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Subject: Rolling review and possible authorisation of the vaccine Gam-COVID-Vac ("Sputnik V") in the EU

Dear Madame Director,
Dear Madame Chair,

alarmed by public statements by representatives of the European Commission and at the same time encouraged by those of you, Ms Wirthumer-Hoche[1], we are contacting you today with a number of questions in connection with the possible authorisation of Sputnik V in the EU. Two letters addressed to Commission President Von der Leyen and Commissioner Kyriakides in this regard unfortunately have remained unanswered so far. And since Commissioner Breton's statement[2] that it is fine for individual Member States to purchase Sputnik V from Russia on the basis of over-hasty national authorisations, we also wondered whether the EMA is not the better addressee for questions, concerns and appeals.

[1] https://www.spiegel.de/wissenschaft/medizin/corona-ungarn-setzt-den-stoff-bereits-ein-expertin-warnt-vor-notfallzulassung-von-sputnik-v-in-europa-a-9c394b63-e5d5-4451-afc5-3b3f9137ffb7
[2] https://www.politico.eu/article/commissions-breton-its-fine-if-eu-countries-buy-vaccines-from-russia-china/

The fact that a representative of the European Commission seems to be okay with individual Member States undermining the competences of the EMA and the EU's authority at the same time is more than worrying, especially in the case of Sputnik V. Authorisation by the EMA is mandatory for a vaccine like this and review processes are more extensive and complex than in the case of countries with which the EMA is associated through MRAs. The fact that only the production capacities in Russia are being questioned by Commission representatives, but not whether the clinical studies carried out in Russia and the data provided by Russia which the allegedly fantastic efficacy is based on correspond to EU standards and are not manipulated, provoke great concern. How can it be that Sputnik V, without scientific testing and assessments of our own, is placed in the public eye on the same qualitative level as those vaccines that have gone through our independent testing procedures? Against this background, how can the claims about the efficacy of the vaccine be communicated as proven fact? These were two of the more general questions to the Commission to which there is still no answer.

In recent years, the authorities of the Russian Federation have demonstrated over and over again (doping of Russian participants at Olympic Games, the attempted murder of Mr Navalny - just to name two examples) that they are more than ready to politicise and manipulate very professionally and at large scale medical and scientific data when it serves a political goal. Against this background, it would be grossly negligent not to check the data provided by the Russian side most diligently for completeness and scientific conclusiveness but also for possible manipulation. Experts in the detection of data falsifications have already made public potential frauds in academic journals.

In this context, we would like to ask you the following questions:

- 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?
- Have the studies mentioned by EMA[3] been carried out exclusively or partially in Russia?
- 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?
- 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?
- Do the Russian authorities provide the EMA with scientific data from the practical application of Sputnik V in Russia, such as side effects?
- How are liability issues regulated if problems arise after a fast-track authorisation procedure for Sputnik V based on potentially manipulated data?

We hope that your answers to these questions will reassure us that the EMA will, no matter the circumstances, carry out its review and a possible authorisation process to the best of its

[3] https://www.ema.europa.eu/en/news/ema-starts-rolling-review-sputnik-v-covid-19-vaccine

abilities and to our highest EU standards, and will in doing so oppose any political pressure and politicisation of the authorisation process. The main responsibility for the authorisation lies with the EMA and if something should go wrong, the EMA will be reminded of this responsibility and held accountable. By apparently bowing to political pressure from some member states, representatives of the European Commission are politicising the EU approval process in an unacceptable way and contribute to an enormous victory for Russian propaganda. EU representatives should instead support the EMA in doing its work according to EU rules and standards - however long that may take and whatever the outcome will be - and support governments and ministers at national level who refuse national solo actions.

With this in mind, we will monitor further developments very closely and thank you very much in advance for your feedback.

Yours sincerely,

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