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NEWS LETTER
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Covaxin, India's 1st Coronavirus Vaccine, May be Available by End of This Year: Health Minister Harsh Vardhan

Union Health and Family Welfare Minister Dr Harsh Vardhan said "test, track, treat" was the government's strategy to move forward, and listed the progress stage of various vaccine candidates, adding that some of them could be available in the first quarter of 2021.

In an interview to the Hindustan Times, Vardhan talked about the current Covid-19 situation in the country, and provided details on the government's vaccine procurement plans. On Thursday, India's Covid-19 caseload went past 28 lakh with a record single-day spike of 69,652 infections, according to the Union Health Ministry data. Asked about when infections are projected to peak across India, following a fall in fresh cases, the Health Minister said that it was difficult to predict that.

India being a large country, he said the outbreak was heterogeneous in different states with respect to their vulnerability, the maturity of outbreak, and the number of confirmed cases. He added that the outbreak was likely to peak at different points in cities and states, and the variety in implementation measures, including the proportion of people taking preventive measures, played a role in this. He said these factors made it difficult to say when a drop in new cases would take place. Various experts across the duration of the outbreak, have said that a vaccine is direly needed for the world to go back to some normality in its operations. Asked about when a vaccine would be ready for use in India, Vardhan said that vaccine trials against Covid-19 were being fast-tracked globally. He said the efficacy of India-made vaccines would be known by the year-end, upon completion of trials. Adding that the Oxford vaccine produced by Serum Institute of India was already being produced on a parallel end, he said this would reduce the time needed to market it.

The Health Minister said that the other two vaccines would require at least a month extra for production, and phased introduction in the market. He pointed out that if the vaccine trial results were successful, it could be "ready to use" by the first quarter of 2021. Developed by Hyderabad-based pharmaceutical firm Bharat Biotech, the human trials of 'COVAXIN' had started two weeks back and could be available by the end of 2020, Vardhan said. He told HT the Serum Institute of India had informed that it was ready to begin human trials in India this month and was hoping to have the AstraZeneca vaccine available by the year-end. The ZyCoV-D from Zydus Cadila could complete its clinical trials in a few months too, he added.

Last week, the European Union agreed to buy at least 300 million doses of AstraZeneca's coronavirus vaccine in its first such advance purchase deal. As other countries move towards similar advance procurement deals, Harsh Vardhan was asked to comment on India's plans for the same. He answered that the details of the procurement plan were being developed by the Ministry of Health and Family Welfare, adding that it was crucial to note that the country was home to the world's vaccine manufacturing industrial base, which provided two-thirds of childhood vaccines used globally.

He told HT the Indian Council of Medical Research (ICMR) was collaborating with Bharat Biotech, and had entered into an MoU which stated that priority would be accorded to provide vaccines, if it was successful, to the Indian Government, at an affordable and subsidised rate. The Minister added that a similar agreement was in the advanced stages of negotiation with the Serum Institute of India for three Covid-19 vaccine trials to be supported by ICMR. "Serum institute and ICMR are to undertake the trials of Oxford vaccine and two others – one produced by Novamox-Serum and another by Serum Institute by itself. Once the results of Phase I and II will be available, the detailed contours of plan to roll out will be finalised," he told Hindustan Times.

Harsh Vardhan said that infections had come down in Mumbai and Delhi, despite high testing, adding that this was corroborated by the downtrend in hospital admissions. He said the government was ahead of its set targets for Covid-19 testing, and said that the country's case fatality ratio was controlled by effective containment, aggressive testing with contact tracing and standardized clinical management protocols based on a "holistic standard-of-care approach". (Source: News 18)

New Covid-19 Vaccine Injected Via Nose Found to Prevent Infection in Mice in Major Breakthrough

Scientists have developed a vaccine against COVID-19 that can be given in one dose via the nose, and is effective in preventing infection in mice susceptible to the novel coronavirus, an advance that may lead to protective candidates that can curb the pandemic.

While there are several COVID-19 vaccine candidates currently under development, the study, published in the journal Cell, noted that unlike these, the one delivered via the nose targets the initial site of infection, and causes more widespread immune response.

According to the researchers, including those from the Washington University School of Medicine in the US, the nasal delivery route created a strong immune response throughout the body, but it was particularly effective in the nose and respiratory tract, preventing the infection from taking hold in the body.

They plan to test the vaccine in non-human primates and humans to see if it is safe and effective in preventing COVID-19 infection. "We were happily surprised to see a strong immune response in the cells of the inner lining of the nose and upper airway — and a profound protection from infection with this virus," said study senior author Michael S. Diamond from the Washington University School of Medicine.

"These mice were well protected from disease. And in some of the mice, we saw evidence of sterilising immunity, where there is no sign of infection whatsoever after the mouse is challenged with the virus," Diamond said.

To develop the nasal vaccine, the researchers inserted the virus' spike protein, which coronavirus uses to invade cells, inside another virus — called an adenovirus — that causes the common cold. But the scientists tweaked the adenovirus, rendering it unable to cause illness.

The engineered adenovirus carries the spike protein into the nose, enabling the body to mount an immune defense against the novel coronavirus without becoming sick, the scientists said. According to the researchers, the new vaccine also incorporates two mutations into the spike protein that stabilise it in a specific shape that is most conducive to forming antibodies against it.

"Adenoviruses are the basis for many investigational vaccines for COVID-19 and other infectious diseases, such as Ebola virus and tuberculosis, and they have good safety and efficacy records, but not much research has been done with nasal delivery of these vaccines," said study co-senior author David T. Curiel.

"All of the other adenovirus vaccines in development for COVID-19 are delivered by injection into the arm or thigh muscle. The nose is a novel route, so our results are surprising and promising," Curiel said. He said it is also important that a single dose produced such a robust immune response. "Vaccines that require two doses for full protection are less effective because some people, for various reasons, never receive the second dose," Curiel added.

When the researchers compared this vaccine administered to the mice between nasal and intramuscular delivery routes, they found that injection via the muscles induced an immune response that prevented pneumonia, but did not prevent infection in the nose and lungs.

They said such vaccines might reduce the severity of COVID-19, but may not totally block infection or prevent infected individuals from spreading the virus. In contrast, the scientists said the nasal delivery route prevented infection in both the nose and lungs, suggesting that vaccinated individuals would not spread the virus or develop infections elsewhere in the body. The researchers cautioned that the vaccine so far has only been studied in mice.

"We will soon begin a study to test this intranasal vaccine in nonhuman primates with a plan to move into human clinical trials as quickly as we can," Diamond said. "In these mouse models, the vaccine is highly protective. We're looking forward to beginning the next round of studies and ultimately testing it in people to see if we can induce the type of protective immunity that we think not only will prevent infection but also curb pandemic transmission of this virus," he added. (Source: News18)

Merck Moves US Court Against Aurobindo Pharma on Diabetic Drug Janumet

Merck Sharp & Dohme Corp, a subsidiary of Merck & Co has filed a petition in a US court against Aurobindo Pharma Limited alleging the Indian drugmaker is planning to come out with generic versions of its blockbuster drug Janumet before expiration of patent. Merck filed the possible patent infringement petition against Aurobidno in the United States District Court for the District of Delaware on four counts last week.

Janumet (metformin hydrochloride and sitagliptin Phosphate) which is indicated to control high blood sugar in people with type 2 diabetes clocked over USD two billion revenues globally including USD 589 million in the USA in 2019, according to Merck's 2019 annual report. Patents of Janumet will expire in July 2022 for theUSA withsix-month pediatric exclusivity, Merck said in theannual report.

Merck in its petition, said that Aurobindo Pharma had submitted ANDAs (abbreviated new drug application)to the USFood and Drug Administration (FDA) seeking approval from thehealth regulator to engage in the commercial manufacture,sale, and/or importation of the intended generic drugs priorto the expiration of the "708" patent. Merck sought the court, among others, apreliminaryand permanentinjunction enjoining Aurobindo, and allpersonsacting in concert with it, from the commercialmanufacture, use, sale, offer for sale, orimportation intothe United States of the Indian drug maker's ANDA Products, orany other drug productcovered by or whose use is covered bythe "708" patent, prior to the expiration.

In June, Merck dragged Dr Reddy's Laboratories to a UScourt over similar patent issues on Janumet and Januvia. UnderParagraph IVPatentCertifications, a companycan seek FDA approval to market a generic drug before theexpiration ofpatentsrelated to the branded medicine thatthe pharma company seeks to copy.

Acity-based pharmaceutical company senior official said patent litigation cases are not uncommon for generic drug makers in the USAand thelawsuit will not have anyimplications on the performance of the company. (Source: News 18)

Pharma Industry to Play a Major Role In 'Atmanirbhar Bharat'

Covid period has been a learning experience for the pharmaceutical and medical equipment industry, says Minister Piyush Goyal, Commerce and Industry Minister, has asked the pharmaceuticals and medical equipment manufacturing industry to keep up their contribution towards making India self-reliant in health and strive to become a reliable global player.

"No doubt all of you have made the nation proud and showed to the world that India can be a trusted partner in global engagement and trade," said Goyal onthe performance of the medical industry during the Covid-19 crisis on Thursday. The Minister was speaking at a CII conference on health.

Goyal said that in Prime Minister Narendra Modi's vision shared on 'Atmanirbhar Bharat', the medical community, especially medical equipment manufacturers, had a particular mention. This was not just in terms of its success in ramping up capacities to meet the present needs during the Covid-19 crisis, but also for the role it would play in the future when the healthcare needs of the nation is upgraded and spending increased, the Minister added.

He said the latest technologies, including 3G, 4G, AI and data analytics, will be used to ensure quality health care for all Indians. This is the time when we have to leverage the tools of technology to recharge out health system with the power of 3 As – Access, Awareness and Availability, he added. The Covid-19 period has been a learning period for the industry, and it has taught us that being self-reliant is important if we want to protect our people, he said.

"Our pharmaceutical industry will evolve from the realisation that Covid-19 has brought upon us... that being self-reliant is important to care for the lives of the people," he said.

During the ongoing health crisis, our pharmaceutical industry has persevered to ensure adequate supply of medicines not only for India but also globally, said the Minister. "The medical equipment industry laboured to provide equipment needed during pandemic. Ventilator is very big example," he added.

Goyal added that the industry has to move on from being the 'pharmacy of the world' to the 'hospital of the world', where the world will be able to use facilities, high quality medical care, and high quality treatment that India will provide. Medical devices industry will be at the forefront of bringing technology to India, and ensuring our rightful place in the global trade for equipment and engagement with hospitals internationally, he said.
(Spurce: Business Line

Indian Pharmacopoeia Drops Redundant' Toxicity Test On Animals for Human Vaccines

Human vaccines will no longer require an "abnormal toxicity test" done on small animals before a batch of the product is released, provided manufacturers adhered to the country's Good Manufacturing Practices (GMP) norms. The development follows a recent amendment to the Indian Pharmacopoeia (IP) and will give a lease of life to several guinea pigs and mice who are put through these tests. The IP is a compilation of official standards of drugs being made or marketed in India, brought out by the Indian Pharmacopoeia Commission, an autonomous institution under the Health Ministry.

Explaining why abnormal toxicity tests had been dropped in other parts of the world as well, a note from People for the Ethical Treatment of Animals (PETA) said, "In the test, animals are injected with a vaccine, and if none of them die, the batch is deemed safe. Animals who don't die during the experiment are killed afterwards. Extensive reviews of historical data from the abnormal toxicity test have shown that compliance with good manufacturing practices is superior to the use of animals for controlling and detecting batch contamination. Dipti Kapoor, PETA's India Science Policy Adviser, told Business Line, the country had already moved in the direction of removing this toxicity test from the general requirements of the IP monographs. But the impact was missing since individual monographs still required it, and the latest IP amendment drops this requirement from individual monographs of the human vaccines as well. The move came into effect from July 22, she said, when the IP amendment was published.

Eliminating this test would not affect the safety or quality of the product being released, provided GMP norms were followed, Kapoor said, adding that these tests had already been dropped from requirements in Europe, the United States and norms outlined by the World Health Organisation. The vaccines impacted by the move included, Diphtheria and its combination vaccines, Hepatitis A, Influenza, Rabies, Japanese Encephalitis, Typhoid, Measles-Rubella, etc, she pointed out. (Source: Business Line)

Gargled Water as Throat Swab for Covid-19 Test? Yes, Says ICMR in Big, Cost Effective Breakthrough

New Delhi: Nasal swabs and throat swabs are most widely accepted as the preferred method for obtaining respiratory samples to detect the presence of SARS CoV2, the virus that causes novel coronavirus. The Indian Council of Medical Research (ICMR) has now arrived at the conclusion that it has certain disadvantages which may be overcome by gargling.

A study done to assess the agreement between gargle lavage and swab as an appropriate respiratory sample for the detection of SARS-CoV-2 has thrown up interesting results. This study was also done to assess the patient acceptability of the two sampling methods. A cross-sectional study was done at a tertiary care hospital in New Delhi, (at Delhi's AIIMS) on 50 confirmed COVID-19 patients. Paired swab (NPS and OPS) and gargle samples were taken within 72 hour of diagnosis. Samples were processed by reverse transcription-polymerase chain reaction (RT-PCR) for detection of SARS-CoV-2. Post-sample collection, a 10-point scale was administered to assess the level of discomfort with either of the collection methods. It was found that all gargle samples were positive and comparable to their corresponding swab samples, irrespective of the symptoms and duration of illness.

A majority (72%) of the patients reported moderate-to-severe discomfort with swab collection in comparison to 24 per cent reporting only mild discomfort with gargle collection. Importantly, the conclusion that has been arrived at is that the gargle lavage may be a viable alternative to swabs for sample collection for the detection of SARS-CoV-2. The ICMR says this is crucial because it will enable easy self-collection, relieve healthcare workers and also lead to substantial cost savings by reducing the need for swabs and personal protective equipment. Gargle is an easy-to-perform procedure, can be performed by the patients themselves without much training and may have better patient acceptability. The adoption of gargle for sample collection will translate to substantial cost savings as it would cut down not only the need for swabs and personal protective equipment (PPE) but also the need to develop and maintain special infrastructure for swab collection, says the ICMR in its study, now published in IJMR.

This was demonstrated in a study conducted in Germany where the authors utilised this method for testing of HCWs for COVID-19. They tested 924 HCWs using gargle and consequently saved 225 PPEs and 1,000 swabs. The current practice of collection of swabs requires trained professionals who get exposed to the virus-containing aerosols and remain at high. That is the biggest advantage of gargled water swabs. A disadvantage of gargling could be the generation of infectious aerosols. Whether the risk of aerosol generation was similar to swab collection (commonly leads to coughing and sneezing) or higher was not clear. To minimise the risk of transmission due to aerosols and to maximise the benefits of this method of collection, it would be best to employ it for home collection. Furthermore, it cannot be used in patients who are critically ill as well as in young children/patients who may not be able to follow instructions/perform gargle, says the ICMR. (Source: News 18)