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Opinion of the European Economic and Social Committee

Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: Addressing medicine shortages in the EU

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1. Conclusions and recommendations

1.1. The position of the European Economic and Social Committee (EESC) is clear – Europeans throughout the EU should not suffer from a lack of access to medicines. The EESC strongly suggests prioritising the accessibility of medicine within the EU. This initiative is crucial for protecting citizens and ensuring a competitive edge for the European pharmaceutical industry in the global market.

1.2. The EESC recommends the creation of a stable and reliable legal and economic environment, complemented by a skilled workforce, to make Europe an ideal destination for pharmaceutical companies from the EU and other regions such as the US and China.

1.3. It is important to make a strategic shift towards self-reliance in producing Active Pharmaceutical Ingredients (APIs) and finished medicines, aiming to reduce dependency on external sources and bolster the EU's pharmaceutical independence. The EU needs to secure funding and financial mechanisms to maintain its large-scale production capabilities for pharmaceutical products, eliminating bureaucratic obstacles and avoiding unnecessary increase in administrative burden.

1.4. The EESC suggests introducing innovative approaches to accessing medicine. These methods should encourage investment in European manufacturing, ensuring a steady supply of essential medicines.

1.5. Enhancing dialogue between the EU's institutions, the pharmaceutical industry, social partners and civil society organisations with a special focus on production capabilities and supply chain challenges is a key priority. This improved communication is vital for navigating potential disruptions and optimising the pharmaceutical sector's efficiency and responsiveness across Europe.

1.6. To enhance the robustness of the pharmaceutical sector, the EESC advocates developing comprehensive EU-wide guidelines and protocols. The EESC suggests continuous data sharing among key stakeholders, emphasising the need for transparent and proactive dialogue.

1.7. The EESC encourages pharmaceutical companies to notify authorities of potential shortages proactively. It is vital for entities such as the European Centre for Disease Prevention and Control (ECDC), the European Medicines Agency (EMA), the European Federation of Pharmaceutical Industries and Associations (EFPIA), Medicines for Europe, and academia to be involved in contingency planning in order to respond to supply chain challenges effectively.

1.8. The EESC highlights the importance of involving patient organisations, healthcare professionals' associations, and organisations representing people with disabilities in policy-making, and calls for their active participation in shaping strategies that improve medicine availability and access and address pharmaceutical waste and overprescription.

1.9. The EU has significantly strengthened healthcare resilience by publishing the Union list of critical medicines. It serves as a vital tool in identifying essential medicines susceptible to shortages.

1.10. The EESC advocates strengthening international partnerships and diversifying pharmaceutical supply chains in response to the evolving global healthcare landscape. These efforts will enhance the security of the EU's pharmaceutical supply and contribute to a more balanced and equitable global healthcare system.

2. **General comments**

2.1. The EESC highlights the health and wellbeing of European Union citizens in its approach to enhancing the pharmaceutical industry. The focus is on ensuring medicine accessibility and affordability for all citizens around the EU, coupled with a globally competitive EU pharmaceutical sector ([1]). The EESC recognises the significance of a pan-European R&D and innovation infrastructure and encourages incentives for pharmaceutical production within the EU ([2]).

2.2. The EESC stresses, even more than before, the importance of prioritising patients in pharmaceutical policy and strategy development, particularly ensuring timely medicine supply. The EESC also advocates supporting pharmacies and wholesalers through incentives and regulatory measures, facilitating their role in managing medicine shortages within the framework of the competition regulations.

2.3. The attractiveness of Europe as a location for the pharmaceutical sector needs to be improved due to intense international competition. This necessitates a stable legal framework, sufficient capital, robust infrastructure and a skilled workforce. Recognising that medicines are a unique commodity, the EESC highlights that Europe's competitiveness hinges on enhanced coordination among industry, social partners, research, public authorities, healthcare professionals' associations and patient organisations to address healthcare needs effectively.

2.4. The strategic sovereignty of the EU requires the mobilisation of resources to ensure that Europe is not solely dependent on the decisions and assets of other regions in the world.

2.5. The EESC proposes a strategic shift in pharmaceutical production to the EU, focusing on Active Pharmaceutical Ingredients (APIs) and finished medicines to strengthen the region's pharmaceutical independence ([3]).

([1]) OJ C 286, 16.7.2021, p. 53.
([2]) OJ C, C/2024/879, 6.2.2024, ELI: http://data.europa.eu/eli/C/2024/879/oj.
([3]) OJ C, C/2024/1568, 5.3.2024, ELI: http://data.europa.eu/eli/C/2024/1568/oj.

2.6. While investment in new manufacturing efforts in Europe will contribute to greater resilience, there is a need for new approaches to access and procurement. These approaches should create the right financial incentives to invest in manufacturing within Europe and maintain large-scale production of critical/essential medicine.

2.7. For the EU to be recognised as a leading hub for the pharmaceutical industry, it is vital to establish a stable and future-proof regulatory environment and ensure fair reimbursement practices for the industry. Transparency in production costs and the availability of well-trained professionals are critical factors.

2.8. The EU must create an attractive and innovative environment for the research, development, and production of medicines. This involves supporting the EU's research and production capacities and enhancing collaboration between science and industry, maintaining large-scale production capacity and technical capability to respond to crises identified by the Health Emergency Preparedness and Response Authority (HERA), and addressing needs.

2.9. The Commission must promote the relocation of value chains to the European Union. Possible measures include prioritising domestic producers in emergency stockpiling, and linking research funding to a mandatory share of domestic production.

3. **EU coordination and dialogue with industry, social partners and civil society organisations**

3.1. This initiative directs significant effort towards increasing understanding of the critical medicine vulnerabilities in the supply chain. The emphasis is on developing a mutual investment plan between the industry and the EU, aiming to reinvest in Europe to reduce these vulnerabilities and maintain critical production capacities.

3.2. A crucial complement to this advocacy is the recommendation to develop EU-wide guidelines or protocols for responding to medicine shortages. This step is integral to achieving a harmonised approach across Member States. There should be a more precise strategy to make greater use of existing data to improve understanding of demand and supply imbalances.

3.3. Another key element emphasises the importance of transparent, proactive and ongoing dialogue. This fosters communication between EU institutions, Member States, pharmaceutical companies, social partners, healthcare professionals' associations, patients' organisations and representatives of people with disabilities to identify vulnerabilities in the supply chain promptly and enhance production flexibility and resilience.

3.4. It is crucial to advocate more transparent information sharing between the pharmaceutical industry and EU institutions about production capacities, distribution networks, and supply chain disruptions. Targeting the specific needs of vulnerable groups is very important, fostering a transparent, collaborative, and resilient pharmaceutical ecosystem.

3.5. Strengthening the bond between the pharmaceutical industry and EU institutions through better information sharing, mainly focusing on cost structures and R&D expenditure, is an important strategic element.

3.6. To ensure a uniform and effective response across the EU, the EESC proposes that pharmaceutical companies and wholesalers notify authorities about potential shortages or disruptions; this should be established at the level of EU legislation (regulation) and automatically incorporated into the national legislation of EU Member States. It is vital for entities like the ECDC, EMA, EFPIA, Medicines for Europe and key stakeholders such as university hospitals to be involved in these efforts.

4. **Immediate and short-term measures**

4.1. The EESC emphasises the urgency of establishing continuous, real-time monitoring systems for medicine supply chains. This imperative underscores the critical need for immediate action to address the challenges posed by dynamic and evolving supply chain scenarios. A real-time monitoring framework is essential in order to promptly identify, assess, and respond to emerging issues, ensuring the resilience of the EU's medicine supply chains.

4.2. The integration of advanced technologies is essential. Incorporating AI and big data analytics into monitoring systems could enhance their responsiveness to supply chain changes. Such technological advancements include developing a medicine shortage monitoring and prevention system that aims for efficient procurement and availability of medicines at optimal prices.

4.3. International solidarity emerges as a key pillar in managing medicine shortages effectively ([4]). In recognising that medicine supply chains are interconnected globally, fostering solidarity ensures a cohesive response to shortages. If the EU could strengthen its pharmaceutical industry in global competition, the EU could contribute globally to a more robust and resilient medicine supply network by imposing specific standards, implementing codes of ethics, and using health diplomacy ([5]) by giving non-EU countries with limited resources access to essential medicines.

4.4. A transformative approach also involves recommending the creation of awareness campaigns and educational programmes to inform the public and healthcare professionals about managing medicine shortages. These initiatives should also focus on preventing hoarding by wholesalers, pharmacists and patients, particularly during crises, and should address the misuse of medicines ([6]), ([7]). It is imperative to implement government and health authority standards to ensure medication distribution aligns with patients' real needs, thereby preventing excess supply ([8]), ([9]).

5. **Structural measures for medium and long-term resilience**

5.1. Current industry projections indicate that, by 2030, half the global pharmaceutical market will be biopharmaceuticals (up from 20 % today); biologics are increasing their market share by around 2 % yearly ([10]).

5.2. Establishing a more attractive environment for science and technology will help Europe generate more breakthrough technologies and compete globally. Transforming its industrial activities toward bio-production could contribute to this goal while providing highly skilled jobs, reducing environmental impact, and increasing security of supply.

5.3. Ultimately, adequate incentives and regulatory and financial measures should be put in place to support European production capacity in order to facilitate the supply of critical medicines and avoid shortages. This applies to the manufacturing of APIs, but also to the biotechnology transition. To achieve greater health autonomy, Europe must be strong in all areas: the production of chemistry-based medicines, generics, biosimilars, vaccines and cutting-edge biopharmaceuticals.

([4]) Soliman, A. et al., 'WHO pandemic accord: full adherence to the principle of sovereignty', *The Lancet*, Volume 402, Issue 10410, pp. 1322-1323.
([5]) OJ C, C/2023/883, 8.12.2023, ELI: http://data.europa.eu/eli/C/2023/883/oj.
([6]) Casati A., Sedefov R., Pfeiffer-Gerschel T., 'Misuse of medicines in the European Union: a systematic review of the literature', *European Addiction Research* 18(5), 2012, pp. 228-45. doi: 10.1159/000337028.
([7]) Wise J., 'Prescription drug misuse in Europe is higher than previously thought', *BMJ*, vol. 354 i4304, 4 August 2016, doi:10.1136/bmj.i4304.
([8]) https://ec.europa.eu/eurostat/statistics-explained/index.php?title=Medicine_use_statistics.
([9]) https://www.europarl.europa.eu/news/en/press-room/20211019IPR15235/deal-on-stronger-role-for-eu-medicines-regulator.
([10]) https://www.globenewswire.com/news-release/2021/12/22/2357003/0/en/Biopharmaceutical-Market-Size-to-Hit-US-856-1-Bn-by-2030.html.

5.4. With the publication of a comprehensive Union list of critical medicines, there is an expectation that this resource will serve as a vital tool in public health management. Its main purpose is to enable the EU to proactively tackle potential supply vulnerabilities by highlighting key medicines.

5.5. Leveraging predictive analytics and scenario planning could significantly enhance the EU's ability to anticipate and manage potential supply-demand imbalances in medicine availability. This forward-looking approach empowers the EU to take preemptive measures, ensuring a more resilient and adaptive medicine supply chain.

5.6. When advocating closer collaboration among healthcare providers, national health authorities, manufacturers, and civil society organisations, the critical need is to utilise digital data and AI to analyse over 10 billion medicine packages sold annually in Europe. Rapid response mechanisms involving the ECDC, pharmacists, physicians and patients are essential for crises, to enhance treatment protocol and overall responsiveness.

5.7. The EESC encourages research and development in pharmaceutical manufacturing technologies, supports digital transformation in supply chain management, and promotes innovative logistics solutions to enhance efficiency.

5.8. The EESC calls for the active engagement of all relevant stakeholders in transparently developing and implementing structural measures for medium and long-term resilience in medicine supply.

5.9. Urgent reform of EU procurement rules is essential, integrating security of supply criteria and is anticipated in future Commission guidance. This reform, crucial for a resilient pharmaceutical sector, should include a streamlined approach to the joint procurement of medicines. The Critical Medicines Act ([11]), aiming to strengthen EU capabilities in medicine production, aligns with the EESC's objectives of enhancing medicine supply security and reducing dependency on external sources.

6. **International partnerships and diversification of supply chains**

6.1. The EESC recommends engaging in bilateral and multilateral agreements focused on trade in medicines, joint research initiatives, and shared manufacturing projects. These collaborations are essential for balancing global medicine distribution and mitigating the risks associated with single-source dependency. With a strong pharmaceutical industry, the EU can contribute to a more equitable and diversified global pharmaceutical landscape.

6.2. The EESC encourages EU pharmaceutical companies to diversify their supplier base and explore alternative sources of raw materials. Developing manufacturing capabilities in various geographical locations enhances supply chain resilience.

6.3. Considering global solidarity obligations and in response to the WHO pandemic treaty, the EESC emphasises the importance of international cooperation and shared responsibility in managing public health crises. This approach aligns with the EU's humanitarian commitments, ensuring that global responses to pandemics are cohesive, equitable, and rooted in solidarity.

6.4. By fostering a unified approach to managing medicine supply globally, with a strong pharmaceutical industry the EU can contribute to streamlined processes and more efficient regulatory practices, benefiting the entire pharmaceutical ecosystem.

6.5. The EESC is in favour of developing global risk assessment models to identify and address potential vulnerabilities in international pharmaceutical supply chains.

6.6. Regarding competitiveness, the EESC encourages promoting transparent fair-trade practices, responsible sourcing and eco-friendly manufacturing processes within the global pharmaceutical industry, to build a more sustainable and ethical supply chain.

([11]) OJ C, C/2024/1568, 5.3.2024, ELI: http://data.europa.eu/eli/C/2024/1568/oj.

7. In pursuit of global pharmaceutical integrity and public health protection, the EESC emphasises the need to harmonise quality and safety standards in pharmaceutical production between EU Member States and third countries. To prevent competitive disadvantages for the European industry, all manufacturers who import into the EU must adhere to the same high quality and safety standards.

8. **Sustainability and single market**

8.1. It is important to reinforce the principles of the single market, underscoring the importance of the free movement of goods, reducing trade barriers, and harmonising regulatory standards, particularly for pharmaceutical products.

8.2. The position of the EESC is clear – Europeans throughout the EU should not suffer from a lack of access to medicines. The EESC acknowledges the potential challenges of implementing single market principles, particularly the lower accessibility of medicines in low-income Member States.

8.3. The EESC calls for healthcare providers, social partners, patient advocacy groups, industry representatives and policymakers to be involved in collaboratively developing and implementing strategies for a sustainable pharmaceutical sector.

8.4. The EESC fosters public-private partnerships; this collaboration is envisaged to drive innovation and investment in the pharmaceutical supply chain, enhancing its sustainability and resilience for long-term stability.

Brussels, 21 March 2024.

The President
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