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COVER NOTE

From:	European Committee of the Regions
date of receipt:	19 May 2021
To:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union
Subject:	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices - *Opinion of the European Committee of the Regions*

Delegations will find attached the opinion adopted by the European Committee of the Regions on the above.

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https://dmsearch.cor.europa.eu/search/opinion

European Committee of the Regions

NAT-VII/015

144th plenary session, 5-7 May 2021

OPINION

A pharmaceutical strategy for Europe and legislative proposal for changing the mandate of the European Medicines Agency (EMA)

THE EUROPEAN COMMITTEE OF THE REGIONS

- welcomes the proposal for a regulation reinforcing the European Medicines Agency's mandate for crisis preparedness and management of medicinal products and medical devices; calls for the greatest possible transparency in the activities of the EMA and its working parties;

- calls for a coordinated approach to the development, production and distribution of medicinal products and medical devices with the potential to prevent, diagnose or treat diseases that present a threat to public health; finds it imperative to ensure that the needs at local and regional level can be expressed and met, and that there are communication channels between the executive steering groups and local and regional authorities;

- strongly supports the Pharmaceutical Strategy for Europe as everyone should have access to safe and effective medicines at affordable prices; cooperation between Member States with the involvement of local and regional level is vital on the evaluation, pricing and procurement of medicinal products;

- supports the strategy seeking to promote competition in the pharmaceutical market, and emphasises that measures to stimulate access to generic and biosimilar medicines are urgently needed; supports an in-depth mapping of the causes of medicine shortages and looks forward to robust proposals for measures to ensure access to medicines both in normal circumstances and in a crisis;

- considers it vital to create the conditions for innovation and use of new technologies for the EU to maintain a competitive pharmaceutical industry, while ensuring that there is sufficient clinical evidence on safety and efficacy when authorising new medicines;

- advocates learning from the COVID-19 pandemic in order to achieve robust multilateral cooperation to support the development and production of safe and effective vaccines, diagnostics and treatments, and for fair and efficient funding and distribution of future vaccines and medicines.

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Opinion of the European Committee of the Regions
– A pharmaceutical strategy for Europe and legislative proposal for changing the mandate of the European Medicines Agency (EMA)

I. RECOMMENDATIONS FOR AMENDMENTS

Proposal for a Regulation of the European Parliament and of the Council on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices
COM(2020) 725 final

Amendment 1
Recital 7

Text proposed by the European Commission	*CoR amendment*
[...] It is therefore important to address the question of shortages and to reinforce and formalise monitoring of critical medicinal products and medical devices.	[...] It is therefore important to address the question of shortages and to reinforce and formalise monitoring of critical medicinal products and medical devices***, at a level that is of the greatest possible benefit to Member States***.

Reason
An EU-wide response to shortages of medicinal products and medical devices is urgently needed. However, monitoring and the administrative burden on Member States during a crisis must be proportionate to the benefits.

Recommendation for amendment 2
Article 3(5)

Text proposed by the European Commission	*CoR amendment*
The Medicines Steering Group shall be supported in its work by a working party comprised of single points of contact related to shortages from national competent authorities for medicinal products established in accordance with Article 9(1).	The Medicines Steering Group shall be supported in its work by a working party comprised of single points of contact related to shortages from national competent authorities for medicinal products established in accordance with Article 9(1). ***The working party shall, where appropriate, maintain contact with local and regional authorities with responsibility for healthcare.***

Reason
In 19 out of 27 Member States, the local and regional level is responsible for healthcare. If the monitoring of medicine shortages is to work properly and add value, this level of government needs to be involved in the process.

Recommendation for amendment 3

Article 11(4)(b)

Text proposed by the European Commission	*CoR amendment*
b) inform the Medicines Steering Group of any measures taken and report on the results of those measures, including information on the resolution of the potential or actual shortage.	b) inform the Medicines Steering Group ***within a reasonable timeframe*** of any measures taken and report on the results of those measures, including information on the resolution of the potential or actual shortage.

Reason
Member States need to have a reasonable period of time to inform the steering group, as compiling the information may impose an administrative burden on the healthcare system when it is under pressure in a crisis.

Recommendation for amendment 4

Article 12(f)

Text proposed by the European Commission	*CoR amendment*
f) liaise with third countries and relevant international organisations, as appropriate, [...]	f) liaise with third countries and relevant international organisations***, in particular the World Health Organization (WHO)***, as appropriate, [...]

Reason
Global cooperation with the WHO is vital, and worth highlighting in this context.

Recommendation for amendment 5

Article 14(5)

Text proposed by the European Commission	*CoR amendment*
The Chair may invite representatives of Member States, members of scientific committees of the Agency and working parties, and third parties, including representatives of medicinal product interest groups, marketing authorisation holders, developers of medicinal products, clinical trial sponsors, representatives of clinical trial networks, and interest groups representing patients and healthcare professionals to attend its meetings.	The Chair may invite representatives of Member States ***and local and regional authorities***, members of scientific committees of the Agency and working parties, and third parties, including representatives of medicinal product interest groups, marketing authorisation holders, developers of medicinal products, clinical trial sponsors, representatives of clinical trial networks, and interest groups representing patients and healthcare professionals to attend its meetings.

Reason
In many Member States, local and regional authorities are responsible for healthcare.

Recommendation for amendment 6

Article 18(c)

Text proposed by the European Commission	*CoR amendment*
c) as part of its regulatory tasks, make use of digital infrastructures or tools, to facilitate the rapid access to or analysis of available electronic health data generated outside the scope of clinical studies, and the exchange of such data between Member States, the Agency, and other Union bodies;	c) as part of its regulatory tasks, make use of digital infrastructures or tools, to facilitate the rapid access to or analysis of available electronic health data generated outside the scope of clinical studies, and the exchange of such data between Member States, the Agency, and other Union bodies***, in accordance with applicable Union legislation on the protection of personal data***;

Reason
The importance of secure data sharing and protection of personal data needs to be highlighted.

Recommendation for amendment 7

Article 19(5)

Text proposed by the European Commission	*CoR amendment*
The Medical Devices Steering Group shall be supported in its work by a working party comprised of single points of contact from national competent authorities for medical devices established in accordance with Article 23(1).	The Medical Devices Steering Group shall be supported in its work by a working party comprised of single points of contact from national competent authorities for medical devices established in accordance with Article 23(1). ***The working party shall, where appropriate, maintain contact with local and regional authorities with responsibility for healthcare.***

Reason
In 19 out of 27 Member States, the local and regional level is responsible for healthcare. If the monitoring of critical medical devices is to work properly and add value, this level needs to be involved in the process.

Recommendation for amendment 8

Article 25(4)(d)

Text proposed by the European Commission	*CoR amendment*
d) inform the Medical Devices Steering Group of	d) inform the Medical Devices Steering Group

any measures taken and report on the results of those measures, including information on the resolution of the potential or actual shortage.	***within a reasonable timeframe*** of any measures taken and report on the results of those measures, including information on the resolution of the potential or actual shortage.

Reason
Member States need to have a reasonable period of time to inform the steering group, as compiling the information may impose an administrative burden on the healthcare system when it is under pressure in a crisis.

Recommendation for amendment 9

Article 26(e)

Text proposed by the European Commission	***CoR amendment***
e) liaise with third countries and relevant international organisations, as appropriate, [...]	e) liaise with third countries and relevant international organisations***, in particular the World Health Organization (WHO)***, as appropriate, [...]

Reason
Global cooperation with the WHO is vital, and worth highlighting in this context.

II. POLICY RECOMMENDATIONS

Part 1: THE EUROPEAN COMMITTEE OF THE REGIONS

On the proposal for a Regulation on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices

1. welcomes the proposal for a regulation reinforcing the European Medicines Agency's mandate for crisis preparedness and management for medicinal products and medical devices. The proposal is consistent with the call that the CoR made in its opinion on an EU Health Emergency Mechanism;

2. calls, in light of experience with the COVID-19 pandemic, for a coordinated approach to be taken in crisis situations to the development, production and distribution of medicinal products and medical devices with the potential to prevent, diagnose or treat diseases that present a threat to public health;

3. notes that, although health policy is a primary competence of the Member States, the EU has an important complementary and coordinating role to play, including in ensuring that the internal market for medicines and medical devices is maintained and functions well even during emergencies;

4. stresses that the proposal for a regulation will have a major impact on local and regional authorities, which in 19 out of 27 Member States are responsible for healthcare and have a central role in their country's crisis preparedness and management. It is therefore imperative to ensure that needs at local and regional level can be expressed and met, and that there are communication channels between the executive steering groups on medical devices and shortages of medicinal products and local and regional authorities;

5. takes the view that the proposal concerning Member States' obligations to monitor and reduce shortages of critical medicinal products and medical devices represents a major commitment. In order for the EMA to have access to relevant, quality-assured data and information on the need for and shortages of medicinal products and medical devices, it must be possible to obtain such information from the local and regional level;

6. draws attention to the fact that healthcare services and local and regional authorities may be under considerable pressure in crisis situations, and that administrative burdens on them should be minimised. Reporting requirements and timelines therefore need to be reasonable and manageable, while at the same time enabling swift action that is of the greatest possible benefit to Member States, in line with the subsidiarity principle;

7. stresses that, while access to and exchange of health data and other information related to crisis preparedness in healthcare is essential in order to effectively deal with crises and other major events, it is important to handle sensitive information with great care and to ensure privacy and data security;

8. very much welcomes the proposal for an Emergency Task Force to support the rapid development and deployment of medicinal products that can help tackle threats to public health, and the fact that the task force will cooperate widely with other EU bodies, the WHO and countries outside the EU;

9. welcomes the proposal's emphasis on cooperation with relevant bodies such as the European Centre for Disease Prevention and Control (ECDC) during public health emergencies, and stresses the need to avoid duplication of effort between authorities;

10. looks forward to receiving more information on how the EMA will interact with the proposed European Health Emergency Preparedness and Response Authority (HERA);

11. calls for the greatest possible transparency in the activities of the EMA and its working parties.

Part 2: THE EUROPEAN COMMITTEE OF THE REGIONS

On the Communication on a Pharmaceutical Strategy for Europe

12. expresses its strong support for the Commission's launch of a Pharmaceutical Strategy for Europe with the overall objective of access to and accessibility of medicinal products for patients, and stresses that all citizens throughout the EU should have access to safe and effective medication;

13. draws attention to the fact that 19 out of 27 Member States have opted to give local and regional authorities primary responsibility for health, care and public health. Even in countries with national health systems, responsibility for social services and social care often lies at local level. Local and regional authorities therefore play key roles in the funding, evaluation, procurement and provision of medicines and in crisis management and preparedness. It is therefore essential for the local and regional level to be involved in the forms of cooperation proposed in the pharmaceutical strategy;

14. is in favour of the strategy promoting accessibility of medicines in the case of unmet needs and stimulating research and innovation in line with the needs of patients and the healthcare system. There is an urgent need for dialogue to agree on which medical fields include unmet needs, so that no area is missed;

15. particularly welcomes the extensive efforts proposed to tackle antimicrobial resistance, and stresses the importance of promoting the prudent and restrictive use of antibiotics and of creating incentives for developing and manufacturing new antibiotics and keeping older ones on the market;

16. sees a need to promote access to medicines for rare diseases and for children, and therefore welcomes the evaluation of the legislation on such medicines. In their current form, the incentives are not having the desired effect, but have instead resulted in medicines with limited evidence of efficacy and safety that are very expensive and therefore difficult for healthcare systems to prioritise;

17. stresses that affordable prices are a prerequisite for patients' ability to get the medication they need and for the sustainability of healthcare systems. At present, there are cases where severely ill patients cannot obtain the medication they need because prices are so high, for example in the case of medicines for severe rare diseases;

18. notes that the pharmaceuticals market is currently dysfunctional, with secret price agreements and a lack of transparency. Companies may choose not to market their medicines in certain countries. It is therefore positive that the strategy seeks to promote competition in the pharmaceutical market in various ways, including through a review of competition law. In this context, measures to stimulate access to generic and biosimilar medicines are urgently needed;

19. considers it vital to promote cooperation between Member States on the evaluation of medicinal products, pricing and procurement, and stresses the importance of ensuring that the local and

regional level, which in many countries is responsible for and funds healthcare, is represented in such forms of cooperation;

20. agrees with the Commission that the European pharmaceutical industry has a vital role in research, public health, employment and trade. It is extremely important to create the conditions for innovation and the use of new technologies, such as gene therapy, artificial intelligence and personalised medicine, if the EU is to maintain a competitive pharmaceutical industry;

21. supports the Commission's proposal for a European health data space to promote cross-border data analysis and thus improve research, healthcare delivery and oversight; stresses the need for healthcare services to be able to benefit from such infrastructure. It is vital to ensure the security of patients' privacy and data rights;

22. stresses that patients must have confidence and certainty that new medicines are safe and effective, and highlights the importance of ensuring that there is sufficient clinical evidence when authorising medicines. If patient safety and efficacy are not adequately documented, it may be difficult for healthcare deliverers and payers to take a decision on new treatments, and patients' access to treatment may be delayed or prevented. Regulatory fast tracking therefore risks having the opposite effect. In this context, it is important for the EMA to cooperate with health technology assessment authorities, but also with representatives of healthcare deliverers and payers at regional level;

23. points out that medicine shortages have long been a problem in healthcare, and that this has become even more evident during the COVID-19 pandemic. The CoR is therefore in favour of an in-depth mapping of the causes of medicine shortages and welcomes the Commission's intention to revise pharmaceutical legislation to enhance security of supply. The Committee notes that the proposals in the pharmaceutical strategy are not particularly concrete, and looks forward to seeing robust proposals for measures to ensure the EU's strategic autonomy in order to safeguard access to medicines both in normal circumstances and in a crisis;

24. reiterates the call it made in its opinion on an EU Health Emergency Mechanism to promote the development and production of essential medicines on European soil and to create incentives for manufacturers, in order to reduce dependency on third countries;

25. advocates, with regard to strengthening the EU's mechanisms for handling health crises, learning as much as possible from the COVID-19 pandemic in order to achieve robust multilateral cooperation to support the development and production of safe and effective vaccines, diagnostics and treatments, and for fair and efficient funding and distribution of future vaccines and medicines;

26. welcomes the proposal for a European Health Emergency Preparedness and Response Authority (HERA), and looks forward to seeing a fleshed-out proposal on the new authority's mandate;

27. welcomes the fact that the Commission is proposing to revise pharmaceutical legislation to strengthen the environmental risk assessment requirements for medicines. It is important for this to cover both the manufacture and the use of medicines. The CoR is very much in favour of

international efforts to address environmental risks related to pharmaceutical emissions from manufacturing in non-EU countries;

28. also sees it as positive that the Pharmaceutical Strategy emphasises that the pharmaceutical industry should contribute to the EU's climate neutrality, with a focus on reducing greenhouse emissions along the value chain;

29. is strongly in favour of the EU developing global cooperation in the field of pharmaceuticals.

Brussels, 7 May 2021

The President
of the European Committee of the Regions

Apostolos Tzitzikostas

The Secretary-General
of the European Committee of the Regions

Petr Blížkovský

III. PROCEDURE

Title	A pharmaceutical strategy for Europe and legislative proposal for changing the mandate of the European Medicines Agency (EMA)
Reference(s)	Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions – Pharmaceutical Strategy for Europe COM(2020) 761 final Proposal for a Regulation of the European Parliament and of the Council on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices COM(2020) 725 final
Legal basis	Article 307(4) TFEU
Procedural basis	Rule 41(a) of the Rules of Procedure
Date of Council/EP referral/Date of Commission letter	14 December 2020
Date of Bureau/President's decision	2 December 2020
Commission responsible	Commission for Natural Resources (NAT)
Rapporteur	Birgitta Sacrédeus (SE/EPP)
Analysis	4 December 2020
Discussed in commission	22 March 2021
Date adopted by commission	22 March 2021
Result of the vote in commission (majority, unanimity)	unanimity
Date adopted in plenary	7 May 2021
Previous Committee opinions	
Date of subsidiarity monitoring consultation	N/A