The Moscow Times
30 YEARS
INDEPENDENT NEWS FROM RUSSIA

WHO Finds Production Infringements at Sputnik V Manufacturer

By Jake Cordell and Pjotr Sauer

June 23, 2021

The World Health Organization has inspected four manufacturing sites involved in production the Sputnik V vaccine. **Anatoly Maltsev / EPA / TASS**

The World Health Organization (WHO) has raised concerns about possible cross contamination and insufficient sterilization checks during an inspection at a factory involved in manufacturing Russia's Sputnik V vaccine.

In an interim report published Wednesday, the organization outlined six production infringements at a Pharmstandard plant located in Ufa — one of nine sites the WHO inspection team visited as part of evaluating Russia's application to have its homemade Sputnik V jab granted emergency authorization.

The WHO said it had "identified concerns with the implementation of adequate measures to mitigate the risks of cross contamination," as well as "concerns with appropriate sterile filtration validation" of the Sputnik V vaccine. It also highlighted possible problems with the

systems used to trace and identify individual vaccine batches and "concerns with ... quality control activities."

The inspection was carried out to assess whether the factory was operating in line with so-called Good Manufacturing Practices (GMP) — a set of regulatory guidelines that dictate the standards which sites involved in manufacturing pharmaceutical products must adhere to.

Related article: Coronavirus in Russia: The Latest News | June 23

The manufacturing breaches highlighted by the WHO could compromise the vaccine's quality, independent experts say.

Pharmstandard said it has already addressed the WHO's areas of concern. Though in a statement published on its website in English, the company said the WHO had highlighted only four specific concerns — not six, as cited in the WHO's report published on the organization's website.

In a statement to The Moscow Times, the WHO said it inspected a total of nine sites across Russia — five connected with the jab's development and design, and four manufacturing plants. Most of the inspections were conducted alongside the European Medicines Agency (EMA).

Only the inspection at the Ufa plant has so far fell short of the WHO's standards. "Findings from the other manufacturing sites of the Sputnik V vaccine that the WHO has inspected are still being assessed, but they have not raised similar concerns," a representative said.

'Technical issues'

Pharmstandard said the WHO's findings were "technical issues, mostly related to one of the filling lines that have all been subsequently fully addressed."

It added that the plant in question is responsible for filling the vaccine fluid into vials, with the fluid itself produced at a different facility. The company claims the WHO "did not raise any questions about the safety and efficacy of the produced and finished vaccine," nor did it "identify any critical issues with the actual vaccine's production, quality, clinical studies [or] possible side effects."

Pharmstandard did not respond to requests for additional comment.

Independent experts said it was wrong to downplay the importance of the filling process as a stage in vaccine manufacturing and that errors could affect the quality of vaccine batches.

Related article: Is the WHO Too Soft on Russia?

"The whole filling process needs to be done in an incredibly sterile environment so that no bacteria or other viruses come into contact with the vaccine liquid and compromise its quality," said Zoltan Kis, a research associate at Imperial College London's Future Vaccine Manufacturing Hub.

“It might sound trivial — just putting some fluid in some vials — but it isn’t,” said Daniel Bracewell, professor of bioprocess analysis at University College London.

“These GMP guidelines are put down for very good reasons and are proven to keep people safe. It would be very dangerous to inject somebody with something that had any trace of bacteria in there at the filling stage. The bacteria would multiply in the vial before it gets used — so that part of the process has to be spot-on,” he added.

Experts interviewed by The Moscow Times noted it was unclear from the WHO’s short report how serious the issues were, but said the problems could be remedied by Pharmstandard — "with some hard work and investment," according to Bracewell.

Seeking authorization

Pharmstandard also reiterated Russian authorities’ claims about Sputnik V’s superiority to its Western competitors, saying “unlike some other foreign vaccines, Sputnik V is consistently demonstrating [an] outstanding safety and efficacy record in real-world use.”

No peer-reviewed data on Sputnik V’s real-world effectiveness has been published. Lab studies have previously indicated Sputnik V, like other vaccines, could be weaker at preventing infections with new, more aggressive strains of the coronavirus.

Russia is currently seeking authorization by both the WHO and the EMA for Sputnik V. As part of its application, both regulators have conducted inspections of the jab’s manufacturing sites. The WHO also confirmed Wednesday that it had taken part in a special ethics probe — a “Good Clinical Practices” check — alongside the EMA to look into the development and clinical trials of the vaccine. Neither the WHO or EMA have published information about the results of those inspections.

Kremlin spokesperson Dmitry Peskov said Wednesday that Pharmstandard had already addressed and corrected all of the WHO’s concerns. The manufacturer said it has invited the WHO to return for a second inspection of the facilities.

The EMA told The Moscow Times it did not inspect the plant in Ufa alongside the WHO, as the site is manufacturing Sputnik V jabs “for use outside the EU.”

Nevertheless, it noted the WHO’s findings could impact the jab’s potential approval for use in the 27-member bloc.

“The review of the European inspection findings for this vaccine is ongoing and will continue until all issues raised by that inspection have been addressed to full satisfaction. The implications of the WHO inspection findings at Pharmstandard are being considered carefully,” an EMA spokesperson said in a statement to The Moscow Times.

The EMA added: “As new information is submitted by the applicant during the rolling review, further inspections may be needed.”

Gaining EMA approval for Sputnik V is seen as a crucial step in enabling millions of vaccinated Russians to travel to the bloc hassle-free as coronavirus restrictions ease, since Brussels is considering a vaccine passport system which only covers those vaccinated with a jab approved

by the EMA.

This story was updated after initial publication to include comments by the WHO, EMA and independent experts.

Original url:
https://www.themoscowtimes.com/2021/06/23/who-finds-production-infringements-at-sputnik-v-manufacturer-a74310