

EN
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Answer given by Ms Kyriakides
on behalf of the European Commission
(6.6.2023)

In accordance with its mandate, the European Medicines Agency (EMA) monitors the safety of COVID-19 vaccines authorised in the EU and publishes any relevant information on its website. Until December 2022 this included monthly safety updates on COVID-19 vaccines¹.

The Commission does not collect data separately as it relies for the safety monitoring of COVID-19 vaccines fully on EMA.

In interpreting figures published by EMA, it is important to highlight that medical events occurring in vaccinated people are not necessarily caused by them. EMA and national authorities evaluate data on reported events to determine if there is any signal indicating causality and take action as appropriate.

Therefore, the figure of fatal cases reported in December 2022 does not mean that those deaths have been caused by the COVID-19 vaccines. By 31 March 2023, EMA's figure for the European Economic Area (EEA) cases reported with fatal outcome is 11,823 which represents an expected increase given increasing exposure and passage of time.

EMA does not recognise the figure of 50,648 referred to in the question, which might have been derived by adding cases linked to different reaction groups from the publicly available European database of suspected adverse drug reactions². As a single case can appear in different reaction groups, this approach would vastly overestimate the number of cases. In addition, if the figure of 50,648 has been miscalculated from the website it would include worldwide cases, while EMA's December 2022 figures are from cases within the EEA.

¹ <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#how-ema-monitors-vaccine-safety-section>

² <https://www.adrreports.eu/en/index.html>