Wednesday, 10 April 2019

Dear Director General Calleja Crespo,
Dear Director General Bucher,

We are writing to express our deep concern following the recent publication of the Strategic Approach to Pharmaceuticals in the Environment by the European Commission. We welcome the fact that it has finally been published, but we strongly feel that it fails to include key measures to mitigate the devastating impact of pharmaceutical pollution on human, animal, and environmental health.

According to the 2019 UN Environment Global Environment Outlook, "pharmaceuticals are commonly mishandled 'from cradle to grave' with over 200 different substances reported in river waters globally".[1] This is also the case in Europe – a recent study shows that several veterinary drugs (mostly antimicrobials) contaminate the majority of the 29 small waterways analysed across 10 EU countries.[2] This is particularly worrying as the discharge of antibiotics and antimicrobial compounds from human and veterinary medicine into the environment is a driver for the development of resistant bacteria.

Today, it is estimated that antimicrobial resistance (AMR) is responsible for over 25,000 deaths a year across the EU and represents an annual cost of more than €1.5 billion to the economy in terms of healthcare costs and productivity losses.[3] But these figures are likely to be a gross underestimate because they are based on data for only five drug-resistant bacteria. By 2050, AMR could kill 10 million people per year worldwide, making it a major cause of death globally.[4]

In 2017, UN Environment identified growing AMR linked to discharge of drugs and particular chemicals into the environment as "one of the most worrying health threats today".[5] Despite this warning, active pharmaceutical ingredients (APIs) are still excluded from EU environmental regulations.

It is clear that the threat is urgent and action must be taken immediately to protect public and environmental health. We have therefore listed below five concrete measures that we urge the European Commission to address:

1. Compel pharmaceutical companies to increase transparency and improve consistency throughout the supply chain

The European Commission should establish a strong legislative framework to increase transparency throughout the entire supply chain and prevent pharmaceutical companies from operating double standards in developing countries. This would allow for proper scrutiny and ensure companies are held to account for the environmental release of pharmaceuticals from their manufacturing plants and those operated by third parties at any stage of production where discharges may occur.

2. Expand the regulatory framework for Good Manufacturing Practice (GMP) to include compulsory environmental criteria

The European Commission should broaden the GMP framework to cover environmental criteria in order to give EU inspectors the ability to control manufacturing discharges at overseas pharmaceutical factories supplying the EU market. The vast majority of EU pharmaceuticals are produced in developing countries with weak environmental standards and regulatory systems.

3. Assess the potential environmental risks of all pharmaceuticals and implement stronger rules on marketing authorisations for medical products for human use

The European Commission should require a compulsory environmental risk assessment (ERA) for all medical products for human and veterinary use, including pharmaceuticals authorised prior to October 2005 when the guidelines came into force. ERA data should be made publicly available and included in the risk-benefit analysis of human medicinal products. The absence of harmful effect from pharmaceuticals in the environment must become an integral criterion in the authorisation procedure.

4. Add pharmaceuticals to the list of substances of concern under the Environmental Quality Standards (EQS) Directive

The European Commission should set environmental quality standards and concentration limits for pharmaceuticals under the EQS Directive. There are currently no limits set for pharmaceuticals in water, yet wastewater treatment plants have limited capacity to remove antibiotic drugs and may be hot spots for horizontal gene transfer, when DNA moves from one bacterium to another. This should also be addressed in the on-going evaluation of the Urban Waste Water Treatment Directive.

5. Introduce an EU monitoring system to collect data on antimicrobials and AMR microorganisms in the environment

The European Commission should introduce a consistent, mandatory scheme to collect and benchmark data on the concentrations of antimicrobials and their residues and AMR microorganisms in the environment in order to bridge the knowledge gap and increase transparency regarding the amounts of APIs discharged into the environment.

Overall, we urge more EU leadership to ensure policy coherence in the fight against AMR as part of the 'One Health' approach. We encourage the AMR One Health Network to better align its vision with the EU environmental strategies, particularly on the issues of pharmaceuticals in the environment and water pollution.

We expect that the Strategic Approach is the first step towards a legislative process that will be taken forward by the next Commission. It needs to become a stepping stone to a more comprehensive legislative framework with ambitious and binding measures to mitigate the increasingly serious impact of pharmaceuticals in the environment throughout their life cycle.

We very much hope that you will be the torchbearers for this ambitious and important legislative process through the upcoming mandate. Failure to act now will have devastating consequences on current and future generations.

We remain at your disposal should you have any questions and we would very much welcome any opportunity to meet with you to discuss our proposals in more detail.

Yours sincerely,

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[1] UN Environment, March 2019, *Global Environment Outlook 6*, p. 89, www.unenvironment.org/resources/global-environment-outlook-6

[2] Casado J., Brigden K., Santillo D., Johnston P., March 2019, *Screening of pesticides and veterinary drugs in small streams in the European Union by liquid chromatography high resolution mass spectrometry*, www.sciencedirect.com/science/article/pii/S0048969719311969#f0020

[3] Kantar Public Brussels, November 2018, *Special Eurobarometer 478 on Antimicrobial resistance*, p. 4, http://ec.europa.eu/commfrontoffice/publicopinion/index.cfm/ResultDoc/download/DocumentKy/84386

[4] The Review on Antimicrobial Resistance, May 2016, *Tackling Drug-Resistant Infections Globally*, p. 4, https://amr-review.org/sites/default/files/160525_Final%20paper_with%20cover.pdf

[5] UN Environment, December 2017, *Antimicrobial resistance from environmental pollution among biggest emerging health threats*, www.unenvironment.org/news-and-stories/press-release/antimicrobial-resistance-environmental-pollution-among-biggest