Original questions to the Croatian national competent authority HALMED and HALMED's reply are in normal font.

Follow up questions in bold font.

HALMED's follow-up replies in blue.

Dear Mrs. Ivana Šipić Gavrilović, mag. comm. ,
In your reply to my letter, you stated the following (my comments and additional questions to the answers you sent me are bolded);

YOUR'S ANSWER: In the attached paper, which has not yet gone through the peer review process; claimed that mRNA vaccines (Comirnaty and Spikevax) contain large amounts of contamination in the form of DNA.

mRNA, which is the active substance of these vaccines, is produced by in vitro transcription from a DNA sample containing the genetic code for the spike protein of the virus. The DNA sample obtained by the well-known DNA plasmid technology from E. coli cells. The DNA sample is not an integral part of the vaccine; an important biological starting material whose production and control is subject to evaluation by regulatory agencies during the approval process and later in case of changes. Since the DNA sample were produced from bacterial cells, the amount of host cell-derived DNA is strictly controlled,

EMA's regulatory documents do not give the impression of strict control. Here is an extract from the EMA report on the Moderna vaccine

"The percentage of covalently closed circular DNA (% cccDNA) is routinely monitored by chromatography after polishing. However, evidence of qualification/validation of the methods used for release testing (REC) must be provided."

https://www.ema.europa.eu/en/documents/assessment-report/spikevax-previously-covid-19-vaccine-moderna-epar-public-assessment-report_en.pdf

No mention is made of the analysis of possibly residual linear DNA, which presents similar risks as covalently closed (i.e. circular DNA); validation of the method is also missing tests to determine the amount of circular DNA. I have not been able to find evidence that the manufacturer supplied it later, which, with numerous purification procedures during of vaccine production, ensures that this contamination not transferred to the finished product - vaccine. Can you provide me with proof of this analysis carried out either by the manufacturer or the EMA (that is, the proof that you took into account the quality control of the product before approval)?

YOUR'S ANSWER: In addition, the manufacturer carries out a routine control of contamination in the form of residual DNA for each batch of the vaccine according to the

quality requirement. This ensures that the amount of contamination does not exceed the level that the EU regulatory agencies and the European Medicines Agency (EMA) during the approval process have assessed to be safe for use in humans.

In the production of a linear DNA template, circular plasmid DNA (covalently closed circular = cccDNA) is first obtained after cell lysis, the quantity of which is controlled at this stage of production for each batch. Circular plasmid DNA linearized after purification. The effectiveness of the linearization process strictly controlled on each batch of linear DNA sample produced, which ensures that even at this stage of production are no contamination in the form of circular DNA in quantities that would represent a safety problem. For the stated reason, and based on the evaluation of the evidence from the entire submitted documentation, it is not necessary to control the content of the circular DNA in the further production process.
Further to the question about the qualification of the %cccDNA testing method, the manufacturer satisfactorily answered all the questions/obligations and recommendations from the conditional approval (including the question from your inquiry) and the mRNA vaccine against the COVID-19 disease has a standard EU marketing approval.
Given that the assessment of vaccines against the disease COVID-19 is within the competence of the EMA, we would advise you to contact EMAs:
https://www.ema.europa.eu/en/about-us/contact/send-question-european-medicines-agency

I have attached a link to another Federal Declaration from April of this year, specifically on how contamination findings be handled.

https://www.dropbox.com/s/i02i4odzoxvzc5q/Federal_Declaration_Mississppi_April_2023.pdf?dl=0

YOUR'S ANSWER: Finally, in accordance with EU regulations, each batch of vaccines is subject to control by the competent laboratory in the EU (Official Medicines Control Laboratory, OMCL). Which checks the production documentation for a specific batch and analyzes samples of each batch of vaccines according to guidelines European Directorate for the Quality of Medicines and Healthcare of the Council of Europe (EDQM). More information is available under the link: https://www.edqm.eu/en/ocabr-activities- related-to-covid-19-vaccines.

Thank you for this clarification, but these facts are common knowledge and my question very specifically referred to the insight into the actual data on the testing of certain series that HALMED or EMA, which, if they have it, must have forwarded the relevant documentation to you. Given that in accordance with the regulations HALMED approved new products - vaccines against COVID-19, I believe that you have the above analyzes in your documentation. Therefore, I clarify my query and again ask for the delivery of the analysis - the results of the analysis based on which vaccines against COVID-19 approved for placing on the market, all in accordance with EU regulations, which will undoubtedly clarify this aspect.

1. Are LOTs in Croatia were contaminated as the samples described in the attachment?

YOUR'S ANSWER: Every series of mRNA vaccines marketed in the EU, including in the Republic of Croatia, has been tested by the manufacturer and the competent laboratory

(OMCL) in the EU according to the OCABR guideline of the EDQM.

I kindly ask you to inspect the documentation - that is, the analysis carried out by the manufacturer, but also the OMCL analysis.

Article 114 of Directive 2001/83, which taken over in the Medicines Act (Article 175), does not allow additional quality checks of batches that are released on the market of the Republic of Croatia if they have been examined by another competent authority in the EU. The regulation on quality control prescribes which documents HALMED reviews before approving the release into circulation. You can find more information in the notification regarding the release of the first batches of Comirnaty vaccines:

https://www.halmed.hr/Novosti-i-edukacije/Novosti/2020/HALMED-dao-suglasnost-i-proveo-potrebne-provjere-u-svrhu-stavljanja-u-promet-prve-serije-cjepiva-Comirnaty-u-RH/2489/

The procedure for issuing the OCABR certificate prescribed by the European Directorate for the Quality of Medicines and Healthcare of the Council of Europe (EDQM) and is in accordance with the documentation on the medicine approved by the European Medicines Agency:

https://www.edqm.eu/en/edqm-helpdesk-faqs.
https://www.edqm.eu/en/edqm-initiatives-in-the-context-of-covid-19-vaccines-and-therapies

To access the documents in the above procedure, we suggest you contact the laboratories authorized to issue OCABR certificates for vaccines against the disease COVID-19:

• for vaccines with non-replicating viral vector ANSM, PEI, RIVM, Sciensano, BASG, ISS

• for vaccines with mRNA technology ANSM, PEI, RIVM, Sciensano, Swissmedic, SUKL, BASG, ISS, NoMA, BDA.

Attached is a document that analyzes the omissions made by the manufacturer to ensure quality and safety standards. There were many omissions and it is dangerous to rely on trust in a manufacturer with such omissions in good manufacturing practice.

https://www.dropbox.com/s/91c5c3p8p9fsgpj/Federal_Declaration_February_22_2023.pdf?dl=0

The rolling review process, as well as the granting of conditional marketing authorization, transparently explained on the websites of HALMED and EMA:

- https://www.halmed.hr/COVID-19/Odgovori-na-najcesca-pitanja/Sto-je-postupna-

ocjena-dokumentacije-o-lijeku-ili-cjepivu/

- https://www.halmed.hr/COVID-19/Odgovori-na-najcesca-pitanja/Sto-znaci-da-se-za-cjepivo-provodi-ubrzani-postupak-odobravanja/
- https://www.halmed.hr/COVID-19/Odgovori-na-najcesca-pitanja/Sto-je-uvjetno-odobrenje-za-stavljanje-u-promet/
- https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirus-disease-covid-19/covid-19-public-health-emergency-international-concern-2020-23/guidance-developers-companies/covid-19-guidance-evaluation-marketing-authorisation
- https://www.ema.europa.eu/en/human-regulatory/marketing-authorisation/conditional-marketing-authorisation

It is clear from the above that due to the extraordinary epidemiological situation allowed for the manufacturer to submit certain data gradually during the evaluation (and not all at once, as is usual for standard procedures). In this way, it was possible for the European Medicines Agency (EMA) gradually evaluate the documentation (as it became available) and to provide timely advice and questions to the manufacturer, all with the aim of speeding up the evaluation process so that the vaccine would be available as soon as possible.
At the time of granting the conditional approval, it was transparently available to the public what information the manufacturers were required to submit after the granting of the conditional approval. For the mentioned data, it assessed that they could not change the risk-benefit ratio, which was determined based on the available data. In addition, conditional approval from the legal side has the possibility of cancellation and withdrawal of the drug from circulation in case the manufacturer does not respect the deadlines for submitting additional data. Conditional authorization been used in the EU since 2006 and has been granted for a number of other medicines. None of these drugs withdrawn for safety reasons.
All the obligations and recommendations from the conditional approvals have been fulfilled by the manufacturers, they have submitted additional data and answers to the questions of the regulatory authorities, and both mRNA vaccines are no longer in the status of conditional approvals, but have standard approvals for placing on the market in the EU:

- https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirus-disease-covid-19/covid-19-medicines#originally-authorised-covid-19-vaccines-section
- https://www.halmed.hr/COVID-19/Odgovori-na-najcesca-pitanja/COVID-19-Odgovori-na-najcesca-pitanja/10/

The document from the link you provided refers to the authorization for emergency use given by the FDA for the US area, which differs from the marketing authorization (registration of the drug) as given in the EU in terms of the amount of data submitted and the necessary checks. It is a regulatory tool allows the temporary use of an unapproved drug (or an approved drug with an unapproved indication) in certain specific types of public health emergencies, such as the COVID-19 pandemic. Emergency use authorizations specifically designed to allow for temporary availability and use in

emergency and last only for the duration of the emergency. They can terminated at any time if the situation develops or based on new information. Regulators who temporarily approve the use and supply of a drug do so before issuing marketing authorization.

YOU'ER ANSWER: Pursuant to Article 13 of the Ordinance on Drug Quality Control (Official Gazette, No. 60/14) in accordance with the recognition of the rights and obligations of the Agency's full membership in the OMCL network and the applicable legal regulations, the Agency recognizes the results of both the EU/ EGP OCABR (Official Control Authority Batch Release) certificate of a special quality check carried out by an official laboratory (OMCL) of a member state of the European Union, the European Economic Area and Switzerland, and through the process of checking administrative and professional data, approves the placing on the market of the vaccine batches in question.

How are the analytical methods defined by the manufacturer transferred to independent laboratories and do you have copies of the so-called validation protocols for the vaccine (Validation protocols)?

In the manufacturer's documentation for granting approval for the drug, documentation on the validation of analytical methods for critical process controls and for quality control/release of intermediate products, active substance and drug is mandatory. These are reports on performed validation/validation protocols and protocols for the transfer of analytical methods. For all the analytical methods mentioned above, the manufacturers of the vaccine against the disease COVID-19 submitted the appropriate documentation.
As for the national laboratories within the competent regulatory bodies, they accredited according to EU standards and are regularly inspected in terms of maintaining that standard (e.g. https://www.halmed.hr/Novosti-i-edukacije/Novosti/2022/Uspjesno-provedena-reakreditacija-HALMED-ovog-Odjela-sluzbenog-laboratorija-za-provjeru-lijekova-%E2%80%93-OMCL/2874/). These laboratories carry out their own validation and/or qualification of the manufacturer's methods, which they will repeat.

This approach ensures a timely and uninterrupted supply of the Croatian market with vaccines of tested and confirmed quality in accordance with pre-set quality requirements.

Please provide me:

(1) Documentation on pre-set quality requirements for the products in question

We refer you to the publicly available European public dossier assessment reports (EPAR) of the vaccines in question:

- https://data.europa.eu/data/datasets/epar-human-medicines?locale=hr
- https://www.ema.europa.eu/en/medicines/human/EPAR/comirnaty
- https://www.ema.europa.eu/en/medicines/human/EPAR/spikevax

(2) The license to manufacture the products in question and the inspection history of the Lonza as the mRNA manufacturer of the products in question. The Lonza production license must therefore explicitly state the active substance mRNA, which means that there should be a trace of prior approval for the aforementioned

by EMA or HALMED.

According to Article 40 of Directive 2001/83, transposed into Article 72 of the Law on Medicinal Products, Member States are obliged to take all measures to ensure that the production of medicinal products on their national territory is subject to the possession of a production permit
Also, according to Article 111 of Directive 2001/83, transposed into Article 193 of the Medicines Act, the competent authority of each member state ensures compliance with the legal conditions that apply to medicines through regular inspections.
All production permits (MIA) and GMP certificates are available in a publicly accessible database Eudra GMP - Public Layout (europa.eu)

(3) Inspection report and possible list of corrections of all critical observations that preceded production approval. If this inspection carried out at all, was it a full physical inspection or remote (virtual) inspections?

Inspection reports are confidential documents and are owned by the competent authorities that carry out the inspection, and in case of meeting the conditions of good manufacturing practice, a GMP certificate is issued, which is available in the database Eudra GMP - Public Layout (europa.eu)

Aspects of the so-called of cold chain storage and delivery related to frozen (Moderna – 20°C) and ultra-frozen (Pfizer/BioNTech -70°C) injections. They did not enter the distribution chain as ready-made, unit-dose products, which is the case with other medicines. Wholesale networks in the EU were not able to withstand such low temperatures. Who did the distribution and did they have wholesale distribution credentials to prove they properly licensed?

HALMED, based on Articles 71 of the Ordinance on good practice in the sale of medicinal products, granting licenses for the wholesale sale of medicinal products, granting licenses for the mediation of medicinal products and issuing a certificate of good practice in the wholesale sale of medicinal products (Official Gazette, No. 83/13), keeps records natural or legal persons with headquarters outside the Republic of Croatia, who in a member state of the European Union have a license to carry out the activity of wholesale distribution of medicines or mediation of medicines and meet the conditions for carrying out the activity of wholesale distribution of medicines or mediation of medicines in the country of their headquarters, and wish to perform the same activity on the territory of the Republic of Croatia. A list of all external wholesalers is available at

https://www.halmed.hr/Promet-proizvodnja-i-inspekcija/Baza-dozvola-za-proizvodnju-i-promet/Evidencija-veleprodaja-i-posrednika-sa-sjedistem-izvan-RH-u-EU/

Those working in vaccination centers had to perform the conversion of frozen/ultra-frozen injections without training or an established quality system. This is unprecedented in the history of the pharmaceutical industry, and the result is that the injections were effectively 'manufactured' outside the GMP safety umbrella without final quality control testing before administration to the patient. This will guarantee defective, dangerous or even deadly products.

The procedure for handling the vaccine before administration is described in detail in the Summary of Product Characteristics (intended for healthcare professionals) and the Package Leaflet (intended primarily for patients), which are also evaluated as part of the approval process. Any information provided in these documents to support by data/test results provided in the documentation. In this way, the quality of the vaccine ensured during handling.

In addition, I am bringing to your attention the observed very large variations in effects from batch to batch in the number of adverse event reports.

1. Pardekooper, C. (2023) How bad is my streak? Serial codes and associated deaths, disabilities and illnesses for Covid-19 vaccines

https://howbadismybatch.com/

2. Schmeling, M. et al. (2023) Batch-dependent safety of BNT162b2 mRNA vaccine against COVID-19. Eur. J. Clin. Invest. p. e13998

https://www.ncbi.nlm.nih.gov/pubmed/?term=36997290

3. Seligmann, H. (2023) Pfizer's worldwide batch data converges with Denmark's three batch-dependent injection qualities. ResearchGate p. 370801525

https://www.researchgate.net/publication/370801525

If manufacturing standards are truly up to par, then COVID vaccines should show no more batch-to-batch variation in the number of side effects than flu vaccines -- in fact, it should be less, since flu vaccines contain multiple brands from multiple manufacturers, while the COVID vaccines are individual brands. But we see that the number of side effect reports is not only much higher on average, but also much more variable. This means that no manufacturer has been able to produce their products with consistent quality.

On this occasion, we would like to point out that the number of reports of suspected side effects does not mean the number of confirmed side effects. Based on data on the rate of reports received in a certain pharmacovigilance system, no conclusions drawn about the occurrence of side effects with a particular vaccine or series of vaccines. The above depends on how motivated a particular group of applicants will be to apply. What the country's pharmacovigilance system is like; the impact of media reporting on individual vaccines, etc., and for data on the frequency of side effects, the reference approved documents on the medicine (summary of the description of the properties of the medicine, instructions on the medicine).

YOUR'S ANSWER: No series of mRNA vaccines have been found to contain DNA contaminants above levels that were found to be safe for human use during approval.

Please provide evidence for this claim. Specifically, what was the concentration, that is, the amount of DNA per vial, measured for each of the batches imported to Croatia?

If the vaccine marketed in the EU, it means that it has passed the OCABR procedure described in the previous answer

(https://www.edqm.eu/en/ocabr-activities-related-to-covid-19-vaccines).

According to the protocol for OCABR for mRNA vaccines, tests carried out at the level of linear DNA and mRNA (active substance) to ensure the appropriate purity of the vaccine with regard to DNA contamination. There is no need to repeat these tests on the drug because there is no possibility of contamination with these contaminants in the later production process. Continuing on cccDNA, the explanation given in the answer to the first question.

"Found to be safe" is arbitrary -- there is most likely a linear relationship between the amount of DNA and the risk. Please expand your claim quantitatively.

We refer to the report mentioned in the answer to the question related to BMI further down the page.

YOUR'S ANSWER: When testing pollution, the manufacturer uses analytical methods approved by EU regulatory agencies based on the evaluation of extensive documentation that includes a detailed description of the method and full validation that includes accuracy, precision (repeatability and intermediate precision), specificity, detection limit, quantification limit, linearity and range of each method. In this way, a strict regulatory assessment ensures that the results of the methods implemented by the manufacturer are reliable, and that the methods are suitable for the purpose for which they are used. Additional regulatory confirmation of the manufacturer's evaluated documentation carried out in the form of inspections of all production sites, including analytical testing sites that must have a production license to carry out these activities.

I appreciate that in a typical medical device approval framework, as you say, 'rigorous regulatory assessment ensures that the results of the methods carried out by the manufacturer are reliable and that the methods are fit for purpose.'

However, in the case of Comirnaty, the medicinal product assessed through the 'Ongoing Review' framework prior to accelerated approval through 'Conditional Marketing Authorization' issued by the European Commission (EC) - that is, the product approved through a political body on the recommendation of the EMA- e, rather than being approved by the usual regulatory process.

We refer you to the previously explained procedure of gradual evaluation and granting of conditional approval. Additionally, we remind you that all subject vaccines, which belong to the category of drugs and not medical products, met the conditions for granting standard approval within the set deadlines:

https://www.halmed.hr/Novosti-i-edukacije/Novosti/2022/Ispunjene-sve-obveze-zadane-u-sklopu-uvjetnih-odobrenja-za-cjepiva-Comirnaty-i-Spikevax-EMA-preporucila-davanje-standardnih-odobrenja-/2980/

https://www.ema.europa.eu/en/news/ema-recommends-first-covid-19-vaccine-authorisation-eu

In light of this, it can be concluded that extreme political pressure may have been applied to the regulatory process in order to achieve a political end - rapid approval of the Covid-19 vaccine. Therefore, the normal safeguards that should ensure the safety of the public prior to marketing authorization may have been devalued. Indeed, public evidence that this was the case provided by documents leaked from the EMA in early 2021 and reviewed by the British Medical Journal, of which you are probably aware.

https://www.bmj.com/content/372/bmj.n627

In the process of evaluating the documentation on each drug, including the vaccine from your inquiry, the EMA asks the applicant a series of questions, to which he is obliged to provide answers, or evidence. In accordance with the above, during the EMA's evaluation of the Comirnaty vaccine, questions related to the integrity of the active substance (mRNA) in the vaccine in question raised. The manufacturer answered the above questions and submitted the necessary information and data on the basis of which the EMA issued a recommendation on the approval of the vaccine in question. The publicly available assessment report discusses the differences observed between the vaccine manufacturing process used in clinical trials and the process used in commercial use and details the EMA's conclusions. Regarding the release of vaccines on the market, an appropriate, scientifically based control limit ("specification") established. In accordance with the above, only a vaccine of acceptable quality, i.e. above the agreed control limit, can be put on the market.

Detailed information on the evaluation of the manufacturing process and the pharmaceutical quality of the vaccine to found in publicly available reports on the EMA website. We refer you to the report from 2021, pages 14-41. and 137.:

https://www.ema.europa.eu/en/documents/assessment-report/comirnaty-epar-public-assessment-report_en.pdf

EMA scientists tasked with manufacturing quality assurance - the chemistry, manufacturing and control aspects of Pfizer's application to the EMA - are concerned about "truncated and modified mRNA species present in the finished product." Among the many files leaked to The BMJ, a November 23 email from a senior EMA official outlined a number of problems. In short, commercial production was not producing vaccines to expected specifications, and regulators were unsure of the implications. The EMA responded by submitting two "major objections" to Pfizer, along with a number of other questions it wanted answered."

Thus, until November 23, 2020, mRNA vaccines not produced according to the expected specifications. However, a large number of batches already been produced by this time and were still on the market after the European Commission granted CMA in December 2020.

There is a significant potential risk that the manufacturer and regulator overlooked problems with DNA contamination above safe levels, as suggested by Dr. McKernan's results, and that the rigorous regulatory assessment to which you refer not carried out. I inform HALMED about the potential risk for the Croatian public, which related to the release of low quality and dangerous medical products, and I invite you to investigate this in detail, in an open and transparent manner, as you would do with any potentially dangerous medical product.

For the vaccines, in question, strict control carried out, as for all other medicines. The data required submitted after approval now submitted and the vaccines have standard marketing approval.

Therefore, I am requesting the following information from HALMED to support your claims:

1. Specifically, what regulatory assessment perfected, reviewed by the EMA ensuring DNA contamination is below a certain threshold?

A thorough scientific and expert evaluation of the documentation on the medicine carried out, as for every medicine, and a GMP inspection of the manufacturer carried out. In addition to the earlier responses and documents to which we refer, we are additionally providing links to publicly available reports for the mRNA vaccines in question detailing all the procedures that EMA has carried out:

- https://www.ema.europa.eu/en/medicines/human/EPAR/comirnaty#assessment-history-section
- https://www.ema.europa.eu/en/medicines/human/EPAR/spikevax#assessment-history-section

2. What methods used and considered suitable for purpose of determining the amount of DNA contamination?

For all tests, the manufacturer can propose the methods himself, and must attach a detailed description and validation in the documentation confirming that the method is suitable for this purpose. The suitability of the method and the validity of the validation are assessed in the approval process, and data on the aforementioned are available in the above- mentioned reports.

3. Provide a list of all batches of Pfizer/BioNTech Bnt162b2 imported into Croatia from December 2020 to May 2021. Only batches for which doses administered are required.

All batches of the subject vaccine that have been put into circulation in the

https://www.halmed.hr/Promet-proizvodnja-i-inspekcija/Promet/Serije-cjepiva-i-lijekova-iz-ljudske-krvi-ili-ljudske-plazme-u-prometu/

4. Provide a valid EU OCABR Certificate, Manufacturing Information (MIF) and Certificate of Conformity (CoC) for each of the batches listed 3.

We advise you to contact the competent OMCLs mentioned above and the European Directorate for the Quality of Medicines and Healthcare of the Council of Europe (EDQM) with your request:
https://www.edqm.eu/en/edqm-helpdesk-faqs, https://www.edqm.eu/en/edqm-initiatives-in-the-context-of-covid-19-vaccines-and-therapies

5. Provide a manufacturing import approval certificate for each manufacturing site, including analytical testing sites, involved in the production of commercial batches of Pfizer/BioNTechs Bnt162b2 product. It should cover all commercial batches that imported into Croatia from December 2020 to May 2021 and should support the claim that each site had a manufacturing license (MIA) to carry out these activities during 2020.

All production permits (MIA) and GMP certificates are available in a publicly accessible database Eudra GMP - Public Layout (europa.eu)

YOU'ER ANSWER: Hereby, we must note that we cannot claim all of the above for the places where the analytical tests were conducted and the analytical methods described in the paper you attached to us, because they do not contain data that would support it. Additionally, it is not possible to determine the origin and method of storage of the vaccine samples examined in the attached work, unless the samples have expired, for example:

Several methods were deployed to assess the nucleic acid composition of four expired vials of the Moderna and Pfizer bivalent mRNA vaccines" […] „A limitation of this study is

the unknown provenance of the vaccine vials under study. These vials were sent to us anonymously in the mail without cold packs.

This is true, but intact, the transformationally competent plasmid DNA cannot be a byproduct of product expiration or improper storage. It must originate from contamination from the plasmid DNA sample, which should been linearized before mRNA transcription or degraded and removed afterwards. Alternatively, the contaminant entered the vials tested by Dr. McKernan after production. However, since Dr. McKernan has openly provided the plasmid DNA sequence and it is a new sequence not present in any public sequence database, and the sequence of the identified Moderna plasmid contamination is different from that of Pfizer, this suggests that the contamination did not come from common sources e.g the McKernan's laboratory.

2. If you have not performed testing for these circumstances, will you do so in the light of new knowledge?

3. If you have already tested and found contamination, are the dangers presented by Dr. Palmer justified?

YOU'ER ANSWER: Given that:

- We cannot confirm the suitability and degree of validation of the methods used in the attached work, while we can, for the manufacturer's methods,

Provide specific details in support of these claims i.e. the suitability and degree of verification of the methods used against the manufacturer's methods.

The above evaluated in the approval procedure. Specific details are publicly available in the reports on the EMA website to which we refer in earlier responses.

YOU'ER ANSWER: - it is not possible to determine the origin and storage method of the samples examined in the attached work, which is traceable and ensured for the samples examined by the manufacturer and competent regulatory laboratories,

There is ample reason to suspect that Pfizer/BioNTEch have produced substandard products and that this is a potential fraud - leading to the release of dangerous medical products. It is your responsibility to investigate this fully and not just present it as baseless. Therefore, I repeat my requests for the delivery of specific documents based on which you made decisions and approved the use of the vaccine mentioned in the text above.

The aforementioned request to send to the EMA, which is responsible for the assessment in the process of granting approval for vaccines against the disease COVID-19.

YOU'ER ANSWER: - during the granting of approval for the vaccines in question, the validation of the production process was checked and evaluated, which included the validation of the capacity of the production process to remove each individual contamination, including DNA contamination,

You can easily test bottles imported to Croatia to check this, using the methods defined by Mr McKernan.

Pursuant to Article 13 of the Ordinance on the Quality Control of Medicinal Products. In accordance with the recognition of the rights and obligations of the Agency's full membership in the OMCL network and current legislation, the Agency recognizes the results and the EU/EEG OCABR (Official Control Authority Batch Release) certificate of the conducted special of the quality control carried out by the official laboratory (OMCL) of a member state of the European Union, the European Economic Area and Switzerland, and through the process of checking administrative and professional data, approves the placing on the market of the series of vaccines in question.

Article 114 of Directive 2001/83, which implemented in the Medicines Act, does not allow the repetition of tests carried out by OMCL in the network. For vaccines against the disease COVID-19, a special quality check within the OMCL network carried out by the following listed laboratories:

• for vaccines with non-replicating viral vector ANSM, PEI, RIVM, Sciensano, BASG, ISS

• for vaccines with mRNA technology ANSM, PEI, RIVM, Sciensano, Swissmedic, SUKL, BASG, ISS, NoMA, BDA.

YOU'ER ANSWER: we believe that it is not necessary to carry out additional tests and checks at this time that mRNA vaccines against the disease COVID-19 are safe for use, given the amount of residual DNA.

Based on which, you declare that despite the submitted doubts. At least from me personally, and I know that other citizens also submitted inquiries and requests to carry out supervision and evaluation of the safety and quality of vaccines, you do not consider it necessary to initiate adequate verification processes, even though according to the Law and your own Statute obliged to carry out ? I invite you to investigate this in order to ensure the protection of Croatian citizens from medical products that are of poor quality, given that you are authorized and responsible for this activity by law.

Adequate vaccine verification processes been implemented in the approval process and at marketing, and vaccines continue to be verified through a number of mechanisms throughout the time they are available on the market. HALMED carries out all activities in accordance with legal provisions and within the scope of its duties and authorizations.

In particular, I must point out the concern related to the impurities found by Mr. McKernan:
"The spiked protein sequence itself is identical to syncytins, and all 15 women who received the injection in the Singapore study all had antibodies to this protein, which is essential for pregnancy. Mattar et al. 2021. There is a major criticism of this study entitled "What Happened in Singapore?".

https://unglossed.substack.com/p/what-happened-in-singapore

Other studies followed that purportedly showed no response—they flawed for experimental design and designed to fail. One used serum diluted 1:800, while Mattar used serum diluted 1:50. Another used a complicated HEK cell expression system that was unnecessary.
Mattar also said they did not have any response even though they clearly did—read the review. This alone can cause a decline in fertility in men - syncytin found in sperm and loss of pregnancy in women. In fact, uterine trophoblast proteins such as syncytin been patented as sterilization vaxx - Aplagen et al.
Hans George Frank.

Plasmids carry the promoter of transfection and translation of human cells - the SV40 promoter from the oncogenic poliovirus. If the plasmids only used as a tool to generate most of the spike sequence, why do they have a human promoter? They do not need it. E. coli must infect only for production purposes—not our cells."

Promoters in plasmids are gene sequences to which RNA polymerase binds together with specific transcription factors to start the transcription process and as such been used for decades in various techniques of molecular biology and genetic engineering. Plasmids used as transmitters of genetic information, which can contain several features, which enable screening of those plasmids that carry the desired information and are the most suitable for further production. Individual genes within the plasmid can therefore be under the control of different promoters in order to enable the expression of individual markers and thus enable the selection of the plasmid. Screened plasmids, in this case those that are efficient in the transcription and translation of the mRNA coding for the spike protein of SARS-CoV-2, screened in this way. The specific choice of promoter for plasmid creation depends solely on the manufacturer and the course of vaccine research and development. All the above data are subject to a strict scientific and professional assessment by the experts of the competent regulatory authorities.

YOU'ER ANSWER: We hope that the provided information will be useful to you."

The information presented in the context of the general explanation of the regulation was useful, and I thank you for that.
However, I have presented you with more than enough evidence that casts doubt that the documents you refer to are authentic, that is, that part of the documents are missing, and thus that your claims about the safety of the product are questionable.
As it is a matter of potentially very dangerous consequences, if the contamination mentioned in the paper found, I believe that you have a duty to carry out again your own independent tests, using the correct methods, to check the quality of the products administered in Croatia (over 5.3 million doses).

An additional check will not cause a significant cost, especially in comparison to the potential damage. Taking into account the cost that all of us as taxpayers have had and will have yet to have for the said product, it is necessary to check the above, because in the event that contamination found, the scope for terminating the contract with the manufacturer due to the delivery of a defective product and

fraud opened. That way, they would have the right to ask for financial compensation and at the same time get out of the contract, which would avoid future costs and protect the health of the population.

The most important thing is that they could warn Croatian citizens, and the wider public, about the dangers of the consequences of the product they received and thereby save many lives and health.

This Sunday, June 18, a mini-series of episodes of the FREE podcast about this topic through a conversation with experts will start on Z1 television from 2 p.m. If you provide me with the answers to the questions by June 27, I will publish them in the introduction to the third show of the miniseries that airs on 2nd of July.

In the hope that you will answer me in accordance with the law on access to information, I warmly welcome you.

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Andrija Klarić

SLOBODNI podcast