EUROPEAN COMMISSION

Ursula von der Leyen
The President

Brussels, 31 MAI 2021
Ares (2021) 1152812

Dear Honourable Member,

I would like to thank you for your letter posing a number of questions on the Sputnik COVID-19 vaccine.

The European Medicines Agency (EMA) confirmed with a clarification published on their website that it has to date not received any application for a marketing authorisation for the Sputnik V vaccine, despite reports stating the opposite.

The EMA has provided the developers of the Sputnik COVID-19 vaccine with scientific advice. The developers subsequently applied for a rolling review of the Sputnik V vaccine following the agreement of the EMA's Human Medicines Committee (CHMP) and the COVID-19 EMA pandemic Task Force (COVID-ETF) for initiation of the rolling review process. This ad hoc procedure can only be used during emergencies and allows the EMA to assess data as they become available, while development is still ongoing. This allows the formal marketing authorisation procedure to take place in a very short time frame, once a valid application for a marketing authorisation is submitted. The EMA started the rolling review of the Sputnik COVID-19 vaccine on 4 March 2021 (EMA webpage on 'Treatments and vaccines for COVID-19: medicines under evaluation').

The possibility to assess data generated in a third country proves that the EU accepts or refuses an application based on scientific and legal considerations, not on political grounds.

As part of the rolling review process, the EMA is currently assessing thoroughly the clinical trials and the complete data material (including raw data) on the safety, efficacy and quality of the vaccine, before giving any opinion on the outcomes of the assessment, as it has done for all other COVID-19 vaccines.

./..

Ms Viola von Cramon-Taubadel, MEP
European Parliament
Rue Wiertz, 60
1047 BRUSSELS

E-mail: viola.voncramon@europarl.europa.eu

The EMA promptly informs the public of any new rolling reviews and assessments of COVID 19 vaccines/medicines started by the Agency. Similarly, the EMA publishes a news announcement when it receives a valid application for marketing authorisation and updates the published list of treatments and vaccines for COVID-19 under evaluation accordingly (EMA webpage on 'Treatments and vaccines for COVID-19: medicines under evaluation'). The Sputnik COVID-19 vaccine is currently included in this list.

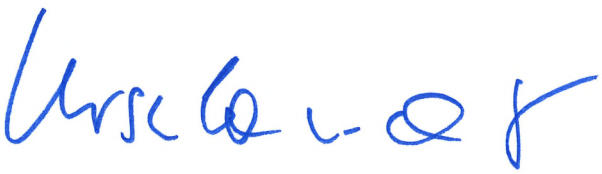
The EMA is committed to applying the same regulatory approach and scientific rigour to all vaccine applications that meet European requirements for safety, efficacy and quality and is in dialogue with more than 50 vaccine developers from across the globe.

Previous dossiers, including those for the four COVID-19 vaccines recently authorised in the EU, contain data from clinical trials that were not entirely performed in the EU. If clinical trials carried out in Russia satisfy all the necessary EU standards, they could be considered for demonstrating safety and efficacy of the vaccine. For more than 10 years, the EMA has a specific working group and a strategy paper on acceptance of clinical trials conducted in third countries. The Agency has therefore long experience in assessing good clinical practice aspects of clinical trials conducted outside the EU/European Economic Area and submitted in marketing authorisation applications to the EU regulatory authorities. Furthermore, the EMA has recently provided further guidance on clinical trial management during the COVID-19 pandemic (EMA webpage dedicated to human regulatory issues/good clinical practice).

Moreover, before any medicinal product can be authorised in the EU, a series of inspections of the production sites is carried out as necessary. In this context, the Sputnik V vaccine will not be treated differently to any other candidate vaccines as regards the strict requirements provided for in the EU legislation.

The Commission has always communicated and recommended that an EU harmonised approach should be maintained in the fight against the COVID-19 pandemic. As indicated by the honourable Member, the Sputnik V vaccine falls under the compulsory scope of the centralised procedure. Emergency use authorisations remain a legal tool available for the Members States in emergency contexts. However, an emergency use authorisation is not a marketing authorisation. It allows for the temporary use of an unauthorised medicine under specific conditions as long as emergency circumstances apply. Its use is restricted to the authorising Member State only – on its own responsibility.

Yours faithfully,



Ursula von der Leyen