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NEWS LETTER
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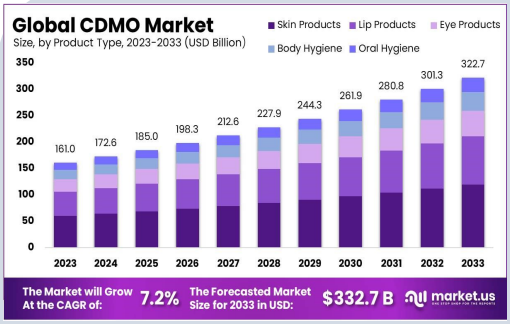
CDMOs See Increase In US Business Enquiries, Says Report



Contract development and manufacturing organisations (CDMO) are seeing a revival in funding, and an increase in business enquiries, says India Ratings and Research, of the companies it reviews.

"The green shoots are already visible, as over 60 per cent of listed pharma have witnessed an increase in the number of enquires for new businesses, and 33 per cent of them believe that the (US Biosecure Act) act, if implemented, can be a business driver," a note on the report said.

Companies have said that they were seeing a revival in funding and clients were shifting projects to India (from China), Nishith Sanghvi, Associate Director and Co-Head Pharma and Healthcare, India Ratings & Research, told businessline. In fact, this is resulting in companies investing in capacity expansions, as well, he added.

A host of Indian drugmakers are in the CDMO space, including Piramal Pharma, Suven Pharma, JB Pharma and Syngene, for example, besides other drugmakers who are not pure-play CDMOs or CROs (contract research organisations).

In fact, the report says, the proposed Act "will lead to re-orientation of supply chains, given the restriction on US federal agencies procuring equipment and services from certain "biotechnology companies of concern," primarily large Chinese pharma companies.

Consequently, the supply of numerous drugs used in clinical trials and critical raw materials is expected to be impacted, given the trade that most pharma companies have with these agencies, the report said, outlining opportunities to act as alternatives.

The report reviewed about 15 drugmakers and sees the revival in business sentiment lift CROs as well, an official said.

However, the report comes even as the USFDA recently red-flagged data integrity concerns from some CROs. It called out the falsified data and poor quality management at some of the CROS they had inspected. Industry-watchers said, such incidents were limited to specific CROs, and industry-representatives worked with multinationals with whom they had long-term partnerships.

Nevertheless, the report points out, significant capacity expansion was being undertaken by its portfolio companies in the CDMO and CRO space, given the "China+1 and onshoring initiatives being undertaken globally".

The companies reviewed also benefitted from "government grants/interest-free loans to bolster onshoring initiatives by North American governments", it added.

"CDMO players, which were impacted due to weaker capacity utilisation during FY22/FY23 owing to higher capex in the past, witnessed operating leverage benefits play out during FY24, despite debt levels remaining unchanged, leading to an improvement in their credit metrics.

While capex requirements will remain high, leverage levels will remain consistent with the revised ratings," said Vivek Jain, Director, Corporate Ratings, Ind-Ra. (Source: Business Line)

Lilly Says Weight Loss Drug Cuts Heart Failure Risk By 38% In Trial

Trial results show Eli Lilly's weight loss drug Zepbound reduces the risk of hospitalization, death and other outcomes for obese adults with a common type of heart failure, the company said on Thursday as it continues to build a case for the medication's wider health benefits.

The drug, also known as tirzepatide, reduced the risk of a composite of heart failure urgent visit or hospitalization, oral diuretic intensification or cardiovascular death by 38% compared to a placebo.

The trial enrolled 731 patients across 10 countries who have heart failure with preserved ejection fraction and obesity. The condition "accounts for nearly half of all heart failure cases, and in the U.S. almost 60% of those impacted also live with obesity," Jeff Emmick, Lilly senior vice president, product development, said in a statement.

Lilly said the study also showed the drug significantly improved heart failure symptoms and physical limitations. Heart failure is a condition in which the heart is unable to pump enough blood to meet the body's needs. It is associated with a high burden of symptoms and physical limitations affecting daily life, including fatigue, shortness of breath, reduced ability to exercise and swelling of extremities.

Trial patients on tirzepatide were given weekly injections of the highest dose they could tolerate, up to 15 milligrams, and were followed for a median of two years.

The drug led to 15.7% weight loss in the combined population of people with and without type 2 diabetes, compared with 2.2% for the placebo, Lilly said. For the non-diabetes patients, weight loss was 13.9%.

Zepbound, also sold under the brand name Mounjaro for type 2 diabetes, is part of a top-selling class of drugs designed to mimic the action of the GLP-1 hormone, which helps regulate blood sugar, slow digestion and decrease appetite.

Lilly said the most common side effects for trial patients on tirzepatide were diarrhea, nausea, constipation and vomiting. The company said it plans to submit the heart failure results to the U.S. Food and Drug Administration and other regulatory agencies starting later this year. The findings will also be presented at an upcoming medical meeting and submitted to a peer-reviewed journal. (Source: Reuters)

Mankind Pharma to Acquire 100% Stake in Biotech CVompany Bharat Serums & Vaccines

Mankind Pharma has entered into a definitive agreement to acquire Bharat Serums & Vaccines (BSV), backed by Advent International for an enterprise value of approximately Rs 13,630 crores. The company announced this in an exchange filing.

"Mankind Pharma Limited has entered into a definitive agreement to acquire a 100% stake in Bharat Serums and Vaccines Limited (BSV) from Advent International (“Advent”), one of the world’s largest and most experienced private equity investors, for an enterprise value of approximately Rs 13,630 crores, subject to closing-related adjustments. This strategic move marks a significant leap for Mankind Pharma, positioning it as a market leader in the Indian women's health and fertility drug market, while also providing access to other high-entry-barrier products in critical care with established complex R&D tech platforms," the company added.

The company stated that Swedish private equity firm EQT and the Abu Dhabi Investment Authority (ADIA) consortium are also bidders in the acquisition process of BSV, with the deal estimated to be valued between $1.5 billion and $2 billion.

Acquiring Bharat Serums & Vaccines will enhance Mankind Pharma's domestic operations by expanding its product portfolio, which includes formulations across acute and therapeutic areas. Established in 1971, the Mumbai-based BSV develops, manufactures, and markets biological, biotech, and pharmaceutical formulations. (Source: Reuters)

Dr Reddy's Signs Non-Exclusive Patent Licensing Agreement With Takeda to Commercialise Gastrointestinal Drug in India

Dr Reddy's will market Vonoprazan tablets under its own trademark VONO™ to be available in two strengths, 10mg and 20mg. Dr Reddy's Laboratories Ltd announced on Thursday that it has entered into a non-exclusive patent licensing agreement with Japan's Takeda Pharmaceutical Company Ltd (Takeda) to commercialise Vonoprazan tablets in India.

Vonoprazan is a novel, orally active potassium competitive acid blocker (PCAB), used to treat reflux esophagitis and other acid peptic disorders, it said in a statement adding that "Dr Reddy's will market Vonoprazan tablets under its own trademark VONO™ to be available in two strengths, 10mg and 20mg."

Also read: Dr Reddy's to work 'closely' with USFDA on biosimilar rituximab to launch it in US

Acid Peptic Disorders (APD), which include Gastroesophageal Reflux Disease (GERD) and Peptic Ulcer Disease (PUD), are very common in India. A pan-Indian cross-sectional survey of clinicians showed APD prevalence to be in the range of 37-39 per cent. It is more common in the 18-59 age group, with heart burn and epigastric pain as common symptoms.

MV Ramana, CEO – Branded Markets (India & Emerging Markets), Dr Reddy's, said, "The non-exclusive patent licensing agreement with Takeda is part of our continuous efforts to make innovative medicines available to patients in India through strategic collaborations to meet unmet needs and enhance standard of care."

Vonoprazan is PCAB, which suppresses the gastric acid secretion by inhibiting the proton pump potassium exchange. Compared to the traditional acid suppressing molecules , Vonoprazan has unique attributes like Complete proton pump inhibition with first dose, longer duration of action resulting in effective control of Nocturnal Acid Breakthrough and meal independent dosing, the statement said. Vonoprazan is proven to be effective and approved.

The treatment of reflux esophagitis, gastric ulcer, duodenal ulcer, prevention of reoccurrence of gastric ulcer or duodenal ulcer during low-dose aspirin administration or NSAIDs administration, as an adjunct to Helicobacter pylori eradication associated with: Gastric ulcer, duodenal ulcer, gastric MALT lymphoma, idiopathic thrombocytopenic purpura, the stomach after endoscopic resection of early stage cancer or Helicobacter Pylori gastritis. (Source: Business Line)

Novo Nordisk's Wegovy Gets UK Approval For Use To Lower Heart Risks

Novo Nordisk's weight-loss drug Wegovy secured the UK regulator's approval for its use to reduce the risk of serious heart problems or strokes in overweight and obese adults, the agency said on Tuesday. Approval from UK's Medicines and Healthcare products Regulatory Agency (MHRA) follows a similar nod from the U.S. Food and Drug Administration in March.

The MHRA's decision makes Wegovy the first GLP-1 weight-loss drug to be prescribed for prevention of cardiovascular events in people with obesity, the agency said.

"This treatment option that prevents heart disease and strokes is an important step forward in tackling the serious health consequences of obesity," Shirley Hopper, MHRA's deputy director of innovative medicines, said. More than 7.6 million people in the UK are living with cardiovascular diseases, according to the British Heart Foundation, while in England, around one in six deaths due to heart and circulatory disease are tied to a high body-mass index.

"Weight loss drugs can be key part of our arsenal to help tackle obesity and manage associated risks, but as global supply issues continue to affect these drugs, it is important that treatments are used correctly, in line with licensing, to ensure that patients with type 2 diabetes can receive the medicines they need," said Stephen Powis, NHS National Medical Director.

The agency's approval was based on a trial that showed Wegovy reduced the risk of major cardiovascular events such as heart attack and stroke by 20% compared to placebo. The study involved more than 17,600 people who were overweight or suffered from obesity, and were given either a once-weekly dose of the drug or placebo for an average of 33 months. (Source: Reuters)

Ozempic Knockoffs Flood US Market Thanks To 'Blind Spot' In FDA Rules

An obscure federal statute is allowing US pharmacies to flood the market with unvetted knockoffs of Ozempic, the pricey weight-loss drug that is reducing and transforming the weight and silhouettes of millions of Americans.

According to a Bloomberg investigation a "blind spot" in Food and Drug Administration (FDA) regulations that allows pharmacies and compounders to reproduce drugs that are in short supply has helped to create a market of unbranded weight-loss drugs worth $1bn annually.

Injectable weight-loss medications including Zepbound, Mounjaro, Wegovy and Ozempic all have been in short supply as of late, according to the FDA's drug shortage list. While they are approved for diabetes but not all formally for weight loss, an estimated 15.5 million US adults – or 6% of the population – have used them as of this past May.

Alongside the shortages, the high cost of the drugs at about $1,000 monthly is not typically covered by insurers, causing people to seek cheaper alternatives. The market for Ozempic alone was estimated at $11bn this year and projected to hit $16.5bn by 2029, according to Mordor Intelligence. The copycat drugs, according to the outlet, are less reliable than brand-name medications created by over-stretched suppliers, including makers Eli Lilly and Company and Novo Nordisk A/S.

Bloomberg reported that one consumer, Lindsay Posey, took one dose of the appetite-suppressant that worked well, a second that didn't and a third that caused her to breakout in acne on her cheeks, nose, chin and forehead. Acne is not listed as a potential side-effect of semaglutide medications, which include nausea, diarrhea, constipation, vomiting, stomach pain, headache, fatigue, dizziness, bloating, belching, gas, heartburn and runny nose or sore throat.

"My skin just went absolutely crazy," Posey said.

When her doctor suggested it might be the medication, she reflected: "That's not really something you want to hear." According to the American Pharmacists Association, "compounding is the creation of a pharmaceutical preparation – a drug – by a licensed pharmacist to meet the unique needs of an individual patient (either human or animal) when a commercially available drug does not meet those needs". That includes when "a patient may require a drug that is currently in shortage or discontinued", the pharmacists association says.

Copycat or reformulated drugs are not tracked through FDA prescriptions systems or by many state pharmacy boards. In a statement, Scott Brunner, chief executive officer of the Alliance for Pharmacy Compounding, told the Guardian: "There's no blind spot or loophole in FDA guidance that allows state-licensed compounding pharmacies to prepare copies of FDA-approved drugs when those drugs are in shortage."

He said: "It's an intentional policy designed to assure patients don't have to do without often life-saving medications when drugmakers can't manage their supply chain. Unfortunately, patients can occasionally experience an adverse event when taking a compounded medication, just as they can with FDA-approved drugs.

"We're not talking about known side effects of a drug, but serious health-threatening effects. When they do occur, they must be thoroughly investigated to determine the cause of the adverse event."

Nonetheless, a pharmacy in Louisiana produced nearly 300 vials of injectable weight-loss shots without doing proper contaminant testing. In Arizona, drugs were mixed in non-sterile conditions. Investigations are underway in Massachusetts and Mississippi.

Drugs produced by compounders have caused problems in the past. In 2012, an outbreak of fungal meningitis was traced to a pharmacy in Massachusetts that had produced injectable steroids.

More than 750 people in 20 states developed fungal infections, and more than 60 people died, according to the CDC.

The extraordinary demand for injectable weight-loss drugs is producing lawsuits. Last year, a Florida judge ruled against Eli Lilly, maker of tirzepatide, the active ingredient in Zepbound, after it tried to use state law to block reformulated versions of the drug. US federal court judge Roy Altman wrote that Lilly was trying to preempt the Federal Food, Drug and Cosmetic Act. Novo Nordisk, maker of Ozempic and Wegovy, has also challenged compounding pharmacies and wellness clinics for marketing altered versions of semaglutide.

Novo has alleged that some compounded drugs had impurities or lower concentrations of semaglutide than they should, while Lilly has said some of the knock-off products are known to have bacteria or high levels of impurities. In May, Lilly settled with Totality Medispa, which it claimed had misled consumers into believing it was selling its FDA-approved drugs. The company said it was "deeply concerned that products fraudulently claimed by compounding pharmacies or counterfeiters to be FDA-approved tirzepatide, Mounjaro or Zepbound may expose patients to serious health risks". In at least one instance, the product was nothing more than sugar alcohol. The agreement, the company said, was "an important step forward".

"This is not a problem that Lilly can solve alone," the company also said, adding that it supported "state and federal regulators taking action to deter and punish compounding pharmacies, counterfeiters and others who put patients at risk by selling unsafe products claiming to be tirzepatide". This article was amended on 23 July 2024. An earlier version said Zepbound, Mounjaro, Wegovy and Ozempic are approved for diabetes but not formally for weight loss. However, Zepbound and Wegovy are FDA approved for weight loss. (Source: The Guardian)