QR-based serialization and anti-counterfeiting system design and rollout support. |

Successfully scaling GLP-1 therapies requires an integrated approach across these capability areas. Organizations that establish a strong foundation across packaging, regulatory compliance, usability, cold-chain management and traceability will be better positioned to enhance patient safety, strengthen regulatory readiness and improve supply-chain resilience.

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# Author information


**Dr. Rejish Ramakrishnan**


Rejish holds a Ph.D. in Packaging Technology from Anna University and brings more than 10 years of global experience in packaging R&D, regulatory compliance and sustainability. He currently serves as Technical Lead at HCLTech, where he leads packaging compliance and product stewardship for a central Extended Producer Responsibility team. He previously held a postdoctoral research scientist position at the E-YUVA Center. His expertise spans sterile barrier systems, ISO 11607, EU MDR/IVDR and multijurisdictional EPR frameworks, including PPWR.