

**Question for written answer E-001396/2022  
to the Commission**

Rule 138

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Subject: Liability for COVID-19 vaccines

In its reply to Question E-006615/2020<sup>1</sup> the Commission ensured 'that it is not prepared to make compromises on the application of the existing rules that apply to bringing a pharmaceutical product into the market'. Therefore, the producer is subject to liability, as Commission Regulation (EC) No 507/2006 on conditional marketing does not provide any derogation<sup>2</sup>.

The Commission confirmed that 'the agreements provide for Member States to indemnify the manufacturer for possible liabilities incurred only under specific conditions set out in the agreements'. While Parliament has not been given access to these conditions, it is clear that the Commission's reply is contradictory in itself. Furthermore, reference is made in the reply to Question E-004950/2020<sup>3</sup> to Article 7(e) of the Product Liability Directive<sup>4</sup>. However, the conditions for this Article cannot be met in the case of conditional marketing as it is the very nature of this approach that not all necessary data are available, confirming the exclusion of any unknown side effects. Otherwise, the conditions for standard marketing would have been met.

1. What is the legal basis for the de facto lifting of the liability provided for under conditional marketing by ensuring compensation from the respective Member State?
2. What is the legal basis for charging the Member State to compensate the producer?

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<sup>1</sup> [https://www.europarl.europa.eu/doceo/document/E-9-2020-006615\\_EN.html](https://www.europarl.europa.eu/doceo/document/E-9-2020-006615_EN.html)

<sup>2</sup> [https://ec.europa.eu/commission/presscorner/detail/en/qanda\\_20\\_2390](https://ec.europa.eu/commission/presscorner/detail/en/qanda_20_2390)

<sup>3</sup> [https://www.europarl.europa.eu/doceo/document/E-9-2020-004950\\_EN.html](https://www.europarl.europa.eu/doceo/document/E-9-2020-004950_EN.html)

<sup>4</sup> <http://data.europa.eu/eli/dir/1985/374/oj>