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PROPOSAL FOR A UNION ACT

submitted under Rule 47(2) of the Rules of Procedure

on the establishment of an independent authority to investigate the side effects of COVID-19 vaccines

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Proposal for a Union act on the establishment of an independent authority to investigate the side effects of COVID-19 vaccines

The European Parliament,

– having regard to Article 225 of the Treaty on the Functioning of the European Union (TFEU),

– having regard to Article 168 TFEU, in particular point (4)(c) thereof,

– having regard to Article 5 of the Decision of the European Parliament of 28 September 2005 adopting the Statute for Members of the European Parliament[1],

– having regard to Articles 3, 11 and 35 of the Charter of Fundamental Rights of the European Union,

– having regard to Rule 47(2) of its Rules of Procedure,

A. whereas freedom of information includes the freedom to receive and impart information without interference;

B. whereas transparency is a core principle of the EU and its Member States; whereas the public should, in principle, have the right to access information about the side effects of COVID-19 vaccines; whereas limited access to necessary information about the side effects of vaccines diminished the opportunity to carry out a proper assessment and arrive at an informed decision;

C. whereas the Commission negotiated the purchase contracts and did not wish for the pharmaceutical companies to incur any liability for the side effects of COVID-19 vaccines[2].

D. whereas it should be possible to disclose clearer and more structured information to the public about the severe side effects of COVID-19 vaccines and about cases where people suffered severe adverse reactions after vaccination; whereas free treatment should be made available to the victims of COVID-19 vaccines;

E. whereas financial compensation should be made available to victims who suffered severe side effects and to the families of people who have died;

F. whereas as of February 2023, the European Medicines Agency (EMA) reported 50 663 fatalities and 5 315 063 injuries in European Economic Area (EEA) and non-EEA countries, following injections of EMA-authorised vaccines[3],

[1] OJ L 262, 7.10.2005, p. 1.
[2] Answer for Written Question E-004950/2020 given by Ms Kyriakides on behalf of the European Commission, 23 November 2020.
[3] European Database of suspected adverse drug reactions reports, accessed 5 June 2023.

G. whereas the EMA has already recorded 2 211 256 cases of people in the EU experiencing adverse reactions from the COVID-19 vaccines, namely 370 537 from the Moderna vaccine (elasomeran)[4], 7 358 from the Moderna vaccine Original/Omicron BA.1 (elasomeran, imelasomeran)[5], 317 from the Moderna vaccine Original/Omicron BA.4-5 (elasomeran, davesomeran)[6], 1 203 897 from the Pfizer-Biontech vaccine (tozinameran)[7], 5 951 from the Pfizer-Biontech vaccine Original/Omicron BA.1 (tozinameran, riltozinameran)[8], 6 423 from the Pfizer-Biontech vaccine Original/Omicron BA.4-5 (tozinameran, famtozinameran)[9], 544 189 from the AstraZeneca vaccine (ChAdOx1 nCoV-19)[10], 70 987 from the Janssen vaccine (Ad26.COV2.S)[11], 1 567 from the Novavax vaccine (NVX-CoV2373)[12], 27 from the Valneva vaccine[13], and 3 from the VidPrevtyn Beta vaccine[14],

H. whereas the EMA has stated that 11 448 people have died in the EU after having taken the COVID-19 vaccines[15];

I. whereas the most significant adverse events of special interest associated with specific mRNA vaccines, including the Pfizer and Moderna vaccines, are myocarditis, pericarditis and anaphylaxis[16];

J. whereas younger vaccinated people more frequently report myocarditis and pericarditis following mRNA COVID-19 vaccines compared with older vaccinated people; whereas

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[4] European Database of suspected adverse drug reactions reports, 'COVID-19 MRNA VACCINE MODERNA (ELASOMERAN)', accessed 5 June 2023.
[5] European Database of suspected adverse drug reactions reports, 'COVID-19 MRNA VACCINE MODERNA ORIGINAL/OMICRON BA.1 (ELASOMERAN, IMELASOMERAN)', accessed 5 June 2023.
[6] European Database of suspected adverse drug reactions reports, 'COVID-19 MRNA VACCINE MODERNA ORIGINAL/OMICRON BA.4-5 (ELASOMERAN, DAVESOMERAN)', accessed 5 June 2023.
[7] European Database of suspected adverse drug reactions reports, 'COVID-19 MRNA VACCINE PFIZER-BIONTECH (TOZINAMERAN)', accessed 5 June 2023.
[8] European Database of suspected adverse drug reactions reports, 'COVID-19 MRNA VACCINE PFIZER-BIONTECH ORIGINAL/OMICRON BA.1 (TOZINAMERAN, RILTOZINAMERAN)', accessed 5 June 2023.
[9] European Database of suspected adverse drug reactions reports, 'COVID-19 MRNA VACCINE PFIZER-BIONTECH ORIGINAL/OMICRON BA.4-5 (TOZINAMERAN, FAMTOZINAMERAN)', accessed 5 June 2023.
[10] European Database of suspected adverse drug reactions reports, 'COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)', accessed 5 June 2023.
[11] European Database of suspected adverse drug reactions reports, 'COVID-19 VACCINE JANSSEN (AD26.COV2.S)', accessed 5 June 2023.
[12] European Database of suspected adverse drug reactions reports, 'COVID-19 VACCINE NOVAVAX (NVX-COV2373)', accessed 5 June 2023.
[13] European Database of suspected adverse drug reactions reports, 'COVID-19 VACCINE VALNEVA', accessed 5 June 2023.
[14] European Database of suspected adverse drug reactions reports, 'COVID-19 VACCINE VIDPREVTYN BETA', accessed 5 June 2023.
[15] EMA, 'COVID-19: latest update – The latest updates on the COVID-19 pandemic from the European Medicines Agency (EMA)'.
[16] Joint Statement from the International Coalition of Medicines Regulatory Authorities and World Health Organization, 'Statement for healthcare professionals: How COVID-19 vaccines are regulated for safety and effectiveness', 17 May 2022.

reports are more frequent following the second dose[17];

K. whereas the development of myocarditis and pericarditis in children and adolescents after vaccination for COVID-19 was more prevalent among males and following the second dose of the Pfizer vaccine; whereas clinical investigations have revealed ST segment elevation, C-reactive protein (CRP) and troponin elevation, as well as the presence of edema and myocardial damage in CMR (cardiac magnetic resonance) imaging[18];

L. whereas the most significant adverse effects of special interest reported for the AstraZeneca, Janssen, Gamaleya and CanSino Biologics COVID-19 vaccines are thrombosis with thrombocytopenia syndrome (TTS), immune thrombocytopenic purpura (ITP) and Guillain-Barré syndrome (GBS)[19];

1. Requests the Commission to submit, by 1 November 2023, on the basis of Article 168 TFEU, in particular point (4)(c) thereof, a proposal for the establishment of an independent authority to investigate the side effects of COVID-19 vaccines;

2. Believes that such a proposal should extend the list of legal grounds for the lawful processing of cases where people have suffered severe adverse reactions or died after the administration of COVID-19 vaccines;

3. Stresses the importance of governmental and independent experts developing guidelines and procedures to recognise injuries resulting from vaccination in order to provide timely and appropriate legal and medical support;

4. Instructs its President to forward this resolution to the Commission, the Council and the governments and parliaments of the Member States.

[17] Lane, S. et al., 'Reports of myocarditis and pericarditis following mRNA COVID-19 vaccination: a systematic review of spontaneously reported data from the UK, Europe and the USA and of the scientific literature' *BMJ Open*, Vol. 12, No 5, 2022.
[18] Fatima, M. et al., 'Development of myocarditis and pericarditis after COVID-19 vaccination in children and adolescents: A systematic review', *Clinical Cardiology*, Vol. 46, No 3, 2023, pp. 243-259.
[19] Joint Statement from the International Coalition of Medicines Regulatory Authorities and World Health Organization, 'Statement for healthcare professionals: How COVID-19 vaccines are regulated for safety and effectiveness', 17 May 2022.

EXPLANATORY STATEMENT

Every citizen of the European Union who suffered severe adverse reaction after COVID-19 vaccines has the right of access to free curative health care and the right to benefit from medical treatment after a well-documented evaluation of such cases and development of concrete scheme of treatment for cases such as, for example, myocarditis or pericarditis, under the conditions established by national laws and practices.

A high level of human health protection shall be ensured through concrete investigation of side effects and implementation of free treatment under all Union policies and activities.

By encouraging the establishment of an independent authority, in all Member States and by ensuring its functioning based on scientific and technical investigations based under an EU legal framework could create the conditions for appropriate patient access to treatment.

Moreover, it will ensure that EU is respecting and practicing its principles of transparency, equality, and equity for all.