



16<sup>th</sup> November 2017

Dear Commissioner Vella,

We, the undersigned health and environmental organisations, are deeply concerned by the threat that pharmaceuticals in the environment pose to the health of the EU citizens, their communities, and the environment. We would like to underline the importance of introducing ambitious legislation through the *Strategic Approach to Pharmaceuticals in the Environment* and to highlight the unintended consequences from the release of increasing amounts of pharmaceuticals into the environment.

In the right place, pharmaceuticals save lives and prevent disease; but pharmaceuticals in the environment also represent a global pollution problem - over 631 different pharmaceutical agents or their metabolites have been detected in 71 countries on all continents.<sup>1</sup> The EU is one of the largest consumers of human medicinal products in the world (24% of the global production), second only to the U.S.<sup>2</sup> Pharmaceutical pollution is an unrestricted cross-border phenomenon that affects all EU countries. This is very well illustrated by a study in the Danube River Basin spanning 14 EU countries that identified 7,767 chemical compounds consisting of 154 different groups of pharmaceuticals and illicit drugs.<sup>3</sup>

According to a recent German Environment Agency report,<sup>4</sup> approximately 4,000 Active Pharmaceutical Ingredients - APIs, the part of the medicine that is biologically active in order to have an effect on the body - are being used in prescription drugs, over the counter therapeutic drugs, and veterinary drugs. APIs are developed to be biologically active, but often remain unchanged during their passage through the body. For example, between 30-90% of an oral dose is excreted in the urine as an active substance.<sup>5</sup> This means they persist in the environment and as a result, can accumulate with long-term consequences. Even low amounts of APIs in the environment can have far-reaching effects on ecosystems – causing reproductive failure, growth inhibition, behavioural changes, and species' population collapse, such as the near extinction of vultures feeding on animals that have been treated with diclofenac in Pakistan.<sup>6</sup>

<sup>1</sup>Aus der Beek T, Weber FA, Bergmann A, Hickmann S, et al. (2016) *Pharmaceuticals in the environment-Global occurrences and perspectives*. Environ Toxicol Chem, 35(4), pp.823-35. [www.ncbi.nlm.nih.gov/pubmed/26666847](http://www.ncbi.nlm.nih.gov/pubmed/26666847)

<sup>2</sup>Académie Nationale de Pharmacie (2008) *Médicaments et environnement*. [www.acadpharm.org/dos\\_public/1\\_Rapport\\_Med\\_Env\\_version\\_JMH\\_def\\_JPC.pdf](http://www.acadpharm.org/dos_public/1_Rapport_Med_Env_version_JMH_def_JPC.pdf)

<sup>3</sup>Storck, et al. (2015) *Emerging substances in surface and groundwater, Joint Danube Survey 3, ICPDR*. [www.icpdr.org/main/activities-projects/joint-danube-survey](http://www.icpdr.org/main/activities-projects/joint-danube-survey)

<sup>4</sup>German Environment Agency (2016) *Pharmaceuticals in the environment - the global perspective*. [www.umweltbundesamt.de/sites/default/files/medien/378/publikationen/pharmaceuticals\\_in\\_the\\_environment\\_0.pdf](http://www.umweltbundesamt.de/sites/default/files/medien/378/publikationen/pharmaceuticals_in_the_environment_0.pdf)

<sup>5</sup>BIO Intelligence Service (2013) *Study on the environmental risks of medicinal products, Final Report prepared for Executive Agency for Health and Consumers*. [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>6</sup>Oaks et al. (2004) *Diclofenac residues as the cause of vulture population decline in Pakistan*. Nature 427 pp. 630-633 [www.nature.com/nature/journal/v427/n6975/full/nature02317.html](http://www.nature.com/nature/journal/v427/n6975/full/nature02317.html)

Municipal landfills contain a wide range of pharmaceutical compounds that are concerning for the environment, wildlife, and human health.<sup>7</sup> The presence of these pharmaceutical compounds in water may also contribute to antimicrobial resistance (AMR) - a serious problem that challenges the sustainability of European health systems.

The growing problem of pharmaceuticals in the environment has been recognised as an emerging policy issue by the UN Strategic Approach to International Chemicals Management (SAICM), which adopted “Environmentally Persistent Pharmaceutical Pollutants” in its process in autumn 2015.<sup>8</sup> Pharmaceutical residues can enter the environment during all stage of their life cycle: production, consumption, and disposal. Pharmaceutical production is an important source of pharmaceutical pollution that can be exacerbated by weak environmental legislation in countries that produce many of the APIs for pharmaceutical products globally.<sup>9</sup> During pharmaceutical consumption (i.e. use), human excretion via wastewater, animal excretion via runoff from agricultural areas, and discharges from aquaculture cause significant environmental contamination.<sup>10</sup> Unsuitable disposal is another pathway for pharmaceuticals to enter the environment; the most common inappropriate disposal methods include flushing medicines down the toilet or sink, or disposed in waste bins destined for landfill sites.

Considering this, we, the undersigned, strongly believe that the following steps are necessary to address the problems posed by pharmaceuticals in the environment and should therefore be incorporated into the strategic approach:

1. Minimise the entry of pharmaceuticals into the environment throughout their life cycle.
2. Ensure zero discharge of pharmaceuticals in the environment during the entire production process.
3. Increase transparency and ensure consistently high standards along the entire pharmaceutical supply chain, including in countries outside the EU where the majority of pharmaceutical manufacturing occurs. This could be achieved by incorporating environmental criteria in the Good Manufacturing Practice (GMP) framework.<sup>11</sup>
4. Extended producer responsibility<sup>12</sup> should apply to the pharmaceutical industry - producers should be accountable for pharmaceutical waste throughout their life cycle.
5. Assess the potential environmental risks of all human and veterinary pharmaceuticals and ensure regular environmental review of authorised pharmaceuticals based on current scientific knowledge.
6. Encourage green procurement as a means of switching to pharmaceuticals with a lower environmental impact.
7. Promote the rational use of pharmaceuticals and education and awareness-raising campaigns about pharmaceuticals and their environmental impact.
8. Improve municipal wastewater treatment facilities in order to prevent environmental pollution caused by excreted pharmaceuticals.
9. Establish collection and take-back schemes, discourage the inappropriate disposal of unwanted pharmaceuticals in the home, and encourage awareness-raising and education programmes to dispose of unused pharmaceuticals safely.

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<sup>7</sup>Eggen T, Moeder M, Arukwe, A (2012) *Municipal landfill leachates: A significant source for new and emerging pollutants*, Sci Total Environ. 408(21) pp.5147-57. [www.ncbi.nlm.nih.gov/pubmed/20696466](http://www.ncbi.nlm.nih.gov/pubmed/20696466)

<sup>8</sup>Environmentally Persistent Pharmaceutical Pollutants (EPPPs) at International Conference on Chemicals Management (ICCM) 4 Autumn 2015 in Geneva

<sup>9</sup>SumOfUs (2015) *Bad Medicine: How the pharmaceutical industry is contributing to the global rise of antibiotic resistant superbugs*. [www.changingmarkets.org/wp-content/uploads/2016/12/BAD-MEDICINE-Report-FINAL.pdf](http://www.changingmarkets.org/wp-content/uploads/2016/12/BAD-MEDICINE-Report-FINAL.pdf)

<sup>10</sup>Kümmerer K (2010) *Pharmaceuticals in the Environment - Annual Review of Environment and Resources*. Environment and Resources, 35(1) pp.57-75. [www.annualreviews.org/doi/full/10.1146/annurev-environ-052809-161223](http://www.annualreviews.org/doi/full/10.1146/annurev-environ-052809-161223)

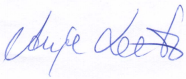
<sup>11</sup>Swedish Medical Products Agency (Läkemedelverket), June 2011, *Platform to enable the initiation of a revision of EU legislation on Good Manufacturing Practice, GMP, in order for legislation also to comprehend environmental considerations* - [www.lakemedelsverket.se/upload/eng-mpa-se/Swedish-platform-GMP-environmental-July-2011.pdf](http://www.lakemedelsverket.se/upload/eng-mpa-se/Swedish-platform-GMP-environmental-July-2011.pdf)

<sup>12</sup>See: [www.oecd.org/env/tools-evaluation/extendedproducerresponsibility.htm](http://www.oecd.org/env/tools-evaluation/extendedproducerresponsibility.htm)

10. Introduce comprehensive legislation to reduce the impact of pharmaceuticals in the environment.
11. Establish a procedure to define threshold values for single and mixture pharmaceutical residues in water bodies.
12. Ensure reduced discharge of pharmaceuticals from animal livestock holdings by promoting husbandry practices that foster animal health and prevent prophylactic antibiotics-use in veterinary medicine.

We, the undersigned, strongly believe that the above recommendations should be incorporated into the *Strategic Approach to Pharmaceuticals in the Environment*. EU citizens have the right to live in a safe environment in order to prevent sickness and the spread of AMR. We therefore call on the European Commission to consider our position on this issue and take immediate action to protect human and environmental health.

Yours sincerely,



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