

# DRUG INFORMATION BULLETIN

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IPA- RAD (Regulatory Affairs Division)

**Emergency use of COVID vaccine developed by M/S. Serum Institute of India and M/S. Bharat Biotech International Limited approved by DCGI today**

## **Editorial:**

It was indeed a very proud moment to witness the historical event of Drugs Controller of India (DCGI) press conference to declare that two COVID vaccines developed by M/S. Serum Institute of India and M/S. Bharat Biotech International Limited have been given Emergency approval for use in India.

These approvals came after the Subject Expert Committee (SEC) of Central Drugs Standard Control Organization made recommendations in respect of Accelerated Approval of Covid vaccines developed by M/S. Serum Institute of India (SII) and M/S. Bharat Biotech International Limited. SII has developed the COVID vaccine with a brand name Covishield with a tie up with Oxford-Astra Zeneca and Bharat Biotech has developed the COVID vaccine Covaxin with a technical tie up with Indian Council of Medical Research (ICMR). The vaccine developed by SII in collaboration Oxford-Astra Zeneca has already been approved by several countries and is in use since last few weeks, but Covaxin has been developed indigenously by M/S. Bharat Biotech International Limited jointly with Indian Council of Medical Research (ICMR). This again has proved the scientific strength of India in the field of Vaccines and Drugs development.

Both the vaccines are easy to store at 2-8 degrees centigrade for its stability, whereas the vaccine developed by Pfizer BioNTech requires to be stored at -70 degree centigrade which needs huge cold chain infrastructure. Govt. of India has already completed dry run in several places to validate the vaccination programme throughout India. Hope these two weapons in the armamentarium, will help India to face COVID pandemic successfully.

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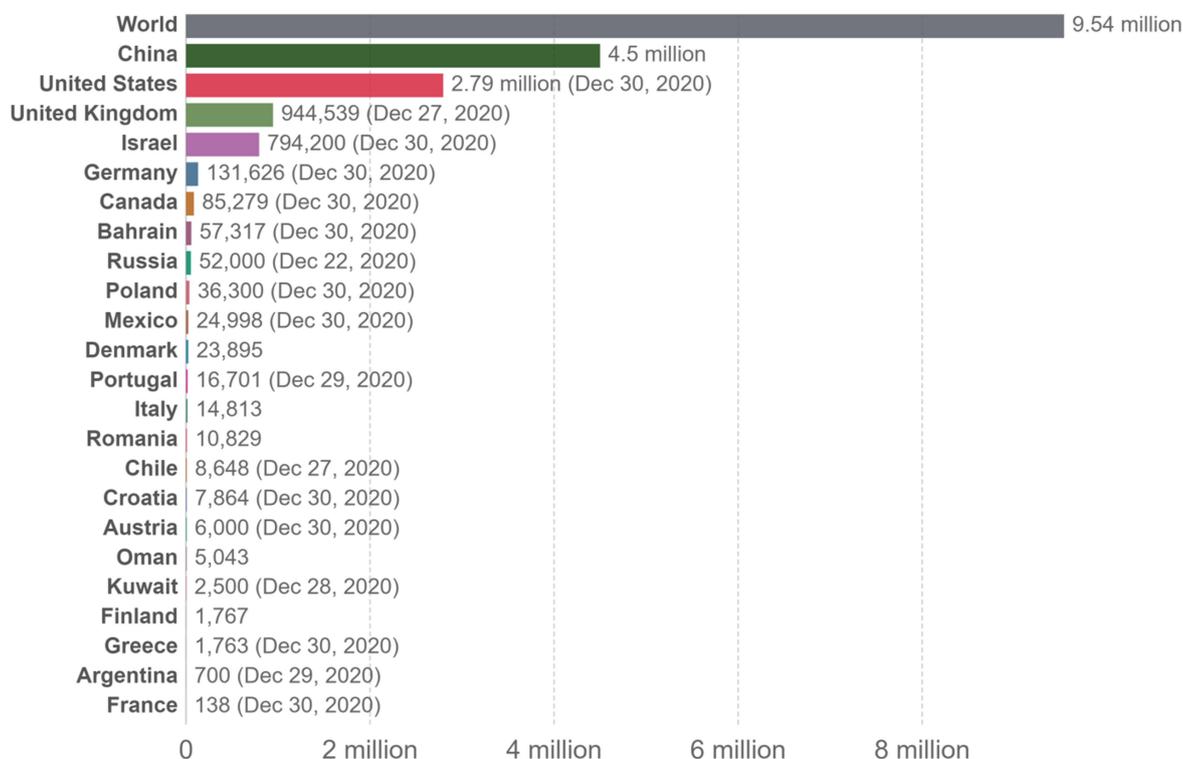
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## COVID-19 vaccination doses administered up to 31<sup>st</sup> December 2020 round the globe



### COVID-19 vaccination doses administered, Dec 31, 2020

Total number of vaccination doses administered. This is counted as a single dose, and does not measure the number of people vaccinated (which usually requires two doses).



Source: Official data collated by Our World in Data. Dates refer to when the data was reported. [OurWorldInData.org/covid-vaccinations](https://OurWorldInData.org/covid-vaccinations) • CC BY

### More than 50 countries launch Covid-19 vaccination campaigns

Around 50 countries around the world have already started vaccinating their people against Covid-19, barely a year after the first alert by China signalled the start of the epidemic.

China, where the pandemic first emerged, was also the first to start vaccinations over the summer, without waiting for a vaccine to be formally authorised but targeting the most vulnerable. To date nearly five million Chinese people have been vaccinated. Beijing on Thursday granted "conditional" market approval to a Sinopharm vaccine with a reported 79 percent efficacy rate against Covid-19.

Russia followed on December 5, rolling out vaccinations for those considered high risk with its contentious Sputnik V vaccine, which has since been approved in Belarus and Argentina, which launched their vaccination campaigns on Tuesday. Algeria is set to follow them in January.

Britain led the way in the Western world, authorising the vaccine made by US-German pharma alliance Pfizer-BioNTech. Its vaccination campaign started on December 8 and by December 27 close to 950,000 people had received their jabs, according to official figures published Thursday.

Britain was also the first on Wednesday to approve the coronavirus vaccine developed by AstraZeneca and Oxford University. It will be administered for the first time on January 4.

Canada and the United States started their vaccination drives on December 14, Switzerland on the 23rd, Serbia the 24th, the vast majority of the European Union on December 27, Norway on Sunday and Iceland on Tuesday. All of them are using the Pfizer-BioNTech vaccine.

The United States and Canada are also the first two countries to have authorised the vaccine by US pharma company Moderna, which is up for approval on January 6 by the EU.

Around 2.8 million Americans have already been given their first dose of the Covid-19 jab. In the 27-nation EU Germany has so far given the most injections, with more than 130,000 in five days.

In the Middle East, the United Arab Emirates were the first to launch their vaccination campaign with doses of China's Sinopharm, on December 14 in the capital Abu Dhabi. Dubai started its vaccinations on December 23, using doses of Pfizer-BioNTech. Saudi Arabia and Bahrain launched their campaigns on December 17, Israel two days later, Qatar on the 23rd, Kuwait the 24th, and Oman on December 27. All are solely using the Pfizer- BioNTech jab, except for Bahrain which is also using China's Sinopharm.

Israel, which has set itself the ambitious goal of inoculating a quarter of its population in a month, has already injected nearly 800,000 people. Bahrain has vaccinated nearly 60,000 and Oman more than 3,000.

Turkey, which has received doses of China's Sinovac, will launch its vaccination drive in mid-January.

In Latin America, Mexico, Chile and Costa Rica were the first to launch, on December 24, jabs with the Pfizer-BioNTech vaccine.

In Asia, Singapore launched its campaign on Wednesday with the same vaccine. Today India has approved two vaccines developed by SII and Bharat Biotech for Emergency Use.

Other countries on the Asian continent however have decided to take their time: India, Japan and Taiwan plan to begin vaccinations in the first quarter of 2021 and the Philippines and Pakistan in the second quarter, while Afghanistan and Thailand plan to start in mid-2021.

In sub-Saharan Africa and in Oceania vaccinations have yet to take off. But in West Africa Guinea this week administered its first few doses of Russia's Sputnik V on a trial basis.

### **No Difference Seen In Fatality Rate with New Strain of Coronavirus: Study**

Case fatality and hospitalisation rate from a new strain of coronavirus spreading rapidly in the UK and elsewhere is no different than that from other strains that do not carry this mutation, a

preliminary study by Public Health England showed.

“Preliminary results from the cohort study found no statistically significant difference in hospitalisation and 28-day case fatality between cases with the variant of concern (VOC) and wild-type comparator cases,” said authors of the study led by Meera Chand of Public Health England. “There was also no significant difference in the likelihood of re-infection between variant cases and the comparator group.”

The preliminary study on the impact of the new mutation of the SARS-Cov-2 in severity of the disease said majority of the cases found of this variant came from residents in private dwellings, and the variant cases were most likely to be part of residential cluster.

The Union health ministry on Tuesday said it will be carrying out genome sequencing of all international travellers to the country in the past fortnight “if symptomatic and tested positive” to widen the scope of its scrutiny for the new, infectious strain of SARS-Cov-2 that’s said to have originated in the United Kingdom.

The exercise may involve tracing an estimated 70,000 people, according to travel experts. This comes a week after the health ministry had announced sequencing of all passengers arriving from the UK.

Additionally, the ministry has also proposed that 5% of positive samples from each district/state detected daily are sent for genome sequencing, irrespective of travel history.

Source: Economic Times

### **Centre Orders 83 Crore Syringes for Covid Vaccination**

In anticipation of the much-awaited COVID-19 vaccine, the government has placed orders for procurement of nearly 83 crore syringes to be used for coronavirus vaccination and the Universal Immunization Programme, a statement from the Union Health Ministry informed.

According to the statement, bids have been invited for 35 crore more syringes and as many as 36,433 ventilators have been delivered to government hospitals across the country in the last nine months, with the cost ranging from Rs 2 lakh to Rs 10 lakh, considerably more cost-effective than the Rs 15 lakh price tag in February-March. "This is important because from the independence of the country till pre-COVID times, all the public health facilities in the country had only about 16,000 ventilators but in less than 12 months 36,433 'Make in India' ventilators have been supplied to all the public health facilities," the statement said.

It also noted that at the beginning of the pandemic in the country, almost all the ventilators, PPE Kits, and N-95 Masks were imported, and there were no standard specifications for these products which are essential in the fight against the pandemic.

"The Central Government recognized the challenges posed by the pandemic in the very initial stages and successfully ensured more than adequate availability and supplies of essential medical items," the statement said.

It further added that from a minuscule domestic PPE-kit production capacity in March, India had

now become the world's second-largest manufacturer, with a production capacity of more than 10 lakh PPE coveralls per day.

"There are already nearly 1,700 indigenous manufacturers and suppliers. Nearly 170 lakh PPE kits have been distributed free of cost and the buffer stock of PPE kits available with the Central and State Governments has grown from about 2 lakh in March to more than 89 lakh at present. The average price to has come down substantially from nearly Rs 600 to about Rs 200 per kit in nine months," it said.

Similarly, till March, there were only three suppliers of N-95 masks capable of producing 1 lakh masks per day. But with over 3,000 manufacturers now, the domestic production capacity has risen to more than 8 lakh N-95 masks per day. These are also being exported from India in large quantities and over 4 crore have been distributed free of cost to different states.

"The average prices of masks have dropped from about Rs 40 in March to Rs 12 per mask during the same period," it added.

Source: The Print

### Reader's Column.....

Dear Dr Subhash Mandal,  
Thank you very much for sharing latest issue of Drug Information Bulletin containing useful information on status of regulatory approval of Anti COVID 19 vaccines Worldwide.  
With regards.

**Dr. C K Katiyar**  
**CEO Health Care (Technical)**  
**Emami Ltd**



**DCGI-Dr. V.G.Somani in a press conference today declaring Emergency approval of Covid vaccines developed by SII and Bharat Biotech**

### DISCLAIMER:

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