VALSTYBINĖ VAISTŲ KONTROLĖS TARNYBA
PRIE LIETUVOS RESPUBLIKOS
SVEIKATOS APSAUGOS MINISTERIJOS

Member of the Parliament of the Republic of Lithuania
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Nr.

To 2025 01 22 Nr. SN-03c

ON THE SAFETY AND QUALITY OF MODIFIED MRNA COVID-19 VACCINES

The State Medicines Control Authority under the Ministry of Health of the Republic of Lithuania (hereinafter referred to as the Authority) has taken note of your letter No. SN-03c " On the safety and quality of modified mRNA COVID-19 vaccines – repeated letter", by which you reiterate your request for a reply to the questions raised in the Communication on behalf of the members of the Nordic Group addressed to the Prime Ministers and Governing Bodies of the Nordic and Baltic countries and the United Kingdom on the safety and quality of a modified mRNA vaccine for the COVID-19 disease (coronavirus infection) (hereinafter referred to as the "Communication").

In reply to your question regarding the information on DNA contamination of mRNA preparations provided to the representatives of the Authority in the Committee for Medicinal Products for Human Use of the European Medicines Agency and in the Pharmacovigilance and Risk Assessment Committee (hereinafter referred to as 'the Committees'), we confirm that the representatives of the Authority have been provided with the information you have mentioned by the Head of the State Medicines Control Authority under the Ministry of Health of the Republic of Lithuania, by order of the Head of the State Medicines Control Authority under the Ministry of Health of the Republic of Lithuania of 3 January 2012.

No 1A-12 (new wording of the order of 29 March 2021). No (1.72E)1A-332) approved by the Rules of Procedure of the Authority (the dates and marks of the familiarization of the representatives of the Authority in the Committees are documented in the document management system of the Authority under the procedures established by internal procedures).

Please note that based on the information published on the European Medicines Agency's website and the information provided by the Authority's representatives in the Committees, the safety monitoring of mRNA vaccines is ongoing, and data from the ongoing post-authorization safety studies are regularly evaluated. However, no issues related to the quality and toxicity of mRNA vaccines have been raised in the Committees recently.

It should be noted that, in the absence of data to scientifically and reasonably confirm the claims made in the Notice and of data that could affect the benefit-risk profile of these vaccines, the Authority has

no reason to initiate additional data collection, studies, or procedures under the opinion of the Scientific Committee on Vaccines of 31 March 2004. Under the provisions of REGULATION (EC) No 726/2004 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 31 March 2004, laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (hereinafter referred to as 'the Regulation'), it is the exclusive prerogative/competence of the European Medicines Agency to initiate and co-ordinate activities, procedures, and studies of this kind in relation to centrally authorized medicinal products in the EU.

To answer the question raised in the Notice concerning the initiation of studies on the possible association of mRNA vaccines with cancer, infertility, and other acute, chronic, and genetic diseases, and taking into account that vaccines against COVID-19 (coronavirus infection) are centrally authorized in the European Union, the Authority will, under the provisions of the Regulation, and taking into account the importance of the issue for the European Union, not only for Lithuania, and the other countries of the European Union, initiate a study on the possible link of mRNA vaccines with cancer, fertility, other acute, chronic and genetic diseases, in the European Medicines Agency, under the provisions of the Regulation and the context of the European Union.

By letter No (1.40Mr)2R-109 "Request for response to NORTH group letter" dated 28 January 2025, we requested the European Medicines Agency (EMA), the authority responsible for the post-authorization safety monitoring of these vaccines, to assess the Notification and to provide its position on the issues raised in the Notification, as well as to share any other relevant information or data that may be relevant for the contents of the Notification.

The Authority will share with you the official position/opinion of the European Medicines Agency on these issues or additional information as soon as it receives it.

Director Dovilė Marcinkė

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