



## After Canada, Germany Halts AstraZeneca Jabs For Under-60s Over Clot Risk



Under-60s can still decide to take the vaccine but only following "consultation with the doctor carrying out the vaccination ... and with an individual risk analysis," said ministers of Germany's 16 states as well as the federal health minister in a policy statement. Berlin, Germany: Germany will deploy AstraZeneca's coronavirus vaccine for general use only for over-60 year olds, the government said Tuesday, imposing restrictions for younger people taking the jab after several severe clotting cases.

Under-60s can still decide to take the vaccine but only following "consultation with the doctor carrying out the vaccination ... and with an individual risk analysis," said ministers of Germany's 16 states as well as the federal health minister in a policy statement.

The World Health Organization and the EU's health watchdog have both deemed the AstraZeneca vaccine safe, but several countries have restricted its use over clotting fears. Chancellor Angela Merkel noted that experts have recorded in recent weeks "very rare but very serious cases of thrombosis" in people vaccinated with AstraZeneca.

"They are findings that (Germany's vaccine commission) and finally us, cannot ignore," she said. Germany's vaccine commission known as STIKO earlier Tuesday recommended that use of the jabs be halted for under-60s because of "currently available data on the occurrence of rare but very severe thromboembolic side effects" in younger vaccinated people. It intends to make another recommendation by the end of April on how to proceed with people under 60 who have already received a first dose of the vaccine, it said.

Pending this decision, ministers said people who are due for their second jab can either choose to take it if cleared by their attending doctor, or they can opt to wait for the commission to make its recommendation. The latest restrictions amounted to a new setback for the vaccine developed by the Anglo-Swedish laboratory. Nevertheless Health Minister Jens Spahn said Germany would be able to meet its goal of offering every adult a coronavirus jab by the end of the summer.

Just after it received approval from European regulator EMA for use in the bloc, Germany restricted the AstraZeneca jab to under-65s because of insufficient data. After clearing it for older people subsequently, Germany along with several EU nations suspended its use again in mid-March because of clotting fears.

Just over a week after allowing its use again, German authorities have now again halted its use among younger people. Merkel insisted however that it is such careful consideration and transparency that can keep the public's confidence in the vaccine.

"Trust stems from the knowledge that every suspicion, every individual case will be examined," she said. The cities of Berlin and Munich, as well as Brandenburg state had announced earlier that they were suspending the vaccine for younger people. Germany's medicines regulator, the Paul Ehrlich Institute (PEI), has now reported 31 cases of blood clots in people who have received AstraZeneca, Der Spiegel magazine reported on Tuesday.

Almost all cases are reportedly in younger and middle-aged women, prompting several German hospitals to suspend the use of the jab for women under 55 this week.

On Monday, Canada also recommended halting the use of the jab for under-55s "pending further analysis". The AstraZeneca vaccine has had something of a rollercoaster ride. Britain, which developed it, staunchly supports its use, South Africa has rejected it outright. France has limited its use to over-55s, while Spain has done the same for under-65s.

Germany's vaccination campaign has been sluggish, with official figures showing around 11 percent of the population have received a first dose so far. (Source: NDTV)

## TB: An Old Foe, But New Hope Lies In The Treatment Pipeline



With over 2.6 million dead, Covid-19 has become the world's leading infectious killer. Thankfully, scientific breakthroughs show that a post-lockdown world is in reach. When that time comes, a familiar and ancient foe is poised to return to the top of the list: Tuberculosis.

TB is also known as kshaya rog(wasting disease) in Hindi. It is a leading global health threat that has been with us for millennia. It kills about 1.4 million people each year. Like Covid-19, this disease is transmitted through the air and often attacks the lungs. Unlike Covid-19, it is a bacterial infection that must be treated with antibiotics.

Tragically, India has been mired in the fight against TB for generations. It leads the world in TB infections, accounting for over one in four of the 10 million people who get sick each year. It also is a leading country for people with drug-resistant forms of TB (DR-TB), which do not respond to commonly used medicines.

DR-TB has continued to grow in the shadow of today's lockdowns. TB patients around the world have faced disruption of their lengthy antibiotic treatments, increasing the risk that their infections stop responding to treatment and the disease is transmitted to loved ones in close quarters.

According to the World Health Organization, 124,000 of the 2.7 million TB cases in India in 2019 were drug resistant. Despite representing a smaller pool of patients, DR-TB places immense burdens on the health system and patients alike. These forms of TB can take much longer to cure (18-24 months instead of six), usually require 5-7 different medicines in the form of thousands of pills and cost over 30 times that of standard care. Worse, the treatment is only successful in about 50 per cent of patients. Those who survive may still face debilitating health consequences such as hearing loss due to the toxicity of the few last-resort medicines that are available.

TB and its drug-resistant forms are a crisis that cannot be ignored. They must be fought with the same spirit of innovation that we have seen in the response to Covid-19. It takes a potent combination of political will, funding, and vision to tackle public health problems of this scale. In 2003, then Health Minister (late) Sushma Swaraj demonstrated strong leadership by announcing large-scale HIV treatment with drugs manufactured by the Indian pharmaceutical industry. That move catalysed one of the largest HIV treatment programmes in the world and has resulted in great strides against HIV.

There are signs of hope for the fight against TB. Prime Minister Narendra Modi has set an ambitious goal of TB eradication in India by 2025, far ahead of the 2030 target of the Sustainable Development Goals. This bold commitment may face headwinds in the context of the unforeseen challenges posed by Covid-19, as well as the low success rates of current DR-TB treatments, which limit the potential of expanding TB services. Short, simple and standardised treatments are urgently needed to change the game. The global TB drug pipeline shows promise with over 30 compounds under active development — more than ever before.

One such treatment regimen that was recently approved by Drugs Controller General of India is a combination of two novel drugs, bedaquiline and pretomanid, with the existing drug linezolid (BPaL). The New England Journal of Medicine reports that this six-month, all-oral regimen has an approximately 90 per cent efficacy rate for the most difficult-to-treat forms of TB. Earlier this month, an update on those results presented at CROI (Conference on Retroviruses and Opportunistic Infections) found that, excepting one relapse, all patients who completed treatment remained free of disease two years later.

About 12 countries across Africa, Central Asia, Eastern Europe and the far East are beginning to implement this treatment regimen at a record-setting pace, reaching patients in less than six months since the WHO recommended pretomanid's use as part of operational research and a little over one year since the first approval by the US Food and Drug Administration (FDA).

To put this in perspective, HIV medicines have taken an average of six years from when they were first approved by a stringent regulatory authority to reach patients in developing countries.

It is noteworthy that the newest of these drugs — pretomanid, developed by the non-profit TB Alliance — is being manufactured in India. This is an inspiring example of how India's manufacturing prowess in healthcare can save lives: From new medicines for TB to vaccines for Covid-19.

Innovations in treatment could allow India to help those who are facing the worst of the TB pandemic. We have seen demonstrations of political will and scientific breakthroughs. Now is the time to seize the moment and bring this devastating disease under control. (Source: Business Line)

## Johnson & Johnson To Take Control Of Unit After 15 Million Doses Ruined



Production at the plant of the vaccine developed by AstraZeneca will be relocated with help from the Biden administration following the mix-up, according to AstraZeneca and a senior federal health official.

Johnson & Johnson will take full control of the production of its coronavirus vaccine at a troubled plant in Baltimore where millions of doses worth of drugs were contaminated, the company said late Saturday.

Production at the plant of the vaccine developed by AstraZeneca will be relocated with help from the Biden administration following the mix-up, according to AstraZeneca and a senior federal health official.

The developments followed the news that a batch amounting to 15 million doses of Johnson & Johnson's vaccine was spoiled at the plant after being contaminated with ingredients for AstraZeneca's vaccine.

The error was caught and no contaminated drugs made it out of the plant, according to the companies involved. The plant is operated by Emergent BioSolutions, a major government contractor. The senior health official said the administration had determined that only one vaccine should be made at the facility.

Johnson & Johnson said in a statement that it was "assuming full responsibility" of the production of its vaccine at the plant and that it was sending additional staff to Baltimore to oversee production. "Specifically, the company is adding dedicated leaders for operations and quality, and significantly increasing the number of manufacturing, quality and technical operations personnel to work with the company specialists already at Emergent," the statement said.

AstraZeneca said in a statement that it was working with the government to find an alternative location for production of its vaccine, which has not yet been authorized by U.S. authorities. "AstraZeneca and the U.S. government continue to work closely together to support agreed upon plans for the development, production and full delivery of the vaccine," the statement said.

Johnson & Johnson said that it still expected to deliver 100 million doses of its single-shot vaccine to the U.S. government by the end of May. President Biden has pledged that all American adults will be eligible for vaccination by that time.

Emergent spokeswoman Nina DeLorenzo confirmed Saturday that the company had been notified that production of the AstraZeneca vaccine would be relocated and that Emergent intended to stop making the vaccine in the next few days.

"We are welcoming additional Johnson & Johnson personnel on-site at Bayview for their technical expertise and support," DeLorenzo said. The changes in vaccine production at the plant were first reported Saturday by the New York Times.

Emergent's coronavirus vaccine production line has not yet been certified by the Food and Drug Administration. Until it is certified, vaccines made there cannot be distributed to consumers. Drugs made at the Baltimore plant have been set aside while the FDA reviews the Emergent plant. The Washington Post reported on Thursday that an FDA investigator flagged problems at the Baltimore facility six weeks before the Trump administration announced a \$628 million deal with Emergent as part of Operation Warp Speed, the government's program to rapidly produce vaccines to fight the novel coronavirus.

Emergent secured deals totaling more than \$740 million with Johnson & Johnson and AstraZeneca to produce vaccines for both companies at the Baltimore site. The Post reported last year that Emergent had benefited from billions of dollars in federal contracts as health officials directed public spending toward the threat of bioterrorism attacks at the expense of some preparations for a pandemic.

Emergent's Warp Speed deal was made as part of a long-standing contract between the company and the office in the Department for Health and Human Services responsible for preparing for public health threats.

At the time of the award, that office was led by Assistant Secretary Robert Kadlec. The Post previously reported that before joining the Trump administration, Kadlec was paid as a consultant to Emergent and formed a startup company with Emergent's chairman. Kadlec did not mention either role in a questionnaire about his career that he completed for the Senate when it considered his nomination by Donald Trump in 2017. Kadlec and Emergent previously told The Post that Kadlec's past work for Emergent had no bearing on the firm's government contracts. (Source: NDTV)

## 1,000 Deaths a Day In Next 2 Weeks': Maharashtra Health Department Predicts Alarming Rise in Active Covid Cases, Fatalities



Active Covid-19 cases in Maharashtra could top 3 lakh by April 4 with Pune district recording the highest number of active infections (61,125) followed by Nagpur (47,707) and Mumbai (32,927), said the state health department. Several districts are likely to face a shortage in treatment facilities. Nagpur and Thane could be among the most-affected district unless they amp up their facilities, it said. The death toll could also rise above 64,000 in next 11 days.

Projections of the public health department were based on the current 1% weekly average growth rate of infections, and has been shared with all districts in the state.

Using a cumulative case fatality rate of 2.27%, the department predicted 64,613 possible mortalities against a total caseload of 28,24,382, indicating a projection of up to 1,000 deaths a day over the next two weeks, said a TOI report. Maharashtra on Wednesday reported record 31,855 new coronavirus cases, its highest ever single-day spike since the outbreak of the pandemic. The total caseload of the state rose to 25,64,881 with 2,47,299 active cases and the death toll rose to 53,684 with 95 new fatalities.

According to the projections of the state health department, there are adequate numbers of non-oxygen beds, ICU beds and ventilators, but the state needs to be outfitted with nearly 4,000 more beds with oxygen support. Nagpur and Thane districts may not match up to the adequate number of Covid-19 beds unless they build up an inventory of beds in the thousands over the next few days, said principal health secretary Dr Pradeep Vyas. A senior critical care physician said that the projections made by the health department were conservative projections as the state has added more than a lakh cases in the last 3-4 days. Currently, over 41% of active cases are in hospital, of which 8% are critical and 0.71% are on ventilator.

Vyas has said allocation of beds at dedicated Covid-19 hospitals and health care centres must be based on clinical condition of the patient and no other consideration. Those who have recovered and have no fever, cough for three days and have more than 95% oxygen saturation should be promptly shifted to stand-down Covid Care Centres, he said, adding that there should be four-hourly, six-minute walk tests and checking of oxygen and temperature of the patients. Thane collector Rajesh Narvekar said that the district administration had begun the task of amping up bed facilities at hospitals and at least 3,000 beds will be added in the next 4 days. Nagpur municipal commissioner Radhakrishnan B said that about 250 new beds were added in private hospitals in the last 2 days, and over 90 beds were made available at the government medical college, and another 45 beds will be added at government hospitals. (Source: News 18)

## Coronavirus: India Temporarily Halts Oxford-AstraZeneca Vaccine Exports



India has placed a temporary hold on all exports of the Oxford-AstraZeneca coronavirus vaccine, foreign ministry sources have told the BBC. They said rising cases meant domestic demand was expected to pick up in the coming weeks, and so the doses were needed for India's own rollout. The move - described as a "temporary squeeze" by officials - is expected to affect supplies until the end of April. Some 190 countries under the Covax scheme are likely to be affected. The scheme, which is led by the World Health Organization (WHO), aims to ensure vaccines are shared fairly among all nations. India's largest vaccine manufacturer, the Serum Institute of India (SII), has delayed shipments of the AstraZeneca jab to several countries in recent days, including the UK and Brazil.

India has exported more than 60 million vaccine doses to 76 countries so far, with the majority of these being the Oxford-AstraZeneca jab. The decision comes as India faces a surge in coronavirus cases. On Wednesday it recorded its sharpest daily rise this year, with more than 47,000 new cases and 275 deaths. It is opening up vaccinations for those over the age of 45 from 1 April, and officials expect demand for vaccinations to increase. "[The export hold] is a temporary measure. Domestic demand will have to take precedence," one foreign ministry source told the BBC's Soutik Biswas. They said there was likely to be a squeeze on vaccine supplies until April, but the situation could ease come May when at least one additional vaccine is expected to be given emergency approval.

The Indian factory making 6,000 syringes a minute There have been no exports from India since Thursday, according to the foreign ministry's website. "Everything else has taken a backseat, for the time being at least," one source at the ministry told Reuters news agency. "No exports, nothing [until] the India situation stabilises." There has been no official comment from the government or the SII on the decision. The SII - the world's largest vaccine manufacturer - has already delayed shipments of the AstraZeneca jab to the UK, Brazil, Saudi Arabia and Morocco. "We will try to supply more later, based on the current situation and the requirement for the government immunisation programme in India," an SII spokesperson said at the time.

The SII has said it will produce one billion doses this year for low- and middle-income countries. And in January, it said it could turn out between 60 and 70 million vaccine doses a month. This figure included the AstraZeneca vaccine as well as the US-developed Novavax jab, which is not yet licensed for use in India. That month, the SII also told the BBC that it was aiming to boost its monthly production to 100 million doses from March. However, a recent check revealed production was still at 60 to 70 million doses and had not increased. The Indian government began its vaccination programme on 16 January, and so far has inoculated over 47 million people amid fears of a possible second wave. The authorities are hoping to administer 600 million doses within seven months - about 85 million doses a month. (Source: BBC)