

Langen, 11 August 2020

## STATEMENT

### REGULATORY APPROVAL IN RUSSIA OF A COVID-19 VACCINE DEVELOPED BY GAMALEYA INSTITUTE

#### Vaccine candidate: Adenoviral vector-based prime/boost vaccine

There has so far been little transparency regarding the conditions of the regulatory approval of the Gamaleya COVID-19 vaccine. No safety or efficacy data from clinical trials with several thousands of trial subjects have so far been released. The regulatory approval therefore needs to be considered with caution.

Together with the WHO and other international experts, the Paul-Ehrlich-Institut warns against too much haste regarding the regulatory authorisation of a COVID-19 vaccine. Despite the current pandemic situation, the Paul-Ehrlich-Institut deems it necessary that all tests and evaluations of COVID-19 vaccines be carried out with the same care as for other vaccines. Any vaccine product should only be authorised if the demonstrated benefits greatly outweigh the possible risks.

The granting of a regular marketing authorisation without comprehensive data of a phase 2/3 clinical trial including several thousand trial subjects should be considered with caution. In addition to efficacy data, regular and controlled clinical trials may also provide data on occasional or rare adverse events. A phase 2/3 clinical trial usually includes several thousand or even several ten thousand trial subjects. Germany and the EU usually require meaningful safety and efficacy data before granting a marketing authorization.

It cannot be ruled out that the regulatory approval announced in Russia might apply to a limited group of persons, which would be equivalent to an emergency use authorisation where additional safety and efficacy data are collected and submitted post authorisation.



## Background

The WHO's "Covid Vaccine Landscape" lists one vaccine project by the Russian Gamaleya Institute among 170 current vaccine projects against SARS-CoV-2. Russian sources state that limited clinical trials with the COVID-19 vaccine candidate Gam-COVID-Vac Lyo have already been completed. The recent regulatory approval of the Russian COVID-19 vaccine is said to be based on the results of these trials. The currently ongoing clinical trials with the Russian vaccine candidate can be found on the "clinicaltrials.gov" website:

<https://clinicaltrials.gov/ct2/show/NCT04436471?term=vaccine&cond=covid-19&draw=4>)

The website shows two early phase 1/2 clinical trials with vaccine components based on the human adenoviral vectors 5 and 26. Both vectors are generally suitable for COVID-19 vaccine development. This also applies to using the genetic information of the SARS-CoV-2 spike protein as antigen – a process used in several ongoing COVID-19 vaccine developments. Clinical trials aim to generate immunogenicity and safety data. However, so far no data have been released on the results of the clinical trials in Russia – neither via press statements nor via the usual scientific publications.

The International Coalition of Medicines Regulatory Authorities (ICMRA), a platform for the exchange of information between globally operating medicines agencies including the Paul-Ehrlich-Institut, has organised several video conferences on regulatory aspects regarding the authorisation of COVID-19 vaccines. The Paul-Ehrlich-Institut regularly takes part in these videoconferences as well as the Russian agency „Roszdravnadzor“, responsible for post-marketing control and surveillance. No details on the Russian vaccine developments have so far been discussed during these videoconferences.