

Committee on the Environment, Public Health and Food Safety  
The Chair

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Ivan Vilibor Sinčić, MEP  
Christine Anderson, MEP  
Francesca Donato, MEP  
Stasys Jakeliūnas, MEP  
Mislav Kolakušić, MEP  
Cristian Terheş, MEP

**Subject: Your 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**

Dear Members,

I refer to your 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, which was referred to ENVI as the committee responsible on 11 July 2023. Pursuant to Rule 47(2), ENVI, as the committee responsible for the subject matter, shall take a decision on further action.

The ENVI coordinators have considered your proposal at their meeting of 17 July 2023. They took note that the European Parliament set up the COVI Committee<sup>1</sup> in March 2022, which was tasked with looking into how the European response to the pandemic and the lessons learned can contribute to future action in several areas, including the ones you describe in your proposal.

They also noted that your proposal refers, *inter alia*, to the public's "right to access information about the side effects of COVID-19 vaccines", the pharmaceutical companies' "liability for the side effects of COVID-19 vaccines" or the need to develop "guidelines and procedures to recognise injuries resulting from vaccination". Following the completion of its extensive work, the COVI Committee's report<sup>2</sup> adopted in July this year, precisely "urges the Commission, the Member States and manufacturers to be transparent about the potential side effects of vaccines, including known side effects identified by the EMA, and to communicate about this, as well as about the benefits and efficiency of vaccinations [...]". Further, the report calls "on the EMA to publish guidelines for aspirating vaccines in order to avoid adverse effects; [...]". In addition, the

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<sup>1</sup> European Parliament decision of 10 March 2022 on setting up a special committee on 'COVID-19 pandemic: lessons learned and recommendations for the future, its responsibilities, numerical strength and term of office (2022/2584(RSO))

<sup>2</sup> European Parliament resolution of 12 July 2023 on the COVID-19 pandemic: lessons learned and recommendations for the future (2022/2076(INI))

report “notes with concern the transfer of financial risks related to liability for serious adverse effects of COVID-19 vaccines to the Member States and the risk of this becoming a standard practice” and emphasises that, for pandemics and publicly procured vaccines, the standard rules for liability for medicines should be upheld”, while urging the Commission, notably the Health Emergency Preparedness and Response, to ensure that product liability remains with manufacturers.

In view of the adoption in plenary of the report of the Special Committee on the COVID-19 pandemic (COVI) on 12 July 2023, ENVI coordinators therefore decided that no further action regarding the matters you raised would be needed at this stage.

To conclude, let me reassure you of the ENVI Committee’s full commitment to deliver in the area of public health, as shown by its record of accomplishments in dealing particularly with the Health Union package of legislative measures. In that regard, the reinforced mandates of the European Medicines Agency, of the European centre for disease prevention and control, as well as the new Regulation on serious cross-border threats to health are the results of our active role in building a Health Union, the essence of which shall be prevention, preparedness and safe response to crisis, including through safe and effective vaccines.

Yours sincerely,

A handwritten signature in black ink, appearing to be 'Pascal Canfin', with a long horizontal stroke extending to the left.

Pascal Canfin