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NEWS LETTER
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U.S. FDA Green Lights Omicron-Targeted COVID Boosters Ahead of Revaccination

The U.S. Food and Drug Administration authorized updated COVID-19 booster shots from Pfizer (PFE.N)/BioNTech (22UAy.DE) and Moderna that target the dominant BA.4 and BA.5 Omicron subvariants, as the government prepares for a broad fall vaccination campaign that could begin within days. The new vaccines also include the original version of the virus targeted by all the previous COVID shots.

The FDA authorized the shots for everyone ages 12 and older who has had a primary vaccination series and is at least two months out from a previous booster shot, shorter than prior recommended intervals.

Dr. Peter Marks, a senior FDA official overseeing vaccines, said he hopes the shots will restore the very good protection against symptomatic disease that the original vaccines offered when launched in late 2020 and early 2021. "We don't know for a fact yet whether we will get to that same level, but that is the goal here," Marks said. The government has begun working on the fall rollout, which could start soon after the U.S. Centers for Disease Control and Prevention's (CDC) outside expert panel meets on Thursday and agency Director Rochelle Walensky makes a final recommendation.

The United States has secured more than 170 million doses of the two shots in an attempt to stave off the worst effects of a potential surge in infections as schools reconvene and people spend more time indoors due to colder weather. This could be the last COVID vaccine provided for free to all Americans as the government plans to shift them to the commercial insurance market next year.

Moderna's retooled vaccine was authorized for those aged 18 and above, while the Pfizer/BioNTech shot will be available for those aged 12 and above, the FDA said. Pfizer said it has some doses ready to ship immediately and can deliver up to 15 million doses by Sept 9. Moderna said it expects its new shot to be available "in the coming days." Experts have said that the updated vaccines will be important for older people and the immunocompromised, but noted there is limited data to support the level of protection the government is hoping for.

"For people who haven't been infected whose last dose was a year ago, yes, it's going to benefit them. How much, I can't tell you," said Dr. Gregory Poland, a vaccine expert at the Mayo Clinic. He said the new shots are unlikely to help those who have been recently infected. The revaccination campaign this fall is expected to target many more people than the previous boosters authorized by the FDA earlier this year. Concerns about long COVID was one reason younger and healthier Americans should get the shot, officials said.

"If anything is going to prevent transmission and long COVID, it's going to be a variant specific vaccine for the variant that's currently circulating," FDA Commissioner Robert Califf said.

DIFFERENT VACCINES IN OTHER COUNTRIES

About 50% of those in the United States over the age of 12 - some 107 million people - have received at least one COVID-19 booster dose so far. Some scientists were critical of the recommendation that would allow for a new booster just two months after a prior shot, saying a longer gap would improve immune responses. FDA officials said the vast majority of Americans are significantly more than two months out from their most recent shot.

Other countries including Canada and the UK also have ordered updated Omicron vaccine boosters for fall campaigns, although some have purchased shots tailored to the BA.1 Omicron subvariant that caused the record surge in COVID cases last winter. The FDA in June asked vaccine makers to tailor shots to the BA.4/BA.5 subvariants of the virus responsible for the most recent surge in infections worldwide. The BA.5 subvariant accounts for more than 88% of U.S. infections.

The vaccine makers have not completed testing of the updated BA.4/BA.5-based boosters in humans. The FDA is basing its decision on safety and effectiveness data from the original shots as well as from clinical trials conducted on boosters using the BA.1 Omicron subvariant. (Source: Reuters)

Pharma Industry Expects to Report 7-9 Percent Revenue Growth in FY23

The CRISIL estimates are based on a study of 184 drug makers accounting for 55 per cent of the 3.4 lakh crore-a-year sector revenue Domestic pharma industry is expected to report moderate revenue growth of 7-9 per cent.

The current fiscal, due to headwinds in export sales in the regulated markets and high-base effect in the domestic formulations business, as per rating agency CRISIL.

The operating profitability will shrink another 200-250 basis points (bps) after the 130 bps decline last fiscal due to continued pricing pressure in the US generics market.

The high input and freight costs which offset moderate revenue growth, it said. The rating agency's estimates are based on a study of 184 drug makers that account for 55 per cent of the 3.4 lakh crore-a-year sector revenue.

CRISIL stated that the domestic formulations market is expected to grow 7-9 per cent this fiscal, on a 15 per cent growth last fiscal, led by a 6-8 per cent average price increase allowed by the National Pharmaceutical Pricing Authority in March 2022 and on the back of new product launches.

While the demand for Covid-19 induced drugs and vitamins is fading, a pickup in lifestyle-related chronic portfolio drugs and a few acute portfolio drugs, such as in the dermatology and ophthalmology segments.

The likely to drive demand this fiscal, it added. CRISIL Research Director Aniket Dani said the growth in the US generics market will moderate given continued pricing pressure.

"The rupee's depreciation saves some blushes, though. Exports to other regulated markets could grow faster as global companies diversify geographically," he added. (Source: Business Line)

New York to Ramp Up Polio Vaccinations After Virus Found In Wastewater

New York Governor Kathy Hochul declared a disaster emergency on Friday in a bid to accelerate efforts to vaccinate residents against polio after the virus was detected in wastewater samples taken in four counties.

Hochul's executive order followed the discovery of the virus last month in samples from Long Island's Nassau County, bordering the New York City borough of Queens. Earlier this year the virus was found in samples from Rockland, Orange and Sullivan counties, all north of the city.

In July, the first confirmed case of polio in the United States in nearly a decade turned up in an adult in Rockland County, according to the state health department.

"On polio, we simply cannot roll the dice," State Health Commissioner Mary Bassett said in a statement. "If you or your child are unvaccinated or not up to date with vaccinations, the risk of paralytic disease is real."

Polio can cause irreversible paralysis in some cases, but it can be prevented by a vaccine first made available in 1955.

TheWhile there is no known cure, three injections of the vaccine provide nearly 100% immunity. (Source: Reuters)

Amgen Says Lumakras Cuts Risk of Lung Cancer Progression By 34%

Amgen Inc's (AMGN.O) Lumakras pill reduced the risk of disease progression in patients with advanced lung cancer by 34% compared with chemotherapy in a clinical trial, the company said on Sunday.

There was no significant difference in overall survival between the two treatments in the confirmatory study required by U.S. regulators as a condition of accelerated approval for Lumakras. But Amgen said the trial was not designed to detect a survival difference.

The company is also testing whether the drug could be effective against lung cancer earlier in the disease, and said last month a small study of Lumakras combined with immunotherapy found high rates of liver toxicity and that further study was needed.

More detailed results from the 345-patient study, including median progression-free survival - the length of time until the cancer begins to worsen - will be presented on Monday at the annual meeting of the European Society for Medical Oncology (ESMO) in Paris. (Source: Reuters)

Covid Survivors At Risk of "Brain Fog", Epilepsy Even Years Later: Study

London: Increased risk of neurological and psychiatric conditions such as dementia and seizures is still higher two years after COVID-19 compared to other respiratory infections, suggests an observational study of over 1.25 million patient health records published in The Lancet Psychiatry journal. The increased risk of depression and anxiety in adults lasts less than two months before returning to rates comparable to those after other respiratory infections. Since the COVID-19 pandemic began, there has been growing evidence that survivors might be at increased risk of neurological and psychiatric conditions.

A previous observational study by the same research group reported that COVID-19 survivors are at increased risk of several neurological and mental health conditions in the first six months after infection. However, until now, there have been no large-scale data examining the risks of these diagnoses over a longer time period.

"In addition to confirming previous findings that COVID-19 can increase the risk for some neurological and psychiatric conditions in the first six months after infection, this study suggests that some of these increased risks can last for at least two years," said Professor Paul Harrison, from the University of Oxford, UK. "The results have important implications for patients and health services as it suggests new cases of neurological conditions linked to COVID-19 infection are likely to occur for a considerable time after the pandemic has subsided," Harrison, lead author of the study, said.

The study also highlights the need for more research to understand why this happens after COVID-19, and what can be done to prevent or treat these conditions. The study analysed data on 14 neurological and psychiatric diagnoses gathered from electronic health records mostly from the US over a two-year period.

Of those with health records in the US-based TriNetX network, 1,284,437 people had a confirmed SARS-CoV-2 infection on or after January 20, 2020 and were included in the study: 185,748 children, 856,588 adults between 18 and 64 years old, and 242,101 adults over 65. These individuals were matched to an equal number of patients with another respiratory infection to act as a control group.

Records from COVID-19 patients infected during different pandemic waves were also compared to investigate differences in the impact of the Alpha, Delta, and Omicron variants on the risk of neurological and psychiatric diagnoses. People who had a first diagnosis of COVID-19 within the period when a particular variant was dominant were compared with a control group of the same number of individuals who had a first diagnosis of COVID-19 in the period just before the emergence of that variant.

The study found that, in adults, the risk of having a depression or anxiety diagnosis initially increased post SARS-CoV-2 infection but returned to the same as with other respiratory infections after a relatively short time. After the initial increase, the risks for a depression or anxiety diagnosis dropped to below that of the control group, meaning that after two years, there was no difference in the overall incidence of depression and anxiety between the COVID-19 group and the other respiratory infections group.

However, the risk of diagnosis of some other neurological and mental health conditions was still higher after COVID-19 than for other respiratory infections at the end of the two-year follow-up. Adults aged 18-64 who had COVID-19 up to two years previously had a higher risk of cognitive deficit, or 'brain fog', and muscle disease, compared to those who had other respiratory infections up to two years previously.

In adults aged 65 and over who had COVID-19 up to two years previously, there was a higher occurrence of 'brain fog', dementia and psychotic disorder compared to those who previously had a different respiratory infection. The likelihood of most neurological and psychiatric diagnoses after COVID-19 was lower in children than in adults, and they were not at greater risk of anxiety or depression than children who had other respiratory infections.

However, like adults, children were more likely to be diagnosed with some conditions, including seizures and psychotic disorders over the two years following COVID-19. Little change was observed in the risks of neurological and psychiatric diagnoses six months post COVID-19 just before and just after the emergence of the Alpha variant.

However, the emergence of the Delta variant was associated with significantly higher six-month risks of anxiety, cognitive deficit, epilepsy or seizures, and ischaemic strokes but a lower risk of dementia when compared to those diagnosed with COVID-19 just before the Delta wave.

The risks during the Omicron wave were similar to those when Delta was the dominant variant. "It is good news that the higher risk of depression and anxiety diagnoses after COVID-19 is relatively short-lived and there is no increase in the risk of these diagnoses in children," said Max Taquet from the University of Oxford, who led the analyses. "However, it is worrying that some other conditions, such as dementia and seizures, continue to be more frequently diagnosed after COVID-19, even two years later," Max Taquet said. (Source: NDTV)

Pharma Firm Distributed Rs 1,000 Crore Freebies To Doctors To Prescribe Dolo 650mg Tablets: NGO To Supreme Court

The Supreme Court on Thursday was told by an NGO that the Central Board of Direct Taxes has accused the pharma company manufacturing the popular Dolo tablets, an anti-inflammatory, fever reducer drug, of distributing Rs 1,000 crore freebies to doctors for prescribing its 650 mg tablets. A bench of Justices DY Chandrachud and AS Bopanna was told by senior advocate Sanjay Parikh and advocate Aparna Bhat, appearing for the petitioner 'Federation of Medical and Sales Representatives Association of India.

The market price of any tablet up to 500mg is regulated under the government's price control mechanism, but the price of drugs above 500mg can be fixed by the manufacturer pharma company.

He said to ensure a higher profit margin, the company distributed freebies to doctors to prescribe Dolo dosage of 650mg capacity. Parikh added that it is an "irrational dose combination" and said he would like to bring more such facts to the knowledge of the court, after a response is filed by the Centre. Justice Chandrachud said, "What you are saying is music to my ears. This is exactly the drug that I had when I had Covid recently. This is a serious issue and we will look into it".

The bench asked Additional Solicitor General KM Nataraj to file his response to the plea in 10 days and gave Parikh one week thereafter to file his rejoinder.

It listed the matter for further hearing on September 29, 2022.

A counsel sought permission from the court to file an intervention on behalf of the pharma companies, which the court allowed, saying it would like to hear them also on the issue. On March 11, the top court agreed to examine a plea seeking direction.

The Centre for formulating a Uniform Code of Pharmaceutical Marketing Practices to curb the unethical practices of pharma companies and ensure an effective monitoring mechanism, transparency, accountability, as well as consequences for violations.

The top court had said it wants to know what the government has to say on this issue. Parikh had said this was an important issue in the public interest and there was a recent judgement by the court which said the bribe-giver or bribe-taker, both were prohibited. He had submitted that pharmaceutical companies said they were not liable as the bribe-takers are the doctors and in foreign countries, they have legislation to curb these unethical marketing practices.

Parikh said the government should look into it and the code should be made statutory in nature as "we all know what happened with Remdesivir injections and other drugs of those combinations.

The top court had then asked the petitioner why can't a representation to the government be made, to which Parikh had said they have already done it. He had said that they have been pursuing the issue with the government since 2009 and till the time the government comes out with a code to regulate, this court may lay down some guidelines.

The plea filed through advocate Aparna Bhat sought direction that till an effective law is enacted, the Court may lay down the guidelines to control and regulate unethical marketing practices by pharmaceutical companies or in the alternative, make the existing code binding, with proper and reasonable modifications/ additions, which should be followed by all the authorities/ courts under Articles 32, 141, 142 and 144 of the Constitution.

The plea added that the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations of 2002 prescribe a code of conduct for doctors in their relationship with the pharmaceutical and allied health sector industry, and prohibit acceptance of gifts and entertainment, travel facilities, hospitality, cash or monetary grants by medical practitioners from pharmaceutical companies.

"This code is enforceable against doctors, however, does not apply to drug companies, leading to anomalous situations where doctors' licenses are cancelled for misconduct, which is actuated, encouraged, aided, and abetted by pharma companies. The pharma companies go scot-free," it added.

The plea said that though termed as a 'sales promotion,' in fact, direct or indirect advantages are offered to doctors (as gifts and entertainment, sponsored foreign trips, hospitality, and other benefits) in exchange for an increase in drug sales.

It said unethical drug promotion can adversely influence doctors' prescription attitudes and harm human health by overuse/ over-prescription of drugs, prescription of higher doses of drugs than necessary, prescription of drugs for a longer period than necessary, prescription of a higher number of drugs than necessary and prescription of an irrational combination of drugs.

It said pharmaceutical companies use high-pressure promotion practices to lure physicians to prescribe an irrational combination of drugs to generate massive sales. (Source: Business Line)