



Uttar Pradesh to Set Up Pharma Park



The Uttar Pradesh government is setting up a pharma park in Lalitpur, Bundelkhand, covering 1,472-acre across five villages, according to the Uttar Pradesh State Industrial Development Authority (UPSIDA). The plan will unfold in two phases, with an initial focus on immediate development efforts covering 300 acre of land, the UPSIDA said. The villages identified for the survey include Saidpur (426 acre), Gadolikala (249 acre), Largan (239 acre), Karounda (116 acre), and Rampur (441 acre). "The establishment of the Pharma park and the acceleration of associated projects mark a strategic move by the Uttar Pradesh government towards fostering industrial growth and economic development," said Mayur Maheshwari, Chief Executive, UPSIDA.

Surveying techniques

"The utilization of modern surveying techniques underscores a commitment to precision and efficiency in the planning and execution of these initiatives. As the survey progresses and development efforts gain momentum, the Pharma Park in Lalitpur is poised to become a key contributor to the pharmaceutical sector, offering economic opportunities and reinforcing Uttar Pradesh's position on the industrial landscape," he added. The UPSIDA has a comprehensive plan to conduct a survey, and is in the process of hiring a surveyor, the note said. "We have invited applications for the selection of a survey agency through e-tender under fixed bids process. The selected agency will complete processes soil testing, contour mapping and topographical investigation," Maheshwari added. According to a person familiar with the development, the park is expected to see an infusion of about ₹8,000 crore by the State. UPSIDA is also taking steps to expedite development projects at site-1 and site-2 in Orai, along with the Plastic City project in Dibiyapur. The plastic park, spread across 274.4 acre, encompasses industrial units, residential areas, and basic infrastructure, the note said. (Source: NDTV)

New Drug-Making Standards For Indian Pharma Firms After Overseas Deaths



New Delhi: Indian pharmaceutical companies must meet new manufacturing standards this year, according to a government notification released on Saturday, although small companies have asked for a delay, citing their debt load.

Jolted by a string of overseas deaths linked to Indian-made drugs since 2022, the Centre has stepped up scrutiny of pharmaceutical factories to clean up the image of the \$50 billion industry.

"The manufacturer must assume responsibility for the quality of the pharmaceutical products to ensure that they are fit for their intended use, comply with the requirements of the licence and do not place patients at risk due to inadequate safety, quality or efficacy," said the notification, dated Dec. 28. Companies must market a finished product only after getting "satisfactory results" on tests of the ingredients and retain a sufficient quantity of the samples of intermediate and final products to allow repeated testing or verification of a batch, it says.

The health ministry said in August that inspections of 162 drug factories since December 2022 found an "absence of testing of incoming raw materials". It said fewer than a quarter of India's 8,500 small drug factories met international drug manufacturing standards set by the World Health Organization (WHO).

The notification said those concerns must be addressed by large drug-makers within six months and small manufacturers in 12 months. Small companies had asked for the deadline to be extended, warning that investments required to meet the standards would shut down nearly half of them because they are already heavily indebted. (Source: NDTV)

Study Reveals Antibiotic Use is Not The Only Driver Of Antibiotic Resistance



Researchers from the Wellcome Sanger Institute, the University of Oslo, the University of Cambridge and collaborators have, for the first time, discovered that antibiotic use is not the only driver of superbugs. In the UK and Norway, researchers compared the impact of antibiotic use on the treatment-resistant bacteria *Escherichia coli* (*E. coli*) over the last two decades.

Antibiotic resistance occurs when strains of bacteria evolve and develop resistance to many different types of antibiotics and can cause infections.

As the most common cause of bloodstream infections globally, 40% of *E. coli* bloodstream infections are resistant to a key antibiotic used in UK hospitals to treat serious infections. The study conducted a high-resolution genetic comparison of bacteria to understand what influences.

The spread of *E. coli*, using over 700 new blood samples and nearly 5,000 previously sequenced bacterial examples. Results showed that the increase in treatment-resistant bacteria varied depending on the type of broad-spectrum antibiotic used. Specifically, the rate of resistance to a commonly used antibiotic to treat urinary tract infections caused by *E. coli* ranged from 8.4% to 92.9%, depending on the country.

Furthermore, country-wide antibiotic usage levels also influenced the rate of resistance. In the UK, non-penicillin beta-lactams were used three to five times more on average per person compared to Norway, leading to a higher incidence of multi-drug resistant infections by a certain *E. coli* strain.

With multi-resistant bacterias, survival depended on which strains of *E. coli* were in the surrounding environment, making it impossible to determine whether one type of antibiotic would have the same effect on antibiotic-resistant bacteria spread in different countries.

“Continuing to use genomics to gain a detailed understanding of the underlying drivers of bacterial success is crucial if we are to control the spread of superbugs,” explained professor Jukka Corander, senior author, Wellcome Sanger Institute and University of Oslo. (Source: Pharma Times)

Record budget For Gates Foundation as Wider Global Health Funding Stalls



The Bill & Melinda Gates Foundation plans to spend more this year than ever before -- \$8.6 billion -- as wider health funding for the lowest income countries stutters after the COVID-19 pandemic.

The 2024 budget agreed by the foundation’s board is up 4% on last year and \$2 billion more than in 2021.

In a statement, the foundation said global health budgets were in decline overall and contributions to health in the lowest-income countries were stalling.

The Gates Foundation is already a key global health funder and has faced criticism over its undue influence, but last year chief executive Mark Suzman said it could not back away until others stepped up, with plans to spend \$9 billion annually by 2026.

“We can’t talk about the future of humanity without talking about the future of health,” said Bill Gates, the technology billionaire who founded the foundation in 2000 with his then-wife Melinda, who still works with him on it.

The Gates Foundation has long focused on innovation in healthcare, and the new funding aims in part to open up access to more new technologies for the world’s most vulnerable people.

After a pivot to COVID during the pandemic emergency, 2024 will see a return to the foundation’s long-established priority areas of tackling wider infectious disease threats and the leading causes of child mortality. Gates said mothers and babies dying simply because of where they live “keeps me up at night”.

He and other Gates executives plan to carry backpacks at the World Economic Forum event in Davos, Switzerland, which starts on Monday, showcasing simple health products that could save millions of lives, from vaccine patches to an artificial intelligence (AI)-enabled ultrasound tool. Gates will also talk about the potential for AI in health more broadly at the event. (Source: Reuters)

NHS Medicines Shortage Putting Lives At Risk, Pharmacists Warn



An unprecedented medicines shortage in the NHS is endangering lives, pharmacists have said, as unpublished figures reveal that the number of products in short supply has doubled in two years. A treatment for controlling epileptic seizures was the latest to be added on Wednesday to a UK drugs shortage list that includes treatments for conditions ranging from cancer to schizophrenia and type 2 diabetes. Causes of the crisis are thought to include the plummeting purchasing value of the pound since the Brexit referendum, which reduces the NHS's ability to source medicines abroad, and a government policy of taxing manufacturers. According to the British Generic Manufacturers Association, there were 111 drugs on a shortages list on 30 October last year and 96 on 18 December, with supply notifications issued for a further 10 treatments to NHS providers in the UK since then.

Its analysis suggests a 100% increase in shortages compared with January 2022, with pharmacists and health charities claiming the conditions of some patients were deteriorating as a result. Delyth Morgan, the chief executive of Breast Cancer Now, said her organisation had been contacted over the past 12 months by several patients unable to source the medicines they needed to control the spread of their disease. She said: "Last year many people shared with us, via Breast Cancer Now's helpline, that they'd been facing difficulties accessing their hormone treatment including letrozole, anastrozole and tamoxifen, causing them huge worry and anxiety. Trying to track down a treatment by travelling to a number of different pharmacies is an added burden for patients at an already difficult time.

"It may also sometimes be that certain brands of drugs are out of stock and people may have to switch to another brand or different drug. In the worst case someone may have a period of time without the medication, a drug which could help reduce the risk of their breast cancer coming back or spreading." Douglas Twenefour, the head of care at Diabetes UK, said: "The ongoing shortages of many GLP-1 medications are having serious implications for many people with type 2 diabetes and are still a major concern. With these shortages likely to last for at least the rest of this year, this will have a significant impact on whether many people with type 2 diabetes can access the best course of treatment for them." The war in Ukraine and problems in global supply chains have generally affected many European countries' drugs supply, with concerns being raised about fresh market instability in light of the violence in the Red Sea, a key shipping corridor for vital ingredients. The EU, of which the UK is no longer a member, recently agreed to create a stockpile for key drugs and to invest in increased domestic production.

There have been well-documented shortages in hormone replacement therapy and attention deficit hyperactivity disorder products due, in part, to higher demand. Janet Morrison, the chief executive of Community Pharmacy England, said the shortages were unprecedented and were beginning to hit patients hard. "Pharmacy teams have been struggling to get hold of prescription medicines for many months but the problem is now worse than ever," she said. "It has become worryingly normal to see hundreds of medicines affected by pricing and other issues every month, with problems now a daily occurrence for pharmacies. Pharmacies are having to spend hours – on average an extra 11 hours a week – tracking down the medicines their patients need. "This all causes worrying delays for patients, and in worst cases it can lead to a deterioration of their health: last year we surveyed people working in pharmacies and 87% told us that their patients' health was being put at risk due to medicine supply issues. This is shocking, and government and the NHS must step in to resolve these issues." The NHS is increasingly having to issue price concessions on products under which it agrees to increase its level of reimbursement to pharmacists due to spikes in demand and market prices.

There were 152 such concessions in December 2023 compared with 20 in June 2016, the month of the Brexit referendum, when the UK's stated intention to leave the EU hit the value of sterling. There are also concerns that a government policy to limit NHS spending on branded drugs is having an effect on the pharmaceutical industry's willingness to invest in supplying the UK. There is a cap on the total allowed sales value of branded medicines to the NHS each year, which grows at an agreed rate of 2% per annum. Any medicine sales above the cap are paid back to the government via a levy charged on companies' sales revenues. A scheme with a 4% cap has been introduced for the next five years after consultations with the pharmaceutical industry.

Morrison said the government was underinvesting in drug supply. She said: "Price concessions are a sign that companies won't, or can't, supply a type of medicine at the price that officials previously thought would be enough. Although they show that the system is responding, they are a symptom of the squeeze that brings disruptions and shortages." Mark Dayan, the Brexit programme lead at the Nuffield Trust, said there was evidence of a drop-off in medical imports from the EU since Brexit that suggested companies had responded by changing their supply chains, potentially leaving the UK more exposed to supply issues. He said: "For the UK, this situation has been exacerbated by pressures on drug prices from 2016, probably associated with the Brexit referendum pulling down the value of sterling. "A payment mechanism to claw money back from companies when sales rose too high saved the NHS money, but it reduced the incentive to sell branded products here. "In the last two years, being outside the single market has added costs at the border with the EU, resulting in a drop in products passing into this country." A DHSC spokesperson said they did not recognise the figures provided by the British Generic Manufacturers Association.

He said: "There are a number of reasons that a limited number of medicines may be unavailable, such as manufacturing difficulties, supply of raw materials, sudden demand spikes or issues with distribution. "The department has well-established procedures to deal with such issues and works closely with industry, the NHS and others to prevent shortages, and resolve any problems as soon as they arise. "This includes working closely with the NHS so they can put suggested plans in place to mitigate the risk of the shortage impacting patients." (Source: The Guardian)

FDA Finds No Evidence That Ozempic, Similar Drugs Cause Suicidal Thoughts in Preliminary Evaluation



The US Food and Drug Administration said that a preliminary evaluation of reports of suicidal thoughts or actions among people taking drugs like Ozempic and Wegovy for type 2 diabetes and weight loss has not found evidence that the drugs cause those effects.

The agency said in a statement that it conducted “detailed reviews” over the last several months of reports received in its FDA Adverse Event Reporting System, or FAERS. It noted that because “the information was often limited and because these events can be influenced by other factors, we determined that the information in these reports did not demonstrate a clear relationship with the use of GLP-1 (receptor agonists).”

GLP-1 receptor agonists are the class of drugs that includes Ozempic and Wegovy, as well as Mounjaro and Zepbound. The FDA also said it reviewed clinical trial results and didn’t find an association. But it noted it couldn’t rule out a “small risk,” since there were so few people who experienced suicidal thoughts or actions in the studies — in both the groups on the medicines and those on placebo — so it said it’s continuing to investigate the issue.

Patients should not stop taking GLP-1 drugs without consulting with their health-care providers, and should tell them if they experience depression, suicidal thoughts or any unusual changes in mood or behavior, the FDA said.

The agency said last week that it was reviewing reports of people experiencing suicidal thoughts while taking GLP-1 drugs, and evaluating the need for regulatory action. In the same report, the agency said it was also looking into cases of aspiration and alopecia, or hair loss, among people on the medicines.

The FDA’s review came as European regulators are also looking into a potential link between the medicines and suicidal thoughts. The European Medicines Agency opened an investigation in July after it received about 150 reports of possible cases of self-injury and suicidal thoughts among people taking GLP-1 receptor agonists. The medicines work by mimicking a hormone, GLP-1, that affects insulin secretion, feelings of fullness and appetite. Researchers have noted that GLP-1 also has an effect on the brain.

The European review is ongoing; the agency said in December that its Pharmacovigilance Risk Assessment Committee was seeking more information from the drugs’ makers, and that “while at this point no conclusion can be drawn on a causal association, there are several issues that still need to be clarified.”

Late last week, a large review of electronic health records from the US found that GLP-1 drugs actually carried a lower risk of patients having suicidal thoughts compared with other medicines that work in different ways for diabetes and weight loss.

Dr. Rong Xu of Case Western Reserve University School of Medicine, who helped run the study, told CNN the reports US and European regulators were looking into “are case reports ... to derive a conclusion, you really need to perform a head-to-head comparison between similar patients.”

The FDA said Thursday that it would also use a “meta-analysis” of data from clinical trials and real-world use, through health insurance claims and patient health records, of all GLP-1 drugs to continue to evaluate their safety. It said it would share “final conclusions and recommendations” after it finishes the review or has more information.

The agency noted the prescribing information for GLP-1 drugs approved for weight loss includes warnings about the risk for suicidal thoughts and actions. It said that’s based on reports of those events “observed with a variety of older medicines used or tested for weight loss.” The agency said health-care professionals should still monitor patients for suicidal thoughts, signs of depression or any unusual mood changes. (Source: CNN)