

WHO spots problems at Russian vaccine plant

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The World Health Organization said Wednesday it had uncovered problems at a Sputnik V COVID-19 vaccine production site which Moscow insisted had been resolved.

WHO approval has been sought for the Sputnik V jab created by Russia's Gamaleya research institute, which is already being used in 40 countries.

The UN health agency inspected four Sputnik V manufacturing sites.

On Wednesday, it released a summary report of its preliminary findings, detailing six issues found during its May 31 to June 4 visit to the Pharmstandard Ufa Vitamin Plant in Ufa, southern Russia.

The inspectors had concerns with the data integrity and testing results from monitoring during manufacturing and quality control, and with the monitoring and control of aseptic operation and filling.

The inspection identified issues with the traceability and identification of vaccine batches.

There were also concerns over the filling lines, sterility assurance, sterile filtration validation and the risks of cross-contamination.

"Communications have been initiated with the relevant manufacturer, the applicant and the respective national regulatory authority with the view that the preliminary findings outlined in this report are investigated and addressed as quickly as possible," the WHO told AFP.

Kremlin spokesman Dmitry Peskov said there were "some shortcomings identified by the inspection group, and from what we know, they were taken into account and all that needed to be changed was changed.

"Of course the necessary controls by the control bodies are in place. It is obvious that this is the strictest control possible", he added.

WHO approval process

The WHO's emergency use listing (EUL) approval is the green light that gives countries, funders, procuring agencies and communities assurance that a vaccine has met international standards.

The WHO said it had so far conducted nine inspections of the Sputnik V manufacturing sites.

They included five clinical trial sites jointly visited with the European Medicines Agency regulator and four manufacturing sites, two of which were joint visits with the EMA.

Out of the latter four inspections, the WHO "found non-compliance with good manufacturing practices at one manufacturing site", it said.

"Findings from the other manufacturing sites of the

Sputnik V vaccine that WHO has inspected are still being assessed but they have not raised similar concerns."

The organisation said it would continue to assess Sputnik V vaccines from different manufacturing sites and publish its decision on EUL status once all the data is available and the review is complete.

EUL paves the way for countries to approve and import a vaccine for distribution quickly, especially those states without an international-class regulator of their own.

It also opens the door for the jabs to enter the Covax global vaccine distribution facility, which aims to provide equitable access to doses in poorer countries.

The WHO has so far given EUL status to vaccines created by AstraZeneca, Pfizer-BioNTech, Moderna, Johnson & Johnson, Sinopharm and Sinovac.

The WHO's vaccine overview shows that of the other vaccines yet to receive EUL status, the Sputnik V is the furthest ahead in the process.

Sputnik V is already being used in 40 countries, according to an AFP count.

Besides Russia, those nations include Argentina, India, Iran, Kenya, Mexico, Pakistan, the Philippines and the United Arab Emirates.

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