Priority question for written answer P-002869/2023
to the Commission
Rule 138
Francesca Donato (NI), **Virginie Joron** (ID), **Marcel de Graaff** (NI), **Sergio Berlato** (ECR), **Mislav Kolakušić** (NI), **Sylvia Limmer** (ID), **Cristian Terheş** (ECR)

Subject: Withdraw the marketing authorisations for the Comirnaty and Spikevax vaccines

On 1 September 2023, the European Medicines Agency updated the marketing authorisations for the Comirnaty[1] and Spikevax[2] vaccines, highlighting in Annex I of the marketing authorisations for both products the increased risk of myocarditis and pericarditis, which sometimes lead to hospitalisation in intensive care or even death, mainly in young people.

The efficacy and safety of these vaccines are also reported as 'uncertain' for immunocompromised people, who belong to the 'vulnerable' category for whom these vaccines are recommended[3].

These updates confirm the possible correlation between the numerous reports of 'sudden illness' and death in young and apparently healthy people and the administration of the aforementioned vaccines, with these deaths mostly not being followed by autopsies.

Furthermore, as expressly reported in the annexes, the safety of these drugs is even dubious, at best, for 'vulnerable' subjects.

Given that the vaccines have been recognised to have very serious and potentially lethal adverse effects on recipients and their safety and efficacy is still uncertain, and considering the very low risk of death from the virus and the current availability of treatment:

1. Will the Commission withdraw the marketing authorisations for these vaccines?

2. How will the Commission address the serious damage to health and prevent the deaths of vaccinated citizens?

Supporter[4]

Submitted: 29.9.2023

---

1 Point 4.4, page 4, https://www.ema.europa.eu/en/documents/product-information/comirnaty-epar-product-information_en.pdf.
2 Point 4.4, page 6, https://www.ema.europa.eu/en/documents/product-information/spikevax-previously-covid-19-vaccine-moderna-epar-product-information_en.pdf.
3 'The efficacy and safety of the vaccine has not been assessed in immunocompromised individuals, including those receiving immunosuppressant therapy. The efficacy [...] may be lower in immunocompromised individuals.'.
4 This question is supported by a Member other than the authors: Ivan Vilibor Sinčić (NI)