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NEWS LETTER
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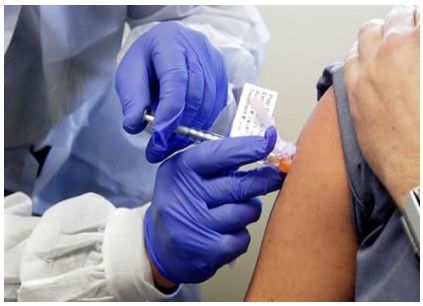
Govt Identifying 30 Crore Priority Beneficiaries for Covid Vaccine, States Told Not to Chart Separate Plans: Report



New Delhi: The coronavirus vaccine, once available, will be distributed under a special COVID-19 immunisation programme with the Centre procuring the doses directly and making it available for priority groups, official sources said. According to them, the Centre will procure the vaccine directly to make it available to the priority groups free-of-charge through the existing network of states and districts. States have been asked not to chart separate pathways of procurement, they said.

The Centre, with the help of state and union territory governments, has started the process of identifying around 30 crore priority beneficiaries who would be given vaccine dose in the initial phase. This special COVID-19 immunisation programme would run in parallel with the Universal Immunisation Programme, but will use its processes, technology and network of the existing vaccine distribution framework, sources said.

The government has demarcated four categories of people for vaccination in the initial phase — around one crore healthcare professionals including doctors, MBBS students, nurses and ASHA workers, etc.; around two crore frontline workers including municipal corporation workers, personnel of the police and armed forces; about 26 crore people aged above 50; and a special group of those below 50 years of age with co-morbidities and requiring specialised care. "States have been asked to enlist by mid-November the priority population groups…. Each person in the immunisation list will be linked with their Aadhaar cards so as to track them," a source said.

The existing digital platform and processes used for the Universal Immunisation Programme (UIP) are being enhanced to track COVID-19 vaccine administration and movement — from procurement to storage to distribution to individual beneficiaries — as and when the vaccine becomes available, Health Ministry officials have said. Also, online training modules are being developed for vaccinators. The digital platform that is being enhanced is Electronic Vaccine Intelligence Network (eVIN), which provides real-time information on vaccinestocks and storage temperatures across all cold chain points in the country under UIP.

Under UIP, children, adolescents and pregnant women are currently vaccinated against vaccine-preventable diseases free-of-cost by the state. The National Expert Committee on Vaccine Administration for COVID-19 has already mapped the existing cold chain being utilised under the government's immunisation programme and has also made a projection of the additional requirement, Health Ministry officials had said earlier.

Presently, the committee is engaged in mapping private sector facilities that could serve the needs of supplementing the cold chain equipment. Union Health Minister Harsh Vardhan has said that the Centre estimates to receive and utilise 40-50 crore doses of COVID-19 vaccine covering around 25 crore people by July next year.

Vardhan had said the government is working round-the-clock to ensure that there is a fair and equitable distribution of vaccines, once they are ready. The biggest benefit that India has is that it has a robust immunisation programme in place and it is implementing the largest immunisation programme of the world, with nearly 27 million newborns targeted for immunisation annually, the minister said. "We have an established infrastructure for supply, storage and delivery of vaccines to the last mile, under our Universal Immunisation Programme, where we are administering around 600 million doses to children every year," he said. "The strength of these experiences in the vaccination landscape, our best practices and the robustness of our health delivery System will be leveraged and augmented using a strong IT backbone to ensure that this humongous national mission of vaccinating the identified priority groups with COVID-19 vaccine is achieved in a timely manner. The Indian government will leverage the integrated IT platform eVin for managing vaccine distribution," Vardhan said. Vardhan re-affirmed the commitment of the Indian government and assured that it has accorded top most priority to the research and manufacturing to ensure that the vaccine reaches to the last person. A controversy erupted on Thursday after the BJP in its manifesto for the Bihar assembly elections promised free COVID-19 vaccines, once it is available, for all.(Source: News 18)

Indian Pharma Exports May Cross $25 Billion this Fiscal

Pharmexil Director General lauds sector's manufacturing abilities Indian pharmaceutical industry is expected to export medicines and other goods worth over $25 billion in the current financial year, up from $20.5 billion in 2019-20, said Ravi Uday Bhaskar, Director General of Pharmaceutical Export Council of India (Pharmexil) , on Monday.

Bhaskar, who participated in a virtual meet in connection with Global Virtual Healthcare & Hygiene Expo 2020 organised by FICCI, said Indian pharmaceutical exports during the first six months were $11.38 billion, nearly 15 per cent more than that in the same period last year. "This is significant considering that 55 per cent of Indian pharma exports is to highly regulated markets," he added.

"During this difficult times Indian pharmaceutical industry is doing very well. The world is looking at India for two reasons. One is for generic medicine front, where we are capable of producing quality medicines at affordable prices. Secondly on Covid-19 vaccine front, most of Indian vaccine companies are working closely with academic institutions and industry outside India," Pharmexil DG said.

Covid vaccines Another advantage is that India is the only country that can produce Covid-19 vaccines in large volumes. Indian medical devices industry too rose up to the occasion. "At the beginning of Covid-19, Indian industry was not capable of producing N95 maks, PPE kits and other devices required for fighting the pandemic. But now Indian industry is capable of manufacturing all these in adequate quantities," Bhaskar said.

Similarly syringes for Covid-19 vaccines. Both the Astra-Zeneca-Oxford University vaccine produced by Serum Institute of India and Covaxin by Bharat Biotech India Ltd being two-dose vaccines, Indian industry would have to produce 260 crore syringes if the entire Indian population is to be covered. Bhaskar said he was confident that the industry would be able to meet the challenge. Earlier talking at the webinar, Pradeep Multani, Co-Chair of FICCI Ayush Committee and Chairman of Multani Pharmaceuticals, said India's Ayurveda product exports, which are at $3 billion currently, are expected to grow by 16-18 per cent per annum over the next five years. (Source: Business Line)

Medicine supply chains to change post Brexit, MPs told

Supply chains bringing medicines into Northern Ireland will change "significantly" after Brexit, MP's have been warned.

They were also assured there will be no disruption to the availability of drugs and the current safety standards will be maintained.

Members of the Northern Ireland Affairs Committee heard evidence from the pharmaceutical industry.

It focused on the impact of Brexit on the supply of medical drugs. They were told at present 80% of drugs come into Northern Ireland from Great Britain through the ports, but that in the future medicines are likely to be "shipped in directly from Europe".

Dr Richard Greville, director of distribution and supply with the Association of the British Pharmaceutical Industry told MP's nothing will change until the end of next year.

This is due to a one year "phasing in" period agreed between the UK and EU. 'Ducks in a row' Under the protocol. Northern Ireland will stay under the EU regulatory regime for medicines following the end of the transition period. "This extra time is particularly helpful and useful for everybody to get their ducks in a row to ensure continuity of supply in Northern Ireland," said Dr Greville.

"It gives the appropriate and sufficient time to change supply chains, because those supply chains will need to be changed significantly."

He added: "It may be that in future that companies, manufacturers would need to make contractual arrangements with wholesalers not necessarily the ones that they currently use in GB, but may choose to distribute via for example through the Republic."

Dr Greville told MP's that medicines sold in Northern Ireland will have to carry a unique identifier under EU regulations which protect against counterfeit drugs. But packs of medicines produced in Great Britain will not have the "obligation of using this unique identifier".

"So basically what I'm saying is that in the future, Northern Ireland will have to be supplied with packs of medicines that are compliant, if not from GB from other parts of Europe," said Dr Greville. (Source: BBC)

Oxford Covid-19 Vaccine to Cost Maximum Rs 1,000 for 2 Doses, Says Serum Institute CEO Adar Poonawalla

Vaccine maker Serum Institute of India's CEO Adar Poonawalla has said the Oxford Covid-19 vaccine should be available for healthcare workers and elderly people by around February 2021 and by April for the general public, and will be priced at a maximum of Rs 1,000 for two necessary doses for the public, depending on the final trial results and regulatory approvals. Probably by 2024, every Indian will get vaccinated, he said at the Hindustan Times Leadership Summit (HTLS), 2020.

"It will probably take two or three years for every Indian to get inoculated, not just because of the supply constraints but because you need the budget, the vaccine, logistics, infrastructure and then, people should be willing to take the vaccine. So these are the factors that lead up to being able to vaccinate 80-90 per cent of the population. It will be 2024 for everybody, if willing to take a two-dose vaccine, to be vaccinated," Poonawalla said. Asked at what price the public will get it, he said it will be around USD 5-6 per dose with an MRP of around Rs 1,000 for the two necessary doses.

"The government of India will be getting it at a far cheaper price at around USD 3-4, because it will be buying in a large volume and get access to the price that is similar to what COVAX has got. We are still pricing it far cheaper and more affordable than other vaccines we have in the market today," Poonawalla said. Asked about the efficacy of the vaccine, he said the Oxford-Astrazeneca vaccine is so far proving to work very well even in elderly people, which was a concern earlier. "It has induced a good T-cell response, which is an indicator for your long-term immunity and antibody response but then again, time will only tell if these vaccines are going to protect you in the long term. Nobody can answer that for any of the vaccines today," Poonawalla said. Responding to a question on the safety aspect, he said there has been no major complaints, reactions or adverse events, adding, "We would need to wait and see. The efficacy and immunogenicity results from the Indian trials will come out in about a month-and-a half."

Asked when the SII will apply for an emergency authorisation, Poonawalla said as soon as the UK authorities and the European Medicines Evaluation Agency (EMEA) approve it for emergency use, it will apply to the drug controller for emergency use authorisation in India. "But that will be for a limited use for frontline workers, healthcare workers and elderly people," he added. Children would have to wait a little longer till the safety data is out, but the good news is that COVID-19 is not so bad and serious for them, Poonawalla said. "Unlike measles pneumonia, which is deadly, this disease is seeming to be less of a nuisance for children but then, they can be carriers and can give the infection to others. We want to vaccinate the elderly people and others who are the most vulnerable first. Once we have enough safety data to go in on children, we can recommend it for children too," he said. Poonawalla said the Oxford vaccine is affordable, safe and stored at a temperature of two to eight degrees Celsius, which is an ideal temperature for it to be stored in the cold storages of India.

He said the SII plans to make about 10 crore doses per month from February. As regards how many doses would be provided to India, Poonawalla said talks are still going on and no agreement has been arrived at in this regard. "India wants around 400 million doses by July. I do not know if it will take all from the Serum Institute. We are gearing up to offer that kind of volume to India and still have a few 100 million to offer to COVAX by July and August. No agreement so far," he said. Poonawala said the SII is not entering into any agreement with other countries at this moment as India is its priority. "We have not signed and committed anything else beyond Bangladesh at the moment. We really do not want to partner right now with many countries because we will not have enough stocks to deliver.We want to handle India as a priority first and manage Africa at the same time and then help out other countries," he said.

Poonawalla said 30-40 crore doses of the Oxford vaccine will be available by the first quarter of 2021. In another session of the summit, AIIMS Director Dr Randeep Guleria said there is some talk going on between Pfizer and the Indian government but not much with Moderna. "It is going to be a huge challenge as far as the Pfizer vaccine is concerned, considering that it needs a cold chain of minus 70 degrees Celsius," he said and pinned hoped on the vaccines that are at various stages of trial in India. On the availability of a COVID-19 vaccine, Guleria said the percentage of population to be inoculated will depend on the number of vaccines getting the regulatory approvals and the number of shots they are producing. He further said the coronavirus goes into the lungs without making a person symptomatic. "We have individuals who are asymptomatic and you can see patches in their lungs at CT scans directly. It really bypasses a person's defence mechanism, which means that you not only have the virus in your nose or throat, but it has gone right into your lungs. A virus which can do that is something we have to be wary of," Guleria said. (Source: News 18)

Why was UK 1st to Authorise Coronavirus Vaccine? All You Need to Know About Its Side Effects, Access

The UK became the first Western country to authorise a Covid-19 vaccine on Wednesday, marking a pivotal moment in the global fight against coronavirus. The Pfizer/BioNTech vaccine has been granted emergency authorisation by British regulators, and the first doses are expected to be rolled out from early next week. Britain has been one of the countries hardest hit by the pandemic, with the highest death toll in Europe, and its government has been heavily criticized for its handling of the crisis. But it has now leapfrogged both the European Union and the United States with this announcement. Here's what you need to know about how it authorized the vaccine:

WHY WAS THE UK FIRST?

The vaccine was granted emergency authorization in the UK by its independent regulator, the Medicines and Healthcare products Regulatory Agency (MHRA), which has played a crucial part in the process. The MHRA began a rolling review of Pfizer and BioNTech data from October, with each "package" of data reviewed as soon as it became available. This allowed regulators to examine the data in detail before a final authorization application was submitted. According to the MHRA, a rolling review "can be used to complete the assessment of a promising medicine or vaccine during a public health emergency in the shortest time possible." This approach helped accelerate the authorization process and a formal review of all the necessary information began in the UK on November 23, leading to Wednesday's announcement. "I think the advantage is that the MHRA has been undertaking a rolling review, which means that as Pfizer accumulated data on how they manufactured the vaccine ... MHRA could keep pace with that," David Salisbury, associate fellow in Chatham House's Global Health Programme, told CNN. "That has allowed the MHRA to be nimble and keep pace." A similar rolling review approach is being used by the European Medicines Agency (EMA). The EMA began its review process of the Pfizer data on October 6 and BioNTech and Pfizer submitted an application to complete the review process on December 1. The EMA has said it will conclude its review by December 29 at the latest. EU member states cannot distribute a Covid-19 vaccine until it has been authorized by the EMA and signed off by the European Commission, according to EMA rules. The European Commission (EC) would then need a few days to prepare legal paperwork and discuss the authorization decision with member states, according to an EC spokesperson.

"The fact that the MHRA has been able to do this quickly will be a reflection at the pace of which Pfizer was interacting with them," Salisbury added. As well as the UK and the EU, Pfizer has also applied to the US Food and Drug Administration (FDA) for emergency use authorization for its vaccine candidate. The request was submitted on November 20. The FDA's Vaccines and Related Biological Products Advisory Committee, a panel of independent experts, is due to meet on December 10 to discuss Pfizer's application. According to a US Operation Warp Speed document obtained by CNN on Tuesday, the first shipments of Pfizer's coronavirus vaccine will be delivered on December 15, if the vaccine is granted emergency authorization. BioNTech's Chief Medical Officer Özlem Türeci said the company expected EMA and FDA responses by mid-December.

Türeci said Wednesday that the rolling review process played "an important role" in the UK's authorization. She said the process allowed authorities to "start right away to go through the dossiers, review the data, come back with questions which we can respond to immediately. And this massively accelerates the process of assessing in depth the data we have provided."

WHEN CAN I GET THE VACCINE IN THE UK?

The UK will begin rolling out the vaccine next week, according to Health Secretary Matt Hancock. But emergency authorization is only the first stage of that process -- doses will be assigned according to clinical priority. Each recipient of the Pfizer/Biontech vaccine will need two doses. An independent panel of experts, the Joint Committee on Vaccination and Immunization (JCVI), has recommended that care home residents and staff are vaccinated first. The panel recommends that people should then be vaccinated according to age, starting with people older than 80 as well as frontline health workers. Age will then continue to be the deciding factor, with older adults vaccinated down to those older than 50.

JCVI experts have also advised that workers in the UK's National Health Service (NHS) and those considered clinically extremely vulnerable to coronavirus should be prioritized under the initial phase of vaccination. Those considered vulnerable include patients with cancer, those who are on drugs that weaken the immune system and those who have severe lung disease, severe kidney disease and other health conditions. Hancock said Wednesday that the timing of how many people can be vaccinated "will be determined by how rapidly (doses) can be manufactured." "We haven't put a figure on the numbers before Christmas," he said. "But what we do know is we can get started next week with that first load, and several millions will be coming throughout December. People will be contacted by the NHS when it's their turn."

"I urge you very strongly to come forward, because obviously being vaccinated is good for you," he added. "It's approved as clinically safe by the regulator and it's good for your community as well to help get this virus finally under control once and for all." There are logistical challenges facing the rollout as the vaccine needs to be kept at temperatures of minus 70 degrees Celsius (minus 94 Fahrenheit) prior to use. Once defrosted, Pfizer says the vaccine can be stored for up to five days at 2 to 8 degrees Celsius in refrigeration units that are commonly available in hospitals. Speaking to Sky News on Tuesday, Hancock said there would be "a combination of three modes of delivery." The vaccine will first go to hospitals -- 50 of which are on standby to receive doses. This will be followed by vaccination centers, which Hancock said were being set up now, before a "community rollout" including doctors' offices and pharmacists. (Source: News18)