

**Question for written answer E-003287/2023
to the Commission**
Rule 138
István Ujhelyi (S&D)

Subject: Holistic approach to health data in the context of the ongoing systematic review of influenza vaccines

Recent years have seen a growing recognition of the role that all types of real-world evidence (RWE) can play in vaccine assessment. This is reflected in the DARWIN EU initiative and in amendments submitted by Parliament to the European Health Data Space report, among others.

In this context, the European Digital and Health Executive Agency (HaDEA) is currently overseeing systematic reviews of scientific evidence on vaccines and capacity-building activities¹. This comprehensive exercise will shape the evidence base behind vaccine recommendations in multiple disease areas, including influenza, and subsequently feed into the decisions taken by national public health authorities.

However, it is concerning to note that the methodology employed uses a narrow evidence base, taking into account only laboratory-confirmed real-world data, and was developed without allowing stakeholders to provide input. For communicable diseases like influenza, laboratory-confirmed and randomised control trial data comprise only a small portion of the evidence base.

1. Could the Commission confirm whether evidence from non-laboratory-confirmed real-world data will be included in the analysis?
2. When is the report expected to be completed and published?
3. Does HaDEA plan to consult relevant stakeholders regarding the methodology used in the systematic reviews?

Submitted: 7.11.2023

¹ <https://ted.europa.eu/udl?uri=TED:NOTICE:510907-2022:TEXT:EN:HTML>.