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

Paul-Ehrlich-Institut

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STATEMENT

USE OF SECONDARY DATA IN COVID-19 VACCINE PHARMACOVIGILANCE

The Paul-Ehrlich-Institut has been receiving various inquiries from the media and public regarding whether and how the Institute uses data from the Associations of Statutory Health Insurance Physicians (ASHIPs) or from the Hospital Remuneration System (Entgeltsystem im Krankenhaus, InEK) to assess the safety of COVID-19 vaccines pursuant to section 13 of the Infection Protection Act (Infektionsschutzgesetz, IfSG).

The Paul-Ehrlich-Institut is fully aware of its responsibility in the field of drug safety (pharmacovigilance) and is committed to fulfilling this responsibility at all times.

From the point of view of the Paul-Ehrlich-Institut, general ICD codes for vaccine adverse events, such as those used in the inquiry of the health insurance company BKK ProVita (T88.0, T88.1, Y59.9 and U12.9), are not very suitable for evaluating the adverse event profile of a vaccine. Therefore, no robust conclusions can be made about certain vaccine-specific adverse events (e.g. myocarditis after mRNA vaccines, immunothrombocytopenia after adenoviral vector vaccines). It is also not possible to reliably distinguish between serious adverse events and short-term, temporary adverse events. For this reason, the Paul-Ehrlich-Institut favours a detailed evaluation of patient data in order to continuously evaluate the safety of COVID-19 vaccines. This should be done in anonymised form in order to respect data protection requirements.

The Paul-Ehrlich-Institut had already completed planning for a COVID-19 vaccine safety based on anonymised health insurance data back in 2020. Funding was approved by the Federal Ministry of Health (BMG). The Paul-Ehrlich-Institut requested the necessary data at that time. The health insurance companies have not yet provided the data to the Paul-Ehrlich-Institut.

The Paul-Ehrlich-Institut expressly welcomes the option introduced in the Infection Protection Act (IfSG) to request pseudonymised data from the Associations of Statutory Health Insurance Physicians (ASHIPs) and to use that data for evaluation. In the future, this data will help to broaden the pharmacovigilance database. However, this requires extensive preparatory work. The Paul-Ehrlich-Institut is currently preparing its address to the ASHIPs and is coordinating on this with the Robert Koch-Institut. The Robert Koch-Institut uses data from the ASHIPs for vaccine surveillance, which allows the Institute to both guarantee data protection while also organising a quick transmission of data that doesn't requirea too much additional effort from each individual ASHIP.

The Paul-Ehrlich-Institut is currently involved in the well-established pharmacovigilance systems, such as the recording and evaluation of suspected cases of vaccine adverse events and complication and the spontaneous reporting system, along with several ongoing (epidemiological) studies on the safety of COVID-19 vaccines, which the Paul-Ehrlich-Institut supervises or conducts itself:

- SafeVac App 2.0 Study:
  Prospective study of the tolerability and (long-term) safety of the authorised COVID-19 vaccines assessed via surveys of vaccinated persons. More than 730,000 vaccinated persons are currently participating, the observation period is 12 months.

- Safety of COVID-19 vaccines during pregnancy:
  This study is being conducted in cooperation with the Pharmacovigilance Centre for Embryonic Toxicology at the Charité Hospital in Berlin.

- Cooperation with the Registry for Children and Adolescents with Suspected Myocarditis (MYKKE):
  Study including long-term course of suspected cases of myocarditis after COVID-19 vaccination in children and adolescents in Germany.

- Evaluation of aggregated hospital discharge diagnoses and correlation with COVID-19 vaccination rates, stratified by postal code, age and gender, over the course of the vaccination campaign.
  In this study, data from the Institute for the Hospital Remuneration System (InEK) is evaluated and correlated with the respective vaccination rate.

Finally, the Paul-Ehrlich-Institut works closely with the regulatory authorities of the European Union (EU), the European Medicines Agency (EMA) and authorities outside the EU. In addition to data from Germany, the safety assessment of COVID-19 vaccines also includes relevant international reports of suspected

adverse events and vaccine complications as well as data from international safety studies.

In order to avoid potential underreporting of suspected adverse events and vaccination complications, the Paul-Ehrlich-Institut created the possibility many years ago for affected persons and their relatives to directly report a suspected adverse event via a reporting portal on the Paul-Ehrlich-Institut website: www.nebenwirkungen.bund.de.