EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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25 March 2021
EMA/180739/2021
European Medicines Agency

Honourable Members of the European Parliament,

Subject: Your letter dated 17 March 2021

Thank you for your letter of 17 March 2021, in which you raise a number of questions regarding Sputnik V.

We would like to underline that EMA's main responsibility is the protection and promotion of public and animal health, through the evaluation and supervision of medicines for human and veterinary use. EMA is strongly committed to carrying out its responsibilities and to adhering to the highest standards of professional and personal integrity, including with regard to the integrity of data submitted to EMA for regulatory purposes.

Please note that we cannot comment on decisions taken by individual Member States to permit temporary supply of Sputnik V. These are governed by national legislation under national emergency use programmes.

We address your questions point by point below.

- Is the start of the rolling review based on results of clinical trials and laboratory studies conducted in Russia or have there been independent studies carried out in the EU before the start of the rolling review?

At this stage we cannot comment on the specific details and studies included in the ongoing review. Please note that if the rolling review leads to a marketing authorisation application, a detailed assessment report will be published at the end of the assessment, describing in detail the data submitted and assessed, the steps taken during the assessment, including information on any inspections conducted, and the reasons why the CHMP recommended approving or refusing authorisation.

- Have the studies mentioned by EMA been carried out exclusively or partially in Russia?

Please refer to our response to the previous question.

- Which additional procedures or control mechanisms the EMA has put in place to ensure that data originating from Russia were carried out according to EU standards and are not manipulated? How does the EMA ensure full transparency of the Russian trial series and authorisation process?

A robust framework exists for the oversight and conduct of clinical trials, no matter where in the world the clinical investigators' sites are located and no matter where patients were recruited. All clinical trials included in marketing authorisation applications are required to meet internationally agreed ethical and data quality standards, such as the so-called good clinical practice (GCP) standards or their equivalents. Although primary responsibility for ensuring that a clinical trial is conducted in accordance with the required standards lies with the sponsor and clinical investigators of the trial compliance will be verified by EMA during its assessment.

If during the review of an application or rolling review of the clinical data (including safety and efficacy data) the assessors identify a need they may request a GCP inspection which will be undertaken if agreed as needed by EMA's scientific committee. Further information can be found in the document "Points to consider for assessors, inspectors and EMA inspection coordinators on the identification of triggers for the selection of applications for "routine" and/or "for cause" inspections, their investigation and scope of such inspections" which describes the criteria used for this decision.

In addition, please note that medicine developers are responsible for ensuring that they and any parties working for them comply with standards of good laboratory practice (GLP) and good manufacturing practice (GMP) for investigational medicinal products. An inspection to verify compliance with any of these standards may also be requested during the review of an application or rolling review if the assessors consider it necessary.

During the COVID-19 pandemic, EMA is implementing exceptional measures to maximise the transparency of its regulatory activities in relation to treatments and vaccines for COVID-19 that are approved or are under evaluation. In particular, clinical trial data underpinning the assessment will be published on the clinical data website (https://clinicaldata.ema.europa.eu/web/cdp/home) after the CHMP outcome.

- Could and would results of studies conducted in Russia be used for a possible later authorisation process? Would authorisation for the EU market be conceivable without clinical trials carried out in the EU or a country associated through an MRA?

Like for any medicines that are developed for use in EU patients, there is no requirement to carry out clinical trials specifically in the EU/EEA. However, as mentioned above clinical trials are required to meet internationally agreed ethical and data quality standards or their equivalents.

- Do the Russian authorities provide the EMA with scientific data from the practical application of Sputnik V in Russia, such as side effects?

Although we cannot comment on Sputnik specifically as this review is ongoing, we would like to advise you that all available data on the safety of a vaccine, including side effects that occur during clinical trials, and from use in countries where the vaccine is authorised, should be submitted as part of the marketing authorisation application and will be assessed.
After authorisation the safety and effectiveness of all COVID-19 vaccines will be very closely monitored through the EU pharmacovigilance system, as vaccines are rolled-out across the Member States and also globally. The pharmacovigilance plan for COVID-19 vaccines sets out how EMA and the national competent authorities in the EU Member States identify and evaluate any new information that arises promptly, including any safety signals that are relevant to the benefit-risk balance of these vaccine (https://www.ema.europa.eu/en/documents/other/pharmacovigilance-plan-eu-regulatory-network-covid-19-vaccines_en.pdf)

Companies are required to provide monthly safety reports to EMA, in addition to the regular updates required by the legislation, concerning reports of suspected side effects from the use of the vaccine. In addition, companies will be required to conduct specific studies to monitor the safety and effectiveness of the vaccines as requested in the conditional marketing authorisation.
Furthermore, independent European studies on safety and effectiveness will be coordinated by EMA and ECDC.
These measures will allow regulators to swiftly assess data emerging from a range of different sources and take appropriate regulatory action to protect public health if needed.

- How are liability issues regulated if problems arise after a fast-track authorisation procedure for Sputnik V based on potentially manipulated data?

EMA takes very seriously any allegations of improprieties that may have an impact on the authorisation and supervision of medicinal products in the area of EMA activities. Allegations may concern, for example, the integrity or reliability of the data in the studies used to support market authorisation. Data integrity is fundamental to building confidence in authorised medicines.

Data integrity problems could arise due to poor training, inadequate implementation of procedures and controls or even falsification of data. For products authorised centrally, in case of suspected improprieties EMA could pursue an inspection of manufacturing and/or clinical sites concerned. In addition, EMA scientific committees could consider obtaining clarifications and reassurances from the marketing authorisation holder/applicant concerned. In some cases, after the approval of a product, a referral procedure under the provisions of Regulation (EC) no. 726/2004 could be considered and a final decision by the European Commission would be taken in respect of maintaining the product on the market. Finally, in the event of intentional breaches and improprieties for the purpose of obtaining a gain, EMA could refer the matter to the anti-fraud office (OLAF) for their possible investigations to prevent, mitigate or even recover damages to the financial interests of the Union.

The applicable EU legislation does not confer to the Union bodies any competence with regard to enforcement of product liability claims against manufacturers of medicinal products. As explained before, EMA and the European Commission could consider adopting regulatory measures in the event that the risks of any medicine outweigh its benefits, at any time during the life cycle of that product.

Liability claims regarding vaccines can be brought forward at national level on the basis of national legislation transposing the provisions of the "Product Liability Directive", i.e. Directive 85/374/EEC.

Once a vaccine is approved for use, EU/EEA national authorities and EMA continually monitor side effects reported in people who have received the vaccine. This ensures that any possible new risks are detected and managed as soon as possible.

EMA monitors new information on the safety of all vaccines available in the EU/EEA from different data sources and specifically from the EudraVigilance database (the European database of suspected adverse reactions). The Agency and the National Competent Authorities in the Member States carefully assess the reported suspected side effects to determine if there is a causal association with the vaccine. This helps to rule out the possibility that it was a coincidence or that it was caused by factors unrelated to the vaccine itself. When needed, EMA and the other European regulators take action, for example, by providing updated guidance to healthcare workers or even restricting the use of a vaccine in certain groups.

We hope the above addresses your questions and we thank you for your trust in the work of EMA.

With best wishes,

Emer Cooke
Executive Director

Christa Wirthumer-Hoche
Chair Management Board

CC: Mr. Noël Wathion, Deputy Executive Director, EMA; Mrs. Lorraine Nolan, Vice-chair Management Board, EMA; Mrs. Hilde Boone, EU Institutional Liaison, EMA