

Tuesday, 13th September 2016

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 Commissioner Health & Food Safety, Vytenis Andriukaitis

Dear Mr. Juncker,

The undersigned organisations would like to express our deepest concern regarding the way the European Commission is carrying out the development of a strategic approach to address the pharmaceutical pollution of water.

According to Article 8c of Directive 2013/39/EU of the European Parliament and of the Council of 12th August 2013¹, the European Commission should have proposed a strategic approach to address the pollution of water by pharmaceuticals by 13th September 2015. Article 8c specifically states the following:

Pursuant to Article 16(9) of Directive 2000/60/EC, and where appropriate on the basis of the outcome of its 2013 study on the risks posed by medicinal products in the environment and of other relevant studies and reports, the Commission shall, as far as possible within two years from 13 September 2013 develop a strategic approach to pollution of water by pharmaceutical substances. That strategic approach shall, where appropriate, include proposals enabling, to the extent necessary, the environmental impacts of medicines to be taken into account more effectively in the procedure for placing medicinal products on the market.

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.² The presence of pharmaceuticals in water contributes to environmental pollution, having an impact on organisms such as fish and may have long-term impacts on human health.³ Pharmaceuticals in water may also contribute to antimicrobial resistance (AMR); this problem is challenging the sustainability of European health systems.⁴

Article 8c also states that:

In the framework of that strategic approach, the Commission shall, where appropriate, by 14 September 2017 propose measures to be taken at Union and/or Member State level, as appropriate, to address the possible environmental impacts of pharmaceutical substances, particularly those referred to in Article 8b(1), with a view to reducing discharges, emissions and losses of such substances into the aquatic

¹ Directive 2013/39/EU: <http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32013L0039>

² Aus der Beek T *et al.* (2015). Pharmaceuticals in the environment-Global occurrences and perspectives.

² Aus der Beek T *et al.* (2015). Pharmaceuticals in the environment-Global occurrences and perspectives.
<http://www.ncbi.nlm.nih.gov/pubmed/26666847>

³ Pharmaceuticals in drinking-water, WHO, 2012:

http://www.who.int/water_sanitation_health/publications/2012/pharmaceuticals/en/

⁴ Larsson DGJ *et al.* (2007). <http://www.ncbi.nlm.nih.gov/pubmed/17706342>

environment, taking into account public health needs and the cost-effectiveness of the measures proposed.

In 2013, the final report of the study on the environmental risks of medicinal products⁵, conducted for the Executive Agency for Health and Consumers, stated that: "Residues of various types of medicinal products (hormones, anti-cancer, antidepressants, antibiotics, etc.) have been detected in various environmental compartments, such as surface water, groundwater, soil, air, and biota."

The report also stated that: "this study together with other relevant studies and reports, will provide the basis to develop that strategic approach".

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. EU citizens have the right to access high quality, safe water in order to prevent sickness and the spread of antimicrobial resistance.⁶

We are concerned that the delay of the strategic approach to address the pharmaceutical pollution of water will mean that the health of EU citizens is put further at risk.

We therefore ask the European Commission to explain the reason for the delay in the development of a strategic approach, which was clearly requested by co-legislators back in 2013. In addition, we would like to be informed why the article 8c was not included in the EC proposals on EMA (COD 2014(0256)) and the related proposal dealing with veterinary medicines.

The undersigned organisations point out the urgent need for the European Commission to publish the strategic approach to address the pharmaceutical pollution of water in order to promote and protect health and patient safety across Europe.

We do not understand why the Commission is delaying the process, and we therefore would like to be informed on the current status of the strategic approach and when we can expect the Commission to deliver on their commitments.

We are looking forward to hearing from you.

Yours Sincerely,



Anja Leetz, Executive Director, Health Care Without Harm Europe

On behalf of:

Jeremy Wates, Secretary General, European Environmental Bureau

Nina Renshaw, Secretary General, European Public Health Alliance

Genon Jensen, Executive Director, Health & Environment Alliance

Geneviève Pons-Deladrière, Director, WWF, European Policy Office

⁵ Study on the environmental risks of medicinal products: http://ec.europa.eu/health/files/environment/study_environment.pdf

⁶ Charter of Fundamental Rights of the European Union (2012): <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:12012P/TXT>