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'I' ITEM NOTE

From:	General Secretariat of the Council
To:	Permanent Representatives Committee
Subject:	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 <i>- Optional consultation of the Committee of the regions¹</i>

1. On 11 March 2025, the Commission submitted to the Council a proposal for 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.²
2. The proposal, which complements the ongoing revision of the EU pharmaceutical legislation, aims to strengthen the security of supply and the availability of critical medicinal products, and to support the availability and accessibility of other medicinal products of common interest.

¹ The sole purpose of this note is to decide on the consultation of another institution/body and not on the substance.

² 6872/25

3. The legislative proposal is based on Article 114 of the Treaty on the Functioning of the European Union (TFEU) and therefore does not require the Opinion of the Committee of the Regions. Nevertheless, given the subject matter of the proposal and its possible impact for European regions, it is considered appropriate to consult the Committee of the Regions.
 4. The Permanent Representatives Committee is therefore invited to decide, in accordance with Articles 304 and 307 of the Treaty on the Functioning of the European Union and Article 19(7)(h) of the Council's Rules of Procedure³, to consult the Committee of the Regions on the above proposal and to request them to give their opinion as soon as possible.
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³ Council Decision 2009/937/EU of 1 December 2009 adopting the Council's Rules of Procedure, OJ L 325, 11/12/2009, p. 35.