

EN

E-002693/2025

Answer given by Mr Várhelyi
on behalf of the European Commission
(3.9.2025)

The Commission proposal COM(2023)193¹ reinforces the current provisions for compassionate use, ensuring a consistent approach of Member States regarding the criteria and conditions for the compassionate use of new medicinal products under the legislation. Whilst procedural rules have been put forward to allow data collection on medicinal products used under compassionate use programmes to evaluate the benefit-risk balance of the medicinal products in question, there are no suggested changes in relation to binding timeframes.

The Commission proposal does not provide specific access obligations regarding compassionate use programmes or early access in emergency clinical scenarios. However, it provides multiple meaningful measures to allow for timely and equitable general access to all safe, effective, and affordable medicines to patients across the EU, and ensure that medicines are available to them.

The role of the Committee for Medicinal Products for Human Use regarding the adoption of scientific opinions on medicines eligible for compassionate use, which includes orphan medicinal products, is maintained in the proposal.

In addition, in situations where a medicinal product has been authorised in another Member State or a non-EU country, and there is an urgent, specific need for that medicine, particularly when no alternatives are available and the patient has exhausted all other treatment options, Article 5(1) of Directive 2001/83/EC² can be used for the patient to receive the medicine. This process is commonly known as ‘named patient use’.

¹ <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52023PC0193>.

² <http://data.europa.eu/eli/dir/2001/83/oj>.