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WHO wants to review Russian vaccine safety data

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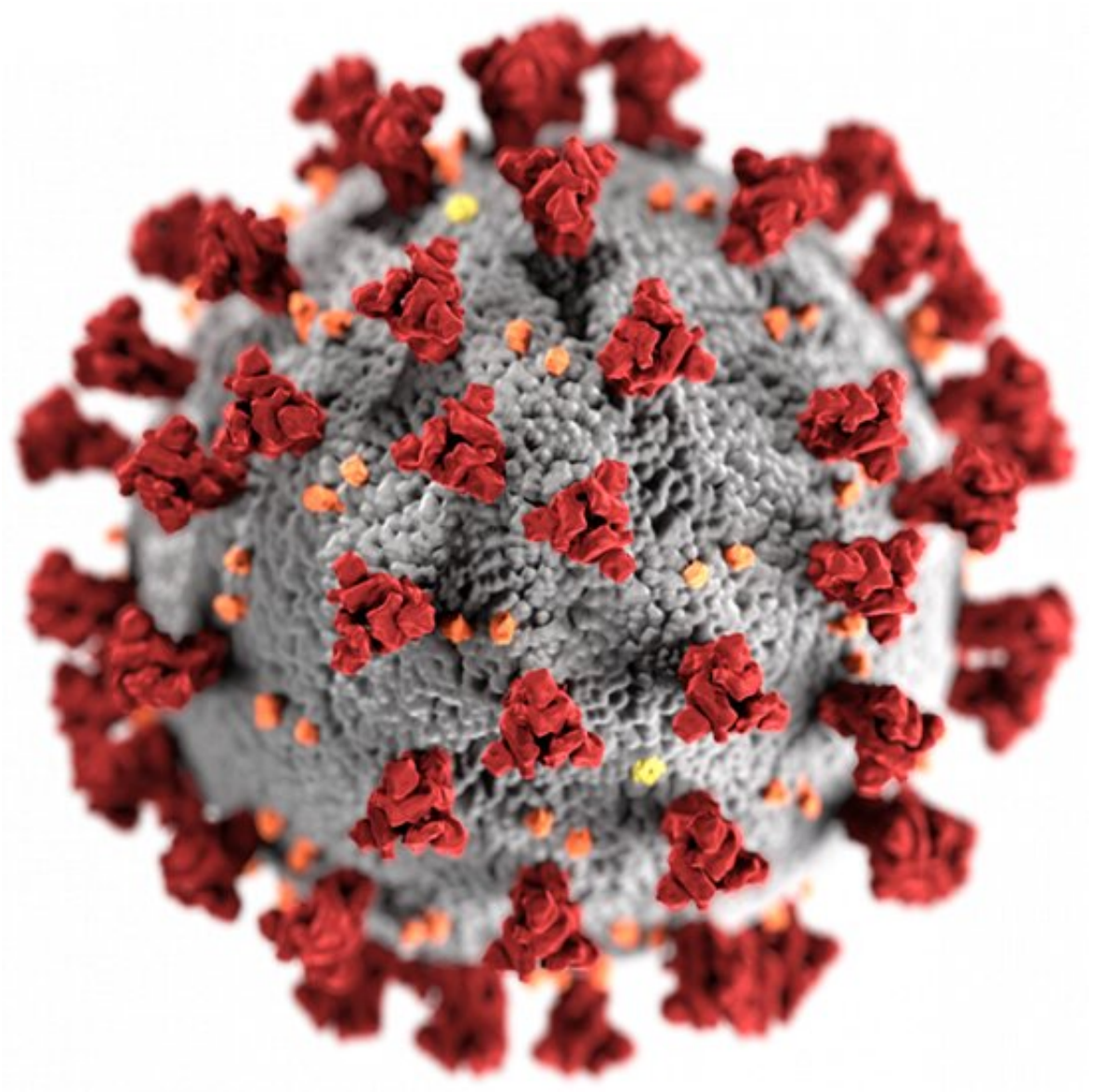

Image of the ultrastructural morphology exhibited by the 2019 Novel Coronavirus (2019-nCoV). Credit: CDC

The World Health Organization said any WHO stamp of approval on a COVID-19 vaccine candidate would require a rigorous safety data review, after Russia announced Tuesday it had approved a vaccine.

President Vladimir Putin said Russia had become the first country to approve a vaccine offering "sustainable immunity" against the new coronavirus.

"We are in close contact with the Russian health authorities and discussions are ongoing with respect to possible WHO pre-qualification of the vaccine," said the United Nations health agency's spokesman Tarik Jasarevic.

"Pre-qualification of any vaccine includes the rigorous review and assessment of all the required safety and efficacy data," he told reporters in Geneva at an online press briefing.

Russia's Sputnik V vaccine has been developed by the Gamaleya research institute in coordination with the country's defence ministry.

A total of 168 candidate vaccines are being worked on around the world, according to a WHO overview published Tuesday.

Of those, 28 have progressed to the various phases of being tested on humans, of which six are the furthest ahead, having reached Phase 3 of clinical trials.

The Gamaleya candidate, which is among the 28 in clinical evaluation, is listed as only being in Phase 1.

Kirill Dmitriev, the head of the Russian Direct Investment Fund which

finances the vaccine project, said Phase 3 trials would start on Wednesday, industrial production was expected from September and that 20 countries had pre-ordered more than a billion doses.

'Stamp of quality'

"Every country has national regulatory agencies that approve the use of vaccines or medicines on its territory," Jasarevic explained.

"WHO has in place a process of pre-qualification for vaccines but also for medicines. Manufacturers ask to have the WHO pre-qualification because it is a sort of stamp of quality.

"To get this, there is a review and assessment of all required safety and efficacy data that are gathered through the clinical trials. WHO will do this for any candidate vaccine."

The pandemic has seen an unprecedented mobilisation of funding and research to rush through a vaccine that can protect billions of people worldwide.

"We are encouraged by the speed by which several candidate vaccines have been developing and as we have been always saying, we hope some of these vaccines will prove to be safe and efficient," said Jasarevic.

"Accelerating progress does not mean compromising on safety," he said.

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