Vlastimil VÁLEK
Deputy Prime Minister and Minister of Health

Ministry of Health, Palackého náměstí 375/4, 128 00 Prague 2
tel./fax: +420 224 971 111, e-mail: podatelna@mzd.gov.cz, https://mzd.gov.cz
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Dear Professor,

In response to your request for information about COVID-19 vaccines, specifically regarding the regulatory and approval processes for medicinal products aimed at vaccination and their safety monitoring, I would like to provide the following information:

The vaccines that prevent COVID-19 utilise mRNA technology, which has not been previously employed in other vaccines. However, this technology has been researched and tested for approximately 20 years to prevent infectious diseases and treat certain tumours.

Clinical studies have previously demonstrated the use of this technology in preventing diseases caused by the Zika virus. Additionally, this platform has been investigated for research aimed at preventing rabies.

In the COVID-19 vaccines, mRNA is delivered into cells using lipid particles. The mRNA instructs human cells to produce proteins commonly found on the surface of the coronavirus, specifically the Spike protein. Although these proteins are not infectious, they stimulate the human adaptive immune system, training the body to recognize and eliminate them, thereby offering protection against COVID-19. RNA molecules are naturally abundant in our cells. For example, cold viruses are also RNA viruses that invade human cells to replicate. During the entire period of a viral infection caused by RNA viruses, such as those responsible for the common cold, these viruses cannot modify human DNA. This is because they cannot enter the cell nucleus, where human DNA is located. Additionally, human cells lack the enzyme necessary to convert mRNA into human DNA.

Vaccines from Pfizer (Comirnaty) and Moderna (Spikevax), known as mRNA vaccines, contain mRNA nucleic acid, instructing cells to synthesise proteins. However, this synthesis occurs in the cytoplasm, a separate cell area, and not in the nucleus, where human DNA resides. Free mRNA does not interact directly with human DNA. It is important to note that mRNA is a naturally unstable molecule and is degraded by the body within a few days through standard cellular mechanisms. Consequently, the production of the Spike protein ceases. Laboratory studies have shown that all mRNA from the vaccine is eliminated from the body within a few days (3 to 9 days), and its levels decrease significantly a few hours after administration.

Regarding concerns about residual plasmid DNA in mRNA vaccines, it's essential to clarify that plasmid DNA is not present in these vaccines. It initially serves as a template for synthesising mRNA, the vaccine's active ingredient. During the manufacturing process, residual DNA is intentionally cleaved and

removed using the DNAase enzyme. The vaccine manufacturing process involves several steps that undergo rigorous quality control, accounting for up to 70% of the entire production time. This careful monitoring ensures the removal of any DNA template from the final product. Consequently, any residual plasmid DNA that may remain is strictly limited to amounts deemed safe for humans. The residual DNA and other parameters are controlled by validated analytical methods for each batch of the active substance produced.

This method reliably detects the amount of residual DNA present. Before each batch of the vaccine is released for use in the EU market, these results are verified. The manufacturer validates the manufacturing process to demonstrate that it can produce an active substance of consistent quality, including residual impurities from the manufacturing process. Validation of the manufacturing process also includes showing the robustness of the purification steps to remove both impurities arising from manufacturing and those related to the product itself.

A detailed description of the entire manufacturing process is always included in the registration documentation, which is mandatory for submission. The mentioned mRNA vaccines fall under the centralized registration process coordinated by the European Medicines Agency (EMA). Additionally, the State Institute for Drug Control participates in evaluating these procedures as a member state and is actively involved in assessing the submitted registration documentation, which it has on hand. Experts from the Institute are members of the EMA's expert platforms involved in the approval and assessment process for products registered through this centralized procedure, including vaccines. These platforms include the Committee for Medicinal Products for Human Use (CHMP), the Pharmacovigilance Risk Assessment Committee (PRAC), and the Working Party for the Assessment of the Quality of Biological Medicinal Products (BWP).

The claim that plasmid DNA in mRNA vaccines could integrate into the human genome is made by Professor Phillip Buckhaults (https://x.com/P_J_Buckhaults/status/1861083163868672204) and further discussed in McKernon et al.'s study (OSF Preprints | Sequencing of bivalent Moderna and Pfizer mRNA vaccines reveals nanogram to microgram quantities of expression vector dsDNA per dose). The preprint article by Kevin McKernan et al. (https://osf.io/b9t7m/) analyses residual DNA in mRNA vaccines, claiming levels higher than those approved by the EMA at the time of registration. However, it is currently not possible to confirm the validity or accuracy of the presented results due to the following findings:

- The vials analyzed were sent to the authors anonymously by mail, without ensuring that the correct storage temperature was maintained, which is a critical factor for this type of vaccine. This lack of proper storage likely led to the degradation of the active substance (mRNA) and the residual DNA in the vials.
- Additionally, the vials that were analyzed had expired.
- The quantification of residual DNA levels mentioned in the article appears to be based on measurements relative to the levels of RNA present. Given the improper handling of the vaccine samples prior to testing, it is highly probable that the analysis will be biased. The residual DNA in the vials is expected to be more stable than mRNA, as mRNA degrades more quickly than DNA. This discrepancy fundamentally impacts the methods used in the study, which report the relative amounts of DNA in comparison to the amount of mRNA in the sample.
- Furthermore, the qPCR method utilized was not validated, relied on a single kit, and did not address discrepancies in the results. No negative control was included to evaluate the background noise of the test.

- The results from the Agilent TapeStation analysis raise questions, as they report DNA values that are 50 times higher than the limits specified for the drug. This discrepancy is concerning since the estimated plasmid size reported by this method differs significantly from the plasmid DNA size provided by the vaccine manufacturers.
- It is also worth noting that the dye used in the analysis preferentially binds to double-stranded DNA (dsDNA) but can also bind to mRNA, which may affect the results.
- The extraction method applied was originally developed for extracting nucleic acids from cannabis leaves, rather than from lipid nanoparticles.

In contrast, repeated testing of commercial batches of Comirnaty by Official Medicines Control Laboratories (OMCL) using the manufacturer's testing method yielded residual DNA content results in line with those reported by the manufacturer, indicating compliance within the specified limits.The claim that mRNA vaccines contain 534 times higher levels of DNA impurities is incorrect (1). This misunderstanding arises from the exceptionally high concentrations of RNA and lipids in these vaccines. The Australian Medicines Agency (TGA) has stated that some laboratories used a residual DNA test called fluorimetry, which tends to overestimate DNA levels in the presence of mRNA. The fluorescent dye used in this test binds to both DNA—often present in trace amounts—and mRNA, which is the primary component of mRNA vaccines against COVID-19. As a result, inaccurate DNA levels are reported in these tests (2).

Your appeal also raises concerns about the presence of the SV40 sequence in the plasmid DNA used for producing mRNA vaccines, particularly regarding the potential for this sequence to be inserted into human DNA and its possible effects on gene function. However, no evidence supporting this claim has been found. SV40 is a naturally occurring virus that is not used in vaccine production. Although the SV40 sequence is present in the plasmid DNA starting material, it is considered a non-functional part of the plasmid structure. Specific sequences of the non-infectious parts of SV40 are commonly found in plasmids used to produce biologically active substances. As mentioned earlier, this sequence, along with other plasmid DNA sequences, is degraded and removed during the manufacturing process. Any remaining fragments of the SV40 sequence are present only as residual impurities at very low levels, which are routinely monitored. No scientific evidence suggests that any of these SV40 fragments can integrate into human DNA or affect gene function.

Regarding the complications listed in your appeal as adverse effects of mRNA vaccines, there is scientific data that establishes a causal link between mRNA vaccines and two specific cardiovascular disorders: myocarditis and pericarditis. Most cases associated with these conditions have been mild, and affected individuals typically recover well. Myocarditis is known to be a complication of COVID-19, occurring more frequently than it does after vaccination. Both myocarditis and pericarditis have been identified as adverse reactions not only to mRNA vaccines but also to recombinant COVID-19 vaccines and vaccines for diphtheria, tetanus, and pertussis.

When it comes to menstrual disorders, these have been repeatedly evaluated as part of pharmacovigilance signals at the European level. So far, the only reaction for which a causal relationship with vaccines has been established is heavy menstrual bleeding, with most cases being minor and temporary.

Blood clotting issues and autoimmune diseases have been extensively assessed since mRNA vaccines received marketing authorization. To date, robust data has not established a causal relationship between these vaccines and the development of these conditions.

Additionally, there is no scientific evidence to suggest that mRNA vaccines can cause so-called "turbo" cancer, diabetes, dementia, or fertility problems.

Regarding the impact of COVID-19 vaccines on fertility, current scientific publications and meta-analyses indicate that vaccination with mRNA vaccines does not affect fertility in either women or men (3) (4) (5). The decline in birth rates observed during the COVID-19 pandemic can be attributed to other factors, including health concerns, increased unemployment risk, heightened financial vulnerability, limited social interactions, a shift to remote work, and uncertainty about various life circumstances, which may have led to the reconsideration of plans for having children (6).

mRNA COVID-19 vaccines have not been linked to an increased risk of postnatal complications in infants born to mothers vaccinated during pregnancy (7).

There is also a wealth of literature and meta-analyses that discuss other reported effects of COVID-19 vaccination. The observed increase in diseases—referred to in the letter as "tumours, infertility, or other acute, chronic, or genetic diseases"—during the COVID-19 pandemic cannot be attributed solely to COVID-19 vaccination. This rise in diseases may be related to several factors, including the effects of the SARS-CoV-2 infection itself, such as the potential for cancer (8) and changes in the availability of medical care and early diagnoses for certain conditions during and after the pandemic.

Best regards.

Citations:

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(2) https://www.tga.gov.au/news/media-releases/addressing-misinformation-aboutexcessive-dna-mrna-vaccines

(3) Ciapponi, A., Berrueta, M., Argento, F.J. et al. Safety and Effectiveness of COVID-19 Vaccines During Pregnancy: A Living Systematic Review and Metaanalysis. Drug Saf 47, 991–1010 (2024).

(4) Zaçe D, La Gatta E, Petrella L, Di Pietro ML. The impact of COVID-19 vaccines on fertility-A systematic review and meta-analysis. Vaccine. 2022 Oct 6;40(42):6023-6034. doi: 10.1016/j.vaccine.2022.09.019. Epub 2022 Sep 12. PMID: 36137903; PMCID: PMC9464596.

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(6) Jasilioniene A, Jasilionis D, Jdanov D, Myrskylä M. Association between the COVID-19 vaccination campaign and fertility trends: a population-level time series analysis for 22 countries. BMJ Public Health. 2025 Feb 12;3(1):e001410. doi: 10.1136/bmjph-2024-001410. PMID: 40017921; PMCID: MC11842981.

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(8) Ogarek N, Oboza P, Olszanecka-Glinianowicz M, Kocelak P. SARS-CoV-2 infection as a potential risk factor for the development of cancer. Front Mol Biosci. 2023 Sep 11;10:1260776. doi: 10.3389/fmolb.2023.1260776. PMID: 37753372; PMCID: PMC10518417.

Dear Sir
Prof. MUDr. Jiří Beran, CSc.
Na Hrázce 746/49a
50009 Hradec Králové

Attn:
Office of the Government of the Czech Republic
nábřeží Edvarda Beneš 128/4
11800 Prague

Electronic signature
Prof. MUDr. Vlastimil Válek
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