EU regulator starts a review of Russia's COVID-19 vaccine

04/03/2021 19:23 by admin

The European Medicines Agency's 'rolling reviews' are aimed at speeding up the approval process by allowing researchers to submit findings in real-time before final trial data is ready.

As the race for the COVID-19 vaccine transitions into ever greater global distribution, the pall of fear brought by the pandemic promises to gradually lift. (File)

Moscow: Europeâ€™s medicines regulator said on Thursday it had started a rolling review of Russiaâ€™s Sputnik V COVID-19 vaccine, an important display of confidence in the shot that paves the way for its potential approval across the 27-nation bloc.

Hungary became the first EU country to grant the Russian vaccine emergency national approval in January, Slovakia has ordered shipments, and Czech Prime Minister Andrej Babis has said his country could move to use Sputnik V.

The European Medicines Agency (EMA) said in a statement it would review data from ongoing trials of the vaccine until there was enough evidence for a formal marketing authorisation application.

EMAâ€™s â€˜rolling reviewsâ€™ are aimed at speeding up the approval process by allowing researchers to submit findings in real-time before final trial data is ready.

â€œWhile EMA cannot predict the overall timelines, it should take less time than normal to evaluate an eventual application because of the work done during the rolling review,â€• it said.

Kirill Dmitriev, CEO of the RDIF sovereign wealth fund that is promoting Sputnik V internationally, hailed the start of EMAâ€™s rolling review as an important moment for Russia which he said showed its application had been a strong one.

â€œSputnik V can act as a bridge between Russia and Europe, but its roll out should not get bogged down in politics,â€• Dmitriev told Reuters, praising Germany, France, Italy and Austria for what he called their pragmatic approach to Sputnik V.

The shotâ€™s efficacy was initially greeted with scepticism by some Western scientists after Russia approved it in August last year without waiting for the results of full clinical trials.

However, some of those initial concerns appear to have faded after scientists said it was almost 92% effective in fighting COVID-19, based on peer-reviewed late-stage trial results published in The Lancet medical journal last month.

The two-shot vaccine uses two different weakened common cold viruses to deliver immune-building protein to the human body.

Dmitriev said Moscow could provide vaccines for 50 million Europeans starting from June if the shot won EU-wide approval, adding he expected several EU countries to approve the use of Sputnik V this month for their national use.

He did not name the countries.

Europe has so far approved vaccines from Pfizer/BioNTech, Moderna and AstraZeneca/Oxford, while ongoing reviews for CureVac and Novavaxâ€™s candidates are underway.

The EMA is expected to give its verdict on J&Jâ€™s single-shot vaccine on March 11.

- AP