Source : www.thehindu.com Date : 2022-05-15

QUAD INITIATIVE FOR VACCINES RUNS INTO ROUGH WEATHER

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There is now an ‘oversupply’ of vaccines in Southeast Asian countries and other regions.K. Murali KumarK. Murali Kumar

More than a year after the first Quad summit hosted by U.S. President Joseph Biden, Prime Minister Narendra Modi, and leaders of Japan launched an ambitious vaccine initiative to produce one billion doses of vaccines for distribution in the Indo-Pacific region, the project is floundering as officials concede that it is unlikely to reach its target by 2022-end for a number of reasons.

While the original plan to produce the single-shot Johnson & Johnson vaccine at the Hyderabad-based Biological E facility for the Quad Vaccine Initiative (QVI) ran into trouble over legal indemnity issues, and then over safety concerns, the other vaccine being produced at the facility, Corbevax, has yet to receive WHO Emergency Use Listing (EUL) needed for distribution.

Experts say there is now an “oversupply” of vaccines in Southeast Asian countries and other regions in the world, bringing down the demand for vaccines. Ahead of the third Quad summit in Tokyo on May 24, officials are reviewing how best to take the initiative forward, sources said.

After the Quad virtual summit in 2021, a U.S. White House “Fact Sheet” on the vaccine announcement had said that the “United States, through the Development Finance Corporation (US-DFC), will work with Biological E Ltd., to finance increased capacity to support Biological E’s effort to produce at least 1 billion doses of COVID-19 vaccines by the end of 2022 with Stringent Regulatory Authorization (SRA) and/or WHO Emergency Use Listing (EUL), including the Johnson & Johnson (J&J) vaccine.”

The fact that the J&J vaccine was named specifically was significant at the time, since Biological E had already signed a separate agreement in August 2020 for the manufacture of the J&J COVID vaccine, and sources said it had produced about 10 million doses by the time. However, subsequently, matters came to a head over J&J’s plans to export additional doses to India, as the Indian government refused to sign a liability waiver which would indemnify J&J from side effects of the vaccine. Recently, J&J faced another blow from the US Food and Drug Administration, which limited the use of the vaccine in the U.S. due to the risk of blood clots.

Stalled production

Sources said that Biological E has not, as a result, produced any more doses of the J&J vaccines, and at present, it’s entire production line is dedicated to producing the U.S.-developed Corbevax vaccine. This poses another problem as Corbevax has not so far received WHO-EUL clearance, and Biological E’s application for the EUL is “under review”, and therefore is ineligible to be included in the Quad Vaccine Initiative.

Yet another problem now is the excess production of vaccines that has led to a sharp drop in demand. According to renowned virologist and Professor at the Christian Medical College, Vellore, Gagandeep Kang, who has been involved in initiative as a board member of the Coalition for Epidemic Prevention and Innovation (CEPI), vaccine shortages ended after a bumper production of about 11 billion COVID doses in 2021.

“If anything, the vaccine industry is a victim of its spectacular success in producing a COVID vaccine very quickly. As a result, those vaccines that came a bit later to the table, even if they are cheaper and safer, are struggling, while donors are trying to find willing recipients,” Ms. Kang told *The Hindu* .

Financing arrangement

When asked, a U.S. health expert who has been part of the initiative denied that the vaccine initiative had reached a dead-end despite the non-production of the J&J vaccine. “One has to look at the intent of the DFC investment, which was “to finance increased capacity to support Biological E’s effort to produce at least 1 billion doses of COVID-19 vaccines by the end of 2022,” said the expert who asked not to be named, adding that the DFC’s financing arrangement finalised in October 2021, for $50 million had achieved its objective of expanding the Hyderabad-based company’s capacity, adding to additional lines of production.

The event in October was attended by the U.S. Chargé d’Af-faires Patricia Lacina, Ministry of External Affairs Joint Secretary Vani Rao, Japanese Consul-General Taga Ma-sayuki, and Australian Consul-General Sarah Kirlew as a mark of the Quad’s commitment. It is unclear how the funding will now be used to complete the production of one billion vaccines with WHO-EUL authorisation in just over seven months.

The Hindu reached out to Biological-E, as well as the Ministry of External Affairs and the U.S. Embassy, all of whom declined to comment. Biological E spokespersons directed all queries on the Quad initiative to J&J, where a spokesperson said the company “believes Biological E will be an important part of our network, where multiple manufacturing sites are involved in the production of our vaccine across different facilities.”

However, despite repeated requests, the spokesperson refused to divulge the status of the Johnson and Johnson production line at Biological-E or comment on how many doses had been produced under the Quad initiative, if any.