

(English version)

**Question for written answer E-002671/26
to the Commission
Christophe Clergeau (S&D)
(29 June 2026)**

Subject: Allowing advanced practice nurses to renew or adapt treatments

EU Member States are increasingly using advanced practice nurses to address challenges in access to care, continuity of care and the management of chronic diseases.

In some Member States, questions remain as to whether these professionals, where provided for in their national legislation, are able to renew or adapt treatments covered by a marketing authorisation granted under the EU centralised procedure.

However, according to Article 168 of the Treaty on the Functioning of the European Union, the organisation and delivery of health services, and the definition of the competences of health professionals, are primarily the responsibility of the Member States.

1. Does the Commission consider that regulation (EC) No 726/2004 and Directive 2001/83/EC preclude a Member State from authorising advanced practice nurses, within the framework of their national competences, to renew or adapt treatments with a centralised marketing authorisation?
2. Does it intend to clarify this point to ensure uniform application of EU law and promote continuity of care in the Member States?

Submitted: 29.6.2026

**Answer given by Mr Várhelyi on behalf of the European Commission
(21 August 2026)**

The EU pharmaceutical legislation, in particular Regulation (EC) No 726/2004 ⁽¹⁾ and Directive 2001/83/EC ⁽²⁾, does not preclude a Member State, acting within the framework of its national competences, from allowing advanced practice nurses to renew or adjust treatments involving a medicinal product that has a centralised marketing authorisation.

The aforementioned EU legislative acts govern the authorisation, supervision and placing on the market of medicinal products and do not regulate the activities of healthcare professionals.

The proposed reform of the EU pharmaceutical legislation ⁽³⁾, which is expected to enter into force by the end of 2026, is designed to complement the current authorisation framework by strengthening the generation and use of real-world evidence throughout the lifecycle of medicines, thereby supporting treatment optimisation while maintaining the high standards of quality, safety and efficacy of medicinal products.

At the same time, by clarifying regulatory obligations and reinforcing the common EU framework, the new pharmaceutical legislation will help ensure the uniform application of EU legislation.

However, continuity of care and the organisation of healthcare services, including prescribing and treatment renewal practices, remain primarily the responsibility of the Member States.

⁽¹⁾ Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency OJ L 136, 30.4.2004, pp. 1-33.

⁽²⁾ Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use OJ L 311, 28.11.2001, pp. 67-128.

⁽³⁾ https://health.ec.europa.eu/medicinal-products/reform-eu-pharmaceutical-legislation_en.