

(English version)

**Question for written answer E-003768/25
to the Commission
Valentina Palmisano (The Left), Ignazio Roberto Marino (Verts/ALE)
(29 September 2025)**

Subject: Medical responsibility and regulatory disparities in the EU

In Italy, doctors and healthcare professionals operate in an environment with high exposure to medico-legal litigation, where even minor negligence has criminal relevance, unlike in most EU Member States, which adopt more balanced models or ‘no-fault’ systems. This pressure fuels defensive medicine, with unnecessary examinations and hospitalisations, increasing costs for Italy’s National Health Service and slowing down treatment. This also creates a disincentive for young people to choose medicine or specialisations at risk of litigation, such as surgery, obstetrics and orthopaedics. More and more places in specialisation schools remain vacant, with the prospect of a serious shortage of professionals.

The lack of EU minimum criteria on medical responsibility leads to inequality and legal uncertainty, particularly affecting doctors in emergency care and public facilities. Neither Directive 2011/24/EU nor communication COM(2024) 206 on the Health Union addresses these challenges. It is now urgent to create a ‘European health space’.

In the light of the above:

1. Will the Commission promote EU guidelines that distinguish between minor and gross negligence, limiting criminal liability to gross negligence in the context of healthcare?
2. Does it believe that an EU observatory or agency on medico-legal litigation and clinical risk management should be set up to improve the quality and safety of care, prevent litigation, harmonise pathways and strengthen patient-doctor trust?

Submitted: 29.9.2025

**Answer given by Mr Várhelyi on behalf of the European Commission
(16 December 2025)**

The Commission acknowledges the challenges faced by healthcare professionals in certain Member States in relation to medico-legal liability and the possible impact this may have on the organisation of the healthcare system.

However, the Commission has not received information pointing at comparatively high occurrence of such challenges and their impact on the performance of the health system in Italy.

Under Article 168(7) of the Treaty on the Functioning of the European Union (TFEU) ⁽¹⁾, Member States remain responsible for the organisation and delivery of health services and medical care, including the regulation of medical liability.

According to Article 4 of Directive 2011/24/EU ⁽²⁾, in case of cross-border healthcare, liability remains subject to the legislation of the Member State of treatment.

As regards the possible approximation of substantive criminal law, Article 83 TFEU confers on the Union the competence to establish minimum rules concerning the definition of certain criminal offences and sanctions.

However, such competence is limited to areas of particularly serious crime with a cross-border dimension (Article 83, paragraph 1, TFEU) or to cases where such approximation is essential for the effective implementation of a Union policy that is already subject to harmonisation measures (Article 83, paragraph 2, TFEU).

The criminal liability of healthcare professionals for negligence does not seem to fall within these categories.

⁽¹⁾ https://eur-lex.europa.eu/eli/treaty/tfeu_2008/art_168/oj/eng.

⁽²⁾ <https://eur-lex.europa.eu/eli/dir/2011/24/oj/eng>.