From: JAZMP Info <info@jazmp.si>
Sent: Friday, February 21, 2025 12:32 PM
To: info@slovenian-lawyers.com
Cc: Gp.Kpv@gov.si; gp.mz@gov.si
Subject: RE: Mednarodna pobuda znanstvenikov za zaustavitev cepljenja z mRNA substancami proti covid-19

TRANSLATION

To whom it may concern,

We would like to start by clarifying that we have not received a letter dated 8.1.2025 or 23.1.2025 addressed to JAZMP (info@jazmp.si), but we are replying to the letter we received on 9.2.2025.

The mission of the medicines agencies, both the national JAZMP and the European EMA, which brings together experts from all EU Member States, including Slovenia, is to ensure safe, effective and high-quality medicines, irrespective of whether the medicine is important for the individual or for society as a whole. As an independent regulatory authority, we carry out this mission with a high degree of professionalism and integrity. As an independent regulatory authority, we carry out this mission with a high degree of professionalism and integrity. When evaluating the benefits and risks of a medicine/vaccine, we always take into account scientifically validated information, the results of analyses carried out using validated methods and peer-reviewed scientific articles published in scientific journals.
In order to obtain reliable information during the development of a medicinal product, studies must be carried out in accordance with Good Laboratory Practice (GLP) and Good Clinical Practice (GCP). In the manufacture of a medicinal product, the manufacturer must follow strict Good Manufacturing Practice (GMP) rules to ensure the necessary safeguards to provide adequate quality of the product. The regulatory authority also monitors and assesses the side effects of a product, both during the clinical trial, before the product receives marketing authorisation, and at all times after the product is on the market, when it is already in clinical use. Our work as experts in medicines evaluation follows EU and wider international guidelines (e.g. ICH guidelines) to ensure that medicines are of high quality, safe and effective.

1. Claims regarding DNA residues in mRNA vaccines

In your letter, you cite new scientific evidence regarding the potential contamination of vaccines with DNA residues. In connection with the results you quate, we would like to point out that validated tests should be used to determine the DNA content in vaccines. Otherwise, the results may be unreliable and incorrect. EMA is aware of the claims regarding exceeded DNA levels in mRNA vaccines, but cannot confirm whether the analytical procedures used in the student research project have been validated.

In response to claims of impurities in mRNA vaccines, the German Paul-Ehrlich Institute issued a

statement warning that a large part of the data and studies in public circulation on alleged contamination of mRNA in COVID-19 vaccines have methodological flaws, meaning that the results are not reliable (source: https://www.pei.de/SharedDocs/Downloads/EN/newsroom-en/notification/231222-testing-mrna-vaccinas-dna-contamination.pdf?__blob=publicationFile&v=3).

The quality of vaccines is not only ensured by the final control of the vaccine, but also by the manufacturing process and the in-process controls. The mRNA molecule in Comirnaty and Spikevax vaccines is made using plasmid DNA, circular molecules that occur naturally in bacterial cells. In the production of mRNA vaccines, the plasmid contains the DNA sequence encoding the target protein. Once the mRNA is produced, the downstream manufacturing process involves steps to degrade and remove the DNA molecule because it is no longer needed. Very small amounts of DNA fragments can remain in the vaccine, which is why EMA has set limits for the allowed content of degraded DNA in mRNA vaccines, which are routinely checked. As an example, the vaccine manufacturer Comirnaty is required to test the residual DNA content of each batch using a validated method of analysis. In addition, specialized Official Medicines Control Agency (OMCL) laboratories, independent of the pharmaceutical industry and linked to the European Network of Official Control Laboratories, are involved in the quality control of vaccines They perform independent analytical testing of each vaccine batch before it is released to the market. In addition to the analytical testing, the official laboratory carries out a review of the manufacturing documentation of each vaccine batch. Once assured of the adequate quality of a vaccine batch under review, the independent Official Control Authority Batch Release (OCABR) certificate is issued by the independent Official Control Authority Batch Release (OCABR) laboratory and recognized by all other members of the European network of control laboratories, including the Slovenian laboratory, i.e. the National Laboratory for Health, Environment and Food (NLZOH). This is the so-called 'harmonised release process', based on independent quality control of each individual vaccine batch before it is released to the market. It is an important part of the strategy to ensure quality vaccines in the European area. To date, EMA has not found any reliable scientific evidence that the DNA exceeds the approved/safe levels for any of the EU approved mRNA vaccines, Comirnaty or Spikevax.

2. Claims regarding DNA integration into a cell genome

EMA is aware of a claim on social media stating that plasmid DNA, which some sources say is present in mRNA vaccines, can be integrated into the cell genome. The claim is based on an antigen-dependent activation of immune cells experiment used in cancer research. Details of this experiment have not been published. Based on the limited unverified information available online, it is not clear what type of plasmid DNA the cells were exposed to and whether it is similar to the DNA residues in mRNA vaccines, which are present within the allowed limits. There is also no information on the state of the vaccine used. Furthermore, it is not clear how the cells used in the experiment are compared with the cells and tissues in humans after vaccination. The social media post where the claim first appeared acknowledged that the outcome of the experiment does not prove that integration occurs in people who were vaccinated. EMA supports ongoing medicines research and regularly monitors new information from the scientific literature. It is important, however, that scientific research is carried out using validated methods and that new data are subject to peer review and published in appropriate peer-reviewed scientific journals. However, it is not possible to assess the claims of individual scientists who post unverified information on social media. As with all medicines, EMA will continue to assess new data on mRNA vaccines against COVID-19. So far, EMA has not seen any verified evidence of adverse effects associated with the presence of low levels of degraded plasmid DNA, and we are not aware of any scientific evidence to suggest that the very small amounts of residual DNA that may be present in vaccine batches could be incorporated into the DNA of vaccinated individuals.

3. Claims regarding the SV40 sequence in plasmid DNA

In your letter you also raise concerns about the presence of the SV40 sequence in the plasmid DNA used in the production of the Comirnaty vaccine and ask whether it could insert into human DNA possibly affecting gene function. EMA has no information to support these claims. SV40 is a naturally occurring virus. Although the SV40 sequence is indeed present in the input plasmid DNA material, the sequence is considered to be a non-functional part of the structure of the original plasmid. In plasmids used for the production of biologically active substances, sequences specific for non-infectious parts of SV40 are often present. The manufacturing process ensures that this sequence and other plasmid DNA sequences are degraded and removed. Fragments of the SV40 sequence may only be present as residual contaminants at very low levels, which are routinely checked. It should also be emphasized that there is no scientific evidence that any of these SV40 fragments can insert into human DNA and affect gene function.

4. Vaccine safety claims

Even after the marketing authorizations of COVID-19 vaccines was approved EMA and EU Member States continue to monitor the safety of vaccines as part of the pharmacovigilance system to ensure the earliest possible detection and management of potential risks associated with vaccines. Monitoring is carried out throughout their use, thus enabling the monitoring of even brand-new adverse reactions unknown before the marketing authorization. Only by knowing and understanding appropriate measures can be implemented to ensure the safe use of the vaccines and, consequently, the protection of public health.

During the pandemic, enhanced pharmacovigilance safety monitoring was carried out for COVID-19 vaccines meaning that in addition to their regular obligations, marketing authorization holders for these vaccines had to carry out additional tasks. COVID-19 vaccines also have a status of medicinal products for which additional safety monitoring is required, which means that all adverse reactions observed after vaccination are collected in order to obtain new safety information more quickly. Data on suspected adverse reactions are collected in the EU database EudraVigilance for all medicines/vaccines authorised in the EU in order to further monitor safety and detect potential safety signals. The management of safety signals is part of routine pharmacovigilance activities and is essential in evaluating the benefit-risk balance of a medicine and providing its up-to-date information. All sources of safety data are considered in the safety assessment, including data from clinical trials, any other ongoing studies and scientific literature.

EMA and EU Member States continuously monitor and assess reports of suspected adverse reactions to determine whether they are caused by the medicine/vaccine. A reported adverse reaction does not necessarily imply a causal relationship with the vaccine, as this requires expert evaluation and assessment of all available data. Only after a detailed assessment the existence of a causal link between the medicine/vaccine and a reported adverse reaction is confirmed or refuted. If there is at least a reasonable possibility the vaccine could have caused a suspected adverse reaction, a further assessment is made as to which pharmacovigilance measures are necessary (e.g. updating of a product information, such as including information on a new possible adverse reaction, informing professional public of new safety risks that may lead to changes in the prescribing regimen, prescribing only for certain population groups where the benefits still outweigh the potential risks, and in extreme cases withdrawing the marketing authorization for safety reasons).

Information on all known adverse reactions to vaccines is included in the vaccine-specific information (summary of product characteristics and package leaflet) available on the EMA website. These documents are regularly updated as new data becomes available. The vast majority of known adverse reactions of COVID-19 vaccines are mild and of short duration. However, serious adverse reactions can occur, but are very rare.

EMA is also aware of a number of claims regarding the safety of mRNA COVID-19 vaccines. Such claims are usually based on the number of reports of suspected adverse reactions and do not consider the fact (although the public is encouraged to report suspected adverse reactions) that a report received does not mean the vaccine actually caused the adverse reaction in question. Furthermore, the claims do not take into account the number of people vaccinated, nor the fact that serious adverse reactions are very rare. There are also allegations on social media that covid-19 vaccines damage the immune system and cause cancer. Based on the safety data received and discussed, no signal for cancer has been confirmed so far. There is also no evidence that covid-19 vaccines cause immune deficiency and an increase in other infections, including pediatric population. Similarly, there is no evidence of an increase in mortality due to vaccination in any age group, including children.. A mass use of covid-19 vaccines led to a rapid accumulation of data on vaccines safety. Based on their assessment, it was confirmed that the clinical safety profile and efficacy of these vaccines are comprehensively established and support a positive benefit-risk ratio.
However, as with all medicines authorised in the EU, new safety data will continue to be carefully monitored and evaluated. In the event of new safety risks being identified, EMA will take all necessary regulatory action, including public information.

Best regards,

JAVNA AGENCIJA REPUBLIKE SLOVENIJE ZA ZDRAVILA IN MEDICINSKE PRIPOMOČKE

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