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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 down 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 - General Approach

In document 14823/25, in page 29, the recital 41 should read as follows:

(41) In order to ensure that this Regulation effectively meets its objectives, it is essential to assess its implementation and impact over time. The Commission should carry out an evaluation of this Regulation **at the latest** five years after its application and every five years thereafter. This evaluation should include an assessment of the extent to which the Regulation's objectives, as set out in Article 1, have been achieved, including its impact on stakeholders, regulatory procedures, and market dynamics. **The evaluation should also include an assessment of the scope, functioning and efficiency of Article 18 as well as coherence of the Regulation with developments within the field of public procurement.** In particular, the Commission's evaluation should take into account the views of Member States, **markets actors, contracting authorities** ~~economic operators,~~ and other relevant stakeholders, ensuring that their feedback contributes to the continuous improvement of the regulatory framework**.**

The results of **the** ~~this~~ evaluation should be presented to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions. In order to facilitate this evaluation, national authorities**, market actors, contracting authorities** and **other relevant stakeholders** ~~economic operators~~ should provide relevant data and information upon request to support the Commission's assessment. **With a view to the future revision of the EU's public procurement framework, the Commission should review the scope, functioning and efficiency of Article 18 in this Regulation as well as coherence with the revised Directive 2014/24/EU no later than [three years] after the date of transposition of the revised directive, or no later than [five years] after the date of application of this Regulation, whichever the earlier. The Commission has right of initiative on the content and timing of any proposal.**

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