

**Question for written answer E-004009/2026
to the Commission**
Rule 144
Merja Kyllönen (The Left)

Subject: Application in Finland of the EU rules on the availability of low doses of medications and the preparation of medications by pharmacies

According to the Finnish Medicines Agency (Fimea), a pharmacy's licence to prepare medications cannot be transferred to a new pharmacist, and reference has been made on this point to the EU's medicines legislation and the case-law of the Court of Justice of the European Union.

The Töysä pharmacy has prepared very low doses of medications that are not commercially available at equivalent strengths. For example, very low doses of doxepin and mirtazapine are required for care of the elderly in particular, where the usual commercial strengths cannot be divided up practicably into smaller doses.

Can the EU rules on medicines reconcile the safety of medicines and patients, the availability of medications, and the opportunities for Member States to respond to situations where the dosage strength required by the patient is not commercially available?

1. How does the Commission interpret the impact of the EU's medicines legislation and the case-law of the ECJ on the right of pharmacies to prepare medications in situations where the dosage strength required by the patient is not commercially available, and does EU law specifically require the termination of a pharmacy's licence to prepare medications in the event of a change of pharmacist?
2. How does the Commission assess the proportionality of the EU rules and the availability of medications to patients, especially elderly patients, in situations where application of the rules could result in certain low or otherwise essential dosage strengths not being available nationally, and could a Member State introduce an exemption or other scheme to safeguard the availability of medications for patients in such situations?
3. Can the Commission explain how the relevant rules on the preparation of medications by pharmacies and the availability of low dosage strengths are applied in other Member States and assess whether the current EU rules require any changes or enhanced clarity in situations where there are no commercial alternatives and the restriction on preparation by the pharmacy could jeopardise the availability of appropriate medical treatment to patients?

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