In the News

Is there room for everyone at the GLP-1 table?
The role that generics and compound pharmacies are playing

By: Cindy H. Dubin
September 30, 2025

This has been a busy few months for all types of players in GLP-1 market. In Big Pharma, Eli Lilly announced Phase 3 results of an oral GLP-1 RA and Pfizer expands its GLP-1 portfolio by acquiring Metsera. In generics, Teva launched a generic liraglutide injection for weight loss. In the world of compounding pharmacies, Novo Nordisk ended its collaboration with Hims and Hers over "illegal mass compounding and deceptive marketing." This begs the question, what role are generics and compound pharmacies playing in the future GLP-1 space and is the $100 billion-plus market large enough for everyone?

Big Pharma expands its portfolio
Earlier this month, Eli Lilly announced detailed results from the Phase 3 ATTAIN-1 trial, evaluating the safety and efficacy of orforglipron, an investigational oral GLP-1 receptor agonist, in adults with obesity, or overweight with a weight-related medical problem and without diabetes. Orforglipron is a once-daily pill that can be taken without food and water restrictions. Lilly is evaluating the safety and efficacy of orforglipron in patients with both Type 2 diabetes as well as obesity or overweight.
“Oral formulations are generally easier to distribute and administer compared to injectable medication, especially in areas with limited cold chain and health care infrastructure,” a Lilly spokesperson tells PharmaCircle. “If approved, orforglipron may offer a convenient alternative

to injectable therapies that supports early intervention and long-term disease management, helping to meet the preference of millions who favor oral medications."

Global submissions for the treatment of obesity or overweight are planned by the end of 2025, with diabetes submissions to follow in 2026. Lilly anticipates that orforglipron could receive approval for its first indication as early as next year. As far as what the oral GLP-1 means for the future of Lilly's injectable Zepbound® (tirzepatide), which saw $5 billion in sales last year (PharmaCircle Key Product Sales), the Lilly spokesperson says: "Orforglipron and Zepbound have distinct mechanisms, formulations, and route of administration. Each may serve different patient preferences and clinical scenarios. While both target metabolic disease, tirzepatide is a GIP/GLP1 dual agonist injectable, whereas orforglipron is a selective, oral GLP1 receptor agonist. Orforglipron is intended to complement, rather than replace, Lilly's existing portfolio."
Pfizer is looking to expand its portfolio of obesity medicines with the just-announced acquisition of Metsera, a clinical-stage biopharma. Metsera has a portfolio of therapeutic candidates and combinations with four programs in clinical development and several next-generation programs with IND-enabling studies ongoing, aimed at addressing key unmet needs via fewer injections while achieving improved efficacy and tolerability. This includes MET-097i, a weekly and monthly injectable GLP-1 receptor agonist, both in Phase 2 development; MET-233i, a monthly amylin analog candidate being evaluated as monotherapy and in combination with MET-097i in Phase 1 development; two oral GLP-1 RA candidates expected to begin clinical trials imminently; and additional preclinical nutrient-stimulated hormone therapeutics.
During a September 22 analyst call, Pfizer Chief Strategy and Innovation Officer and Executive Vice President Andrew Baum said: "Differentiated science and scalable platforms with potent and durable peptides that may enable tenfold lower doses than some approved products for a very attractive cost of goods. We believe this portfolio offers the potential to reshape the treatment landscape, bring innovative products to patients and deliver attractive returns to our shareholders."
Also this month, the European Medicines Agency approved Novo Nordisk's oral semaglutide (Rybelsus®), the first to reduce cardiovascular death, heart attack, and stroke, according to the company's website. In the US, a decision is expected later this year for a label extension for the cardiovascular indication for Rybelsus. Novo Nordisk has also submitted an application in the US for a once-daily 25 mg oral formulation of semaglutide (Wegovy® in a pill) in adults living with obesity or overweight and cardiovascular disease. A decision is expected at the end of this year/early next year (Novo Nordisk).

Generics face possible delayed brand patent expirations
Brian Hart, vice president, Communications, Association for Accessible Medicines, a group that works to ensure accessibility of generics and biosimilars, tells PharmaCircle that while brand manufacturers' products are showing tremendous clinical benefit across a wide array of conditions, there may be an underlying reason for exploring these products. He says: "Brand manufacturers are investigating and seeking approval for next generation GLP-1s that differ in route of administration (e.g., pills instead of today's injectables) and exploring a range additional indications (cardiovascular, neurological, etc.) that could significantly extend the amount of time these products will enjoy monopoly pricing. And as we have seen with other brands facing the loss of exclusivity, manufacturers have enormous incentives to engage in tactics to artificially extend patent protection well beyond what policymakers intended."

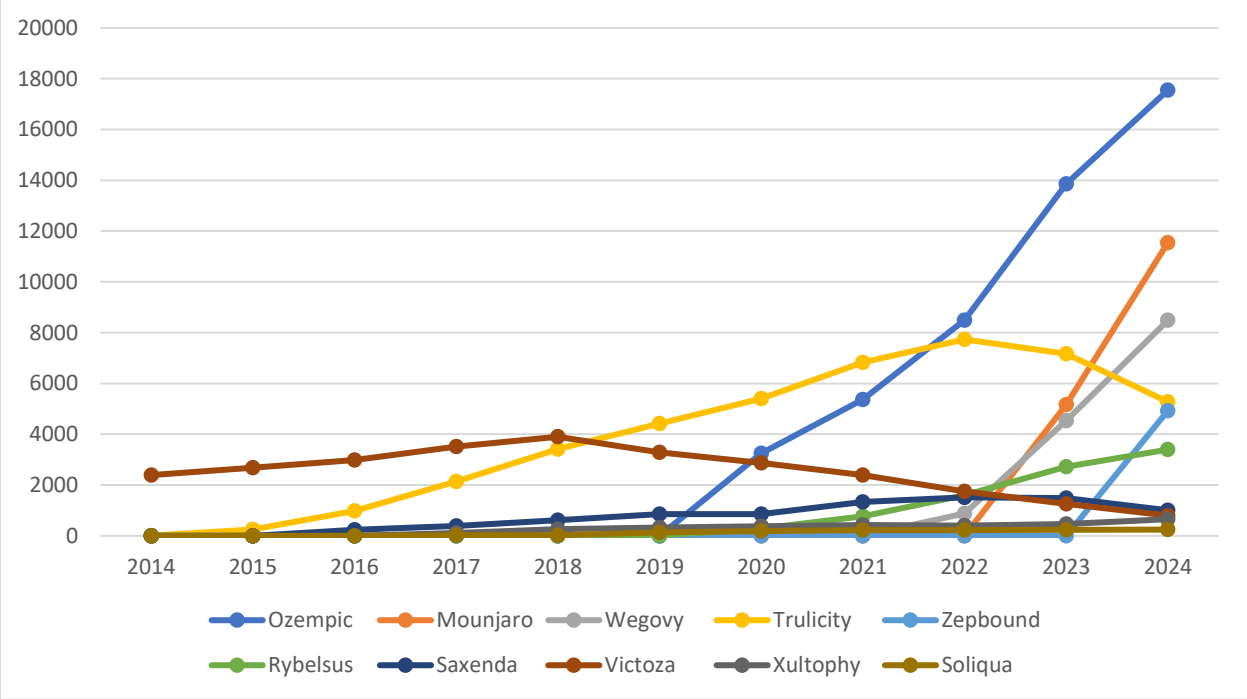
As a result, he says brand manufacturers could significantly delay generic entry and great cost and access barriers for patients. “That’s why Congress should explore solutions that remove these barriers – such as removing red tape that slows FDA approval of new generics and reforming the patent system to prevent gaming. While the FDA recently approved the first generic GLP-1 medication, patent expirations for the most popular GLP-1s are still years away – at the earliest.”

That first generic GLP-1 (Victoza) was launched by Teva Pharmaceuticals last year. Teva was also the first to launch generic Saxenda® (liraglutide injection) specifically indicated for weight loss this past July. Saxenda reached more than $1 billion in sales last year (PharmaCircle Key Product Sales). **Figure 1** shows brand name GLP-1 sales for the last decade.

Meitheal Pharmaceuticals also launched a generic liraglutide injection GLP-1 receptor agonist of Victoza earlier this year for Type 2 diabetes. According to the company, the FDA and the American Society of Health-System Pharmacists list Victoza as being in “active shortage.” Victoza realized 2024 sales of $800 million (PharmaCircle Key Product Sales). Meitheal launched the injection (18mg/3mL) in a three-pack and plans to bring additional pack sizes to market later this year.

“It is difficult to predict the role that generics will play in such a costly and dynamic class of medicines,” says Hart. “How and when brand manufacturers deploy these strategies will impact the role of generics in the GLP-1 space.”

Figure 1: Top 10 GLP-1 Drug Sales ($M), 2014-2024



Source: PharmaCircle Key Product Sales

Compounding pharmacies fill a gap

Coming under scrutiny is the role compounding pharmacies are, and will be, playing in the GLP-1 space. While patients and health care professionals may look to unapproved versions of GLP-1 drugs, including semaglutide and tirzepatide, as an option for weight loss, this can be risky as unapproved versions do not undergo FDA's review for safety, effectiveness, and quality before they are marketed (FDA).

A Brookings Institution report highlights that many compounded semaglutide products rely on synthetic API imported from facilities in China that lack FDA oversight or quality controls. Alarmingly, 60% of Chinese manufacturers importing semaglutide for use in compounding or further manufacture are not even permitted to distribute that API in China for use in human drugs. According to FDA data, all semaglutide imported into the US designated for use in compounding since June 2023 originated from suppliers in China (Brookings Institution).

In April, the FDA clarified its policies regarding compounders as national GLP-1 supply began to stabilize. Part of the FD&C Act restricts compounded drugs that are "essentially copies of commercially available drugs," but certain amounts are permissible if the compounding is not done regularly or in inordinate amounts (FDA).

Irregularities are the reason behind Novo Nordisk severing ties with Hims & Hers Health, a telehealth company that operates compounding pharmacies. In April, Novo Nordisk announced a collaboration with Hims & Hers Health to make obesity care treatments more accessible and affordable. Then – in perhaps one of the fastest partnership reversals – in June, Novo Nordisk ended the collaboration due to Hims & Hers selling illegitimate, knockoff versions of Wegovy that put patient safety at risk. Hims & Hers Health is now facing a securities class action lawsuit.

Novo Nordisk and Lilly are both pledging to root out GLP-1 imitators that defy FDA guidelines. In a statement made earlier this year, Dave Moore, executive vice president of US Operations at Novo Nordisk said: "As the FDA has warned, compounders cannot rely on mere pretextual differences between unapproved compounded drugs and FDA-approved medicines — under the guise of making 'personalized' drugs – in order to evade federal law."

Likewise, Lilly intends to monitor the situation: "There is no generic version of Mounjaro or Zepbound, Lilly's FDA-approved tirzepatide medicines, and mass compounding of tirzepatide is unlawful," says the Lilly spokesperson. "Compounded products are not FDA-approved and FDA warns they "pose a higher risk" to patients than FDA-approved medicines. We continue to find critical safety and effectiveness issues in mass compounded tirzepatide knockoffs — including bacterial contamination, high endotoxin levels, and other impurities. No one should ever be exposed to those risks, and we urge FDA and other regulators to stop unlawful compounding before more people get hurt."

PharmaCircle reached out to the Alliance for Pharmacy Compounding (APC) to respond and was directed to its website for comment (APC): "Compounding pharmacies have stepped up and provided millions of patients access to what is undeniably a wonder drug at a time when the drug makers could not meet the demand, and at a price point that the patient could afford, and with a track record of safety that is not out of sync with what we're seeing with the FDA-approved drug," says APC CEO Scott Brunner. "APC's position is that compounding should not be competition for FDA-approved drugs. It's a secondary therapy designed to fill gaps in drug supply that FDA-approved drugs can't fill."

About PharmaCircle

PharmaCircle is a thought leader in drug delivery and formulation development, publishing the *PharmaCircle Weekly Intelligence*, which has a worldwide readership, and in-depth reports in all areas of drug delivery, including new and novel technologies and devices. PharmaCircle is a leading information provider to the pharmaceutical and medical device industries, providing business prospecting and analysis tools, pipeline and products intelligence, regulatory data, and other information solutions to our clients. PharmaCircle's Premium database service delivers a comprehensive view into drug, biologics and combination product development and innovation, combining scientific, clinical, safety, regulatory, supply chain, and commercial data and insights into one solution. PharmaCircle recently launched MedTech Explorer, a hand-curated database that assembles the latest intelligence on medical devices, diagnostic tests and drug delivery device technologies in development and on the market.

For more information about the content of this analysis, contact PharmaCircle's Editorial Department at mailto:editorial@pharmacircle.com.

For more information about PharmaCircle and our subscription database services, contact mailto:info@pharmacircle.com or visit our websites – http://www.pharmacircle.com and http://www.medtechexplorer.com.

PHARMACIRCLE™

The Difference is in the Details