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From: AskEMA No-Reply <AskEMA.noreply@ema.europa.eu>
Date: On Monday, January 19th, 2026 at 16.24
Subject: AskEMA - Response to ASK-288590 - Question on possible conflict of interest concerning EMA
To: rauli.makela@protonmail.com <rauli.makela@protonmail.com>

Dear Rauli Mäkelä,

Thank you for reaching out to the European Medicines Agency (EMA) about the publication by Eero Poukka et al "COVID-19 vaccine effectiveness among adolescents" Pediatrics 2024,153(2) e2023062520.

We appreciate the opportunity to clarify the points you raised:

EMA funding of the manuscript and study design
EMA supports research projects to enhance scientific understanding and public health decision-making. EMA-funded studies are performed with scientific independence, in line with EMA's Policy 0044 - Handling of competing interests scientific committees (https://www.ema.europa.eu/en/documents/other/policy-44-european-medicines-agency-policy-handling-competing-interests-scientific-committees-members-experts_en.pdf) and the ENCePP Code of Conduct (https://encepp.europa.eu/document/download/e504e741-1813-4327-85d5-0f7ac8214ca1_en?filename=ENCePPCodeofConduct.pdf), and the following aspects are reflected in the study contracts:

- the primary purpose of the study is to generate evidence of scientific or public health importance and not to promote the use of a medicinal product or any specific outcome;
- the design of the research shall aim at minimising any potential bias;
- any financial, commercial, institutional or personal interest in the results and their interpretation at the level of the researcher(s) conducting the study shall not influence any decision on the scientific aspects of the study in any direction, including data collection and analysis, interpretation and dissemination of the study results.

As part of the contract, EMA is included in all the steps of evidence generation and dissemination, including the development and submission of the findings to peer-reviewed journals. The investigators also share study protocols with EMA's pharmacoepidemiology experts to check that the design is sound and any biases are addressed by the analyses.

The study was performed by a well-recognised and independent research team, with a track record of robust real-world data studies. Internationally agreed study designs for COVID-19 observational studies (as reflected by the peer-reviewed literature and the scientific community) were applied, such a short 'unvaccinated' (or not yet immunised) period after vaccination to account for the time needed to build protection. This practice is recognised by experts in the field and used in a majority of such studies and allows for an accurate measure of true vaccine effectiveness and avoids bias. Vaccine safety was out of scope of this study. However, EMA continuously monitors the safety of all medicines including COVID-19 vaccines carefully and takes action to ensure the benefits outweigh the risks of the medicines.

Conflict of interest concerns
EMA's role is to ensure the quality, safety and efficacy of medicines in the EU. Funding research projects does not compromise this role; rather, it supports evidence generation for public health. All funded projects are subject to strict transparency and governance rules to avoid conflicts of interest. Study protocols and reports are publicly available on the HMA-EMA Catalogues of real-world data studies (https://catalogues.ema.europa.eu/node/3325/administrative-details).

At the stage of selecting a procurement procedure, EMA always verifies whether an economic entity has a conflict of interest. Declarations of interests are evaluated at the individual level for each investigator. EMA is committed to supporting independent research, and this is also reflected in the disclaimer of the publications: "*Views expressed in this paper are the personal views of the authors and may not be understood or quoted as being made on behalf of or reflecting the position of the European Medicines Agency or one of its committees or working parties*".

We hope you find this information useful. For further questions on the study design please contact the corresponding author.

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-8a76-4425-26ed-93ab3c955448

European Medicines Agency

Domenico Scarlattilaan 6, 1083 HS Amsterdam, The Netherlands
Send us a question.

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

We received your question(s) on:19/12/2025

Subject of your enquiry:Question on possible conflict of interest concerning EMA

Your question(s):Dear Ms Emer Cooke, We hope to reach you, the Executive Director of EMA through this EMA online form. Recently a thesis entitled 'COVID-19 Vaccine Effectiveness in Finland During Pandemics' was presented for the public examination in Helsinki on December 13, 2025, by Eero Poukka from the Finnish Institute for Health and Welfare. This work includes five original publications, number III of which is funded by EMA as stated in the article. The publication III (i.e., Eero Poukka et al "COVID-19 vaccine effectiveness among adolescents" Pediatrics 2024,153(2) e2023062520) is a register -based study on the effectiveness of the COVID-19 vaccines against hospitalization at 6-month follow-up in the in age group of 12-17 years. We request EMA to clarify the following ethical and legal issues: 1. Was EMA aware of the manuscript before it was published? If yes, did it recognize numerous flaws related to the study design and the fact that thousands of serious, and fatal adverse events (reported to health authorities some of which published in peer reviewed medical literature) were not acknowledged? The most serious flaw in the study concerns the classification of vaccination status. Vaccinated individuals were considered unvaccinated for 1 or 2 weeks after they had actually received the COVID-19 vaccine. 2. Isn't there a severe conflict of interest? How can the EMA, in its supervisory position, fund such promotional research on products like COVID-19 vaccines, the safety of which it is supposed to ensure? We believe that answers to all open questions can be found (if you search for them separately) in your records. We intend to share this inquiry and your response with domestic and international communities. Helsinki, December 19, 2025 Signatories Nina Bjelogrlic, MD, MSc, PhD, specialist doctor in neurology Rauli Mäkelä, MD, specialist doctor Sylvi Silvennoinen-Kassinen, MD, PhD, specialist doctor in clinical microbiology, associate professor (docent) Tamara Tuuminen, MD, PhD, specialist doctor in clinical microbiology, associate professor (docent)