

(English version)

**Question for written answer E-003127/25
to the Commission
Gerald Hauser (Pfe)
(29 July 2025)**

Subject: Insufficient monitoring of side effects from medicinal products in the EU

In the EU, the monitoring of side effects of all medicinal products, including vaccines, is subject to statutory pharmacovigilance. The aim of this system is to detect adverse reactions at an early stage and to take measures to protect the population. Cases of suspected adverse reactions are first recorded at national level and then sent to the European database EudraVigilance, which publishes the data with a view to identifying and assessing side effects.

This system is facing increasing criticism, especially in relation to the experience of the COVID-19 vaccination campaign. This criticism includes a lack of transparency, excessive strain due to high volumes of data and, in particular, insufficient coverage of reported adverse reactions and sometimes late or missing responses to potential safety risks.

1. How will the EU's EudraVigilance system be improved going forward, in order to ensure that adverse drug effects are recorded and evaluated in a more effective, transparent and timely manner?
2. Why was a temporary restriction imposed on the use of the IXCHIQ vaccine in adults aged 62 to 89, even though as of 2 May 2025 there had only been reports of 17 serious adverse events following its administration worldwide?
3. Why can BioNTech/Pfizer's COVID-19 vaccine continue to be freely administered to all population groups, even though around 2.5 million predominantly serious side effects and around 30 000 deaths have been recorded in the EMA database?

Submitted: 29.7.2025

**Answer given by Mr Várhelyi on behalf of the European Commission
(23 September 2025)**

EU legislation provides a robust system to constantly monitor medicines, including vaccines, for potential new risks (and the impact on the benefit/risk balance), throughout their life cycle.

The EudraVigilance is a central pillar, enabling effective monitoring of suspected adverse reactions and detection of risks related to medicines.

Timely detection and assessment of safety signals from EudraVigilance complement the routine benefit-risk evaluation of authorised medicines performed by the European Medicines Agency's Pharmacovigilance Risk Assessment Committee through periodic safety update reports and risk management plans submitted by the marketing authorisation holder as per legal obligations. EudraVigilance screening continues to be the major source of potential signals ⁽¹⁾.

However, the European Medicines Agency (EMA) continuously explores ways to improve the operation of EudraVigilance to gain efficiencies in an already robust system.

When deciding on temporary measures, several factors are considered, including the risk's severity, evidence strength, and population exposure.

Direct comparisons of reported adverse drug reactions between vaccines lack scientific robustness due to variations in affected population, demographics of the vaccinated population, and reporting practices between products (as it is for example the case for the COVID-19 vaccines compared to chikungunya virus vaccines).

EMA's scientific committees scrutinise whether available evidence indicates a link to a new or serious adverse event and consider this evidence alongside the benefits of the vaccine.

For more information, including where to find reliable information about side effects ⁽²⁾, please consult the EMA website.

⁽¹⁾ For more information, please refer to the public annual report on EudraVigilance providing comprehensive details on EudraVigilance-related activities and outputs (see: <https://www.ema.europa.eu/system/files/documents/report/2024-annual-report-eudravigilance-en.pdf>).

⁽²⁾ COVID-19 vaccines: key facts <https://www.ema.europa.eu/en/human-regulatory-overview/public-health-threats/coronavirus-disease-covid-19/covid-19-medicines/covid-19-vaccines-key-facts>.