



**FVE feedback on the European Commission's
Proposal for a Regulation on a reinforced role for the European
Medicines Agency in crisis preparedness and management for
medicinal products and medical devices**

The Federation of Veterinarians of Europe (FVE) welcomes the European Commission's Proposal for a Regulation on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices and our opportunity to comment on it.

General remarks:

- FVE **welcomes extending the mandate** of the European Medicines Agency (EMA) to mitigate better shortages of medical products and medical devices in order to ensure a more effective and coordinated public health emergency reaction.
- FVE **misses in the proposal the much needed One Health approach^{i,ii,iii}**. Undoubtedly the Covid-19 pandemic, likewise SARS and MERS indicate that health of humans, animals and the environment are inextricably linked. Our planet becomes more populated, more interconnected via the increasing global trade and challenged by climate change. This leads to increasing contacts between wildlife and intermediate hosts, animals and humans, which enhances the possibility for outbreaks of zoonotic diseases. The majority (72%) of emerging diseases of humans are caused by zoonotic pathogens, with most originating in wildlife, especially non-human primates, rodents and bats, rather than in livestock. This crisis revealed the need for a paradigm shift, including holistic consideration of our environment and the intersectoral collaboration between doctors, veterinarians and environmental experts using the One Health approach.

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- Medicinal products and medical devices used in human and veterinary medicines are very similar with many overlaps (the same active substances used in human and veterinary medicinal products, medical devices which are both used in human and veterinary medicine). The impact on veterinary medicines of putting medicines on the critical list should be taken into consideration.
- Following the One Health approach, **having enough and well-distributed veterinary medicines or vaccines** will be vital for certain public health emergencies. Therefore, the proposal should clarify that medicines mean all human and veterinary medicines, which are important for a certain public health emergency. As emerging diseases often start in animals, it is important to control them in animals, so that they do not move to human and potentially initiate a pandemic (e.g., some of the influenza viruses). This means that occasions can occur where **certain veterinary medicines are critical or veterinary devices are critical to detect diseases at the origin and to prevent/control that in animals.**
- It is important to ensure a well-developed **division of tasks and good coordination between the different agencies** (European Medicines Agency, European Centre for Disease Prevention and Control, and the future Health Emergency Response Authority (HERA) to avoid competing competences and overlap.
- Due to the urgency, this proposal has been done without a proper impact assessment. Over the years, EMA has already been given a lot of extra tasks without a proper budget attached. In the recent year, the workload to assess therapeutics and vaccines for covid and the measurement of the post-authorisation safety, has made that the agency had a much higher workload than normal and led to the need to postpone or stop some other lower-priority activities. To extend this mandate, **proper resources should be dedicated.**
- Healthcare professions, including veterinarians, are often the first to notice shortages. Therefore, the Agency should establish a robust system for the exchange of information on the availability of human and veterinary medicines and medical devices with relevant health professions.

Specific proposals:

Commission proposal	Suggested amendment
<p>Whereas</p>	<p>(new)</p> <p>As the health of humans, animals and the environment are inextricably linked and similar medicines and medical devices are used for humans and animals, it is crucial to take a ‘One Health’ approach. This is also paramount as we know that the majority (72%) of emerging diseases of humans are caused by zoonotic pathogens, with origin in animals, mostly wildlife.</p>
<p>Article 1: Subject matter</p> <p>(a) prepare for and manage the impact of major events on medicinal products for human use and of public health emergencies on medicinal products for human use and on medical devices;</p> <p>(b) monitor and report on shortages of medicinal products for human use and medical devices;</p> <p>(c) provide advice on medicinal products for human use with the potential to address public health emergencies;</p>	<p>(a) prepare for and manage the impact of major events on medicinal productsfor human use and of public health emergencies on medicinal products and on medical devices;</p> <p>(b) monitor and report on shortages of medicinal products for human use and medical devices;</p> <p>(c) provide advice on medicinal products for human use with the potential to address public health emergencies;</p>
<p>Article 2 definitions</p>	

<p>(b) 'medicinal product' means a medicinal product as defined in point (2) of Article 1 of Directive 2001/83/EC of the European Parliament and of the Council;</p>	<p>(b) 'medicinal product' means a medicinal product as defined in point (2) of Article 1 of Directive 2001/83/EC and Directive 2001/82/EC of the European Parliament and of the Council;</p>
<p>(d) 'shortage' means that supply of a medicinal product for human use or a medical device does not meet demand for that medicinal product or medical device;</p>	<p>(d) 'shortage' means that supply of a medicinal product for human use or a medical device does not meet demand for that medicinal product or medical device;</p>
<p>Article 13</p> <p>The Agency shall, via its web-portal and other appropriate means, in conjunction with national competent authorities, inform the public and interest groups with regard to the work of the Medicines Steering Group.</p>	<p>A warning system should be established to collaborate with relevant stakeholders, including health professionals in respect to shortages and critical medicines.</p> <p>The Agency shall, via its web-portal and other appropriate means, in conjunction with national competent authorities, inform the public and interest groups with regard to the work of the Medicines Steering Group.</p>

Note: The Federation of Veterinarians of Europe (FVE) represents the veterinary profession in Europe. FVE represents about 300 000 veterinarians from 39 countries through their national veterinary associations and Sections. One Health is a core priority of FVE ([FVE Strategy 2021-2025](#)). Additionally, FVE has been long working and promoting One Health for many years already, e.g.

- COVID-19 and One Health: can we do better?
https://fve.org/cms/wp-content/uploads/FEAM-FVE-WEBINAR-Summary-report_Final.pdf
- EU Health Policy Platform Joint Statement on Antimicrobial Resistance (AMR)
https://epha.org/wp-content/uploads/2018/02/antimicrobial-resistance-joint-statement_final.pdf
- Natural disasters and “One –Health” Are we prepared?
https://fve.org/cms/wp-content/uploads/Conclusions_FINAL.pdf

The above information only represents a small part of overall FVE One-Health initiatives.

References:

- ⁱ The Berlin principles on one health – Bridging global health and conservation
<https://www.sciencedirect.com/science/article/pii/S0048969720364494?via%3Dihub>
- ⁱⁱ A European One Health Action Plan against Antimicrobial Resistance (AMR)
https://ec.europa.eu/health/sites/health/files/antimicrobial_resistance/docs/amr_2017_action-plan.pdf
- ⁱⁱⁱ Council conclusions on the next steps under a One Health approach to combat antimicrobial resistance
<https://www.consilium.europa.eu/en/press/press-releases/2016/06/17/epsco-conclusions-antimicrobial-resistance/>