Parliamentary question - E-001537/2023

European Parliament

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Toxic secondary effects and mortality: are there differences between batches of COVID-19 vaccines?

10.5.2023

Question for written answer E-001537/2023
to the Commission
Rule 138
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In a study dated 13 April 2023, Peter Riis Hansen from the Cardiology Service at the University of Copenhagen stated that there may be differences between batches of Pfizer's COVID-19 vaccine[1].

Following analysis of the 579 deaths and 14 509 severe adverse effects reported after administration of that vaccine between 27 December 2020 and 11 January 2022 in Denmark, the study concluded that some of the 52 batches distributed in Denmark seemed to have had significantly more side effects than others. Five batches were reported to have concentrated worrying frequencies of reported adverse effects in 7 to 8% of doses.

Let us not forget that Japan withdrew three batches – a total of 1.6 million doses – after it detected foreign components in 39 doses[2]. The European Medicines Agency (EMA) also reportedly expressed concerns about batch-to-batch reproducibility in April 2021[3].

On the basis of the aforementioned study, five German professors of chemistry state that the tolerance limits set by the European Medicines Agency (EMA) for all active ingredients and excipients seem disproportionate to them[4].

1. Has the EMA carried out checks and how do the batches delivered to Denmark by Pfizer differ as regards their composition?
2. Has the EMA investigated this possible link between batches of COVID-19 vaccines and side effects in other countries in connection with Pfizer/BioNTech or separately?

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[1] https://onlinelibrary.wiley.com/doi/10.1111/eci.13998
[2] Bruce YY, Taraban MB, Briggs KT. All vials are not the same: potential role of vaccine quality in vaccine adverse reactions. *Vaccine*. 2021; 39:6565-6569.
[3] Dr Amine Umlil quotes the European Medicines Agency as stating, 'the European Medicines Agency was awaiting further evidence on the characteristics of the active substance and the finished product, consolidation of the control strategy to provide consistent product quality, additional validation data to confirm the reproducibility of the manufacturing process for the finished product [...] to confirm their purity profile and to ensure batch-to-batch reproducibility throughout the life cycle of the finished product'. Dr Amine Umlil, https://www.assemblee-nationale.fr/dyn/15/comptes-rendus/ots/l15ots2122142_compte-rendu.pdf p.20.
[4] https://www.berliner-zeitung.de/wirtschaft-verantwortung/chemiker-fragen-biontech-gibt-es-unterschiede-bei-den-chargen-des-impfstoffs-li.345576