VALSTYBINĖ VAISTŲ KONTROLĖS TARNYBA
PRIE LIETUVOS RESPUBLIKOS
SVEIKATOS APSAUGOS MINISTERIJOS

To a member of the Seimas of the Republic of Lithuania
Rimas Jonas Jankūnas
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Nr.

To 2024 12 10 letter
2024 12 20 Nr. S-3863

Copy:
To the Chancellery of the Government of the Republic of Lithuania
The Health of the Republic of Lithuania
Ministry of Health

ON THE NOTIFICATION TO THE PRIME MINISTERS AND GOVERNING BODIES OF THE NORDIC AND BALTIC COUNTRIES AND THE UNITED KINGDOM OF SPECIAL CONCERNS REGARDING THE SAFETY AND QUALITY OF THE MODIFIED MRNR VACCINE AGAINST COVID-19

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 letter No. S-3863, forwarded to the Ministry of Health, dated 20.20.20, a letter from Rimas Jonas Jankūnas, Member of the Seimas of the Republic of Lithuania, forwarding a communication on behalf of the members of the Nordic Group, addressed to the Prime Ministers and governing bodies of the Nordic countries, the Baltic countries and the United Kingdom, concerning the safety and quality of a modified mRNA vaccine against COVID-19 disease (coronavirus infection) (the "Communication").

The Authority, which is responsible for ensuring that only high-quality, effective, and safe medicinal products are available on the market, keeps a continuous record of all suspected adverse reactions, including those following vaccination with vaccines against COVID-19 disease (coronavirus infection), which are reported to the Authority by patients, health care professionals and pharmacists, and submits them to the European Medicines Agency's Eudravigilance database for further expert evaluation by the European Medicines Agency. Based on the data on adverse reactions following vaccination with vaccines against COVID-19 disease (coronavirus infection) received in Lithuania, the Authority does not have any data to scientifically and reasonably confirm the claims made in the Notice or initiate additional pharmacovigilance procedures.

As regards the possible solutions to the issues raised in the Notice, it should be noted that all vaccines against COVID-19 disease (coronavirus infection) are centrally authorized in the European Union and are subject to post-authorization monitoring by the European Medicines Agency and to all relevant questions and concerns, including safety and quality issues.

By the European Medicines Agency (EMEA) provisions of 31 March 2004. Article 20 of the 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 ("the Regulation"), it is the prerogative of the European Commission to initiate pharmacovigilance or a non-pharmacovigilance procedure in respect of the concerns raised in the Notice concerning a centrally authorized medicinal product.

The Authority recognizes the relevance and importance of the issues raised in the Notice to the public in accordance with the provisions of the Regulation and the Law on Pharmaceuticals of the Republic of Lithuania. If required, the Authority is ready to actively contribute to and participate in the resolution of the issues raised in the Notice.

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