

EN
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Answer given by Mr Várhelyi
on behalf of the European Commission
(8.7.2025)

The assessment of a medicinal product is based solely on scientific evidence¹, not political pressure. There is a robust procedure established that must be followed before granting a marketing authorisation².

When an application for a marketing authorisation of a medicinal product is submitted in the EU, the information included in a dossier is carefully assessed by the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use³. This assessment is summarised in a publicly available report (European Public Assessment Report⁴) that also includes the verification of the compliance of good clinical practices. The criteria used to consider the need of an inspection are published on the EMA website⁵. In some cases, inspections may not be feasible or necessary. Instead, alternative methods that provide the required level of assurance, including inspections conducted by other globally recognised regulatory authorities, may be considered. The decision is based on the triggers identified. During COVID-19, the need for inspections was assessed and decided on a case-by-case basis.

In the EU, there is a robust safety monitoring and risk management (pharmacovigilance) system to supervise every medicinal product throughout its use in healthcare practice. For each medicinal product, safety updates are regularly assessed through the Periodic Safety Update Reports (PSURs⁶). These assessments are carried out by the EMA's Pharmacovigilance Risk Assessment Committee⁷ and permit to identify any new potential risks.

The safety and efficacy of all medicinal products, including COVID-19 vaccines, have always been a top priority for the Commission.

¹ How EMA evaluates medicines for human use <https://www.ema.europa.eu/en/about-us/what-we-do/authorisation-medicines/how-ema-evaluates-medicines-human-use#assessment-process-13164>.

² Authorisation of medicines <https://www.ema.europa.eu/en/about-us/what-we-do/authorisation-medicines>.

³ Committee for Medicinal Products for Human Use (CHMP)

<https://www.ema.europa.eu/en/committees/committee-medicinal-products-human-use-chmp>.

⁴ European public assessment reports: background and context <https://www.ema.europa.eu/en/medicines/what-we-publish-medicines-when/european-public-assessment-reports-background-context>.

⁵ https://www.ema.europa.eu/en/documents/other/points-consider-assessors-inspectors-european-medicines-agency-inspection-coordinators-identification-triggers-selection-applications-routine-cause-inspections-their-investigation-scope-such_en.pdf.

⁶ <https://www.ema.europa.eu/en/human-regulatory-overview/post-authorisation/pharmacovigilance-post-authorisation/periodic-safety-update-reports-psurs>.

⁷ <https://www.ema.europa.eu/en/committees/pharmacovigilance-risk-assessment-committee-prac>.