

EN

P-002470/2023

Answer given by Ms Kyriakides  
on behalf of the European Commission  
(6.11.2023)

EudraVigilance is a database collecting *suspected* side effects reported by the European Economic Area's (EEA) patients and healthcare professionals, i.e. medical events reported following the use of a medicine in the EEA. The fact that these events were observed following the use of the medicine does not mean that they were *caused* by it. They may have been caused by underlying medical conditions of the individual, by other medicines taken in parallel or due to other events entirely. Scientific studies investigate potential causal links in these temporal associations and most suspected side effects are not eventually *confirmed* as side effects.

An unprecedented high number of people has been administered COVID-19 vaccines<sup>1</sup> and the number of reported suspected side effects is consequently much higher than for other medicines.

As of 30 September 2023, EudraVigilance shows 11,977 spontaneous reports of suspected side effects with reported fatal outcome for all authorised COVID-19 vaccines.

Only in very exceptional cases, deaths have been reported to be caused by the vaccine. One example is 'thrombosis with thrombocytopenia syndrome' with adenoviral vector COVID-19 vaccines<sup>2</sup> for which warnings and contraindications have been included in the product information to inform healthcare professionals and patients and reduce risk of adverse consequences.

There is no evidence that COVID-19 vaccines are causing excess mortality<sup>3</sup> and no safety signal for increased mortality with any of the authorised COVID-19 vaccines has been identified by EMA to date. In fact, COVID-19 vaccines have saved millions of lives.

---

<sup>1</sup> Almost 768 million vaccine doses administered in EU and EEA countries.

<sup>2</sup> <https://www.nature.com/articles/s41541-022-00569-8>

<sup>3</sup> [https://www.icmra.info/drupal/strategicinitiatives/vaccines/safety\\_statement](https://www.icmra.info/drupal/strategicinitiatives/vaccines/safety_statement)