Coronavirus

Travel restrictions reimposed

EU probes BioNTech's request for extra dose

THE HAGUE, Netherlands, Jan 3, (AP): The European Union medicines watchdog said last Thursday that German company BioNTech has applied for clearance in the 27-nation bloc to administer up to six doses of its COVID-19 vaccine from each vial, instead of the five doses currently approved.

In an email to The Associated Press, the European Medicines Agency said that BioNTech, which developed its vaccine together with US drugmaker Pfizer, has "submitted a request for change" which will be reviewed by the agency's human medicines committee "in the shortest possible timeframe."

It said that if the committee establishes that six doses can be consistently extracted from each vial of vaccine, it will recommend changing the authorization that clears the vaccine for use in EU nations.

In a written statement, Pfizer said its vials contain enough vaccine for at least five doses and the amount remaining can vary depending on the type of needles and syringes used.

Spahn

"Decisions regarding label updates and/or other temporary approvals regarding dose preparation and administration belong to local health authorities," the company said.

German weekly Der Spiegel first reported this week that BioNTech has asked European regulators to change the conditions of approval to allow doctors to use excess vaccine in the vials to draw a sixth dose if possible, rather than tip the leftovers away after five as currently required.

This could result in hundreds of thousands of additional doses in Germany alone during the first quarter, Spiegel reported.

Regulators in the United States, Switzerland and the UK already allow up to six doses of 0.3 milliliters each to be drawn from vials.

"The vaccine is manufactured with enough volume for five doses," the UK regulator MHRA said in an email. "However, it is normal for some vials to contain a slight excess volume, and in some cases this could allow a full sixth dose to be extracted."

Forbidden

"However, care needs to be taken to ensure a full 0.3 ml dose can be administered to the individual," it added. "Where this cannot be achieved when diluted as recommended, the vial and its contents should be discarded after the fifth dose has been extracted."

Mixing leftovers from multiple vials is forbidden by all regulators, though.

German Health Minister **Jens Spahn** on Wednesday backed the idea of extracting additional doses if possible.

BioNTech intentionally fills the vials with more vaccine than necessary to ensure that even inexperienced doctors can get at least five doses out of them.

Meanwhile, a prominent doctors' organization in Britain expressed anger that family physicians will have to rebook tens of thousands of appointments for second vaccine dose jabs for vulnerable patients following the British government's decision Wednesday to extend the period between the required two doses to up to 12 weeks.

"This group of very elderly patients is at the highest risk of death if they contract COVID-19, which is why GPs are so concerned for them," Dr. Richard Vautrey, chair of the British Medical Association's general practitioners' committee, said. "It is grossly and patently unfair to tens of thousands of our most at-risk patients to now try to reschedule their appointments."

The UK's chief medical officers defended the decision to delay the second jab, saying one dose of the Pfizer/BioNTech vaccine gave at least 70% protection, with the second acting as a booster and prolonging immunity,

In a letter to the medical profession, the top medical advisers for England, Scotland, Wales and Northern Ireland said that with vaccine stocks limited around the world. "a model where we can vaccinate twice the number of people in the next 2-3 months is obviously much more preferable in public health terms than one where we vaccinate half the number but with only slightly greater protection. "

A senior vaccine researcher at Berlin's Charite hospital, Dr. Leif-Erik Sander, also said the UK's strategy makes sense as a temporary strategy.

"That way we could vaccinate (more people) faster and win valuable time in the fight against COVID-19," Sander said.

He said the vaccines made by BioNTech-Pfizer and Moderna have a strong protective effect about 10 days after the first shot. The Moderna vaccine has not yet been approved in the European Union or the UK.

"In my view, the booster vaccination can be delayed without problem for a little while, without having to expect any significant reduction in effectiveness," he said, noting that attention should be paid to ensuring everyone does eventually get their second dose.

Also:

SYDNEY: More Australian states and territories are reimposing travel restrictions to prevent the spreading of the coronavirus from new outbreaks in **New South Wales** and **Victoria** states.

The Australian Capital Territory has shut out non-residents who have been on the northern beaches of Sydney, where the outbreaks are most concentrated, Greater Sydney and other smaller centers, unless they have an exemption.

The island state of **Tasmania** has barred anyone directly linked to the latest Victorian cases, listing exposure sites where confirmed cases are known to have been. The move followed Tasmania's declaration of Greater Sydney and the Wollongong area south of Sydney as medium-risk zones, requiring travelers to quarantine for 14 days on arrival, while those from Sydney's northern beaches are barred from entering.

Victoria reported three new cases of community transmission on Sunday, down from Saturday's 10. In total, there have been 21 locally acquired Victorian cases over recent days, all linked to the New South Wales outbreak.

Victoria's border is now closed to all travelers from New South Wales.

On Sunday, New South Wales recorded eight new local cases. There are 161 active cases in the state, most of them in the northern beaches of Sydney, and 13 emanating from liquor store that are not connected to the beaches cluster.

The news that the state is battling two separate outbreaks in Sydney comes on the first day of mandatory mask restrictions across Greater Sydney, with enforcement to begin at midnight Sunday.

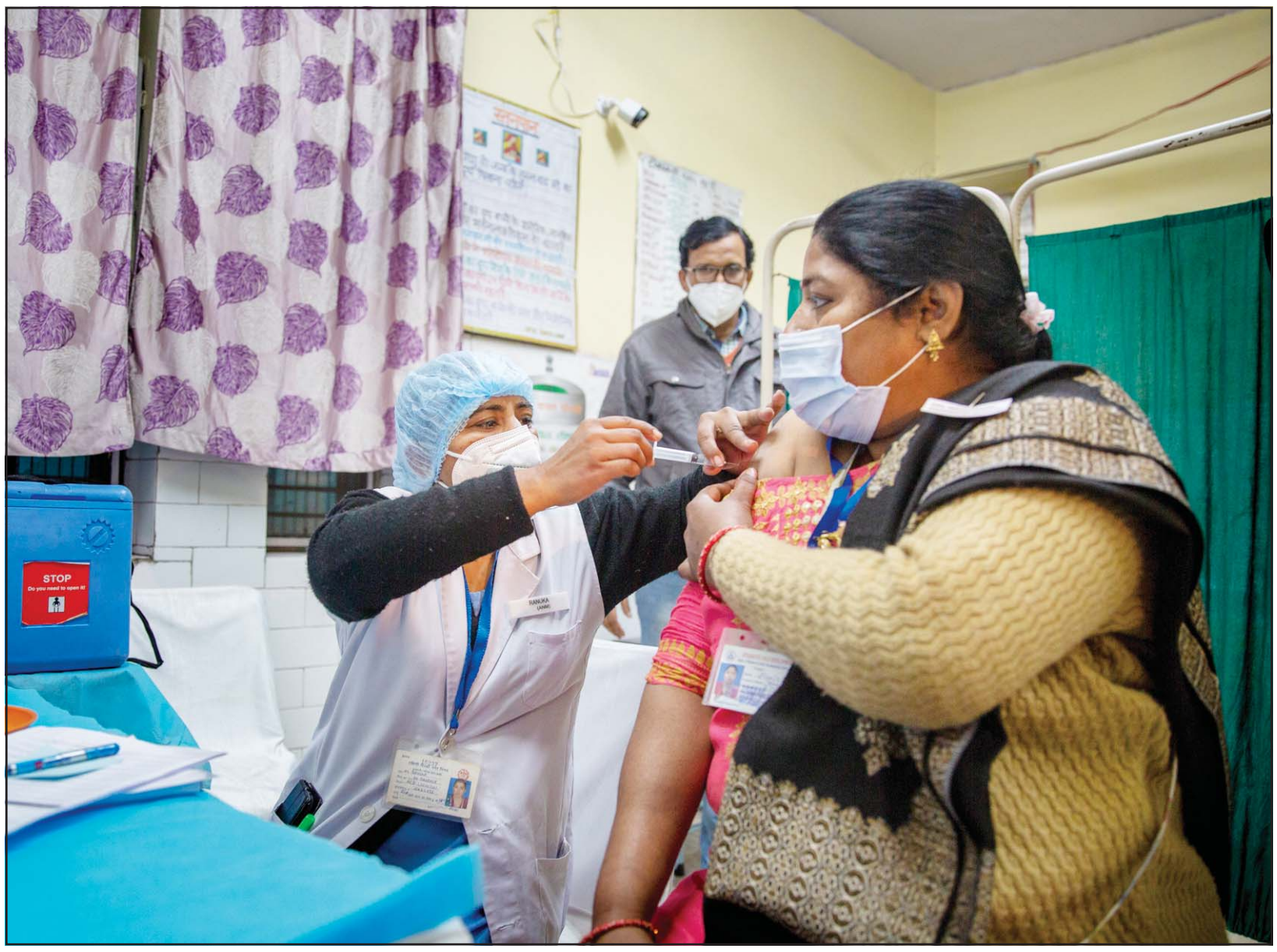
Masks will be mandatory in shopping centers, on public transport, in places of worship, hair and beauty premises and entertainment venues such as cinemas. All hospitality staff are also required to wear one.

Australia's leading medical group says the New South Wales state government has put the rest of the country at risk by its decision not to go "hard and early" in its response to the COVID-19 outbreak on Sydney's northern beaches, which is suspected to have also caused new cases in neighboring Victoria state.

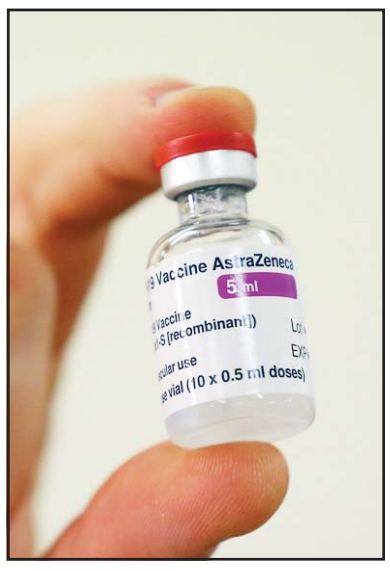
On Saturday, Victoria recorded 10 new local cases, bringing active cases in the state to 29. Trace testing has linked the new **Melbourne** coronavirus cluster to the New South Wales outbreak.

Australian Medical Association Vice President **Chris Moy** said the New South Wales government was "playing the odds" by relying heavily on its contact tracing system instead of imposing a quick lockdown to stop the spread across Sydney.

"They have put themselves and put the rest of the country at risk," Moy told Fairfax Media. "I can completely understand why Victoria has reacted (by) closing the border very quickly, because they are very worried about this."



A health worker engages in a COVID-19 vaccine delivery system trial in New Delhi, India, Saturday, Jan. 2. India tested its COVID-19 vaccine delivery system with a nationwide trial on Saturday as it prepares to roll-out an inoculation program to stem the coronavirus pandemic. Saturday's exercise included necessary data entry into an online platform for monitoring vaccine delivery, along with testing of cold storage and transportation arrangements for the vaccine, the health ministry had said. (AP)



A vial of the COVID-19 vaccine developed by Oxford University and UK-based drugmaker AstraZeneca is checked as they arrive at the Princess Royal Hospital in Haywards Heath, England, Saturday Jan. 2. The UK has 530,000 doses available for roll-out from Monday. (AP)

Discovery

Demand for backyard chickens: The coronavirus pandemic is coming home to roost in America's backyards.

Forced to hunker down at home, more people are setting up coops and raising their own chickens, which provide an earthy hobby, animal companionship and a steady supply of fresh eggs.

Amateur chicken-keeping has been growing in popularity in recent years as people seek environmental sustainability in the food they eat. The pandemic is accelerating those trends, some breeders and poultry groups say, prompting more people to make the leap into poultry parenthood.

Businesses that sell chicks, coops and other supplies say they have seen a surge in demand since the pandemic took hold in March and health officials ordered residents to stay home.

Allison and Ron Abta of Northern California's Marin County had for years talked about setting up a backyard coop. They took the plunge in August.

The couple's three kids were thrilled when their parents finally agreed to buy chicks.

"These chickens are like my favorite thing, honestly," said 12-year-old Violet, holding a dark feathered hen in her woodsy backyard. "They actually have personalities once you get to know them."

The baby birds lived inside the family's home for six weeks before moving into the chicken run in the yard. A wire-mesh enclosure now houses the five heritage hens - each a different breed - and protects them from bobcats, foxes and other predators.

Mark Podgwaite, a Vermont chicken breeder who heads the American Poultry Association, said he and other breeders have noticed an uptick in demand for chicks since the pandemic began. His organization, which represents breeders and poultry-show exhibitors, has seen a jump in new members.

"Without question, the resurgence in raising backyard poultry has been unbelievable over the past year," said Podgwaite, who keeps a flock of roughly 100 birds. "It just exploded. Whether folks wanted birds just for eggs or eggs and meat, it seemed to really, really take off." (AP)

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Conservationists attacked: The conservationist group Sea Shepherd said Friday that two fishermen were injured off Mexico's Baja California coast when they rammed their small boat into a larger vessel used by the group in efforts to protect the endangered vaquita porpoise.

The attack is the latest round in an escalating spiral of protests by fishermen who use banned gill nets in the Gulf of California, the only place the vaquita is found. Only as few as a dozen vaquitas are believed to remain, making them the world's most endangered marine mammal.

Fishing nets confiscated by Sea Shepherd vessels are expensive, so fishermen often harass the conservationists' boats to try to get them back. The fishermen claim they have not received compensation from the Mexican government for lost fishing income. Groups representing fishermen were not immediately available to comment. Mexico's president is **Andrés Manuel López Obrador.** Sea Shepherd said its vessel, the Farley Mowat, was pulling illegal gill nets out of the waters of the gulf, also known as the Sea of Cortez, on Thursday when people on a group of about a half dozen small, open fishing boats began tossing gasoline bombs at the vessel, setting the bow and another part of the ship afire.

The attackers also threw lead net weights at the crew, the group said.

It released a video showing one fishing boat approaching the Farley Mowat at high speed and slamming into the side of the vessel.

Two of the boat's occupants were pulled from the water by Sea Shepherd crew members and Mexican marines, who usually accompany the crew on such trips. One was given resuscitation, because he wasn't breathing, and both were taken by the navy to a hospital. (AP)

Podgwaite

Obrador

COVID-19

Approval paves way for huge inoculation program

India OKs AstraZeneca, local vaccines

NEW DELHI, Jan 3, (AP): India authorized two COVID-19 vaccines on Sunday, paving the way for a huge inoculation program to stem the coronavirus pandemic in the world's second most populous country.

The country's drugs regulator gave emergency authorization for the vaccine developed by Oxford University and UK-based drugmaker AstraZeneca, and another developed by the Indian company Bharat Biotech.

Drugs Controller General Dr. Venugopal G. Somani said that both vaccines would be administered in two dosages. He said the decision to approve the vaccines was made after "careful examination" by the Central Drugs Standard Control Organization, India's pharmaceutical regulator.

Prime Minister Narendra Modi called the vaccine approval a "decisive turning point to strengthen a spirited fight."

"It would make every Indian proud that the two vaccines that have been given emergency use approval are made in India!" Modi tweeted.

AstraZeneca has contracted Serum Institute of India, the world's largest vaccine manufacturer, to make 1 billion doses of its vaccine for developing nations, including India. On Wednesday, Britain became the first country to approve the shot.

Analyzed

But questions have been raised by health experts over the vaccine developed by Bharat Biotech. They point out that clinical trials began only recently, making it almost impossible for the firm to have analyzed and submitted data showing that its shots are effective in preventing illness from the coronavirus.

India has confirmed more than 10.3 million cases of the virus, second in the world behind the US, though its rate of infection has come down significantly from a mid-September peak. It also has reported over 149,000 deaths.

The country's initial immunization plan aims to vaccinate 300 million people - healthcare workers, front-line staff including police, and those considered vulnerable due to their age or other diseases - by August 2021. For effective distribution, over 20,000 health workers have been trained so far to administer the vaccine, the Health Ministry said.

But the plan poses a major challenge. India has one of the world's largest immunization programs, but it isn't geared around adults, and vaccine coverage remains patchy. Still, neither of the approved vaccines requires the ultra-cold storage facilities that some others do. Instead they can be stored in refrigerators, making them more feasible for the country.

Although Serum Institute of India doesn't have a written agreement with the Indian government, its chief executive, Adar Poonawalla, said India would be "given priority" and would receive most of its stockpile of around 50 million doses.

Partial results from studies for the Oxford-AstraZeneca shot in almost 24,000 people in Britain, Brazil and South Africa suggest that the vaccine is safe and about 70% effective. That isn't as good as some other vaccine candidates, and there are also concerns about how well the vaccine will protect older people.

The other vaccine, known as COVAXIN, is developed by Bharat Biotech in collaboration with government agencies and is based on an inactivated form of the coronavirus. Early clinical studies showed that the vaccine doesn't have any serious side effects and produces antibodies for COVID-19. But late clinical trials began in mid-November. The second shot was to be given 28 days after the first, and an immune response prompted two weeks later.

That time frame means that it isn't possible that the company submitted data showing that the shots are effective in preventing infection from the virus, said Dr. Gagandeep Kang, an infectious diseases expert at the Christian Medical College at Vellore.

All India Drug Action Network, a public health watchdog, issued a statement demanding greater transparency.

Should all volunteers of COVID-19 vaccines now get the 'real' thing?

NEW YORK, Jan 3, (AP): Tens of thousands of Americans have volunteered to test COVID-19 vaccines, but only about half of them got the real thing during trials.

Now, with the first vaccine rollouts and a surge in coronavirus infections, experts are debating what to do about the half that got a dummy shot.

Should everyone now be offered a vaccine? Or should the two groups in the Pfizer and Moderna studies remain intact in order to collect long-term data on how well the vaccines work?

"There's a real tension here," said Dr. Jesse Goodman, an infectious disease specialist and former chief scientist at the US Food and Drug Administration. "There's not an easy answer."

How vaccine studies work

New drugs, vaccines or treatments usually go through rigorous tests and evaluations before reaching regulators for approval.

For vaccines, researchers compare what happens when a large group of volunteers gets the shots, versus what happens to another large group that doesn't. They compare side effects in each group. And they measure the vaccine's effectiveness by looking at how many in each group pick up infections.

To do this fairly, researchers randomly assign participants to receive a vaccine or a dummy shot, usually a dose of salt water.

Volunteers know there's a 50-50 chance they could be put in either group - and they are not told which group they landed in. Often, the researchers or others involved in the testing are also "blinded" and don't know either.

Should test volunteers be told?

About 17,000 of Moderna's study participants received a placebo, as did about 22,000 people in Pfizer's trial.

With the ongoing coronavirus crisis, health experts worry about leaving them in the dark and unprotected. They argue they should be given a vaccine now in recognition of their willingness to be a part of the trials during the pandemic.

"Volunteers have been instrumental," said Moncef Slaoui, chief scientist of the government's Operation Warp Speed program. "They should be rewarded for it."

The companies would have to "unblind" or "unmask" the studies, revealing whether participants got the vaccine or the dummy shot.

Unmasking is usually done at the end of testing. Moderna and Pfizer, though, designed their studies to last two years to do long-term follow-up.

"I don't think there's anybody who thinks it's reasonable or feasible to keep the people blinded for two years," said Susan Ellenberg, an expert in clinical trials at the University of Pennsylvania.

"Given we have a pandemic, people are ready to settle for the short-term results."

Pros and cons of "unmasking"

With the rollout of vaccines and the uncertainty of their status, volunteers could decide to drop out once they are eligible to get one. They might stay in the study if they're told what they got, said Dr. Ana Iltis, a bioethicist at Wake Forest University.

"Participants could leave in droves. They could say, 'If you don't tell me what I got, I'm out of here,'" said Iltis. "You cannot force people to stay."

In an ideal world, participants could hold off to discover whether they received the dummy shot or the vaccine. But experts agree the current circumstances are extraordinary.

Still, unmasking participants would undoubtedly affect the trials' scope and results.

If someone learns they've already been vaccinated, for example, they may stop social distancing or wearing masks - increasing their potential exposure to the virus and possibly spreading it. It's not yet known if vaccinated people can still carry and transmit the virus.

On the flip side, if a person finds out they only received the dummy shot, they might take precautions they wouldn't otherwise.

Either outcome, Goodman said, "means the trial has basically come to an end."