



US Pharmacies Reportedly Set Purchase Limit on Emergency Contraception Pills



Pharmacy companies such as Walmart, CVS and Rite Aid are reportedly putting a cap on the number of morning-after birth control pills each consumer can buy in the US, in the wake of the supreme court's decision overturning Roe v Wade. Meanwhile, online retailer Amazon has placed a temporary limit of three units a week on emergency contraception pills, the company said. Walmart put a cap of four or six units of their morning-after pills for orders scheduled for delivery through the end of the month, but no such caps exist for deliveries beginning in July.

A Walmart representative said, "during times of fluctuating demand" their limits for online purchases change. They added that there is an online limit the store has to prevent people from stockpiling and re-selling their products for a higher price. No such limit exists in stores, but store managers can make that decision to ensure availability of the products. Rite Aid has also said they are putting a limit of three per customer for the two brands Plan B and Option 2. CVS said it had implemented a temporary purchase limit of three on emergency contraception pills Plan B and Aftera. "Immediately following the supreme court decision, we saw a sharp increase in the sale of emergency contraceptives and implemented a temporary purchase limit to ensure equitable access," said Matt Blanchette, CVS spokesperson. He said the company is in the process of removing the limits as sales have "since returned to normal". He added: "We continue to have ample supply of emergency contraceptives to meet customer needs."

Meanwhile, Walgreens said in a statement that the company does not have any such limits. "Walgreens is still able to meet demand in-store, including leveraging digital-first solutions like curbside pickup. At this time, we are working to restock online inventory for ship-to-home," the statement said. But many in the US are stockpiling. Soon after the leak that tipped off advocates and healthcare providers that Roe would be overturned, Bedatri D Choudhury, a culture journalist in New York, decided to stock up on morning-after pills.

The service she uses for her birth control recently offered her emergency morning-after pills at no additional cost. Even though Choudhury is on birth control, she thought, "Why not, even if I don't need it, someone else might." For her, it was about her community of freelancers, immigrants, those without insurance – a group she herself had been a part of. "I have been there – paying for birth control and I know they'd rather pay rent than put money into buying birth control pills," she said. "I get it, I did it too, before I had insurance." Now her friends have been instructed to inform anyone in need that she has spare packs. Choudhury's worries echo what many advocates have been saying about who the ban will hurt most: people of color, the poor, and immigrants. Concerns like Choudhury's are not uncommon, especially given that Justice Clarence Thomas' opinion on Friday urged the supreme court to "reconsider" past rulings legalizing same-sex marriage and contraception. "To ensure equitable access and consistent supply on store shelves, we've implemented a temporary purchase limit of three on these products", a CVS Health employee told NBC News, while noting they had "ample supply" of morning-after emergency medication. Since the ruling, experts have warned that restrictions over contraceptives access could be next. Wendy Parmet, director of the Center for Health Policy and Law at Northeastern University, told NBC that states that are trying to ban abortion from the moment of conception could try to challenge Plan B, emergency contraception and even IUDs.

The end of the right to abortion in the United States will have devastating consequences around the world. A half century ago, the Supreme Court's landmark Roe v Wade decision inspired a new era of reproductive freedom in dozens of countries. The court's reversal will empower anti-abortion voices everywhere, threatening reproductive freedom and the right to control one's destiny. The Guardian views reproductive choice as a fundamental human right and will pursue this story even after it recedes from headlines, with a focus on the people most impacted by restrictions. But we need your help to do this work. Unlike many others, the Guardian has no shareholders and no billionaire owner. Just the determination and passion to deliver high-impact global reporting, always free from commercial or political influence. Reporting like this is vital for democracy, for fairness and to demand better from the powerful. And we provide all this for free, for everyone to read. We do this because we believe in information equality. Greater numbers of people can keep track of the events shaping our world, understand their impact on people and communities, and become inspired to take meaningful action. Millions can benefit from open access to quality, truthful news, regardless of their ability to pay for it. (Source: The Guardian)

U.S. FDA Authorizes Novavax COVID Vaccine for Adults

NOVAVAX



The U.S. Food and Drug Administration authorized the use of Novavax Inc's (NVAX.O) COVID-19 vaccine on Wednesday, clearing the way for a shot whose more traditional technology has raised hopes of wider acceptance among vaccine skeptics. Shares of Novavax rose 1.3% to \$70.89 after its two-dose vaccine became the fourth COVID shot to be authorized for use in adults in the United States.

The U.S. Centers for Disease Control and Prevention (CDC) still needs to sign off on the use of the vaccine before it can be made available to people. A panel of CDC advisers on vaccines is expected to meet on Tuesday, but the agenda has not been released yet.

Earlier this week, the U.S. government said it had secured 3.2 million Novavax vaccine doses, which it plans to release once the company finishes quality testing in the next few weeks. More than two-thirds of the U.S. population has been fully vaccinated with shots from Moderna Inc (MRNA.O), Pfizer-BioNTech, or Johnson & Johnson (JNJ.N).

U.S. Health officials hope that people who have opted not to take Pfizer and Moderna's vaccine, which are based on the groundbreaking messenger RNA (mRNA) technology, will instead opt for Novavax's protein-based shot.

The vaccine, already approved in Europe, is based on a technology that has been used for decades to combat diseases including hepatitis B and influenza. "Today's authorization offers adults in the United States who have not yet received a COVID-19 vaccine another option that meets the FDA's rigorous standards," FDA Commissioner Robert Califf said in a statement.

In Europe, however, demand for the shot has not been significantly high, with about 242,000 doses of the vaccine administered since its launch in December, prompting Novavax to increase its focus on lower-income countries.

The company's initial application for U.S. authorization of the shot was delayed by almost a year on development and production problems, making it a late entrant in the country's market for COVID vaccines.

Novavax has projected between \$4 billion and \$5 billion in sales this year. Analysts expect sales at the lower end of that range, according to Refinitiv. (Source: Reuters)

Florida Fish Are On An Alarming Number of Prescription Drugs, Scientists Discover



Seventeen different prescription drugs were discovered in a single fish in Florida during research into pharmaceutical contamination of marine species. The findings came out of a three-year study of bonefish in Biscayne Bay and the Florida Keys by Florida International University (FIU) and the Bonefish & Tarpon Trust (BTT). Researchers examined the blood and other tissues of 93 bonefish which typically swim in shallow, tropical coastal and island waters.

They found an average of seven pharmaceuticals per bonefish, and 17 pharmaceuticals in a single fish. The list of drugs includes blood pressure medications, antidepressants, prostate treatment medications, antibiotics, and pain relievers. Medications were also found in the species that bonefish prey upon including crabs, shrimp and other fish, suggesting that more Florida marine species are exposed. The pharmaceuticals end up in the ocean from human wastewater with contaminants insufficiently captured by water treatment plants.

Even at low doses, exposure to pharma drugs can impact fish behavior and be detrimental to their reproduction, migration and survival. Lead researcher Jennifer Rehage, a coastal and fish ecologist and associate professor at the FIU Institute of Environment, called the findings "truly alarming".

Pharmaceuticals are an invisible threat, unlike algal blooms or turbid waters. Yet these results tell us that they are a formidable threat to our fisheries, and highlight the pressing need to address our longstanding wastewater infrastructure issues," Prof Rehage said in a statement.

The researchers noted that while five billion prescriptions are filled each year in the US, there are no environmental regulations for disposal of these drugs worldwide. And it isn't only Florida fish that are being impacted by drugs. A study, published earlier this year in the academic journal *PNAS*, found pharmaceuticals present at over 25 per cent of testing sites along 258 rivers around the world, including the Amazon and the Thames.

A quarter of the sites had contaminants including the antibiotics, sulfamethoxazole and ciprofloxacin, and the allergy medicine loratadine. Some of the active pharmaceutical ingredients most frequently detected at sites included the diabetes drug metformin, epilepsy medicine Carbamazepine, and caffeine. (Source: Independent)

Who Can Take India's Upcoming Cervical Cancer Vaccine, At What Gap And At What Expected Price:



For the first time, India is going to have its own vaccine to prevent cervical cancer which ranks as the second most frequent cancer among women in the country. The announcement came on Tuesday evening when the chief of India's largest vaccine manufacturing company, SII's Adar Poonawalla, said the vaccine is going to be "both" – accessible and affordable. Reacting to the tweet, Soumya Swaminathan, chief scientist at the World Health Organization, wrote that it was "good news". Serum Institute of India's (SII) Cervavac — a quadrivalent human papillomavirus (qHPV) vaccine — is expected to cost low and, hence, will be more affordable for Indian households as the available options manufactured by foreign drug makers are much more expensive.

The cost of HPV's regimen is expected to come down to at least half as India's very own vaccine product gears up to enter the market," said a government official privy to the development and approval of the vaccine. "The product was expected to hit the shelves by November, this year. However, as per our latest discussions, it seems that maybe by September it can be rolled out." Experts told News18.com that presently a person is required to spend at least Rs 5,000 to Rs 8,000 for the complete regimen of HPV vaccines approved in India.

There are two options available: Merck Sharp and Dohme's Gardasil (qHPV vaccine) and GSK's Cervarix (bivalent HPV vaccine). Gardasil costs Rs 3,927 and Cervarix Rs 2,640 for one vial. The injection has to be given in two or three doses several months apart. If the dose regimen is not completed, a person will not be fully protected against HPV.

DEVELOPMENT OF INDIA'S OWN HPV VACCINE

Human papillomavirus (HPV) infection is now a well-established cause of cervical cancer and HPV types 16 and 18 are the most frequent and responsible for about 70% of all cervical cancer cases worldwide.

Cervavac is an indigenously developed quadrivalent prophylactic (preventive) HPV vaccine indicated in girls and boys 9 to 26 years of age. It's a VLP (virus-like particles) based vaccine, similar to the hepatitis B vaccine, and provides protection by generating antibodies against the HPV virus L1 protein. In India, SII's vaccine trials were started in 2019 and more than 2,000 participants in the age group of 9-26 years were included in these tests across 12 sites, including the All India Institute of Medical Sciences, New Delhi, Christian Medical College, Vellore, and Tata Memorial Hospital and Cancer Research Institute in Maharashtra.

"Phase III results show a robust immune response in 100% of the vaccine recipients with excellent safety records," the official quoted above said. SII conducted a phase II/III multi-centric study with a two-dose schedule (0 and 6 months) for cohort 1 (aged 9-14 years) and a three-dose schedule (0, 2, and 6 months) for cohort 2 (aged 15-26 years) having three treatment arms in each cohort. A total of 600 subjects were enrolled, such that 200 girls or women were enrolled in a randomised and blinded manner in a 1:1 ratio to either SII's qHPV vaccine or MSD's Gardasil vaccine and 100 boys/men were enrolled in a non-randomised and unblinded manner into each age cohort to receive SII's qHPV vaccine.

Analysis of the reactogenicity and safety data of all 600 subjects was collected at seven months whereas long-term follow-up data was obtained till 36 months.

Cervical cancer in india About 5% of women in the general population are estimated to harbour cervical HPV infection at a given time, and 83.2% of invasive cervical cancers are attributed to HPVs (16 or 18). According to data by WHO, fewer than 1 in 10 women have been screened for cervical cancer in the last 5 years. In 2019, more than 45,000 women died due to this form of cancer. The data also shows that the age-standardised cervical cancer incidence per 100 000 women stood at 18 years in 2020 whereas crude cervical cancer incidence per 100,000 women stood at 18.7. According to the WHO's cervical cancer elimination strategy targets for 2030, 90% of girls should be fully immunised with the HPV vaccine by the age of 15.

Also, 70% of women should be screened with a high-performance test by 35 years of age and again by 45 years of age. It also states that 90% of women identified with the cervical disease receive treatment. The data also shows that India lacks the infrastructure to handle such patients. For instance, it shows that in 2019, radiation oncologists per 10,000 cancer patients stood at only 3. "The new vaccine by an Indian manufacturer will go a long way in bringing down the cervical cancer burden in India," said Dr Shweta Goswami, gynaecologist and director of IVF chain Zeeva Fertility. "Because it is affordable, it will increase the coverage and it is very much likely that the vaccine will be included in the national immunisation programme."

However, experts pointed out that it is extremely important to create awareness about this vaccine among young girls and their parents so that girls in their teens can be vaccinated, which would prevent them from cervical cancer at a later stage. "Cervical cancer is a preventable cancer and 99.99% related to HPV infection. This vaccine is very effective and would prevent a large number of females from cervical cancer," said Dr Goswami. (Source: News18)

New Covid Sub-Variant BA 2.75 Detected In India, Says WHO



United Nations: A new sub-lineage BA.2.75 of the Omicron variant of the coronavirus has been detected in countries like India and the World Health Organisation is following this, Director-General Tedros Adhanom Ghebreyesus said.

"On COVID-19, globally reported cases have increased nearly 30 per cent over the past two weeks. Four out of six of the WHO sub-regions saw cases increase in the last week," Mr Ghebreyesus said at a press briefing on Wednesday.

"In Europe and America, BA.4 and BA.5 are driving waves. In countries like India a new sub-lineage of BA.2.75 has also been detected, which we're following," he said. On the emergence of the potential Omicron sub-variant BA.2.75, WHO Chief Scientist Soumya Swaminathan said in a video posted on Twitter that there has been an emergence of a sub-variant that is being called the BA.2.75 "first reported from India and then from about 10 other countries."

She said there are still limited sequences available of the sub-variant to analyse, "but this sub-variant seems to have a few mutations on the receptor-binding domain of the spike protein. So obviously, that's a key part of the virus that attaches itself to the human receptor. So we have to watch that. It's still too early to know if this sub-variant has properties of additional immune evasion or indeed of being more clinically severe. We don't know that." "So we have to wait and see," she said, adding that WHO is tracking it and the WHO Technical Advisory Group on SARS-CoV-2 Virus Evolution (TAG-VE) is constantly looking at the data from around the world.

"And at any time if there is an emergence of a virus that looks very different from a previous one, enough to be called a separate variant of concern, then the committee will do that." The WHO weekly epidemiological update on COVID-19, released July 6, said that globally, the number of new weekly cases increased for the fourth consecutive week after a declining trend since the last peak in March 2022.

During the week of June 27 to July 3, over 4.6 million cases were reported, a figure similar to that of the previous week. The number of new weekly deaths declined by 12% as compared to the previous week, with over 8100 fatalities reported. As of July 3, 2022, over 546 million confirmed COVID19 cases and over 6.3 million deaths had been reported globally. The COVID update said that among Omicron lineages, the proportions of BA.5 and BA.4 continue to increase. BA.5 has been detected in 83 countries. Although BA.4, which has been detected in 73 countries, is also rising globally, the rate of increase is not as high as that of BA.5.

The South-East Asia Region has been reporting an increasing trend in cases since early June, with over 157,000 new cases reported, a 20% increase as compared to the previous week. Five of 10 countries (50 per cent) for which data are available showed increases in the number of new cases of 20% or greater, with the greatest proportional increases observed in Bhutan, Nepal and Bangladesh.

The highest numbers of new cases were reported from India (112,456 new cases, an increase of 21 per cent), Thailand (15,950, an increase of 6 per cent) and Bangladesh (13,516 new cases, a 53 per cent increase). The number of new weekly deaths in the region increased by 16 per cent as compared to the previous week, with over 350 new deaths reported. The highest numbers of new deaths were reported from India (200 new deaths, a 39 per cent increase), Thailand (108 new deaths, a decline of 14 per cent), and Indonesia (32 new deaths, an increase of 7 per cent). WHO Incident Manager COVID-19 Abdi Mahamud said that now is not the time to declare that the pandemic is over.

"We're still in the midst of the pandemic and the virus has a lot of force left. So whether it is the BA.4 or BA.5 or BA.2.75, the virus will continue. It does what it does good," he said adding that people and communities must continue to wear masks, avoid crowds and ensure that the most vulnerable and high-risk population is protected. Mr Ghebreyesus said compounding the COVID-19 challenge are a number of factors, including that testing has reduced dramatically in many countries. "This obscures the true picture of an evolving virus and the real burden of COVID-19 disease globally. It also means that treatments are not given early enough to prevent serious illness and/or death."

He said secondly, new treatments, especially promising new oral antivirals, are still not reaching low- and low-middle income countries, depriving whole populations that need them. Further, as the virus evolves, vaccine protection – while still really effective at preventing serious disease and death – does wane.

"Decreasing immunity underscores the importance of boosters, especially for the most at-risk," the WHO chief said adding that each wave of the virus leaves more people with the long-COVID or post-COVID condition." "This obviously impacts individuals and their families but it also puts an extra burden on health systems, the wider economy and society-at-large. These challenges require action at a global, national and local level," he said. (Source: NDTV)