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Onderwerp: Reasoned Opinion from the Swedish Riksdag on COM (2025) 102

Dear colleagues,

On 17 June, the Swedish Riksdag issued a Reasoned Opinion on the Commission's proposal for a Regulation laying a framework for strengthening the availability and security of supply of critical medicinal products as well as the availability of, and accessibility of, medicinal products of common interest, and amending Regulation (EU) 2024/795. More information is available on [IPEX](#).

Please find in attachment a courtesy translation of the Reasoned Opinion, as well as a letter from Christian Carlsson, chair of the Committee on Health and Welfare, which I invite you to forward to the chair of the competent committee in your parliament.

Thanks in advance for your cooperation!

Best wishes

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Riksdagens representant vid EU:s institutioner • Sekretariatet för EU-samordning • Riksdagsförvaltningen

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17 June 2025

Dear Colleague,

I would like to inform you that the Committee on Health and Welfare has examined the Commission's Proposal for a Regulation of the European Parliament and of the Council laying a framework for strengthening the availability and security of supply of critical medicinal products as well as the availability of, and accessibility of, medicinal products of common interest, and amending Regulation (EU) 2024/795 (COM(2025) 102).

The Committee unanimously considers that the Commission's amended proposal is not compliant in all its parts with the principle of subsidiarity. Therefore, the Committee has submitted a proposal for a reasoned opinion to the Chamber of the Swedish Parliament. Today, on 17 June 2025, the Chamber made the decision to issue the reasoned opinion.

Please find a courtesy translation of the reasoned opinion attached to this letter.

I look forward to receiving the results of your scrutiny of this proposal, preferably on IPEX or in any way you deem appropriate.

Yours sincerely,

5.1.2.e

Christian Carlsson
Chair of the Committee on Health and Welfare
Swedish Parliament

Christian Carlsson

Member of Parliament • Swedish Parliament

Reasoned opinion from the Riksdag

The Riksdag has examined the Commission's Proposal for a Regulation of the European Parliament and of the Council laying a framework for strengthening the availability and security of supply of critical medicinal products as well as the availability of, and accessibility of, medicinal products of common interest, and amending Regulation (EU) 2024/795, COM (2025) 102.

The Riksdag is positive to the general ambitions of the proposal and welcomes the Commission's efforts to strengthen security of supply and access to critical medicinal products in the EU. The Riksdag shares the view that matters relating to shortages of medicines are highly topical in the Union, and understands that certain measures are required at EU level to ensure coordinated and effective responses to cross-border challenges of this kind.

In the opinion of the Riksdag, the proposal for a regulation is largely compliant with the principle of subsidiarity. However, the Riksdag considers that certain parts of the proposal are not compliant with the principle of subsidiarity. The Riksdag makes the assessment that the provisions relating to national planning and building processes, provisions facilitating administrative and permit-granting processes for strategic projects and regulations concerning environmental assessments conflict with the principle of subsidiarity.

As regards the content of the proposal relating to provisions on national planning and building processes, the Riksdag considers that the Commission does not clearly justify how planning and building processes could constitute obstacles to security of supply of medicines. The Riksdag regards it as problematic that the regulation would regulate planning and building processes and questions the fact that a definition that includes these has been included in the proposal.

The Riksdag also has doubts about the parts of the proposal containing provisions designed to facilitate administrative and permit-granting processes, that is, prioritisation of financial support for strategic projects. Currently, these processes are regulated nationally, and the provisions of the proposal may be assessed as excessively far-reaching. Regarding environmental assessments, the Commission further proposes an overall assessment where the competent authorities will be required to take decisions within tight deadlines. The Riksdag sees a risk that such regulations may be assessed to be excessively far-reaching for Swedish administration.

The Riksdag therefore considers that the proposal is not compliant in all its parts with the principle of subsidiarity.