

What's Happening with COVID-19 Vaccine Supply?



Shortages of COVID-19 vaccine supplies are being felt globally, not excluding the EU and the UK. Do companies fulfil their obligations and where will new manufacturing facilities be created?

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A new <u>report</u> from the European Centre of for Disease Prevention and Control (ECDC) shows that 96% (26 out of 28) of the European countries are experiencing "challenges related to the limited supply of COVID-19 vaccines, as well as frequent changes in timing of deliveries from vaccine producers". At the same time, the EU is the world's biggest COVID-19 vaccine exporter that has sent about 77 million doses abroad, including 21 million to the UK since December, according to European Commission President Ursula von der Leyen.

At a summit last week, the EU took course on toughening COVID-19 export controls stopping short of banning vaccine exports altogether. Potential restrictions include rationing vaccine exports according to a country's need, i.e. based on the number of people already vaccinated and on whether a country has been in turn sending vaccines and ingredients to the EU. "We recognise the importance of global value chains and reaffirm that companies must ensure predictability of their vaccine production and respect contractual delivery deadlines. We confirm the pro-rata population key for the allocation of vaccines," the <u>statement</u> released after the summit read.

This move comes in the middle of the bloc's clash with AstraZeneca with the later not fulfilling its contractual obligations. The EU was hoping to get 120 million doses from the company but for now can only expect about a fourth of that amount. Ursula von der Leyen said the company must "catch up" on deliveries to the EU before exporting doses to other countries. This also exacerbates the growing opposition between the EU and the UK regarding the supply of the vaccine, but the countries are reported to be seeking a mutually satisfying solution.

New Sites in Europe

Following the summit, the European Medicines Agency's human medicines committee (CHMP) has <u>approved</u> measures to open new or expand existing vaccine manufacturing sites in Europe.

Specifically, a new facility in the Netherlands will be producing active substance of the AstraZeneca COVID-19 vaccine. This will become the fourth manufacturing site to be licenced for the production.

Another site located in Germany has been approved for the production of both active substance and the finished product of Comirnary, the BioNTech/Pfizer COVID-19 vaccine. Currently, three facilities in the EU manufacture the vaccine's active substance. EMA has also relaxed requirements for the vaccine's transportation and storage allowing for the temperatures between -25 to -15°C (standard pharmaceutical freezers) for a one-off period of two weeks. For longer terms, Comirnaty must be stored in special freezers at ultra-low temperatures of -90 to -60°C, a condition that has been complicating the vaccine logistics and management.

Moderna will add new manufacturing lines to its facility in Switzerland that produces both active substance of the COVID-19 vaccine and finished product, and has seen other changes to its manufacturing process approved by EMA that will allow for the production scale-up.

'U.S. First'

U.S. President Joe Biden last week doubled his goal for his first 100 days in the office now aiming for 200 million inoculations. By the end of March, the U.S. will have received 240 million doses of vaccine from all three manufacturers whose product has been granted the emergency use authorisation earlier, i.e. Pfizer, Moderna and Johnson & Johnson. The first two have committed to deliver 100 million doses each, but Pfizer may increase the number to 120 million. J&J is aiming for 20 million, Bloomberg reports.

At the same time, the U.S. has preordered 300 of millions of AstraZeneca vaccine which has yet to apply for the emergency use authorisation in the country. Other countries and the company itself have called the U.S. to share the doses, but these requests have been rejected at least until every American gets inoculated. Instead, the U.S. has loaned its AstraZeneca vaccines to Mexico and Canada on the condition that the countries give doses back in the future when or if the U.S. needs them. "After we do take care of the really difficult situation we've had in our own country with over 535,000 deaths, we will obviously, in the future, have surplus vaccine," according to Anthony Fauci, head of the National Institutes of Allergy and Infectious Diseases. The Lancet Commission, however, recommended that the U.S. is more involved in the global vaccination efforts and "should accelerate the rejoining of WHO, expand its role in COVID-19 Vaccines Global Access, and contribute funding and vaccines to this global effort".

COVAX and LMICs

The World Health Organization has warned that the COVAX programme that distributes the COVID-19 vaccines to low and middle-income countries will face delays in deliveries of COVID-19 vaccines produced by the Serum Institute of India (SII) in the coming months, as India is trying to contain a new wave of COVID-19 infections. SII is the largest COVAX supplier and is licenced by AstraZeneca to manufacture the vaccine which is branded as Covishield and being delivered to 64 lower-income economies participating in the Gavi COVAX AMC. So far, 28 million doses of Covishield have been supplied through COVAX out of the total of 32 million doses. Similar delays are expected with the AstraZeneca-manufactured doses. The company is planning to supply its vaccine to 82 countries through COVAX having stricken multiple agreements for manufacturing around the world.

Several countries, including France and India, are going to donate a share of their vaccine doses to poorer states. In addition, The Lancet Commission called the countries with excess vaccines to consider their assignment to COVID-19 Vaccines Global Access.

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