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# EMA: No Application Received For Sputnik V Vaccine

*Confusion Reigns As Russian Developers Appear To Have Used The Wrong Portal*

by Ian Schofield

There is considerable confusion over the application system used to file the Russian vaccine for approval in Europe.

The European Medicines Agency says it has not received an application for either a marketing authorization or a rolling review of the Sputnik V COVID-19 vaccine.

The EMA's statement contradicts claims by the vaccine's Russian backers that they filed for registration of the vaccine in the EU on 29 January and have "started submitting the information to EMA for the rolling review."

It appears that the team behind Sputnik V has indeed submitted some kind of a marketing authorization application. However, it seems it has done so using the portal intended for filings with individual member state authorities – the Common European Submission Portal (CESP) – rather than via the EMA's eSubmissions Portal, which is the centralized application route for products seeking pan-EU approval.

> ***"[We have] started submitting information to the EMA for the rolling review" – Russian Direct Investment Fund***

The Russian Direct Investment Fund is financing development of the vaccine. It said in a 9

February statement that the EU registration filing was made on 29 January, that it had "started submitting information to the EMA for the rolling review", and that it had received "an official confirmation from EMA that its application has been accepted." (Also see "*Coronavirus Notebook: EU Filing For Russian Vaccine, UK Links With CureVac Against Virus Variants*" - Pink Sheet, 9 Feb, 2021.)

However, it was not clear at that stage whether the EMA had formally accepted a marketing authorization filing for review, and the agency did not respond to two *Pink Sheet* requests for comment.

> ***"To date [we have] not received an application for a rolling review or a marketing authorization for the vaccine" – European Medicines Agency***

The following day, the EMA issued a statement declaring that it had "to date not received an application for a rolling review or a marketing authorization for the vaccine developed by the Gamaleya National Centre of Epidemiology and Microbiology in Russia, the Sputnik V vaccine (Gam-COVID-Vac), despite reports stating the opposite."

## Scientific Advice Given

The EMA noted that the vaccine's developers had "received scientific advice from EMA providing them with the latest regulatory and scientific guidance for the development of their vaccine." (Also see "*Sputnik V COVID-19 Vaccine Team Discusses EU Development Plan With EMA*" - Pink Sheet, 20 Jan, 2021.) It added that it was "in dialogue and collaborating with the company to define the next steps" for the vaccine and that the "developers have expressed their interest that the vaccine be considered for a rolling review."

The agency also pointed out in its statement that its human medicines committee, the CHMP, and the COVID-19 EMA pandemic Task Force (COVID-ETF) must give their agreement before developers can submit their application for initiation of the rolling review process.

Shortly afterwards, the Sputnik V Twitter account tweeted: "In response to the EMA statement that they cannot find Sputnik V application for review, we attach the receipt of such application 1379253 from January 29, 2021 below. 24 countries have already registered Sputnik V."

It attached a screenshot of part of the 1379253 submission through the CESP showing the status

as “complete” on 29 January.

However, the CESP is the portal that is used for submissions to individual EU national regulatory agencies. Products going through the centralized approval system need to use the eSubmission Gateway/Web Client, which is a direct route to the EMA for the assessment of human and veterinary medicines. This has been the case since 2015. (Also see "*EMA mandates use of electronic forms, eSubmission Gateway for human drugs*" - Pink Sheet, 7 Jul, 2015.)

It is not clear why the RDIF took the CESP route for Sputnik V, or what its intentions are regarding an EMA submission. It had not replied to a request for comment at the time this article was published.

It is also not clear what specifically the RDIF has applied for via the CESP.

## EMA On New COVID-19 Announcements

The EMA said in its statement that it would “promptly inform the public of any new assessments of COVID-19 vaccines or medicines started by the agency.” It added that it always publishes a news announcement “when, following agreement by CHMP and COVID-ETF, an application for rolling review is received from the developers and the assessment starts.” Under a rolling review, data are submitted as they become available, and once there are enough data the applicant can file a marketing authorization application.

> *“[We are] in dialogue with more than 50 vaccine developers from across the globe” – European Medicines Agency*

The agency will also publish a news announcement whenever it receives a valid application for marketing authorization for a COVID-19 product, and the list of treatments and vaccines under evaluation will be updated at the same time. “This means that if EMA has not communicated, the status of a given COVID-19 medicine/vaccine remains unchanged.”

The EMA added that it was “committed to applying the same regulatory approach and scientific rigor to all vaccine applications that meet European requirements for safety, efficacy and quality and is in dialogue with more than 50 vaccine developers from across the globe.”