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NEWS LETTER
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Indian Government Likely To Float Global Tender For HPV Vaccine In April; Merck, Serum Institute May Participate

The Health Ministry intends to roll out HPV vaccine against cervical cancer in the national immunisation programme for girls aged 9 to 14 years in June for which a global tender is likely to be floated in April, official sources have said.

Serum Institute's made-in-India HPV vaccine "CERVAVAC" was launched by Union Home Minister Amit Shah on January 24, in presence of the Pune-based firm's CEO Adar Poonawalla and Prakash Kumar Singh, its Director-Government and Regulatory Affairs.

"The ministry is likely to float in April a global tender for 16.02 crore doses of HPV vaccine, which will be supplied by 2026. Apart from domestic manufacturer Serum Institute of India, global vaccine manufacturer Merck is also likely to participate in the tender," an official source said.

In July last year, India's drug regulator granted market authorization to Serum Institute of India's indigenously developed HPV vaccine. It has also been cleared by government advisory panel National Technical Advisory Group on Immunisation (NTAGI) for use in the public health programme.

Prakash Kumar Singh, on the sidelines of a South Asia meet on HPV last month, had said that the price of CERVAVAC will be affordable compared to the international HPV vaccine available in India.

Currently, India is fully dependent on foreign manufacturers for HPV vaccines. Globally, three foreign firms manufacture HPV vaccines out of which two sell their doses in India.

Each dose of the vaccine available in the market costs more than ₹4,000, sources said. In September 2022, Poonawalla had said that each dose of its "CERVAVAC" vaccine would cost ₹200 to ₹400.

India, which is home to about 16 per cent of the world's women, accounts for about a quarter of all cervical cancer incidences and nearly a third of global cervical cancer deaths.

Indian women face a 1.6 per cent lifetime cumulative risk of developing cervical cancer and a one per cent cumulative death risk from cervical cancer, according to officials.

Recent estimates state that every year almost 80,000 women develop cervical cancer and 35,000 die in India due to it. On what prevented India from introducing the HPV vaccine till now, NTAGI chief Dr NK Arora had said that the vaccine supply has been a limiting factor globally.

Fortunately, over the last five years, the global supply of the HPV vaccine has been improving gradually.

India has taken a lead in this direction. Serum Institute of India, one of the major Indian vaccine manufacturers, with support from the Centre's Department of Biotechnology has developed four valent HPV vaccine. The vaccine has received regulatory approval and cleared by NTAGI for use in public health programmes.

"We are given to understand that three other Indian vaccine manufacturers are also in various stages of developing the HPV vaccine," an official had said. (Source: Business Line)

Raise Investment in Pharma R&D, Find Cure for Substandard Drugs: Glenmark India Biz Head

Learning lessons from Covid, the pharmaceutical industry is expecting policy measures to increase investments in research and development, Glenmark Pharmaceuticals India's business head told News18.com. The company is working on two new breakthrough drug compounds – possible inhaling treatment for chronic obstructive pulmonary disorder and solid tumours – which are likely to move to the next phases this year. Alok Malik, executive vice president and business head, India formulations, told News18.com that "the industry-friendly measures will boost the on-ground execution of the government's vision of discovering India through pharma innovation."

"As one industry, we are looking forward to having policy measures for strengthening public-private partnerships even more and increased investment in pharma research and development," he said in the exclusive interaction. As the world lauded India's success in vaccinating the majority of its population in record time, the pharma sector had a major role in the nation's fight against the pandemic, he said.

Along with partnerships, Malik appreciated the government's move of tightening regulations. "It will be imperative in tackling the problem of substandard and counterfeit drugs," he added.

'2022 WAS SPECIAL'

Malik, who is an industry veteran and has worked in several healthcare companies including Abbott, Macleods, and Piramal Enterprises, believes that 2022 was indeed a "special year" for the pharmaceutical industry and also for Glenmark. "The year 2022 saw a transformational journey for the pharma industry from being a volume creator to a value provider, as the world opened up to normal functioning post the Covid-19 pandemic," he said.

Malik said that the past year saw success in public-private partnerships and collaborations between the government and the industry at large, which played an important role in strengthening the pharma sector's place in the global landscape. "India was one of the few countries globally that continued supplying affordable medicines and aid in times of crisis to more than 200 countries, living up to its reputation as the world's pharmacy," he said.

'AIM TO BE IN TOP 10'

Glenmark aims to "outperform India's pharmaceutical market" while maintaining a leadership position across its focused therapy categories of dermatology, respiratory, cardiovascular, oncology, and diabetes, Malik said. "While the year 2021 focused on Covid-19 therapies, in the year 2022 Glenmark's focus extended to other therapies including diabetes, hypertension, dermatology, auto-immune and cancer," he said. Malik said that the company aims to be in the top 10 players by revenue in the Indian pharmaceutical market in a few years while maintaining a focus on key therapeutic areas. Currently, Glenmark ranks at number 15 in terms of revenue.

The company will continue to focus on innovative product launches in India, he emphasised, while adding that it is also working towards enhancing "360-degree stakeholder management with improved doctor engagement, through Omni channel presence by virtual and in-person connect". "In addition, geographical expansion within India will provide a broader base to continue the momentum going forward. In 2022, Glenmark introduced a number of innovative and first-in-the-market products in diabetes, respiratory, and dermatology therapeutic areas," he said.

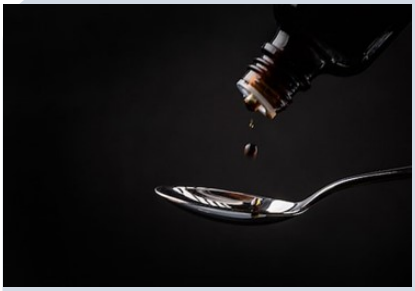
Malik added that the company has a strong legacy of bringing in effective, affordable and first-to-the-market treatment options for the unmet needs of diabetic patients in India. For instance, he said, since 2015, the company has introduced multiple first-to-the-market treatment options for uncontrolled type 2 diabetes including the latest big hit Sitagliptin and its combinations, post loss of exclusivity. Glenmark has won the 'Indian Pharma Innovation of the Year' award for the second year in a row. The award was conferred by the Department of Pharmaceuticals, Ministry of Chemicals & Fertilisers after recognising the company's multiple patents and commercialised innovations over the past three years.

'ONCOLOGY AND RESPIRATORY TOP FOCUS AREAS'

Moving forward, to strengthen innovation and advance its clinical stage pipeline, the company established the 'Global Innovative Medicines Group' last year. "This group is focused on developing a broader gambit of small molecules which are therapeutically aligned with Glenmark's portfolio," Malik said. Oncology and respiratory are the key focus therapy areas for the company when it comes to driving innovation, he said. "Our innovation pipeline has two assets in the clinics, with multiple assets in preclinical stages," he said while listing the molecules in the different stages of research and development.

For instance, he said, in the respiratory segment, "GRC 39815 (RORγt inhibitor) is a new chemical entity (NCE) being evaluated as an inhaled compound for the possible treatment of chronic obstructive pulmonary disorder (COPD). It is currently under Phase 1 clinical development in the US..."n oncology, he said, "GRC 54276 (HPK1 Inhibitor) is being developed as an orally administered treatment for patients with solid tumours." "Pre-clinical in-vitro and in-vivo profiling was completed in the first quarter of the financial year 2022," Malik said. "It received approval from the drug controller for initiation of the Phase 1 study with first patient visits being planned from the first quarter of 2023." (Source: News18)

WHO Recommends Not Using 2 Indian Cough Syrups, Issues Toxic Substance Alert After 19 Deaths in Uzbekistan



Following 19 deaths in Uzbekistan allegedly linked to two cough syrups made by the Noida-based Marion Biotech, the World Health Organisation (WHO) has reportedly recommended not using the syrups for children. According to a Reuters report, World Health Organisation's recommendations come after analysis by Uzbekistan's health ministry that showed that the syrups - Ambronol and DOK-1 Max, both contained a toxic substance - ethylene glycol.

In a medical product alert on Wednesday, the WHO said the "substandard medical products", manufactured by Marion Biotech, "are products that fail to meet quality standards or specifications and are therefore out of specification."

Additionally, the analysis suggests that the syrups were in fact administered in doses higher than the standard for children, either by their parents, who mistook it for an anti-cold remedy, or on the advice of pharmacists, reports Reuters.

According to a press release by the WHO, "Diethylene glycol and ethylene glycol are toxic to humans when consumed and can prove fatal. The substandard products referenced in this Alert are unsafe and their use, especially in children, may result in serious injury or death. Toxic effects can include abdominal pain, vomiting, diarrhoea, inability to pass urine, headache, altered mental state and acute kidney injury which may lead to death."

Uzbekistan has so far arrested four people in an investigation into the deaths of 19 children who consumed the said cough syrups, the Uzbek state security service said on Friday.

The agency also claims that Marion has not yet provided guarantees to the WHO on the safety and quality of these products. However, Marion Biotech said last month, shortly after the series of deaths, that it had halted production of the syrup.

The directive came from the health ministry that called for suspension of production at the company. Recent reports also suggest that Uttar Pradesh has suspended Marion's production license.

According to Reuters, Marion did not immediately respond to request for comment. The Uzbekistan case comes after deaths of at least 70 children in Gambia that a parliamentary committee had linked to cough and cold syrups manufactured by New Delhi-based Maiden Pharmaceuticals. The company had denied any wrongdoing and central government inspectors found no contamination in test samples. (Source: News18)

Indian Company Recalls Eye Drops Linked To Infection Death In US

An Indian company has recalled a line of eye drops from the US market after the country's health protection agency said they could be contaminated with a drug-resistant bacteria that have been linked to reports of permanent vision loss and one death from a bloodstream infection.

The US Centers for Disease Control and Prevention (CDC) is testing unopened bottles of EzriCare Artificial Tears eye drops, manufactured by Chennai-based Global Pharma Healthcare, while the US Food and Drug Administration (FDA) said it has moved to restrict imports of products made by the company.

"FDA is warning consumers and health care practitioners not to purchase and immediately stop using EzriCare Artificial Tears or Delsam Pharma's Artificial Tears due to potential bacterial contamination. Using contaminated artificial tears increases risk of eye infections that could result in blindness or death," the agency said on Thursday.

In a statement, Global Pharma Healthcare said the company "is voluntarily recalling all lots within expiry of their Artificial Tears Lubricant Eye Drops, distributed by /EzriCare, LLC- and Delsam Pharma, to the consumer level, due to possible contamination".

Doctors around the country have been alerted to an unprecedented outbreak of Pseudomonas aeruginosa, affecting at least 55 people across a dozen states, and at least one death, CBS News reported.

So far, at least five of the 11 patients who have had infections directly in their eyes have lost their vision, a CDC spokesperson was quoted as saying by the network.

Pseudomonas aeruginosa can cause infections in the blood, lungs, or wounds and the germ has been proving tougher to treat in recent times because of antibiotic resistance, Insider.com reported.

The bacterium usually spreads to people in hospitals or other healthcare settings when they're exposed to contaminated water or soil, where it typically lives, according to the CDC.

The India-made brand of eye drops are the latest pharmaceutical product from the country to land under scrutiny after dozens of deaths among children in Gambia and Uzbekistan last year linked to cough syrups. (Source:NDTV)

FDA Under Fire Over Approval Of Alzheimer's Drug Aduhelm

US drug regulators failed to follow their own guidance and practices when they approved the controversial Alzheimer's drug Aduhelm, a congressional report said on Thursday. The US food and drug administration's (FDA) process of approval, it said, had been "rife with irregularities", and the FDA's interactions with maker Biogen had been "atypical". US health agency accused of bowing to drug industry with new opioid guidance The report follows an 18-month regulatory review conducted by two House committees focused on the drug's approval, pricing and marketing.

Biogen, the report found, had set an "unjustifiably high" price by initially pricing Aduhelm at $56,000 (£46,438) a year. The pricing was established despite a lack of demonstrated clinical benefit in a broad patient population. The report said that the company's own projections showed that it expected Aduhelm to be a burden to the government's health insurer Medicare and costly to patients. After Biogen halved the cost, the federal insurer continued its coverage of the drug.

"The findings in this report raise serious concerns about FDA's lapses in protocol and Biogen's disregard of efficacy and access in the approval process for Aduhelm," the report concluded. FDA regulators approved Aduhelm in June 2021 under an accelerated process. The certification came over objections raised by a panel of outside advisers that had expressed doubts about its benefit to people suffering from Alzheimer's-related dementia. Aduhelm's authorization was based on evidence that it could reduce brain plaques – or clumps of folded amyloid proteins, considered a probable contributor to Alzheimer's – but not on proof that it slowed the progression of the disease. The report found that Biogen had wanted to introduce a "blockbuster" to "establish Aduhelm as one of the top pharmaceutical launches of all time" and was prepared to commit several billion dollars – or more than two-and-a-half times what it had spent to develop the drug – promoting it to doctors, patients, advocacy groups, insurers and policymakers.

Biogen also planned to promote the drug to racial minority communities that had been underrepresented in drug trials, according to the report. The report "documents a typical FDA review process and corporate greed that preceded FDA's controversial decision to grant accelerated approval to Aduhelm", said a statement from Democratic congressman Frank Pallone, the chairperson of the House energy and commerce committee. In a statement, the FDA said it would "fully cooperate with the committees' evaluation", and its responsibility is to frequently interact with companies to collect accurate information.

"The agency has already started implementing changes consistent with the committee's recommendations," the statement said. In a statement after the report was published, Biogen said it stood by "the integrity of the actions we have taken", adding: "Alzheimer's is a highly complex disease, and we have learned from the development and launch of Aduhelm."Recommendations in the report included that the FDA maintain documentation of its interactions with drug companies, that companies communicate safety and efficacy concerns to the FDA, and that the actual value of a drug be considered when setting prices. "The American people rely on the FDA for assurance on the safety and efficacy of the medications they take and it is incumbent upon drug companies such as Biogen to ensure that the wellbeing and safety of patients are prioritized," the report said. (Source: The Guardian)

Covid Spike In China: Pharma Firms Running 24/7 To Meet Demand For Medicines

A pharmaceutical firm in China - Youcare Pharmaceutical Group - said on Tuesday (January 10) that it is running its production line 24/7 to ensure an adequate supply of medicines as the country faces a spike in Covid infections. During a government-organised visit of journalists to Youcare's factory, the pharmaceutical's Vice General Manager Zhang Jiang said the firm has mobilised all of its staff to work overtime. "It is not only for now.

We will continue during the Lunar New Year holiday as well, we have told our staff at meetings that they won't be given time off," Jiang said on Tuesday, news agency Reuters reported on Wednesday. Jiang added that the workers will be paid three times their salary so that the firm can ensure an adequate supply of medicines. Youcare, meanwhile, also said that in the past month, it had boosted the output of anti-fever drugs five-fold to one million boxes a day. Pharmaceutical firms in China are confident of meeting the surge in demand for Covid-related medicines. Another firm, Beijing Double-Crane Pharmaceutical Company, said on Tuesday that it had ample production capacity.

"At present, we have ample production capacity, especially solid tablet production, we are producing close to one million (pill packs). At the moment, our usual production capacity is able to meet current demand. In terms of business, as a whole, we are a large, comprehensive pharmaceutical company, so we supply the whole country and we produce nearly 200 kinds of products. So, for products like this, we can fully meet demand by expanding production within a quarter," Lu Wenchao, the Director General of China Resources at Beijing Double-Crane Pharmaceutical said, Reuters reported.

The government's abrupt decision to lift strict Covid restrictions in China caused an increased spread of the virus which forced citizens to turn to the black market for antiviral medicines. Citizens have been seeking out get generic versions of medicines online made elsewhere and not approved for sale in China. To address the shortage, administrations in cities started distributing fever and cold medicines to people free of cost last month.

Despite the worsening pandemic situation, the government reopened borders and ended quarantine requirements for overseas travellers. Last Sunday (January 8), an official from the National Health Commission (NHC) said that emergency and severe Covid cases may peak in China's small and medium-sized cities, and pointed out that the country's medical services to treat the virus were facing an unprecedented challenge. (Source: Wion)