



Fwd: AskEMA – Response to ASK-275574 – ICD

Fra [REDACTED]@stichtingcoronaschade.nl <[REDACTED]@stichtingcoronaschade.nl>

Dato Ons 09-04-2025 22 44

Til [REDACTED] >

----- Oorspronkelijk Bericht -----

Van: AskEMA No-Reply <AskEMA.noreply@ema.europa.eu>

Aan: [REDACTED]@stichtingcoronaschade.nl

Datum: 07-04-2025 13 55 CEST

Onderwerp: AskEMA - Response to ASK-275574 - ICD

Dear Ms [REDACTED],

Thank you for contacting the European Medicines Agency with your query, in which you ask us to urge the World Health Organization to include post-vaccination syndrome on the ICD list.

Although we sympathise with people who have experienced these react, we are not able to accommodate your request.

As with all medicines, EMA closely monitors the safety of COVID-19 vaccines. This includes the potential occurrence of long-lasting side effects. COVID-19 vaccination is associated with side effects in some people, some of which may be serious. However, from the very large body of evidence assessed by international regulators, there is no evidence suggesting that COVID-19 vaccination may be linked to adverse reactions manifesting as long-lasting symptoms.

Regarding the news item you link, we stress that it does not refer to a published study, but to a pre-print. As is noted on the pre-print server (<https://www.medrxiv.org/>): *'Preprints are preliminary reports of work that have not been certified by peer review. They should not be relied on to guide clinical practice or health-related behavior and should not be reported in news media as established information.'* Information included in pre-prints has not yet gone through peerreview, which is an essential part of the scientific process to evaluate the robustness of the data. Pre-prints very often undergo significant changes after peer-review before they are finalised and published, and peer-reviewer comments and may even require the journal to reject the submitted paper.

Specific to the publication, EMA notes that, based on the methods presented, the LISTEN study has several important methodological flaws that severely impact the reliability of both the data and the conclusions. These flaws include, but are not limited to, the very small number of people included, the homogenous demographic background of this population and the method in which it was recruited, the fact that a previous SARS-CoV-2 infection that can cause comparable symptoms cannot be ruled out in the people with long-lasting symptoms, and the fact that the analyses do not distinguish between people with these symptoms who did and who did not have a confirmed previous SARS-CoV-2 infection.

EMA will continue to monitor the safety of COVID-19 vaccines. If emerging evidence supports the existence of long-lasting symptoms, appropriate regulatory action will be taken.

With kind regards,
On behalf of Juan Garcia Burgos
Head of Public and Stakeholders Engagement Department

We would be grateful if you could take part in a short survey on our service.
Please access the survey through the following link:
<https://ec.europa.eu/eusurvey/runner/AskEMASurvey5137ad0a-8a76-442526ed-93ab3c955448>

European Medicines Agency

[REDACTED]

Go to www.ema.europa.eu/contact Telephone: +31 (0)88 781 6000

We received your question(s) on: 20/03/2025

Subject of your enquiry: ICD

Your question(s): Dear sir/madam, As PVS (post-vaccination syndrome) becomes a known term on medical and scientific platforms (like the recently published Yale research: <https://news.yale.edu/2025/02/19/immune-markers-post-vaccinationsyndrome-indicate-future-research-directions>) the importance to include this medical condition to the ICD list becomes more evident. As a foundation, we find thousands of people in the Netherlands alone suffering from this condition. Since PVS is still, 5 years after its first appearance, not included on the ICD list, these patients are gas-lighted by their doctors and do not get any medicines or treatments covered by their medical insurance since they do not have an 'official' condition. We'd therefore ask you to urge the WHO to include PVS on the ICD list as soon as possible, so our patients in need might finally get the help, care and assistance they deserve. Best regards, [REDACTED]

Met vriendelijke groeten,

[REDACTED]
Vertegenwoordiger



**STICHTING
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