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COVER NOTE

From:	European Economic and Social Committee (EESC)
To:	General Secretariat of the Council
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 *- Opinion of the European Economic and Social Committee*

Delegations will find attached the opinion adopted by the European Economic and Social Committee on the above-mentioned proposal. Other language versions, if needed, will soon be available on the following website: **https://dmsearch.eesc.europa.eu/search/opinion**

European Economic and Social Committee

OPINION

European Economic and Social Committee

Critical Medicines Act

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 final)

CCMI/240

Rapporteur: **Veselin MITOV (BG, Gr. II)**

Co-rapporteur: **Elżbieta SZADZIŃSKA (PL. Cat. 3)**

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Advisor	Mihai IVAȘCU (for the rapporteur, Group II)
Plenary Assembly decision	21/1/2025
Legal basis	Rule 52(2) of the Rules of Procedure
Referral	European Commission, 12/3/2025
Legal basis	Article 14 and 294 of the Treaty on the Functioning of the European Union
Section responsible	Consultative Commission on Industrial Change
Adopted in section	4/6/2025
Adopted at plenary session	18/6/2025
Plenary session No	597
Outcome of vote (for/against/abstentions)	130/1/3

1. RECOMMENDATIONS

The European Economic and Social Committee (EESC) recommends:

1.1 that the EU significantly increase the proposed funding for the implementation of the Critical Medicines Act to support its ambitious objectives, ensuring that resources extend beyond coordination efforts to actively support large-scale production shifts.

1.2 that the EU establish a dedicated European fund for starting materials, Active Pharmaceutical Ingredients (APIs) and critical medicines, managed by a central EU body, with financial contributions from Member States, the European Investment Bank (EIB) and the private sector to compensate for the cost differences between pharmaceutical production in the EU and Asia. A dedicated and strong financial instrument is needed to support:

- Investments in new and expanded EU-based production facilities.
- Subsidies or tax incentives to offset higher regulatory and operational costs.
- Research and development in cost-efficient, sustainable production technologies.

This fund should be included in the next Multiannual Financial Framework (MFF) and coordinated with defence-related financing mechanisms, as referred to in point 1.13.

1.3 that public funding mechanisms be strategically aligned with the EIB, multilateral financial institutions and private sector banks to enhance access to financing for high-risk pharmaceutical projects, fostering innovation and strengthening supply chain resilience.

1.4 that a fully interoperable EU-wide database for critical medicines be created, integrating national databases and enhanced cybersecurity measures. This system should provide real-time visibility of supply chain vulnerabilities while ensuring data protection and resilience against cyber threats.

1.5 that significant funding for the implementation of dedicated real-time tracking systems and early warning mechanisms be adopted and allocated, utilising big data analytics, artificial intelligence and blockchain technology to enhance supply chain transparency, predict shortages and improve crisis response.

1.6 that a comprehensive, evidence-based impact assessment of the Critical Medicines Act be conducted, covering the entire pharmaceutical supply chain from production to patient access and addressing the socio-economic impact of the proposed measures. Given the urgency of the issue, the assessment must proceed alongside legislative work and should not delay the adoption of the proposed regulation. While assessing the short-, medium- and long-term effects of the Act, key provisions are essential for ensuring their effectiveness and guiding necessary adjustments.

1.7 that the EU establish dedicated competence centres and invest in large-scale upskilling and reskilling programmes to support workers in adapting to the increasing digitalisation and automation of the pharmaceutical sector.

1.8 that increased funding be secured for education and vocational training by supporting vocational schools, apprenticeship programmes, universities and industry-focused initiatives, including scholarships for graduate studies, commitments under the Pact for Skills and the development of curricula aligned with the pharmaceutical sector's future needs.

1.9 that the European Shortages Monitoring Platform (ESMP) provide real-time data on stock levels, product status (unfinished/finished medicines), availability for redistribution and stock utilisation.

1.10 that a unified EU framework for contingency stockpiling be created to ensure coordinated and equitable distribution of critical medicines across Member States, reduce unnecessary financial burdens on manufacturers and uphold the principle of European solidarity. Additionally, mechanisms should be established to compensate manufacturers for the added costs of stockpiling and to ensure an optimised rotation system that minimises waste, particularly for medicines with a short shelf life.

1.11 that a systematic review mechanism be introduced to evaluate the impact of existing and proposed EU legislation, particularly environmental regulations, on security of supply for critical medicines.

1.12 that joint procurement be used selectively while mitigating its potential downsides, such as pricing pressures and market limitations. Additionally, the EU should adopt an implementing act providing clear guidelines on procurement criteria and establish support mechanisms to promote best manufacturing practices.

1.13 that an analysis be carried out of the proposal to integrate the Critical Medicines Act into the EU's broader strategic autonomy and security framework, recognising pharmaceutical supply chains as a matter of public health and economic and military security. To ensure sufficient financial backing, the EU could leverage defence-related funding mechanisms to reinforce Europe's capacity to produce and supply critical medicines.

1.14 that entities responsible for the production of medicines be protected against restrictions on the supply and consumption of energy, gas and heat to ensure continuous manufacturing. Any disruption in energy supply could lead to shortages of critical medicines and risks to public health.

1.15 that action be taken to harmonise quality, safety and environmental standards for pharmaceutical production between EU and third-country manufacturers exporting to the EU. To ensure fair competition and prevent disadvantages for European producers, the Critical Medicines Act should include stronger regulatory measures requiring third-country manufacturers to adhere to standards equivalent to those in the EU for all imported medicines and active pharmaceutical ingredients.

1.16 stronger measures to guarantee the affordability of essential medicines, including those for rare diseases, ensuring that consumers do not face financial burdens due to shortages. The EU should introduce mechanisms to regulate medicine pricing, enhance transparency in pharmaceutical costs and prevent price inflation caused by supply disruptions.

1.17 that the EU should foster a more collaborative innovation ecosystem that integrates SMEs, start-ups and deep-tech innovators, alongside established pharmaceutical companies to strengthen the industry's resilience and competitiveness.

1.18 that the role of the Critical Medicines Coordination Group be expanded to include civil society representatives and independent experts.

2. EXPLANATORY NOTES

Arguments in support of recommendations 1.1, 1.2 and 1.3

2.1 The proposal for a regulation rightly emphasises reshoring pharmaceutical production and securing supply chains within the EU. However, the proposed budget of EUR 83 million for 2026-2027 is insufficient to drive substantial changes in pharmaceutical manufacturing or supply chain security. Ensuring a realistic and well-funded approach will help prevent a situation where legislative ambition is not matched by actionable results.

2.2 Higher production costs in the EU – due to stricter environmental regulations, higher labour costs and investment in advanced manufacturing – place European producers at a disadvantage compared to low-cost manufacturing hubs in Asia. Medicines are not just economic goods but a strategic asset for public health. The additional costs of EU-based production should be seen as an investment in security, similar to defence or energy infrastructure.

2.3 Aligning public funds with EIB financing, Horizon Europe and the Strategic Technologies for Europe Platform (STEP) would create a comprehensive financial ecosystem to support the pharmaceutical sector. A blended financing approach, combining grants, loans and guarantees, would support long-term investment in pharmaceutical innovation and infrastructure.

Arguments in support of recommendation 1.4 and 1.5

2.4 Currently, fragmented national databases limit the EU's ability to track and manage critical medicine shortages effectively. A harmonised EU database would enable real-time information sharing across Member States.

2.5 Cybersecurity risks in pharmaceutical supply chains are increasing. A centralised system with strong cybersecurity protocols will safeguard sensitive data and ensure operational resilience in the event of cyberattacks.

Arguments in support of recommendation 1.6

2.6 The absence of a thorough impact assessment limits understanding of how the Critical Medicines Act will affect manufacturing, distribution, pricing and access to medicines. A detailed assessment would provide data-driven insights to support better policymaking and ensure that the Act meets its objectives.

2.7 Providing evidence-based findings would ensure accountability and support informed revisions of the Act as needed, and increase confidence among stakeholders, including industry, healthcare professionals and patients.

2.8 AI and big data analytics can identify patterns in medicine shortages and supply chain disruptions, allowing proactive interventions rather than reactive crisis management. Blockchain technology ensures secure and transparent tracking of medicines from production to distribution.

2.9 Logistics optimisation through real-time tracking and collaborative partnerships will reduce inefficiencies, ensuring timely delivery of critical medicines.

Arguments in support of recommendations 1.7 and 1.8

2.10 Competence centres can serve as hubs for research, innovation and specialised training, providing direct support to pharmaceutical companies and ensuring industry-wide best practices.

2.11 A structured upskilling and reskilling framework will ensure that the workforce remains competitive and adaptable. Investing in worker skills will enhance EU production resilience, ensuring that manufacturing scale-up phases are efficient and that stringent pharmaceutical quality standards are met. Greater consideration should be given to how the regulation supports job creation and regional development within the EU.

2.12 Strengthening collaboration between academia, vocational training providers and industry will ensure that educational programmes align with real-world industry needs. Apprenticeship programmes are urgently needed in the EU medicines production sector to address critical skills shortages and support industrial resilience. Scholarships and training programmes will increase accessibility for students and workers, particularly those from low-skilled backgrounds, helping address labour shortages in highly technical pharmaceutical roles.

Arguments in support of recommendation 1.9

2.13 Having detailed tracking of stock phases (unfinished vs. finished products) would help manufacturers and policymakers optimise production and distribution strategies. The coordinated redistribution of surplus medicines would prevent unnecessary wastage and ensure equitable access across all EU countries, ensuring that supply imbalances do not disproportionately affect smaller or economically weaker Member States. Tracking stock usage and expiration will help prevent medicine wastage, allowing Member States to implement more effective inventory management.

Arguments in support of recommendations 1.10

2.14 A centralised EU approach to contingency stocks would enhance supply chain stability and prevent stockpiling policies from disrupting market balance. Reimbursement mechanisms, such as state-backed reserves or direct financial compensation, would ensure that manufacturers are not disproportionately burdened.

2.15 A first-in, first-out (FIFO) system should be implemented to avoid unnecessary disposal of medicines, particularly for drugs with a limited shelf life. An EU-managed system would allow for strategic redistribution, ensuring that medicines reach regions facing acute shortages while reducing overall waste.

Arguments in support of recommendations 1.11

2.16 The EU's environmental policies impose necessary sustainability measures but may unintentionally burden pharmaceutical manufacturers, making EU-based production less competitive. Stricter regulations on emissions, wastewater treatment or restrictions on key substances could increase production costs or force companies to relocate outside the EU, exacerbating medicine shortages.

2.17 A well-balanced regulatory framework will ensure that Europe remains competitive while safeguarding patient access to critical medicines. A data-driven approach would help fine-tune environmental policies to safeguard medicine availability while maintaining high sustainability standards.

Arguments in support of recommendations 1.12

2.18 Excessive reliance on joint procurement can reduce market diversity by discouraging smaller pharmaceutical firms from participating, ultimately limiting innovation and flexibility in supply.

2.19 An implementing act outlining procurement rules would ensure fair competition, predictability and transparency across all Member States.

Arguments in support of recommendations 1.13

2.20 The COVID-19 pandemic and geopolitical tensions have demonstrated that medicine shortages pose serious risks to public health and national stability. The proposed funding amounts and sources are insufficient to support large-scale reshoring and supply chain diversification.

2.21 Maintaining uninterrupted production of medicines has a direct impact on military security. By linking medicine security with defence funding, the EU can accelerate investments in local production, increase preparedness for future health crises and ensure stable access to medicines across Member States.

Arguments in support of recommendations 1.14

2.22 In accordance with the European Commission's Communication on *Save gas for a safe winter*[1], industries considered critical or strategic from a societal perspective should be prioritised in the event of disruptions — particularly when such disruptions could negatively affect supply chains with repercussions for health, safety, the environment, security, defence and other critical sectors

1 COM(2022) 360 final.

such as food and refineries. The European Commission referred to the pharmaceutical sector as an example of a societally critical industry.

Arguments in support of recommendation1.15

2.23 Third-country manufacturers often operate under less stringent regulatory requirements, allowing them to produce medicines more cheaply and creating an unequal competitive environment. Enforcing equal production standards for imported medicines will protect European manufacturers from unfair competition while maintaining high-quality pharmaceutical products in the EU market. EU-based production requirements should not lead to trade barriers or unintended disruptions in global supply chains; a risk assessment framework should be incorporated.

Arguments in support of recommendation 1.16

2.24 A recent survey from consumer organisations in Belgium, Italy, Spain and Portugal revealed that 40% of respondents struggled to obtain medicines, often resorting to more expensive substitutes. While the Critical Medicines Act aims to address supply chain vulnerabilities, it lacks specific provisions to prevent excessive possible price increases for consumers.

2.25 The EU should introduce measures to monitor and regulate the pricing of critical medicines. Strengthening pricing transparency, regulating cost increases and preventing financial burdens on consumers will help create a more equitable and resilient healthcare system across the EU.

Arguments in support of recommendation 1.17

2.26 A pharmaceutical ecosystem that relies solely on large players can become rigid and more vulnerable to disruptions (e.g., supply bottlenecks or production shutdowns). SMEs and start-ups play a crucial role in medicine production, innovation and supply chain diversification. Deep-tech innovators bring high-potential, science-based solutions that established firms may not be positioned to develop internally. Integrating them into the innovation ecosystem accelerates the development of resilient, cutting-edge supply chain solutions.

Arguments in support of recommendation 1.18

2.27 The current proposal for the Critical Medicines Coordination Group primarily focuses on industry and governmental actors, leaving patients, healthcare professionals and independent experts without direct representation.

2.28 Including civil society organisations, patient advocacy groups and independent researchers would increase public trust in the decision-making process, ensuring that policies reflect the needs of all stakeholders.

3. PROPOSED AMENDMENTS TO THE LEGISLATIVE PROPOSAL OF THE EUROPEAN COMMISSION

Amendment 1
linked to recommendations 1.1, 1.2, 1.3 and 1.13
Article 16, paragraph 1, new paragraphs 2 and 3

Text proposed by the European Commission	EESC amendment
1. For the duration of the Multiannual Financial Framework 2021-202724 strategic projects may be supported by Union funding, including but not limited to such Union programmes as the EU4Health Programme, Horizon Europe, and the Digital Europe Programme provided that such support is in line with the objectives set out in the regulations establishing those programmes.	1. For the duration of the Multiannual Financial Framework 2021–2027, strategic projects may be supported by Union funding, including but not limited to such Union programmes as the EU4Health Programme, Horizon Europe, and the Digital Europe Programme, provided that such support is in line with the objectives set out in the regulations establishing those programmes. ***The Union shall work to significantly increase funding to support the implementation of this regulation and enable large-scale production shifts.*** ***2. A dedicated European fund for starting materials, APIs and critical medicines shall be established under the next Multiannual Financial Framework. It shall be managed by a central EU body, with contributions from Member States, the European Investment Bank and the private sector.*** ***3. Strategic projects intended to reinforce Europe's capacity to produce and supply critical medicines may also benefit from EU instruments supporting strategic autonomy and security. To this end, the Commission shall explore the integration of this regulation into the Union's broader strategic autonomy and security framework. Where appropriate, defence-related funding mechanisms may be leveraged, in accordance with Union law, to support pharmaceutical production as a matter of public health and economic and military security.***

Reason
Ensuring a realistic and well-funded approach will help prevent a situation where legislative ambition is not matched by actionable results. Aligning public funds with EIB financing, Horizon Europe and the Strategic Technologies for Europe Platform would create a comprehensive financial ecosystem capable of supporting the pharmaceutical sector. A blended financing approach, combining grants, loans and guarantees, would support long-term investment in pharmaceutical innovation and infrastructure. By linking medicine security with defence funding, the EU can accelerate investments in local production, increase preparedness for future health crises and ensure stable access to medicines across Member States.

Amendment 2

linked to recommendations 1.4 and 1.5

Article 29, paragraphs 2 and 3

Text proposed by the European Commission	EESC amendment
2. The Commission and national authorities of the Member States shall aim to avoid duplication of the information requested and submitted.	2. The Commission and national authorities of the Member States shall aim to avoid duplication of the information requested and submitted ***and shall ensure that such information is integrated into a fully interoperable EU-wide database, incorporating national databases and providing real-time visibility of supply chain vulnerabilities through secure and resilient digital infrastructure***.
3. The Commission and national authorities of the Member States shall assess the merits of duly substantiated confidentiality claims made by marketing authorisation holders and other economic operators, requested to provide information per paragraph 1, and shall protect any information that is commercially confidential against unjustified disclosure.	3. The Commission and national authorities of the Member States shall assess the merits of duly substantiated confidentiality claims made by marketing authorisation holders and other economic operators, requested to provide information per paragraph 1, and shall protect any information that is commercially confidential against unjustified disclosure. ***They shall also ensure that digital systems used for data collection and analysis include appropriate cybersecurity measures.***

Reason
A harmonised EU database would enable real-time information sharing across Member States. A centralised system with strong cybersecurity protocols will safeguard sensitive data and ensure operational resilience in the event of cyberattacks.

Amendment 3
linked to recommendation 1.6
Article 30, title, new paragraph 1

Text proposed by the European Commission	EESC amendment
Evaluation	***Impact assessment and e**valuation* ***1. The Commission shall, in parallel with the legislative process, carry out a comprehensive, evidence-based impact assessment of this regulation. This assessment shall not delay the adoption or implementation of the regulation and shall cover the short-, medium- and long-term socio-economic impacts of the proposed measures, with particular attention to the resilience, sustainability and accessibility of the pharmaceutical supply chain.***

Reason
A detailed assessment would provide data-driven insights to support better policymaking and ensure that the Act meets its objectives. Providing evidence-based findings would ensure accountability, support informed revisions of the Act as needed, and increase confidence among stakeholders, including industry, healthcare professionals and patients.

Amendment 4
linked to recommendations 1.7 and 1.8
Recital 4

Text proposed by the European Commission	EESC amendment
(4) Industrial challenges and a lack of investments in manufacturing capacities in the Union have contributed to increased dependency on third country suppliers, in particular, for key raw pharmaceutical materials and active substances. Setting up new, or modernising existing manufacturing capacities in the Union for critical medicinal products, their key inputs and active substances, which have often been on the market for a long time and are considered to be relatively inexpensive, is currently not seen as a sufficiently attractive option for private investment, also in view of lower energy costs, lesser environmental and other legal requirements elsewhere in the world. Workforce shortages and the need for specialised skills in pharmaceutical manufacturing	(4) Industrial challenges and a lack of investments in manufacturing capacities in the Union have contributed to increased dependency on third country suppliers, in particular, for key raw pharmaceutical materials and active substances. Setting up new, or modernising existing manufacturing capacities in the Union for critical medicinal products, their key inputs and active substances, which have often been on the market for a long time and are considered to be relatively inexpensive, is currently not seen as a sufficiently attractive option for private investment, also in view of lower energy costs, lesser environmental and other legal requirements elsewhere in the world. Workforce shortages and the need for specialised skills in pharmaceutical manufacturing

further add to the industrial challenges to manufacturing in the Union. Targeted financial incentives, simplified administrative processes, and better Union-level coordination can contribute to supporting efforts to increase manufacturing capacities in the Union and strengthen the supply chains for critical medicines.	further add to the industrial challenges to manufacturing in the Union. ***In this context, the establishment of dedicated competence centres and large-scale upskilling and reskilling programmes is essential to help workers adapt to increasing digitalisation and automation in the sector. Action shall be taken to promote increased funding for education and vocational training, including support for vocational schools, apprenticeship programmes, universities, industry-led initiatives, scholarships for graduate studies, commitments under the Pact for Skills and the development of curricula aligned with the pharmaceutical sector's future needs.*** Targeted financial incentives, simplified administrative processes, and better Union-level coordination can contribute to supporting efforts to increase manufacturing capacities in the Union and strengthen the supply chains for critical medicines.

Reason
Competence centres can serve as hubs for research, innovation and specialised training, providing direct support to pharmaceutical companies and ensuring industry-wide best practices. A structured upskilling and reskilling framework will ensure that the workforce remains competitive and adaptable. Greater consideration should be given to how the regulation supports job creation and regional development within the EU. Strengthening collaboration between academia, vocational training providers and industry will ensure that educational programmes are aligned with real-world industry needs. Scholarships and training programmes will increase accessibility for students and workers, helping address labour shortages in highly technical pharmaceutical roles.

Amendment 5

linked to recommendation 1.9

Context of the proposal, Consistency with existing policy provisions in the policy area

Text proposed by the European Commission	**EESC amendment**
The proposed Regulation also builds on the EMA's extended mandate. In this respect, the launch of the European Shortages Monitoring Platform was a key requirement of this extended mandate to enhance the monitoring of shortages across the EU. This platform will enable both marketing authorisation holders and national competent authorities to submit data on the supply, demand and availability of centrally and nationally	The proposed Regulation also builds on the EMA's extended mandate. In this respect, the launch of the European Shortages Monitoring Platform was a key requirement of this extended mandate to enhance the monitoring of shortages across the EU. This platform will enable both marketing authorisation holders and national competent authorities to submit data on the supply, demand and availability of centrally and nationally

authorised medicines during crises and preparedness situations. The platform will be further expanded in the context of the revision of the EU's pharmaceutical legislation.	authorised medicines during crises and preparedness situations. The platform will be further expanded in the context of the revision of the EU's pharmaceutical legislation***, including with a view to providing real-time data on stock levels, product status (unfinished/finished medicines), availability for redistribution and stock utilisation***.

Reason
Having detailed tracking of stock phases (unfinished vs. finished products) would help manufacturers and policymakers optimise production and distribution strategies. The coordinated redistribution of surplus medicines would prevent unnecessary wastage and ensure equitable access across all EU countries, ensuring that supply imbalances do not disproportionately affect smaller or economically weaker Member States. Tracking stock usage and expiration will help prevent medicine wastage, allowing Member States to implement more effective inventory management.

Amendment 6

linked to recommendation 1.10

Article 20

Text proposed by the European Commission	**EESC amendment**
Measures on security of supply applied in one Member State shall not result in any negative impact in other Member States. Member States shall, in particular, ***avoid such an impact*** when proposing and defining the scope and timing of any form of requirements for companies to hold contingency stocks. Member States shall ensure that any requirements they impose on companies in the supply chain to hold contingency stocks are proportionate and respect the principles of transparency and solidarity.	Measures on security of supply applied in one Member State shall not result in any negative impact in other Member States. ***To this end, a unified EU framework for contingency stockpiling shall be established to ensure coordinated and equitable distribution of critical medicines across Member States.*** Member States shall, in particular, ***align with this framework*** when proposing and defining the scope and timing of any form of requirements for companies to hold contingency stocks. Member States shall ensure that any requirements they impose on companies in the supply chain to hold contingency stocks are proportionate and respect the principles of transparency and solidarity. ***Mechanisms shall also be established to compensate manufacturers for the additional costs incurred, and to ensure an optimised stock rotation system that prevents waste, especially for medicines with a short shelf life.***

Reason
A centralised EU approach to contingency stocks would enhance supply chain stability and prevent stockpiling policies from disrupting market balance. Reimbursement mechanisms, such as state-backed reserves or direct financial compensation, would ensure that manufacturers are not disproportionately burdened. A first-in, first-out system should be implemented to avoid unnecessary disposal of medicines, particularly for drugs with a limited shelf life. An EU-managed system would allow for strategic redistribution, ensuring medicines reach regions facing acute shortages while reducing overall waste.

Amendment 7

linked to recommendation 1.12

Article 19, paragraph 1

Text proposed by the European Commission	EESC amendment
1. By 6 months after entry into force of this Regulation each Member State shall establish a national programme supporting security of supply of critical medicinal products, including in public procurement procedures. Such programmes shall promote the consistent use of procurement requirements by contracting authorities within a given Member State as well as multi-winner approaches, where beneficial in light of the market analysis. Such programmes may also include measures for pricing and reimbursement supporting security of supply of those critical medicinal products that are not purchased through public procurement procedures.	1. By 6 months after entry into force of this Regulation each Member State shall establish a national programme supporting security of supply of critical medicinal products, including in public procurement procedures, ***based on an implementing act issued by the Commission, which will provide clear guidelines on procurement criteria***. Such programmes shall promote the consistent use of procurement requirements by contracting authorities within a given Member State as well as multi-winner approaches, where beneficial in light of the market analysis. Such programmes may also include measures for pricing and reimbursement supporting security of supply of those critical medicinal products that are not purchased through public procurement procedures.

Reason
An implementing act outlining procurement rules would ensure fair competition, predictability and transparency across all Member States.

Amendment 8

linked to recommendation 1.14

Article 7

Text proposed by the European Commission	EESC amendment
Strategic projects shall be considered as contributing to the security of supply of critical	Strategic projects shall be considered as contributing to the security of supply of critical

medicinal products in the Union and, therefore, to be in the public interest. The Member States' authorities shall ensure that the relevant permit granting processes related to strategic projects are carried out in the fastest way possible, making available, in particular, any form of accelerated procedures that exists in applicable Union and national law.	medicinal products in the Union and, therefore, to be in the public interest. The Member States' authorities shall ensure that the relevant permit granting processes related to strategic projects are carried out in the fastest way possible, making available, in particular, any form of accelerated procedures that exists in applicable Union and national law. ***The Member States shall provide strategic projects located within their borders with all necessary administrative and technical support to mitigate unplanned interruptions in the supply of energy, gas and heat required for the creation or expansion of manufacturing capacity.***

Reason
The EESC believes that, as part of the priority status granted to strategic projects under Article 7, appropriate administrative support must be provided, including but not limited to fast-track procedures and assistance in obtaining necessary authorisations. Moreover, strategic projects must be protected from restrictions on access to energy, gas or heat. Without a binding obligation on Member States to implement these measures, the objective of ensuring the security of supply of critical medicinal products within the Union will remain unattainable.

Amendment 9

linked to recommendation 1.15

Article 27

Text proposed by the European Commission	**EESC amendment**
Without prejudice to the prerogatives of the Council, the Commission, shall explore possibilities of concluding strategic partnerships aiming to diversify sourcing of critical medicinal products, their active substances and key inputs to increase the security of supply of critical medicinal products in the Union. The Commission shall also explore the possibility of building on existing forms of cooperation, when possible, to support security of supply and reinforce efforts to strengthen the production of critical medicinal products in the Union.	Without prejudice to the prerogatives of the Council, the Commission, shall explore possibilities of concluding strategic partnerships aiming to diversify sourcing of critical medicinal products, their active substances and key inputs to increase the security of supply of critical medicinal products in the Union. The Commission shall also explore the possibility of building on existing forms of cooperation, when possible, to support security of supply and reinforce efforts to strengthen the production of critical medicinal products in the Union. ***To ensure fair competition and avoid disadvantages for EU producers, the Commission shall, within the framework of strategic partnerships, promote the harmonisation of quality, safety and environmental standards for pharmaceutical production between the Union***

	and third countries. These partnerships shall include stronger regulatory measures requiring third-country manufacturers exporting to the EU to comply with standards equivalent to those applicable in the Union for imported medicinal products and active pharmaceutical ingredients.

Reason
Enforcing equal production standards will protect European manufacturers from unfair competition, while maintaining high-quality pharmaceutical products in the EU market.

Amendment 10
linked to recommendation 1.16
Article 4, paragraphs 1 and 3

Text proposed by the European Commission	**EESC amendment**
1. The security of supply and availability of critical medicinal products for patients is a strategic objective of the Union.	1. The security of supply***, affordability*** and availability of critical medicinal products for patients is a strategic objective of the Union.
2. The Member States and the Commission shall work together to strengthen the security of supply and continuous availability of critical medicinal products in the Union through measures that take full advantage of the potential of the internal market.	2. The Member States and the Commission shall work together to strengthen the security of supply and continuous availability of critical medicinal products in the Union through measures that take full advantage of the potential of the internal market.
3. The Commission shall support the coordinated efforts of the Members States.	3. The Commission shall support the coordinated efforts of the Members States***, including through initiatives that enhance pricing transparency and promote fair and affordable access to critical medicinal products.***

Reason
While the Critical Medicines Act aims to address supply chain vulnerabilities, it lacks specific provisions to prevent excessive possible price increases for consumers. Strengthening pricing transparency, regulating cost increases and preventing financial burdens on consumers will help create a more equitable and resilient healthcare system across the EU.

Amendment 11
linked to recommendation 1.17
Article 27

Text proposed by the European Commission	**EESC amendment**
Without prejudice to the prerogatives of the Council, the Commission, shall explore	Without prejudice to the prerogatives of the Council, the Commission~~,~~ shall explore

possibilities of concluding strategic partnerships aiming to diversify sourcing of critical medicinal products, their active substances and key inputs to increase the security of supply of critical medicinal products in the Union. The Commission shall also explore the possibility of building on existing forms of cooperation, when possible, to support security of supply and reinforce efforts to strengthen the production of critical medicinal products in the Union.	possibilities of concluding strategic partnerships aiming to diversify sourcing of critical medicinal products, their active substances and key inputs to increase the security of supply of critical medicinal products in the Union. The Commission shall also explore the possibility of building on existing forms of cooperation, when possible, to support security of supply and reinforce efforts to strengthen the production of critical medicinal products in the Union. ***As part of these partnerships, the Commission shall promote a collaborative innovation ecosystem that integrates small and medium-sized enterprises, start-ups and deep-tech innovators alongside established pharmaceutical companies in order to enhance resilience, foster technological advancement and boost the competitiveness of the Union's pharmaceutical sector.***

Reason
A pharmaceutical ecosystem that relies solely on large players can become rigid and more vulnerable to disruptions (e.g., supply bottlenecks or production shutdowns). SMEs and start-ups play a crucial role in medicine production, innovation and supply chain diversification. Deep-tech innovators bring high-potential, science-based solutions that established firms may not be positioned to develop internally. Integrating them into the innovation ecosystem accelerates the development of resilient, cutting-edge supply chain solutions. A collaborative approach allows for shared resources, co-development opportunities and open innovation, which reduces duplication of efforts and fosters more sustainable and cost-efficient R&D.

Amendment 12

linked to recommendation 1.18

Article 25, new paragraph 3

Text proposed by the European Commission	**EESC amendment**
	3. The Critical Medicines Group shall also include civil society representatives and independent experts with relevant experience in public health, patient advocacy and pharmaceutical supply chains. They shall participate in an advisory or consultative capacity.

Reason
The current proposal for the Critical Medicines Coordination Group primarily focuses on industry and governmental actors, leaving patients, healthcare professionals and independent experts without direct representation. Including civil society organisations, patient advocacy groups and independent researchers would increase public trust in the decision-making process, ensuring that policies reflect the needs of all stakeholders.

Brussels, 18 June 2025.

The President of the European Economic and Social Committee
Oliver RÖPKE

APPENDIX I to the OPINION

of the
European Economic and Social Committee

The following amendment, which received at least a quarter of the votes cast, was rejected in the course of the debate (Rule 74(3) of the Rules of Procedure):

AMENDMENT 1

Tabled by:
PILAWSKI Lech

CCMI/240
Critical Medicines Act

Amendment 13
Article 8, New paragraph 3

Section opinion	*Amendment*
	3. Member States should consider, in accordance with their competences, recommending that employees of strategic projects necessary for creating or increasing manufacturing capacity are exempted from active military service in Member States or are provided with a mobilisation assignment at current strategic project.

Reason
The EESC believes that this is a necessary solution to ensure that, during an armed conflict, the production of medicines, especially critical ones, is not interrupted due to a lack of specialist staff.

Outcome of the vote:

In favour:	33
Against:	88
Abstentions:	8