

(English version)

Question for written answer E-001944/26
to the Commission
Barbara Bonte (P/E)
(11 May 2026)

Subject: Safety and prescription of SSRIs and SNRIs in the EU, in particular to adolescents and pregnant women

The use of selective serotonin reuptake inhibitors (SSRIs) and serotonin-norepinephrine reuptake inhibitors (SNRIs) has increased significantly in the European Union in recent years. A systematic review in 2025 (European Child & Adolescent Psychiatry) in eight EU Member States showed a relative increase in antidepressant use among young people during and after the COVID-19 pandemic ranging from 23 to 52%. SSRIs were by far the most commonly used category (73.9 to 90.9%), with a more marked increase among adolescent girls.

At the same time, recent publications in the Nature portfolio (Nature Communications, 2025; Nature Mental Health, 2025; Neuropsychopharmacology, 2026) highlight gaps in our understanding of the impact of prenatal SSRI/SNRI exposure on foetal brain development. Moreover, a 2025 systematic review focusing on post-acute withdrawal syndrome (PAWS) reported persistent withdrawal symptoms after discontinuation, whilst the EMA's latest EU-wide safety assessment dates back to 2005.

1. Does the Commission possess any up-to-date EU-wide data on the prescription of SSRIs and SNRIs to minors and pregnant women?
2. What conclusions does it draw from the documented increased use among adolescents?
3. Is the Commission prepared to request that the European Medicines Agency (EMA) initiate a safety reassessment of these medicinal product classes, with a particular focus on long-term use, post-acute withdrawal syndrome, and perinatal exposure?

Submitted: 11.5.2026

Answer given by Mr Várhelyi on behalf of the European Commission
(8 July 2026)

The Commission does not hold EU-wide prescription data for medicines, including serotonin reuptake inhibitors (SSRIs) and serotonin-norepinephrine reuptake inhibitors (SNRIs).

The collection and monitoring of prescription trends fall within the competence of Member States and are not centralised at EU level.

All medicines authorised in the EU are subject to continuous and rigorous safety monitoring with cooperation of the national regulatory authorities, the European Medicines Agency and the Commission, to ensure that any possible risks are detected and managed as early as possible.

This includes a comprehensive analysis of the benefit-risk balance taking into account new or emerging safety information. These regular reviews include use in children and adolescents.

On that basis, the Commission regularly updates the product information of medicines. Where a specific safety concern needs to be investigated further, the marketing authorisation holder may also be required to conduct a post-authorisation safety study (PASS) ⁽¹⁾ to identify, characterise or quantify the concern, the results of which are assessed by the Pharmacovigilance Risk Assessment Committee (PRAC) ⁽²⁾ and can lead to regulatory action.

Moreover, if new safety concerns emerge, a referral procedure ⁽³⁾ may be started and a scientific assessment by the European Medicines Agency can be requested.

Mental health is a priority for the Commission. In 2023, it presented its comprehensive approach to mental health ⁽⁴⁾ to support Member States and stakeholders in the prevention and management of mental health problems, including among young people. The Commission is currently implementing this initiative.

⁽¹⁾ Post-authorisation safety studies (PASS): <https://www.ema.europa.eu/en/human-regulatory-overview/post-authorisation/pharmacovigilance-post-authorisation/post-authorisation-safety-studies-pass>.

⁽²⁾ Pharmacovigilance Risk Assessment Committee (PRAC): <https://www.ema.europa.eu/en/committees/pharmacovigilance-risk-assessment-committee-prac>.

⁽³⁾ Referral procedures: <https://www.ema.europa.eu/en/human-regulatory-overview/post-authorisation/referral-procedures-human-medicines#related-content-71604>.

⁽⁴⁾ <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52023DC0298>.