

An email sent to Representative Pia Sillanpää on 9.12.2024 from the Ministry of Social Affairs and Health:

BACKGROUND

Pia Sillanpää, Member of Parliament, has approached the Ministry of Social Affairs and Health, Fimea and the National Institute for Health and Welfare (THL) by e-mail on 25.11.2024. Sillanpää refers to a letter of concern addressed to Prime Minister Petteri Orpo, Ministers of Social Affairs and Health Sanni Grahn-Laasonen and Kaisa Juuso, and other prime ministers and administrations in the Nordic and the Baltic countries and the UK regarding the quality and safety of COVID-19 mRNA vaccines. In a letter dated 25 November 2024, a number of politicians, doctors and other interested parties have expressed concerns about the quality and safety of COVID-19 mRNA vaccines. The letter sets out views on the efficacy and safety of the vaccines:

"Excessive levels of residual DNA have been detected in Australian samples, confirming data from France, Germany, Canada and the United States. The introduction of foreign DNA into cells via lipid nanoparticles (LNPs) can damage human DNA, which can lead to genomic instability, cancer and other very serious diseases."

Concerned enquirers are asking ministers for answers on two issues in particular:

1. what is needed to initiate an independent and transparent inquiry into the regulatory processes that led to the approval of these products?
2. Is there anything to prevent the Minister from initiating and prioritising research into the possible links between mRNA vaccines and cancers, infertility or the various chronic diseases to which they have been linked?

REPLY

Question 1: According to THL, the evidence base for the concerns raised about the safety of mRNA vaccines is overstated. The vaccines have undergone a rigorous evaluation process. Vaccines based on mRNA technology have been granted marketing authorisation on the basis of a centralised assessment by the European Medicines Agency (EMA). When a marketing authorisation is granted, the product is subject to an overall assessment where the benefits of the product must outweigh the known harms. The quality of vaccines is verified at several stages before they are introduced. During the marketing authorisation evaluation, a control strategy for the product is evaluated and approved. During production, the manufacturing process and the finished vaccine are subject to extensive monitoring in accordance with the pre-agreed control strategy, also by an independent authority (OMCL laboratory). In the event of anomalies being detected during the manufacturing process or in the final product, the batches concerned are rejected and not released for consumption.

According to the World Health Organisation (WHO), more than 13 billion doses of mRNA Covid vaccines have been administered worldwide since 2020. Authority surveillance data has shown these vaccines to be sufficiently safe and highly effective in protecting against severe coronavirus disease and deaths caused by the SARS-CoV-2 virus.

In Finland, about 15.7 million doses have been administered since 2020 and about 7,000 serious

adverse reaction reports have been received.

As with all vaccines, rare serious adverse events have been reported for Covid vaccines. These adverse events are described in Faksova et al. (2024), a refereed publication in the letter, based on an analysis of data from more than 99 million vaccinees. The publication is the result of the Global Vaccine Data Network (GVDN), a global vaccine safety research collaboration in which THL is a member. In the light of the published safety signals and benefit-harm analyses repeated on the basis of up-to-date data, Covid vaccination recommendations in Finland have been designed so that the benefits and cost-effectiveness of the vaccine in each SARS-CoV-2 epidemiological setting outweigh the potential serious rare adverse events caused by the vaccine. For example, the mRNA vaccine developed by Moderna was no longer recommended for men under 30 years of age because of the risk of myocarditis, and AstraZeneca's adenovirus vector technology-based vaccine was completely discontinued because of the associated risk of blood coagulation disorders.

Question 2. mRNA vaccine contamination and possible links to cancers, infertility or several chronic diseases have been discussed in detail on the GVDN website (see also Plasmid-gate: Debunking the DNA contamination claims in mRNA vaccines | Global Vaccine Data Network). In Finland, Fimea is responsible for monitoring vaccine safety signals. THL is responsible for the confirmation of signals and further epidemiological studies, if deemed appropriate. This is also the case for Covid vaccines.

In conclusion it can be stated that this so-called Plasmid-Gate (referring to the residual DNA in vaccines) is more an attempt to raise fear than to seek scientifically based answers to the questions raised. Residual DNA in vaccines is a known fact, clarified by the pharmaceutical authorities; the amount of DNA in mRNA vaccines is very small and is not known to pose a safety risk to humans in the light of research. DNA in vaccines is not capable of altering human DNA or causing cancer-like diseases. The human environment is full of DNA from other organisms, which we get through food and water into the microbiome of our bodies.