Question for written answer E-004821/2020
to the Commission
Rule 138
Joanna Kopcińska (ECR)

Subject: The Commission and consideration of tort law relating to liability of Member States for damages caused by a vaccine

In 2017, in the case of 'N.W v. Sanofi Pasteur MSD SNC', the Court of Justice of the European Union (CJEU) examined the requirement under Article 4 of the Product Liability Directive (Council Directive 85/374/EEC), according to which a claimant must prove that damage caused to them resulted from a defect in the product. The case concerned a vaccine for viral hepatitis which, according to the claimant, led to multiple sclerosis.

French courts have previously admitted evidence of a causal link by means of 'presumptions of evidence' in cases such as those where the patient had no illness and the onset of the disease occurred shortly after administration of the vaccine. This has allowed the claimants to establish a causal link, despite the fact that there is no scientific or medical evidence that hepatitis can actually cause multiple sclerosis. The CJEU has recognised that national courts have a wide discretion in determining which evidence must be provided in order to prove a causal link, subject only to ensuring that the evidentiary requirements do not have the effect of reversing the burden of proof.

In light of the above, how will the Commission take account of tort law relating to the liability of the Member States for damages caused by a vaccine in the context of the CJEU ruling of 2017 when the COVID-19 vaccine is placed on the European market?