Original Message -------
On Friday, October 21st, 2022 at 14.30, AskEMA No-Reply <AskEMA.noreply@ema.europa.eu> wrote:

Dear Rauli Mäkelä,

Many thanks for contacting EMA with your questions in relation to alleged impurities found in COVID-19 vaccines and the latest publication in this respect (Hughes DA 2022 What is in the so-called COVID-19 "Vaccines"? Part 1: Evidence of a Global Crime Against Humanity. IJVTPR 2(2):455-586).

As an initial remark the journal that published the article is not a known scientific journal (there is only one edition and the journal is not indexed by the databases Medline, PubMed or Embase and is not included in either citation analysis databases SJR or Scopus). The publication makes several allegations which are known anti-vax misinformation. EMA is aware of the problem caused by misinformation about COVID-19 vaccines including claims in non-scientific publications that misrepresent data or provide incorrect information. Misinformation can come from various sources and EMA always encourages members of the public to use information from trusted sources.

The publication refers to a number of reports such as the reports by Professor Dr Pablo Campra (https://www.globalresearch.ca/detection-of-graphene-in-covid-19-vaccines/5761969 https://www.globalresearch.ca/graphene-oxide-detection-aqueous-suspension/5749529) and a report by the German Working Group for COVID Vaccine Analysis dated 06.07.2022. These reports describe the analysis of vials of COVID-19 vaccines and suggest the presence of impurities.

These reports have been analysed by EMA's working party for biological medicines (BWP) with input from the European Directorate for Quality of Medicines (EDQM) and the independent national testing laboratories responsible for batch release (OMCLs). In addition, the marketing authorisation holders of the authorised vaccines were asked to provide input on the quality of the batch(es) in question.

Regarding the reports by Professor Dr Pablo Campra and the alleged presence of the impurity graphene the analysis found that the currently available data do not show presence of graphene in the concerned vaccines.

In particular, there are serious concerns about the origin, traceability and authenticity of the product samples and the testing methodology described in the report. The source of the vaccine samples is not identified, some of the vaccine vials were not sealed, some batch numbers were missing and some of the batch

numbers quoted do not exist. This raised concerns about the security of the supply chain and the possibility of inadvertent or deliberate contamination or falsification.

Furthermore, the report does not provide sufficient details on the way the samples were prepared, the study included no positive or negative controls or reference standard, and the results were not critically evaluated or verified. The conclusions of the report are based on assumptions that are not sufficiently scientifically sound.

Graphene oxide is not used in the manufacture or formulation of any of the COVID-19 vaccines or other medicines, so it would not be present at manufacturing facilities and there is no obvious way that it could get into the vaccines.

Quality control testing and quality assurance review, by the vaccine manufacturers and OMCLs responsible for batch release, confirm that each batch met all quality standards prior to release. No product complaints have been received for the batches mentioned in the paper. The presence of graphene or graphene derivatives in the vaccines therefore are not plausible.

Regarding the report by the German Working Group for COVID Vaccine Analysis, the BWP concluded that there was no evidence of presence of impurities in the concerned vaccines.

Many batch numbers referred to in the document do not correspond to actual batches and some of the vial labels do not correspond to approved clinical or commercial labels. There are therefore serious concerns about whether the vaccine samples are genuine and questions about the reliability and scientific correctness of the whole document.

The report showed deficiencies concerning the source, authenticity and handling of the product samples as well as lack of important details of the analytical methods used (analytical methods have not been validated and controls are absent) which means that a proper assessment cannot be carried out.

The marketing authorisation holders and OMCLs have confirmed that all batches that were tested and released to the EU market complied with their specifications and no quality defects have been reported for these batches.

You also ask about the appearance of red blood cells, an issue also highlighted in the report by the German Working Group for COVID Vaccine Analysis. The group claims that an analysis of the blood of vaccinated and unvaccinated people showed that the blood of vaccinated subjects had “peculiarities” and “phenomena that have similarities with pathogenic and often highly pathogenic clinical presentations “ (i.e. novel structures, deformation of cell membranes of erythrocytes, blood clots, decomposition process) not observed in the blood of unvaccinated subjects.

EMA's analysis found that there were no data presented in support of the claimed difference between blood samples from vaccinated individuals and unvaccinated controls.

In conclusion, none of the reports mentioned above presented relevant information that changes our assessment of the quality or the benefit/risk balance of COVID-19 vaccines. EMA therefore does not consider that any further actions are necessary at this stage.

Regarding question 4 on the quality control of vaccines please note that, in line with EU legislation, to obtain a marketing authorisation, medicine developers have to submit specific data on their medicine which are the basis for EMA's assessment on whether or not a medicine is safe, effective and of good quality. In addition to the requirements set out in EU legislation (e.g. Annex I to Directive 2001/83), EMA provides companies with guidance on the type of data and information they need to include in a marketing authorisation application. This includes data on:

- the quality of the medicine including its chemical and physical properties, such as its stability, its purity and biological activity;
- compliance with international requirements for laboratory testing, medicine manufacture and conduct of clinical trials ('good laboratory practice', 'good clinical practice' and 'good manufacturing practice').

In addition, during an evaluation EMA's scientific committees may request inspections of the medicine's manufacturing sites, the site where a non-clinical or clinical study was performed or the pharmacovigilance (safety monitoring) processes involved in the application, and such inspections would then be carried out as part of the assessment.

Based on the outcome of any inspection and the assessment of the extensive information provided by the companies, EMA decides whether or not a medicine is safe, effective and of good quality and is therefore suitable for use in patients.

Once a vaccine has received approval, batches can only be marketed and released following quality control testing if the product is in line with the specifications that were approved as part of the respective marketing authorisation. This control is carried out by the manufacturer. For centrally authorised vaccines, EU legislation requires that a Member State's Official Medicines Control Laboratory performs an additional independent control for each batch before it can be released to the EU market. This independent control is referred to as Official Control Authority Batch Release (OCABR[1]) and includes testing of agreed quality parameters (specifications) and a compliance check of the manufacturer's own test results.

EMA's ongoing pharmacovigilance activities which include the continuous monitoring of suspected side effects and the scientific literature have so far not found any evidence substantiating the above claims. The article by Hughes does not add any new elements requiring further investigation. The latest information on the safety of each COVID-19 vaccine can be in the vaccine's monthly safety update: https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirus-disease-covid-19/treatments-vaccines/vaccines-covid-19/safety-covid-19-vaccines

We hope that the above reassures you that EMA has a robust quality assurance system in place and that COVID-19 vaccines comply with the stringent scientific requirements for quality, safety and efficacy.

Kind regards,

Juan Garcia Burgos

Head of Public and Stakeholders Engagement Department

Also on behalf of EU Commissioner Stella Kyriakides, CHMP Chair Harald Enzmann, CHMP Vice-chair Bruno Sepodes, PRAC Chair Sabine Straus, PRAC Vice-chair Martin Huber

European Medicines Agency

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We received your question(s) on: **06/10/2022** Subject of your enquiry: **Quality control of experimental mRNA SARS-CoV-2 vaccine injections**