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Answer given by Ms Kyriakides
on behalf of the European Commission
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The European Medicines Agency (EMA) and the Member States continuously monitor reports of suspected side effects of medicinal products, including COVID-19 vaccines, to detect any safety issues. Suspected side effects, which are reported by a vaccinated person or by healthcare professionals, are collected in the EudraVigilance database¹.

Information about possible side effects is included in the vaccine's publicly available product information. This information includes the likelihood of the side effect occurring and how to reduce the possible risk. Quick regulatory action, such as suspension or revocation of the marketing authorisation or prohibition of the supply of the medicinal product, can also be taken as appropriate.

Under EU law, in case of demonstrated breach by marketing authorisation holders of their regulatory obligations, which include an obligation to supply new information that may influence the evaluation of the risks and benefits balance of the products, the Commission may take certain actions and/or impose financial penalties according to the legislation².

¹ <https://www.adrreports.eu/>

² Article 84a of Regulation (EC) 726/2004, OJ L 136, 30.4.2004, p. 1.