



Thank you for your willingness to respond to this public consultation on pharmaceuticals in the environment. In this document you will find information and suggested responses from [HCWH Europe](#), developed by our experts drawing on our many years of experience working to protect the environment from pharmaceutical pollution.

By responding to the European Commission (EC)'s consultation, you are helping to ensure that the voice of European citizens is heard and you are joining fellow Europeans in protecting human and environmental health from the damaging effects of pharmaceuticals in the environment.

You can find some information about the consultation process itself (from the EC) [here](#).

The consultation is to be completed online, and **should not take more than 20 minutes**.

[Click here](#) to access the consultation form

Once you have completed the first 10 questions (entering your personal information and experiences), you will be asked to comment on your awareness of this issue and what you believe should be done to help combat pharmaceuticals in the environment.

HCWH Europe has provided some suggested responses to questions 11, 13-19 **highlighted in yellow** that will ensure the EC considers the expert opinions on how to tackle this issue – please read through them and use these suggestions as the basis for your own answers.

Question 17 relates to action taken at a national level. Please list any actions/initiatives that you are aware of here. If you are not aware of any, you may wish to consult HCWH Europe's report: [Unused Pharmaceuticals: Where do they end up?](#) to find out about unused pharmaceuticals in your country.

We have also provided links to some of HCWH Europe's publications for question 19 which you may wish to list.

General questions on the issue

Awareness of the issue

***11. What has made you aware of the issue of pharmaceuticals and the environment?
(Please mark all that apply.)**

- Seeing this consultation
- Reports in the press, on television or social media
- Campaign material from organisations such as NGOs
- Work
- Information from pharmacist/doctor/dentist/hospital/vet
- Talking with friends/family
- Other

***If other, please specify:**

500 character(s) maximum

HCWH Europe publications/events/infographics/webinars/Safer Pharma campaign
(www.saferpharma.org).

***13. Do you see a connection between this issue and the development of antimicrobial resistance (AMR)? (Resistance means, for example, that existing antibiotics may no longer be effective against disease-causing bacteria.)**

- Yes
- No
- Not sure

14. What (other) aspect of the issue (of pharmaceuticals in the environment) concerns you most?

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- Companies do not disclose the origin of their drugs
- There are no monitoring requirements or emission limits for the release of active pharmaceutical ingredients from manufacturing plants
- Information regarding the environmental impact of pharmaceuticals is not publicly available
- There are no concentration limits for pharmaceuticals in drinking, surface and wastewater
- There is no obligation for EU member states to monitor pharmaceuticals in sewage, sludge or manure used in agriculture

Relative importance of actions

***15. How do you see the need for actions (including research) to address the risk from pharmaceuticals in the environment?**

A) For human pharmaceuticals

- Not necessary
- Necessary but not urgent
- Urgent
- No opinion

***B) For veterinary pharmaceuticals**

- Not necessary
- Necessary but not urgent
- Urgent
- No opinion

If you wish to, please explain your answer:

1500 character(s) maximum

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.

In line with this, the current state of knowledge and the scientific data clearly show that there is an urgent need for action regarding the hazards and risks posed to the environment and possibly to human health by the production, use and disposal of pharmaceuticals.

Despite over 20 years of scientific publications and several EU funded projects in this field, the European Commission is questioning yet again the need for action, even when a Strategic Approach was due in September 2015, according to Article 8c of Directive 2013/39/EU.

Compulsory requirements are needed for the existing legislation to guarantee that several measures are implemented at both the EU and national levels. Measures that are based on voluntary action are also important, but not enough - the Strategic Approach should be in line with the European Commission's commitment to protect both the environment and the health of EU citizens.

16. Please give each of the twelve possible actions below a score between 5 and 0, where 5 = high priority action, 3 = medium priority action, 1 = low priority action, 0 = not in favour). All actions must be scored. *Please note that the actions have been numbered to indicate which action areas they relate to in the background document, but are in most cases more specific.*

	5	4	3	2	1	0
*1. More research to better understand the risks	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
*2. "Greener" design of pharmaceuticals, e.g. to make them more biodegradable	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*3. More stringent conditions for putting a pharmaceutical on the market	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*4. Cleaner manufacturing	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*5. Better risk mitigation, e.g. not allowing over-the-counter sale of pharmaceuticals that pose an environmental risk	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*6. Better/more thorough post-market monitoring of pharmaceuticals in the environment and feedback to the regulatory process	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*7. (a) Better training for medical professionals, e.g. about pharmaceuticals that are less harmful for the environment	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*7. (b) Better information for the public, e.g. about how to dispose of unused medicines	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*7. (c) Smaller packaging sizes, to reduce unnecessary waste/disposal	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*8. Improved handling of waste pharmaceuticals	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*9. (a) Improved sewage and wastewater treatment	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*9. (b) Improvements in livestock farming to reduce the use/emission of pharmaceuticals	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

If you wish to, please explain your scoring or add brief comments on the listed actions, referring to their number.

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Each measure should be high priority and should be addressed in the Strategic Approach because these measures are aimed at addressing the entire life cycle of pharmaceuticals and their entry into the environment. If not included in the Strategic Approach, there will be significant gaps in the tackling the problem.

Considering the available research on issues relating to pharmaceuticals in the environment and AMR, I believe there is enough scientific data that the precautionary principle should be applied to propose legislative measures to tackle pharmaceutical pollution. Postponing action

to conduct more research or waiting for more green pharmaceuticals to become available will further delay the EU legislative framework that is urgently needed to protect environmental and the human health.

17. If you are aware of any actions already being taken in your own country, please mention them and provide details.

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If you are aware of any actions in your country, please list them here. If not, please point this out also as it is important that the Commission understands the lack of awareness/information.

You can find more information about pharmaceutical collection schemes in specific European countries in HCWH Europe's 2013 report *Unused Pharmaceuticals: Where do they end up?* here: <https://noharm-europe.org/sites/default/files/documents-files/4646/2013-12%20Unused%20pharmaceuticals.pdf>.

18. Please feel free to suggest further actions, in addition to those included in this questionnaire and the background document, or in your answer to Q.17, to address the impacts of pharmaceuticals in the environment.

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1. Develop and promote guidelines on how to identify and design "green pharmaceuticals" (i.e. pharmaceuticals that pose lower risk to the environment).
2. Encourage Member States to review their ethical procurement policies at national level with a view to including environmental criteria in contractual requirements.
3. Demand more transparency in the pharmaceutical supply chain. The pharmaceutical industry should disclose the origin of their pharmaceuticals by providing information regarding where the active pharmaceutical ingredients were produced, therefore ensuring a complete traceability profile for all pharmaceuticals. This will improve both production practices and patient safety.
4. Ensure that adequate information about the environmental impacts of pharmaceuticals is made publicly available.
5. Ensure that all pharmaceuticals (including their metabolites and transformation products, and regardless when they were put on the market) require a reliable and publicly available evaluation of their environmental risks.
6. Set emissions limit values for active pharmaceutical ingredients.
7. Set up monitoring requirements and limit values for pharmaceuticals in sewage, soil and manure.
8. Ensure that pharmaceutical waste is classified as hazardous waste.

19. We invite you to suggest information sources on pharmaceuticals and the environment (titles of publications and web links are appreciated) in order to increase the evidence base on the topics addressed in this questionnaire.

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Safer Pharma campaign: www.saferpharma.org

Infographic | *Pharmaceuticals in the environment* (2016): <https://noharm-europe.org/issues/europe/pharmaceuticals-environment-infographic>

Webinar | *Pharmaceutical pollution - the need for sustainable procurement* (2017): <https://noharm-europe.org/issues/europe/webinar-pharmaceutical-pollution-need-sustainable-procurement>

Webinar | *Safer pharma: How healthcare can reduce pharmaceutical pollution* (2016): <https://noharm-europe.org/issues/europe/webinar-safer-pharma-how-healthcare-can-reduce-pharmaceutical-pollution>

Guide | *How doctors can help reduce pharmaceutical pollution* (2014): <https://noharm-europe.org/sites/default/files/documents-files/3026/HCWH%20Europe%20-%20%20Pharma%20Leaflet%20for%20Doctors.pdf>

Position paper | *Recommendations on pharmaceuticals in the environment* (2016): <https://noharm-europe.org/sites/default/files/documents-files/4304/2016-09-27%20HCWH%20Europe%20Pharmaceuticals%20in%20the%20environment%20position%20paper.pdf>

Report | *Unused pharmaceuticals: Where do they end up?* (2013): <https://noharm-europe.org/sites/default/files/documents-files/4646/2013-12%20Unused%20pharmaceuticals.pdf>

Status Report on Pharmaceuticals in the Baltic Sea Region: <http://www.helcom.fi/action-areas/industrial-municipal-releases/pharmaceuticals/status-report>