

(English version)

**Question for written answer E-002808/24
to the Commission
Tomáš Zdechovský (PPE)
(6 December 2024)**

Subject: Ensuring EU competitiveness in pharmaceutical innovation

The pharmaceutical industry significantly contributes to Europe's economy, generating EUR 311 billion in gross added value and supporting 2.3 million jobs in 2022. However, recent analyses, including Mario Draghi's report on the future of EU competitiveness, highlight a widening innovation gap between Europe and global leaders such as the US and China.

The revision of the EU's pharmaceutical legislation is aimed at fostering innovation. Reducing the regulatory data protection (RDP) baseline from eight to six years, however, may counteract this goal. Stakeholders warn it could result in EUR 2 billion less in research and development investment annually and a potential loss of 50 treatments for European patients. This contrasts sharply with other regions strengthening intellectual property rights to attract investment and innovation.

In this context:

1. How does the proposed reduction in regulatory data protection align with the conclusions of Mario Draghi's report on European competitiveness, which emphasises fostering innovation in key sectors such as pharmaceuticals?
2. Does the Commission agree that shortening the RDP baseline could undermine EU competitiveness by deterring pharmaceutical investment and widening the innovation gap between the EU and other regions?

Submitted: 6.12.2024

**Answer given by Mr Várhelyi on behalf of the European Commission
(24 February 2025)**

1. The Draghi report recognises the merits of the EU pharmaceutical reform ⁽¹⁾ as it envisages a '*modern and simplified regulatory framework with faster authorisation of new medicines*' ⁽²⁾. The report highlights elements such as simplification of the framework, speed of procedures, enabling the use of digitalisation and Artificial Intelligence, a conducive Research & Development (R&D) investment environment. The proposed reform will reduce administrative burden for medicine developers and authorities and make the framework simpler and future-proof. The reform also proposes increasing the speed and efficiency of the processes while maintaining high standards for quality and safety of medicines in the EU.

2. The Commission fully shares the Draghi report's finding in relation to the intellectual property in the pharmaceutical sector. The report points out that '*given the long development times of medicines, stability in the incentives offered by this framework is needed. At the same time, pharmaceutical markets are dynamic, driven by scientific developments. Their competitive functioning evolves in parallel, implying that future changes to this framework are likely.*' The Commission is following the discussions in the European Parliament and the Council, which will facilitate the agreement in this spirit. The future pharmaceutical legislation should support the creation of a new European health industry that is globally competitive and puts patients always in the centre.

⁽¹⁾ https://health.ec.europa.eu/medicinal-products/pharmaceutical-strategy-europe/reform-eu-pharmaceutical-legislation_en
⁽²⁾ The future of European competitiveness, In-depth analysis and recommendations (Sept. 2024), pg. 195.