

To the attention of:
Vice-President for Promoting our European Way of Life Margaritis Schinas
Commissioner for Health and Food Safety Stella Kyriakides
European Commission
Rue de la Loi, 200
1049 Brussels

Date

RE: The Pharmaceutical Strategy is a chance to tackle antimicrobial resistance that Europe cannot miss

Dear Vice-President Schinas,
Dear Commissioner Kyriakides,

We welcome the initiative taken by the European Commission to release a new Pharmaceutical Strategy for Europe later this year in order to create a future-proof pharmaceutical regulatory framework that promotes R&I while addressing market failures and shortages and ensuring environmental sustainability.

Antimicrobial resistance (AMR) is a key cross-border health issue for Europe and the world. This silently growing pandemic is already affecting our health today and will increasingly do so in the future. Without effective action, AMR will take us back to a pre-antibiotic age when death by infection was much more common.

Each year, 750,000 people die globally as a consequence of drug-resistant bacteriaⁱ – with 33,000 annual deaths in Europe.ⁱⁱ The World Bank estimates that AMR could push 28 million people into extreme poverty by 2050ⁱⁱⁱ with an annual economic impact of more than USD \$1 trillion after 2030.^{iv}

The COVID-19 crisis has exposed the weaknesses of our healthcare systems and revealed underlying inequalities, but these are not new and have long been recognised in the fight against AMR. The Pharmaceutical Strategy provides a momentum to bring positive change.

To make it happen, the Pharmaceutical Strategy needs to integrate both the development of, and access to affordable and quality antimicrobials in a sustainable environment as a key component. In line with the recently adopted EP resolution on the EU's public health strategy post-COVID-19^v, we are calling on the European Commission to adopt the following recommendations:

- **Strengthen the EU's role in global discussions about antibiotic shortages, with a focus on making supply chains resilient to disruptions**

The EU should play a bigger role in multilateral discussions to address shortages of antibiotics which can force treatment providers to prescribe, as an alternative, broad-spectrum antibiotics that hasten the development of resistance. It should ensure diversity of supply, promote joint procurement practices, and rethink economic models.

- **Address the market failures in antibiotic research and innovation (R&I), particularly in the later stages of clinical research**

The EU should adopt an end-to-end approach and support the development of needs-driven models to fix the antibiotic development pipeline, while ensuring both responsible use and equitable and affordable access. In this context, the EU should put forward new models that delink the R&I cost from the prices of products through alternative mechanisms such as milestone prizes.

- **Reduce our dependence on antibiotics through prevention activities, research into alternatives, and consumption targets**

The EU should put the emphasis on prevention activities across sectors and foster research into alternatives, such as phage therapy, to reduce our dependence on antibiotics. It should also set EU-wide consumption targets to reduce inappropriate prescribing practices and support improved control mechanisms to ensure these targets are effectively met.

- **Ensure transparency in the pharmaceutical industry throughout the value chain**

The EU should establish a strong legislative framework to increase transparency in the pharmaceutical sector, from R&I aspects (where public funding should be linked to conditions) through market authorisation to environmental risks. This needs to be ensured throughout the value chain, including in the supply chain where worrying antibiotic manufacturing pollution scandals have been observed.

- **Mitigate environmental risks from production, use and disposal of antibiotics**

The EU should develop binding measures to mitigate the development of resistance in the environment. This means strengthening manufacturing requirements, including the risk for the development of AMR in Environmental Risk Assessments, and setting quality standards and concentration limits in water and soil.

AMR is a key area where European citizens rightly expect firm European action. As it cannot be tackled efficiently at national level, we call for the Pharmaceutical Strategy to be a stepping stone to an ambitious regulation that would address human, animal, and environmental health in a 'One Health' approach and include non-pharmaceutical aspects such as monitoring and surveillance, infection prevention and control, and access to rapid and affordable diagnostic tools.

Yours sincerely,

Sarah Wiener MEP, Chair of the MEP Interest Group on AMR

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ⁱ A conservative estimate that includes resistance to antibiotics (also in tuberculosis), but which excludes drug-resistant HIV, extrapolated from four data sources: Phumart P. et al., (2012), [Health and economic impacts of antimicrobial resistant infections in Thailand: A preliminary study](#), Journal of Health Services Research & Policy, pp. 352–360; Centers for Disease Control and Prevention (CDC), (2013), [Antibiotic resistance threats in the United States](#); European Centre for Disease Prevention and Control (ECDC) & European Medicines Agency (EMA), (2009), [The bacterial challenge: Time to react - A call to narrow the gap between multidrug-resistant bacteria in the EU and development of new antibacterial agents](#); World Health Organization (WHO), (2017), [Global tuberculosis report](#).

ⁱⁱ Cassini A. et al., (2019), [Attributable deaths and disability-adjusted life-years caused by infections with antibiotic-resistant bacteria in the EU and the European Economic Area in 2015: A population-level modelling analysis](#), The Lancet Infectious Diseases, pp. 56-66.

ⁱⁱⁱ World Bank, (2017), [Drug-resistant infections: A threat to our economic future](#).

^{iv} World Bank, (2019), [Pulling together to beat superbugs knowledge and implementation gaps in addressing antimicrobial resistance](#).

∨ European Parliament, (2020), [Resolution on the EU's public health strategy post-COVID-19](#).

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