Bundesinstitut für Impfstoffe und biomedizinische Arzneimittel
Federal Institute for Vaccines and Biomedicines

Paul-Ehrlich-Institut

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Information for Doctors and Pharmacists

FALSE REPORT IN THE GUISE OF A DEAR DOCTOR LETTER CURRENTLY IN CIRCULATION

Alleged liability risks connected to the administration of mRNA vaccines

The Paul-Ehrlich-Institut (PEI) has been made aware that the Medizinische Behandlungsverbund GmbH (MBV) issued a call in the medical community on 1 December 2023, to notify doctors of the alleged liability risks connected to DNA contamination in mRNA-based COVID-19 vaccines. The letter, as well as the conclusions derived therefrom, are incorrect. The call does not constitute officially verified and authorised information, but instead serves to foster uncertainty through targeted disinformation. The Paul-Ehrlich-Institut asks that the false information not be heeded. The "Rote Hand" (red hand) logo was used without authorisation from the German Pharmaceutical Industry Association (Bundesverband der Pharmazeutischen Industrie, BPI). The Paul-Ehrlich-Institut explicitly stresses that the benefits of COVID-19 mRNA vaccines clearly outweigh any potential risks. This statement also matches the international consensus. The COVID-19 mRNA vaccines have been recommended by the national vaccination commissions, such as the Standing Vaccination Commission (Ständige Impfkommission, STIKO) in Germany.

The contents of the letter are incorrect.

Pursuant to section 32 of the Medicinal Products Act (Arzneimittelgesetz, AMG), a vaccine batch may only be placed on the market in Germany if it has been tested and released by the competent higher federal authority, the Paul-Ehrlich-Institut.

When a vaccine product is authorised, a determination is made as to which parameter specifications must be met before manufacturer can issue an in-house release for each individual vaccine batch. Only when the required specifications have been reached can the manufacturer submit an application for batch release

to the medicines testing authority. In the case of centrally authorised vaccine products, such as the COVID-19 mRNA vaccines, the responsible medicines testing authority is the Official Medicines Control Laboratory (OMCL) in the European OMCL network designated for the official batch testing of each vaccine product.

The specifications set out in the authorisation include a DNA limit per dose. Each manufacturer of an EU-authorised COVID-19 mRNA vaccine product is required to verify compliance with the relevant limit set out in the authorisation for each batch during manufacture.

The European Directorate for the Quality of Medicines and HealthCare (EDQM), which coordinates batch testing in the OMCL network, publishes guidelines specifying which of the authorisation limits are to be tested solely by the manufacturer or by both the manufacturer and the OMCL laboratories.

In the case of manufacturer-tested parameters, such as residual DNA content in the vaccine, the OMCL checks the manufacturer's test results to see whether the limit values specified in the authorisation have been complied with in the specific batch (document check).

All batches of the EU Commission-authorised COVID-19 vaccine product Comirnaty (in all indications and concentrations) put on the market in Germany were tested in accordance with OMCL guidelines and authorisation specifications and, after successful testing, all batches were granted federal batch releases for Germany.

The red hand logo (Dear Doctor Letter logo) was used without authorisation from the German Pharmaceutical Industry Association (BPI). The logo is a registered figurative mark, which stems from an initiative of the BPI. The Paul-Ehrlich-Institut was also not consulted regarding the use of the logo. Dear Doctor Letters are only (pursuant to section 63b subsection 3 of the German Medicinial Products Act (Arzneimittelgesetz, AMG)) issued to communicate pharmacovigilance information by the pharmaceutical company after consultation with the higher federal authorities, in this case the Paul-Ehrlich-Institut, and possibly the federal states on the basis of section 63b subsection 3 of the AMG. The Paul-Ehrlich-Institut publishes Dear Doctor Letters at www.pei.de/rhb.

The Paul-Ehrlich-Institut asks that the false information not be heeded. Do not send vaccines that could still be used to the address given in the letter. Doing so

would divert valuable vaccines from their actual intended use. The tests mentioned in the letter were carried out by unauthorised laboratories and the conclusions presented do not correspond to the current state of scientific knowledge.