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On contamination of modified mRNA Covid-19 vaccines with plasmid DNA

The Ministry of Health has reviewed the North Group's 2025 13 February repeated letter of concern regarding mRNA Covid-19 vaccines contamination with plasmid DNA and provides its views based on information provided by the National Medicines Agency.

We would like to inform you that the competent authority for mRNA vaccines, as well as for any biotechnology-derived medicinal product, which carries out the scientific evaluation of the data, is the European Medicines Agency (hereinafter "EMA"), in accordance with whose recommendations the European Commission takes legally binding decisions on the marketing authorisation (or, where this is justified, the withdrawal of marketing authorisation) of the medicinal product in all European Union (EU) Member States. At present, the competent authorities of Latvia do not see any justifiable reason to suspend the distribution and use of the registered Covid-19 vaccines. A marketing authorisation valid in the EU for any medicinal product means that the balance of risks and benefits is favourable if it is used in accordance with the conditions approved in the summary of product characteristics. Removing vaccines from the market of EU Member States, unjustifiably denying their use to health professionals and the public, and without due consideration of available safety and efficacy data, would be a major loss and harm to public health in the EU.

We would like to clarify once again that due to the

biotechnological processes used in the manufacturing process, the mRNA vaccines against Covid-19 registered in Latvia, like many other biological medicines, may contain a tiny residue of DNA fragments. Each batch of these vaccines or any other biological medicinal product is controlled according to specifications approved by the competent authorities. The competent authorities of Latvia or other EU Member States have not identified any cases of mRNA vaccines against Covid-19 with inappropriate residual DNA fragment content being distributed in any EU Member State. Neither do the competent authorities have any evidence of a causal link between mRNA vaccines and any type of malignant tumors. There is no evidence that the use of mRNA vaccines or biological medicines in general has led to the integration of residual DNA into the human genome. The presence of such residues is not unique to mRNA vaccines, but is also common in other biologic medicines, such as insulin, which is used daily by millions of people around the world. Based on an assessment of the available data, the EMA, in collaboration with other competent authorities in the European Economic Area (EEA), have not identified any evidence to suggest that other reported adverse events may be related to the presence of DNA material in mRNA vaccines.

In addition, in the combined reproduction and development preclinical studies, no adverse effects on fertility or viability of male or female animals or on fetal death, birth defects or delayed development were observed at doses above the clinical dose of mRNA vaccines.

Evidence from more than 13 billion doses of Covid-19 vaccines administered to people worldwide shows that these vaccines have a very good safety profile in all age groups. The benefits of registered vaccines outweigh the potential risks.

We would also like to clarify that all registered biological medicinal products are subject to the OCABR (*Official Control Authority Batch Release Certificate*) procedure. Samples of each batch released are sent to an official medicines control laboratory (OMCL - *official medicines control laboratory*) operating in the EU/EEA, which carries out analyses according to approved specifications and analytical methods. If the results are satisfactory, the competent authority shall issue an OCABR batch release certificate to the holder of the registration certificate. Such a certificate means that the OMCL has undergone batch testing and examination in accordance with OCABR guidelines and that it

complies with the approved specifications set out in the relevant European Pharmacopoeia monographs and in the dossier for the registration of the medicinal product. The holder of the registration certificate must provide a copy of the OCABR certificate to the Member State in whose market the batch is intended to be placed on the market. This certificate is recognised by all members of the EU/EEA Medicines Regulatory Network. If the analytical results are not satisfactory, the batch is not placed on the market and all members of the OCABR network receive the relevant information.

The EMA and EU Member States continuously monitor the safety of all Covid-19 vaccines to ensure that potential risks are detected and managed as early as possible. The EMA and EU Member States are carefully evaluating reported adverse reactions to determine whether they could have been caused by the vaccine. Therefore, based on the scientific evidence and the regulatory authorities' assessment, Covid-19 mRNA vaccines are considered to be safe and effective, with benefits (significantly reduced severe disease, hospitalisation and mortality) that far outweigh the potential risks to public health, and any decisions related to changes in the safety of Covid-19 vaccines are promptly communicated to Member States.

We would like to assure you that the Latvian Medicines Agency is also closely following the latest information, so please be respectful of the decisions taken by EU Member States according to the EMA assessment and follow the news on the Latvian Medicines Agency website for future decisions on changes to the safety of Covid-19 vaccines.

In addition, please be informed that according to Section 7(1) (5) of the Submissions Act, if the substance of the submission remains unchanged, the institution has the right to leave the submission without consideration.

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*The document is signed with a secure electronic signature and contains a time stamp