



HCWH Europe,
1 Rue de la Pépinière
B1000, Brussels,

19th January 2017

To the President of the EU Commission Jean-Claude Juncker
c/c First Vice-President Frans Timmermans,
c/c Commissioner Environment, Maritime Affairs, and Fisheries Karmenu Vella
c/c Director General for Environment Daniel Calleja Crespo

Dear Mr. Juncker,

I am writing to you to on behalf of the undersigned organisations to express our deepest concern regarding the development of the strategic approach to address the pharmaceutical pollution of water, which (according to Article 8c of Directive 2013/39/EU), the European Commission should have proposed by 13th September 2015.¹ In its capacity as the guardian of the Treaty, the European Commission is required and expected to "ensure a high level of human health protection", along with consistent and coherent policymaking to support it. The undersigned are extremely concerned by the delay of the strategic approach to address this issue, and request a reply with answers for the delay.

According to a recent German Environment Agency report, approximately 4,000 active pharmaceutical ingredients are being used in prescription drugs, over the counter therapeutic drugs, and veterinary drugs.² It is well known that pharmaceutical residues have been detected in surface water, sewage effluents, groundwater, drinking water, manure, soil, and other environmental matrices globally, including within the European Union. The presence of pharmaceuticals in water contributes to environmental pollution, impacting on organisms such as fish and vegetation, and may have long-term impacts on human health. Pharmaceuticals in water may also contribute to antimicrobial resistance (AMR) - a serious global threat challenging the sustainability of European health systems.

¹ Directive 2013/39/EU of the European Parliament and of the Council of 12th August 2013

² German Environment Agency (2016) *Pharmaceuticals in the environment: The global perspective* p3

Pharmaceutical residues can enter the environment during their production, use, and disposal. Pharmaceutical manufacturing is a source of pharmaceutical pollution that can be exacerbated by weak environmental legislation in countries producing many of the active pharmaceutical ingredients (APIs) for pharmaceutical products globally.³ A Danube River Basin study, spanning 14 EU countries, identified 7,767 chemical compounds, many of which were pharmaceuticals or their transformation products.⁴ Pharmaceuticals also enter the environment during use: human excretion via wastewater, animal excretion via runoff from agricultural areas, and discharges from aquaculture.⁵ Another entry route is through incorrect disposal, most commonly when unused medicines are flushed down the toilet, sink, or disposed of in waste bins destined for landfill. Considering this, we also strongly believe that the following steps are necessary to address the problems posed by the presence of pharmaceuticals in the environment and should therefore be incorporated into the strategic approach:

1. Minimise pharmaceuticals entering the environment throughout their life cycle.
2. Ensure zero pharmaceutical discharge into the environment during the entire production process.
3. Increase transparency and ensure consistently high standards along the pharmaceutical supply chain - a considerable share of pharmaceutical manufacturing is outsourced beyond the EU, incorporating environmental criteria in the Good Manufacturing Practice (GMP) framework should be applied.⁶
4. Apply extended producer responsibility to the pharmaceutical industry, making it accountable for pharmaceutical waste throughout the life cycle.
5. Assess the potential environmental risks of all human and veterinary pharmaceuticals and ensure regular environmental reviews 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 rational use of pharmaceuticals and education & awareness-raising campaigns about the environmental impact of pharmaceuticals.
8. Improve wastewater treatment facilities in order to tackle pharmaceuticals in the environment.
9. Encourage safe disposal of unused pharmaceuticals through awareness-raising, educational programmes, and establishing collection and take back schemes.
10. Reduce pharmaceuticals' environmental impact with comprehensive legislation.

³ SumOfUs (2015) *Bad Medicine: How the pharmaceutical industry is contributing to the global rise of antibiotic resistant superbugs* www.s3.amazonaws.com/s3.sumofus.org/images/BAD_MEDICINE_final_report.pdf

⁴ Storck et al, (2015) *Emerging substances in surface and groundwater*, Joint Danube Survey 3, ICPDR, Vienna. Austria.

⁵ 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

⁶ Swedish Medical Products Agency (Läkesmedelverket), June 2011, Platform to enable the initiation of a revision of EU legislation on Good Manufacturing Practice (GMP) www.lakemedelsverket.se/upload/eng-mpa-se/Swedish-platform-GMP-environmental-July-2011.pdf

11. Establish a procedure defining threshold values for single and mixture pharmaceutical residues in water.
12. Ensure reduced pharmaceutical discharge from animal livestock holdings by promoting husbandry practices that foster animal health and by preventing prophylactic use of veterinary antibiotics disguised as methaphylactic use.

EU citizens have the right to access high quality, safe water to prevent sickness and the spread of antimicrobial resistance. Delaying the development of a strategic approach is putting citizens' health and the environment at risk; we therefore expect a swift response to our call for the European Commission to take immediate action - act now to protect human and environmental health.

Yours sincerely,



Anja Leetz,
Executive Director, HCWH Europe,
On behalf of:

Jeremy Wates, Secretary General - European
Environmental Bureau

Nina Renshaw, Secretary General - European
Public Health Alliance

Genon Jensen, Executive Director - Health
and Environment Alliance

Susan Haffmans, Senior Advisor
Pesticides/Veterinary Pharmaceuticals -
Pestizid Aktions-Netzwerk (PAN Germany)

Natasha Hurley, Campaign manager -
Changing Markets

Christophe Schoune, Secretary general-
Fédération Inter-Environnement Wallonie

Mikhail Durkin, Executive Secretary -
Coalition Clean Baltic

Dr. Peter Kälin, President - Doctors for the
Environment, Switzerland

International organisations also supporting this cause

Kim Perrotta, Executive Director - Canadian
Association of Physicians for the
Environment

Siddika Sultana, Executive Director -
Environment & Social Development
Organization (Bangladesh)

Naji Kodeih, Senior Environmental Expert -
IndyACT (Lebanon)

Eugeniy Lobanov, Director - Center for
Environmental Solutions (Belarus)

Pavel Harbunou, Chair of the Board - Minsk
Cycling Community (Belarus)