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matters

Monday, 2 July 2018

Dear President Juncker,

In light of recent media reports<sup>1</sup> indicating a weakening of the European Commission's resolve to tackle the very serious impacts of pharmaceutical pollution on the environment, we are writing to urge you to ensure that key measures to address these are included in the upcoming strategic approach on pharmaceuticals in the environment (PiE). Active pharmaceutical ingredients (APIs) are currently excluded from EU environmental regulation, which is untenable in light of the risk these pose to the environment and to human and animal health.

According to the AMR Review, antimicrobial resistance (AMR) poses one of the gravest threats to global public health this century. Unless drastic measures are taken to contain the proliferation of drug-resistant microbes, the resulting annual death toll is expected to rise

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<sup>1</sup> The Guardian, 1 June 2018, Antibiotic apocalypse: EU scraps plans to tackle drug pollution, despite fears of rising resistance <https://www.theguardian.com/environment/2018/jun/01/antibiotic-apocalypse-eu-scraps-plans-to-tackle-drug-pollution-despite-fears-of-rising-resistance>; Tagesschau, 01.06.2018, Medikamente in Umwelt – Nebenwirkungen weiter zu befürchten <http://www.tagesschau.de/inland/arszneimittel-umwelt-101.html>

from today's level of 700,000 to 10 million people worldwide by 2050,<sup>2</sup> significantly more than the number of deaths currently caused by cancer. UN Environment recently identified growing antimicrobial resistance linked to discharge of drugs and particular chemicals into the environment as "one of the most worrying health threats today."<sup>3</sup>

The macro economic implications of the antibiotic resistance crisis are hugely significant. Drug-resistant infections are predicted to cost the world \$100 trillion in lost output between now and 2050,<sup>4</sup> which is more than the current global economy. The WHO estimates that in the EU alone, the issue is costing more than \$1.5 billion in healthcare expenses and productivity losses.<sup>5</sup>

The negative implications of antibiotic resistance for the health insurance sector as well as investors in the pharma sector, food producers and food retailers are material.

Against this backdrop, we are very concerned that a number of crucial aspects identified in the European Commission's own study<sup>6</sup> in preparation for the strategic approach are reported to have been weakened or removed altogether from the draft circulating internally within the Commission. This would constitute a fatal weakening of the strategic approach and we therefore call on you to ensure that the following key elements are included in the Commission's proposal:

- Provisions on broadening the Good Manufacturing Practices (GMP) framework to cover environmental impacts of pharmaceutical manufacturing.

The inclusion of environmental criteria in GMP is imperative to curb the environmental and human health impacts of pharmaceutical manufacturing, which include the global spread of drug-resistant bacteria. This is particularly key in light of the fact that the vast majority of EU pharmaceuticals are produced in third countries where environmental controls are lax and poorly enforced.<sup>7</sup> Several studies have shown that polluting factories breeding resistant bacteria are exporting to EU markets and directly selling drugs to EU-based health providers, such as German insurance companies.<sup>8</sup>

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<sup>2</sup> AMR Review, December 2014, *Antimicrobial Resistance: Tackling a Crisis for the Health and Wealth of Nations*, [http://amr-review.org/sites/default/files/AMR%20Review%20Paper%20-%20Tackling%20a%20crisis%20for%20the%20health%20and%20wealth%20of%20nations\\_1.pdf](http://amr-review.org/sites/default/files/AMR%20Review%20Paper%20-%20Tackling%20a%20crisis%20for%20the%20health%20and%20wealth%20of%20nations_1.pdf)

<sup>3</sup> UN Environment, 05.12.2017, *Antimicrobial resistance from environmental pollution among biggest emerging health threats, says UN Environment*, <https://www.unenvironment.org/news-and-stories/press-release/antimicrobial-resistance-environmental-pollution-among-biggest>

<sup>4</sup> World Bank, 20.09.2016, *By 2050, drug-resistant infections could cause global economic damage on par with 2008 economic crisis* <http://www.worldbank.org/en/news/press-release/2016/09/18/by-2050-drug-resistant-infections-could-cause-global-economic-damage-on-par-with-2008-financial-crisis>

<sup>5</sup> WHO, AMR in the WHO European Region, <http://www.euro.who.int/en/health-topics/disease-prevention/antimicrobial-resistance/about-amr/amr-in-the-who-european-region>

<sup>6</sup> Deloitte, September 2017, *Background document for public consultation on pharmaceuticals in the environment* [https://ec.europa.eu/info/sites/info/files/background\\_document\\_public\\_consultation\\_pharmaceuticals\\_environment.pdf](https://ec.europa.eu/info/sites/info/files/background_document_public_consultation_pharmaceuticals_environment.pdf)

<sup>7</sup> China produces 80-90% of antibiotic APIs and Indian companies lead the production of finished dose products. There have been numerous high-profile pollution scandals at antibiotics production sites in both China and India, resulting in the spread of drug-resistant bacteria (Changing Markets, <https://changingmarkets.org/portfolio/bad-medicine/>). Possible downstream pollution from manufacturing plants has been observed in the EU and other parts of the world (BIO Intelligence Service, 2013, [https://ec.europa.eu/health/sites/health/files/files/environment/study\\_environment.pdf](https://ec.europa.eu/health/sites/health/files/files/environment/study_environment.pdf)).

<sup>8</sup> See: ARD Das Erste, 08.05.2017, *The invisible enemy - deadly superbugs from pharma factories* (engl. subtitles)

- The Watch List monitoring data should inform the inclusion of specific pharmaceuticals posing an EU-wide risk in the list of priority substances under the Water Framework Directive.

The surface water Watch List monitoring data should be one of the sources used in the prioritisation exercise. The results of the Watch List will help filling the current data gap to inform future measures to more effectively manage the environmental impacts of pharmaceutical residues in the environment. While the pharmaceutical industry favours a voluntary approach aimed at establishing “acceptable” concentrations of pharmaceuticals in the environment, we take the view that monitoring of real-world effects is required to inform better policy-making.

- Stronger rules on marketing authorisations for human and veterinary pharmaceutical products which would mean that Environmental Risk Assessments are considered in a meaningful way.

Marketing authorisations for human pharmaceuticals must be made conditional on the existence of a robust Environmental Risk Assessment (ERA) for those substances. This should be coupled with compulsory ERAs for products put on the market before 2006. The same applies to veterinary pharmaceuticals put on the market before 2005. Information on ecotoxicological properties is lacking for most pharmaceuticals that are currently on the market. Existing information provided in the Environmental Risk Assessments performed by industry is scarce, scattered in individual reports, heterogeneous, incomplete and not publicly available. Environmental impacts are only included in the reporting of adverse events of the veterinary pharmacovigilance system and, in any case, are reported relatively infrequently through the established tools.

In addition to these points, we also call on the Commission to consider the joint statement by European civil society organisations in May this year: *Europe must align policies to tackle Pharmaceuticals in the Environment and Antimicrobial Resistance*.<sup>9</sup>

The delivery of the Strategic Approach was due nearly 3 years ago and it represents just the first step in the legislative process that will be taken forward by the next Commission. We urge you to publish the Strategic Approach before the summer recess with a view to leaving all the relevant legislative options on the table and committing to further work in the next legislative cycle. Your own research and the work of Member States, such as Sweden, Germany and the Netherlands, has shown that pharmaceutical pollution represents a significant environmental and health threat, which should be addressed in line with the precautionary approach.

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<http://www.daserste.de/information/reportage-dokumentation/dokus/videos/der-unsichtbare-feind-video-104.html>

<sup>9</sup> EPHA, 17.05.2018, Joint Statement: Europe must align policies to tackle Pharmaceuticals in the Environment and Antimicrobial Resistance <https://epha.org/joint-statement-europe-must-align-policies-to-tackle-pharmaceuticals-in-the-environment-and-antimicrobial-resistance/>

We remain at your disposal for any questions and would like to arrange a meeting to discuss this further.

Yours sincerely,

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