

London, Brussels, 02 June 2017

**Re: Strategic approach to pharmaceuticals in the environment and AMR**

Dear Commissioner Bienkowska,

We write with regard to the recently published roadmap on a Strategic Approach to Pharmaceuticals in the Environment and the forthcoming Antimicrobial Resistance (AMR) Action Plan. We would like to underline the importance of introducing ambitious legislation to reduce pharmaceutical pollution, including the spread of AMR - a major global health crisis – and highlight other potential unintended consequences arising from the release of increasing amounts of pharmaceuticals into the environment.<sup>1</sup>

Recent research has demonstrated that there is a clear link between the presence of antibiotics in the environment and the proliferation of drug-resistant bacteria. A study published in March 2017 by German scientists showed that insufficient wastewater management by drug manufacturing facilities in India is leading to “unprecedented” contamination of water resources with antimicrobial pharmaceuticals.<sup>2</sup> The researchers found concentrations of antibiotics and antifungal substances that were several hundred times, or even several thousand times, higher than the levels predicted to select for resistance. In addition, 95 per cent of all samples tested positively for multi drug-resistant bacteria.

This is just the most recent in a series of alarming studies pointing to a relationship between emissions from pharmaceutical manufacturing and the spread of AMR. The Changing Markets Foundation has also carried out research and on-the-ground investigations which have revealed uncontrolled pollution at factories in India and found antibiotic-resistant bacteria around pharmaceutical manufacturing sites in four Indian cities.<sup>3</sup> The Foundation has also investigated factories in China, where a substantial share of the world’s antibiotic Active Pharmaceutical Ingredients (APIs) are produced and where pollution is also rife. This is not a problem that only affects India and China: supply chain investigations have shown that polluting factories in Hyderabad (India) supply to virtually all the world’s major pharmaceutical companies.<sup>4</sup> Pharmaceutical companies and health insurers benefit from low-cost antibiotics with a hidden cost of AMR.

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<sup>1</sup> The German Environment Agency published a database with over 600 pharmaceuticals and their metabolites that have been detected globally on all continents

<https://www.umweltbundesamt.de/en/database-pharmaceuticals-in-the-environment-0>

<sup>2</sup> Study: <http://link.springer.com/article/10.1007%2Fs15010-017-1007-2>

<sup>3</sup> <https://changingmarkets.org/portfolio/bad-medicine/>

<sup>4</sup> <https://www.thebureauinvestigates.com/stories/2017-05-06/big-pharmas-pollution-is-creating-deadly-superbugs-while-the-world-looks-the-other-way>

As AMR spreads rapidly around the globe, threatening to undermine numerous advances made in modern medicine, we need to act with urgency and ensure that all causes of AMR are addressed. Asia is expected to suffer the highest number of fatalities from AMR, with more than 4.7 million annual deaths by 2050, while in Europe the number is predicted to rise from the current level of 25,000<sup>5</sup> to almost 400,000 annual deaths.<sup>6</sup>

As indicated by the “Davos Declaration” and the recent B20 statement, some member companies of the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) are well aware of the issue and have proposed a “self-policing” initiative to tackle antibiotic resistance, including that caused by pollution from factories in their own supply chains. However, the absence of some of the worst offender companies from the voluntary initiatives and scant detail demonstrate that these will be ineffective and that binding regulatory measures and sanctions for non-compliance are urgently needed.

We therefore call on the European Commission to show leadership at a global level with the following initiatives:

1. Move beyond the non-legislative Antimicrobial Resistance Action Plan and launch a legislative process to stop pharmaceutical pollution in the environment throughout supply chains for antimicrobial medicines.
2. Propose ambitious legislation to tackle pharmaceutical pollution linked with EU consumption of pharmaceuticals. The best way to address this problem is to include environmental criteria in the market authorisation of pharmaceuticals presented to the EMA for products sold within the EU, i.e. a strict target of zero waste discharge, including antibiotic, via water and air, and effective inspections in Good Manufacturing Practices (GMP) framework. These controls already regularly take place in third countries that export to the EU market. Given the seriousness of the AMR threat and clear evidence that polluting factories are contributing to AMR, inspections need to be extended to cover pharmaceutical pollution in addition to product safety and the frequency of inspections needs to be increased.
3. Require an Environmental Risk Assessment for ‘old’ and new pharmaceuticals for both human and veterinary use, covering all stages of the pharmaceutical substance’s life cycle as a mandatory part of the marketing authorisation process for all drugs, but especially for antimicrobials and make it a requirement for public R&D funding.
4. Enable more transparency in pharmaceutical supply chains by making the origins of the APIs provided to EMA publicly available. Companies should mention the origin of the API on the drug packages. Transparency is the first step towards positive change, as companies can be held responsible for pollution that is present in their supply chains.

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<sup>5</sup> 25,000 is probably a significant under-estimate, as AMR deaths are not consistently reported.

<sup>6</sup> AMR Review <https://amr-review.org/Publications.html> and AMR action plan roadmap

5. Engage on the international level to ensure that major drug producing countries take the issue of pharmaceutical pollution and AMR seriously and include environmental criteria relating to manufacturing emissions in any new trade agreements. In addition, promote technology transfer of better production methods and waste-water treatment systems to these countries.
6. Support research into the various transmission dynamics of AMR via the environment and the establishment of appropriate surveillance mechanisms. Only a few projects have been launched in this area over the last decade.

Lastly, we would encourage you to train and communicate to EU public health authorities the better implementation of the European public procurement directive 2014/24/EU to set standards for production and transparency demands in the call for tender. However, this should just be seen as a first step, while other potential legislative options are being assessed. The overall goal of EU legislation should be to protect EU citizens and the environment and to reduce the economic burden to the EU (number of death, healthcare cost, environmental cost).

We therefore request a meeting with you in the coming weeks to discuss these issues more in detail. We would be grateful for an indication of your availability in June.

Best regards,

Nina Renshaw, Secretary General, European Public Health Alliance  
Anja Leetz, Executive Director, Health Care Without Harm Europe  
Nusa Urbancic, Campaigns Director, Changing Markets Foundation