European Committee of the Regions

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DRAFT OPINION

Addressing medicine shortages

Rapporteur: **Erika Von Kalben (DE/Greens)**
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Deadline for tabling amendments:

3 p.m. (Brussels time) **on 4 June 2024**. Amendments must be submitted using the online tool for tabling amendments (available through the Members' Portal at https://memportal.cor.europa.eu/).

Number of signatures required: 32

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Draft opinion of the European Committee of the Regions – Addressing medicine shortages

I. INTRODUCTION

THE EUROPEAN COMMITTEE OF THE REGIONS

1. welcomes the European Commission's communication on addressing medicine shortages in the EU[1];

2. recalls the final report of the Conference on the Future of Europe recommending that European decision-makers ensure[2] strategic autonomy at EU level in order to avoid dependency on third countries for medicines (in particular active ingredients) and medical devices and to guarantee their availability for citizens;

3. highlights that the European Committee of the Regions has for years called for action[3] to decrease medicine shortages and to strengthen Europe's resilience and strategic autonomy;

4. welcomes the outcome of the November 2023 EPSCO Council debate on improving the EU's open strategic autonomy in the field of health, and backs the ministers' call for increased EU cooperation to ensure security of supply[4];

5. reiterates that the Treaties and the Charter of Fundamental Rights of the European Union guarantee access to preventive healthcare and to medical treatment under the conditions established by national laws and practices; points out that medicines are a vital part of this guarantee and stresses that all citizens, regardless of socioeconomic background and including those living in rural or the most peripheral areas of the Union, have the right to access appropriate, safe and affordable medical treatment;

6. celebrates its Memorandum of Understanding with the UN WHO Office for Europe and draws attention to the UN Sustainable Development Goals, and in particular Goal Nr. 3 aiming to 'provide access to safe and affordable medicines and vaccines for all'; points out that the EU, through its international agreement, is committed to implementing the SDGs in all policies and encourages the Member States to do the same;

7. points out that security of supply chains in health is one of the objectives of the New Industrial Strategy for Europe[5], updated in 2021, recognising that 'access to medical products and pharmaceuticals is crucial to Europe's security and autonomy in today's world'; independence

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1 **Error! Hyperlink reference not valid.**https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM%3A2023%3A672%3AREV1.

2 https://commission.europa.eu/strategy-and-policy/priorities-2019-2024/new-push-european-democracy/conference-future-europe_en.

3 https://cor.europa.eu/en/news/Documents/NAT%20Bulletin%20No.%202/COR-2020-01740-00-00-WEB-TRA-EN.pdf.

4 https://www.consilium.europa.eu/en/meetings/epsco/2023/11/30/.

5 https://commission.europa.eu/strategy-and-policy/priorities-2019-2024/europe-fit-digital-age/european-industrial-strategy_en.

in the supply of medicines should be part of the European security strategy in order to ensure the EU's actual and perceived security in the long term;

General comments

8. calls on EU leaders to firmly set EU sovereignty in the field of health within the security and defence, as well as resilience and competitiveness, agendas; expects the June European Council to have 'health' embedded in the Strategic Agenda 2024-2029;

9. is convinced that European independence in the health sector is an indivisible part of the wider EU's strategic autonomy and calls on the regional governments to gear their investment priorities towards pharmaceutical research and manufacturing;

10. clarifies that the delivery and supply bottlenecks occur predominantly in the field of generics, due to more complex supply chains and razor thin profit margins; clarifies that generics are developed to be the same as a medicine that has already been authorised. A company can only market a generic medicine once the 10-year exclusivity period for the original medicine has expired;

11. reiterates that supply bottlenecks can have an impact on the supply and availability of medicinal products and active substances as well as medical devices; points out that the unavailability of a medicine can lead to a shortage if there are no suitable treatment alternatives;

12. calls for a harmonised definition of a shortage (with supply and demand defined according to Article 2 of Regulation 123/2022/EU), as well as the implementation of EU-level methodologies to define 'critical medicines' (both at Member State and Union level);

13. highlights Europe's dependence on foreign suppliers, reaching up to 80% of volume with a very high trade concentration; warns that this degree of dependence makes Europe extremely vulnerable and significantly reduces its room for geopolitical manoeuvre in case of e.g. tension in the region of Taiwan Strait; reiterates its call for a comprehensive regulatory and support framework to support EU sovereignty in the field of health, respecting the subsidiarity principle;

14. warns against national legislation in some EU Member States introducing new obligations on pharmaceutical companies to maintain safety stocks of up to six months for certain medicines; instead finds the obligation for market authorisation holders to maintain the stability of supply across all countries where they market their product better suited; is concerned that national stockpiling further reduces the availability of the medicines concerned on the market and might make manufacturers unable to respond to demand surges in other countries; in addition considers such national stockpiles as being contrary to the idea of European solidarity and supports instead the EU solutions that work for the whole Union;

15. is convinced that the setting up of safety stocks of critical medicinal products should not hamper the availability and affordability of these products or harm the environment by inappropriate disposal at both European and global level. Given the global nature of pharmaceutical supply

chains, safety stocks should be proportionate and take into account the potential impact on shortages in other Member States and third countries. Marketing authorisation holders should set up and maintain a minimum safety stock of critical medicinal products which should be sufficient to cover two months' demand in all Member States where the product has been placed on the market. In order to avoid any interruption of access to critical medicinal products, national competent authorities may, in duly justified cases, grant an exemption from stockpiling obligations to the marketing authorisation holder, upon request, or adopt other complementary measures on the safety of stocks;

16. calls on the European Commission to develop and implement appropriate measures to reduce the amount of discarded and unused medicines; is convinced that reducing the amount of discarded medicines can help to support the efficient allocation of medicines while increasing the environmental impact and sustainability of the pharmaceutical sector; the measures called for are in line with the European Green Deal's objectives to reduce resource use and should therefore be part of an ecological, economic and social future for the EU;

The Role of Local and Regional Authorities (LRAs) and community pharmacies

17. reiterates that regional government, especially in federal states, often bears responsibility for regional health systems, including budgetary oversight and the management of healthcare services; any long-term shortages affect the resilience of local hospitals and may lead to negative health outcomes for patients;

18. points out that shortages keep getting more frequent and lasting longer; in 2023 every pharmacy across the EU spent on average almost 10 hours per week dealing with medicine shortages; compounded by the decrease in the number of community pharmacies, this affects patients' treatment and quality of care, especially in rural and remote areas;

19. Is concerned that the scarcity of pharmaceuticals and medical devices, coupled with a lack of qualified personnel, is absorbing additional capacities for the procurement of medicinal products or medical devices that then lack elsewhere;

On the EU Health Budget and the European Health Union

20. reiterates that the EU4Health programme 2021–2027[6] sets out four general objectives: 1) improving and fostering health; 2) protecting people; 3) access to medicinal products, devices and crisis-relevant products; and 4) strengthening health systems; recalls the CoR position in relation to the programme and its univocal support for a greater financial envelope than the one suggested by the Council;

21. condemns the Council's proposal to reallocate EUR 1 billion from the EU4Health budget to other policy areas in the current MFF; is shocked at the proposed volume of cuts (20% of the

6 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2021.107.01.0001.01.ENG.

health budget) and questions the commitment of the Council to EU strategic security in the field of health;

22. calls on the Belgian Presidency of the EU and its successor, Hungary, to protect the EU4Health budget and to continue to prioritise 'strengthening the EU's resilience to future health threats by reinforcing crisis management, supporting healthcare systems, and improving the security of medicines supply[7]' in the current and future term of office;

23. calls on the Commission to complete the European Health Union in order to meet the expectations of European citizens, as expressed in the final report of the Conference on the Future of Europe, improving effectiveness of European governance, in particular, in strengthening the EU's response to serious cross-border health threats, and taking into account the role of local and regional authorities and including public health among shared competences;

The role of the European Medicines Agency and security of supply

24. points to Regulation (EU) 2022/123[8] that empowers the EU to better prepare for and react to health crises quickly, efficiently and in a coordinated manner, assigning the European Medical Agency (EMA) the task of monitoring and mitigating potential or actual shortages of critical medicinal products and medical devices;

25. draws attention to the notices published by the EMA on critical shortages monitored at EU level by the Medicine Shortages Single Point of Contact (SPOC) Working Party;

26. recommends that national authorities monitor and communicate information on the impact of shortages of medicinal products on patients and consumers, and share relevant information through the EMA's Medicines Shortages Steering Group (MSSG); sees the role for the EMA too to communicate the necessary information to patients, consumers and healthcare professionals, including on estimated duration and available alternatives, and to manage those critical shortages, whether the medicinal product concerned by the critical shortage is covered by a centralised marketing authorisation or a national marketing authorisation, and to register such information on the European Shortages Monitoring Platform;

27. welcomes the launch of a European Voluntary Solidarity Mechanism for medicines (EVSM)[9], allowing any Member State facing a critical shortage of any medicine to notify the MSSG and request assistance in procuring medicine stocks; at the same time, points out that the administrative procedures are very cumbersome, and in many cases it is difficult to meet the criteria for initiating the process;

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7 https://belgian-presidency.consilium.europa.eu/en/programme/priorities/.

8 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32022R0123.

9 https://www.ema.europa.eu/en/documents/other/mssg-solidarity-mechanism_en.pdf.

28. highlights however that this mechanism has been ‘developed as a measure of last resort’ to be used only ‘under very limited conditions’ where no other possibilities remain on the table; the CoR is in favour of the modalities being unbureaucratic, practical and standardised in terms of communication and procedures;

29. Calls on the Commission to ensure that the approval process for new medicines is regulated in such a way that essential medicines are available in a timely manner; while maintaining the current level of medication safety;

On the Critical Medicines Alliance and Act

30. welcomes the launch of the Critical Medicines Alliance (CMA) and its objective to provide the Commission and other EU decision-makers with sound and independent scientific advice on the most appropriate action and instruments to tackle medicines shortages; considers the Alliance to be an intermediate, pragmatic step towards future, more effective, legislation;

31. requests that the Commission revise the CMA terms of reference to explicitly include the CoR in Article 6.1 as one of the organisations ‘invited to participate in the Forum’;

32. calls on the future President of the European Commission to commit to a future, fully-fledged Critical Medicines Act as an important element of the European Health Union building on from the Critical Raw Materials Act;

33. commends the Belgian Presidency of the EU for its efforts to lay the groundwork for the Critical Medicines Act and calls on Hungary and Poland to keep the work going to ensure the security of supply of critical medicines and crisis-relevant medical countermeasures;

34. argues that particular attention should be paid to the specific challenges of remote rural areas, mountainous and island areas, and outermost regions; while medicine shortages have a negative impact on all territories, their impact is multi-fold in more vulnerable areas;

35. Calls on the EMA to ensure that the stockpiling of critical medicines does not harm the population; an artificial or regulatory shortage of supply must be prevented;

On important projects of common European interest

36. points out that the US and Europe are leaders in the publication of research papers, but the former leads in terms of patents (7 to 1); European innovative technologies are also less likely to be developed in Europe because of limited access to private funding;

37. welcomes in this regard the launch of the Important Projects of Common European Interest (IPCEI) and its health call, designed to bring together the public and private sectors to undertake large-scale projects of significant benefit to Europe and its citizens; the funding should cover R&D and early industrial deployment phases;

38. calls on all Member States to join the IPCEI Health and promote innovation, circularity and the overall sustainability of healthcare products and technologies;

39. recognises at the same time that the IPCEI modality is not a panacea for all, as the instrument tends to favour larger companies, as well as countries with more fiscal and administrative resources, to the detriment of small and medium enterprises for example; calls for SMEs to have equal opportunities for funding and to receive funding advice and knowledge;

On State aid and procurement

40. looks forward to the EU's guidance on procurement[10], which is announced for early 2024 and expected to focus 'on procurement practices that can make a direct contribution to security of supply and availability through effectively integrating supply security as an award criterion';

41. calls on the Commission to relax State aid rules (tax concessions and funding), in order to encourage companies to operate in Europe, from the manufacturing to the packaging and distribution stages to foster European competitiveness, innovation and further develop European industry;

42. is convinced that the Commission should procure medicines jointly with Member States in crisis situations; underlines that the larger the buyer the better chance of obtaining the necessary medicine at a reasonable price; emphasises that joint procurement does not involve mandatory participation; expresses its support to open up joint procurement modalities in the field of medicines to willing Member States wishing to procure medicines together;

43. Recommends that in public procurement law, the production location and the safeguarding of European security of supply are given greater weight than economic criteria; contracting authorities should give preferential treatment to the production of active ingredients in the EU Member States;

44. calls on the European Commission to establish a quota criterion of origin by means of a lottery procedure for the procurement of medicines; this is in line with the Agreement on Government Procurement[11] (GPA), as illustrated by the special exemptions for health protection;

45. calls for more funding for basic research into new medicinal products located in Europe and to foster an appealing environment for the research, development, and manufacturing of pharmaceuticals within the Union while reducing regulatory and administrative burdens; recommends more attention be given to the question of patenting in the EU; recommends too that funding and public support for pharmaceutical research be linked to manufacturing in Europe, creating new opportunities for R&D institutes to test their inventions and market them

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10 https://commission.europa.eu/system/files/2023-10/Communication_medicines_shortages_EN_0.pdf.

11 https://www.wto.org/english/tratop_e/gproc_e/gp_gpa_e.htm.

first in the Union; State aid for projects relating to pharmaceuticals could also be linked to production in Europe;

46. agrees with the European Commission's draft proposal on shortening market exclusivity for patent holders in the EU; calls on the co-legislators to carefully weight the benefits of more accessibility and affordability to patients vs profitability of patent holder companies;

47. Calls for more transparency to the results and pricing of pharmaceutical products, as well as making it clear how much government support has been invested in research and production; supports the Commission's view that the evaluation of the existing Transparency Directive offers the opportunity to look at pricing and reimbursement;

48. recommends that State aid target the existing vulnerabilities, prioritising e.g. the development of therapeutical alternatives, or boosting production at other sites;

On diversification and reshoring

49. considers the diversification of production sites and supply partners to be important tools to strengthen supply chain resilience and efficiency in the complex and globalised pharmaceutical industry setting;

50. argues that increasing local production in the EU not only improves security of supply but can also offer higher quality, improved flexibility to react to short-term changes in demand, and the opportunity to steer production to the most critically needed medicines and devices; Moreover, it strengthens local economies and ensures higher protection of labour rights and the environment through the applicability of European legal frameworks;

51. emphasises also that APIs produced in Europe would bring savings in terms of transportation and time, through faster and more reliable deliveries;

52. is aware of the higher production costs in the EU compared to Asian suppliers, particularly for generic medicines, and calls on Member States to take this into account when pricing medicine products; the actual value of medicines should be reflected and price setting should be more transparent;

53. calls for more transparency in the supply chains and the 'made in the EU' seal to increase consumers' awareness and enable them to make informed choices where options are available and possible;

54. recommends that the Commission conduct an in-depth analysis of the three projects supporting API production in the Member States and evaluate their impact and long-term viability;

55. calls on academia to come forward with new, clean ways of sourcing active ingredients, compatible with the EU Green Deal, environmental and labour legal frameworks;

56. agrees that strategic partnerships with third countries for the production of critical medicines and APIs can also reduce reliance on a handful of foreign providers; expects more global competition to be beneficial for the overall security of supply;

57. calls for, in the event of emergencies, regulations on the packaging of medicines to be relaxed pragmatically and unbureaucratically in order to enable flexible allocation to bottlenecks; added QR-Codes on packaging could help here;

On foreign direct investment

58. calls on the Commission and the Member States to screen foreign direct investment (FDI) in pharmaceutical manufacturing plants, which are part of Europe's critical health infrastructure;

59. welcomes in this regard the publication of the proposal for a new regulation, repealing and replacing the current EU FDI Screening Regulation, published on 24 January 2024 and including critical medicines; calls on the Council and the Parliament not to delay work on this file;

Digitalisation and data collection and monitoring

60. calls on the Commission and the Council to draw up recommendations addressed to the Member States on the basis of stress tests designed to assess the resilience of public health systems, in order to identify risk factors and address vulnerabilities, also including medicine shortages;

61. calls on the Member States to establish IT systems for data collection and monitoring for human medicines, and to ensure they are interoperable with the European Shortages Monitoring Platform;

62. recommends accelerating digitalisation of national systems and better data sharing along the whole chain; calls on the four remaining Member States that have no online register for human medicines available to set one up as soon as possible; national and regional systems must be interoperable to enable better data exchange across the EU;

63. suggests also creating more user-friendly, transparent and publicly available catalogues of medicine shortages, including information on the tentative duration of shortages and the reasons for them;

64. calls on the Commission to investigate how the data collected within the European Medicines Verification System (EMVS) could feed automatically into the European Shortages Monitoring Platform; recommends exploring all possible avenues to bring together data from existing databases before creating additional demands on public authorities and business operators; is aware of the industry preference to use the EMVS system to detect shortages; considers however that it does not provide sufficient data for the authorities;

65. Reiterates its call that all national datasets must be based on European interoperability standards so that these data are semantically and syntactically consistent with existing systems;

66. Calls for clear definitions of unavailability and shortage to be agreed Europe-wide on the basis of the data; calls also for a debate on more standardised pathways of how to act in face of a shortage and for more communication between the Member States on mending the fragmentated EU healthcare systems and pharmaceutical market;

67. advocates that medicinal products can be clearly assigned via the complete supply chain; the numerical assignment should include the destination of the delivery and the manufacturing country;

68. stresses that public authorities need the right type of data to regulate the market; finds it important that marketing authorisation applicants submit, unless where duly justified and ethical, data from active-control clinical trials in order to avoid the unnecessary repetition of clinical studies, and that they uphold high scientific standards and ethical principles;

69. calls on the Commission to include in the EU Statistics on Income and Living Conditions (EU-SILC) data on self-reported unmet needs regarding access to medicines, to complement the statistics on unmet needs regarding treatment and care;

70. calls on Member States to collect the relevant data at regional level in order to facilitate more granular research into the causes and consequences of the lack of access to medicines across different EU regions.

Brussels,

II. PROCEDURE

Title	Addressing medicine shortages
Reference document	COM(2023) 672 final
Legal basis	Own initiative on the basis of the Commission Communication (Article 41(b)(i))
Procedural basis	
Date of the Council/EP referral/ Date of Commission letter	
Date of Bureau/President's decision	
Commission responsible	NAT commission
Rapporteur	Erika Von Kalben (DE/Greens)
Discussed in commission	22/3/2024
Date adopted by commission	22/3/2024
Result of the vote in commission	unanimity
Date adopted in plenary	Scheduled for 19-20 June2024
Previous CoR opinion(s)	• CDR-5487-2020: European Health Union: Strengthening the EU's resilience • CDR-5525-2020 Europe's pharmaceutical strategy and legislative proposal amending the mandate of the European Medical Agency (EMA) • CDR-4928-2019 HERA • CDR-4155-2020 Experiences and experiences from regions and cities during the COVID-19 crisis
Subsidiarity reference	No subsidiarity or proportionality concerns.