

# Public consultation on pharmaceuticals in the environment

Fields marked with \* are mandatory.

## About this consultation

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This consultation is part of a study aimed at supporting the development of a European Union (EU) strategic approach to pharmaceuticals in the environment, and in turn at helping the EU achieve the United Nations Sustainable Development Goals, in particular SDG 6 ("Clean Water and Sanitation"), as well as objectives in EU legislation such as the "good status" objective in the Water Framework Directive. Adoption of the approach is to be followed by proposals for specific measures, as appropriate, which would be subject, as necessary, to full impact assessment.

Pharmaceuticals can enter the environment during their production, use and disposal. The need for a strategic approach has been prompted by concern about risks to the environment itself, and possibly to human health via the environment. Any actions to address those risks must also ensure that humans and animals can continue to benefit from the appropriate use of pharmaceuticals and that the competitiveness of EU healthcare systems is maintained.

This consultation aims to collect feedback and further information from stakeholders on their perception of the problem, the need for action, and on some of the actions that could be prioritised.

A **background paper**, provided with this questionnaire, describes 30 possible policy options grouped into 10 action areas. These have been identified on the basis of a review of the recent literature and preliminary consultation of stakeholders. You may wish to read the summary of the paper, or the paper itself, before answering the questions, but this is not essential.

Your responses will help the European Commission (EC) to formulate the strategic approach and prioritise areas for action. Thank you in advance.

## Important note on the publication of answers

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Please note that the responses received will be published on the EC's website, together with the identity of the contributor unless the contributor objects to the publication of personal data.

### \* 1. Please indicate your preference as regards publication of your contribution

- My contribution may be published, mentioning my name or the name of my organisation as well as country of residence

- My contribution may be published anonymously

Please note that, whatever option chosen, your answers may be subject to a request for public access to documents under [Regulation \(EC\) N°1049/2001](#). Please also read the specific privacy statement referred to on the consultation webpage.

## About the respondent

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**\* 2. Are you replying as:**

- An individual  
 An EU institution  
 A national/regional/local public authority  
 A company  
 A business or workers' organisation  
 An NGO, environmental or consumer group  
 A research organisation  
 Other

**\* 3a. Please state your name or the name of your organisation (published)**

Health Care Without Harm Europe

**\* 3b. Please provide your email address (Please note that your email address will not be published regardless of the option chosen in question 1)**

adela.maghear@hcwh.org

**\* 5. How many members does your organisation or group represent?**

89

**\* 6. Is your organisation registered in the Transparency Register of the European Commission?**

- Yes  
 No

**\* 7. Please enter the identification number**

57514749088-82

**\* 8. What is your main field of activity or main area of expertise or interest?**

- Pharmaceuticals  
 Human healthcare (including pharmacy)  
 Veterinary care (including veterinary pharmacy)  
 Water and waste water management  
 Waste management

- Other
- No specific relevant expertise

**\*9. What is your main country of residence or activities? (published)**

- Austria
- Belgium
- Bulgaria
- Croatia
- Cyprus
- Czech Republic
- Denmark
- Estonia
- Finland
- France
- Germany
- Greece
- Hungary
- Ireland
- Italy
- Latvia
- Lithuania
- Luxembourg
- Malta
- Netherlands
- Poland
- Portugal
- Romania
- Slovak Republic
- Slovenia
- Spain
- Sweden
- United Kingdom
- Other

**\* If other, please specify (published):**

International

## General questions on the issue

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### Awareness of the issue

**\*10. How would you describe your level of awareness of the issue of pharmaceuticals and the environment?**

- Nil (It hasn't been on my/our radar until now)

- Low (I/we have heard a bit about it)
- Moderate (I/we have heard a fair amount about it)
- High (I/we have been looking at it in detail)

**\* 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 has organised workshops and webinars, published position papers, reports, brochures and infographics, as well as attended meetings with the European Commission. Internationally, we responded to specific consultations presented by the EC or EMA. We are aware of scientific articles on the issue of the fate and occurrence of pharmaceuticals in the environment and EU projects dealing with the topic.

**\* 12. Has awareness of the issue made you do any of the following? (Please mark all that apply.)**

- Start taking unused medicines to the pharmacy (if you were not already)
- Stop flushing unused pharmaceuticals down the sink or toilet
- Talk to your pharmacist or doctor about the issue
- Talk to friends or family about the issue
- Change your consumption of over-the-counter (non-prescribed) medicines
- Other

**\* If other, please specify:**

*500 character(s) maximum*

HCWH Europe has been working to tackle pharmaceuticals in the environment for the past six years. The goal of our work on pharmaceuticals is to support their safe production, management and disposal, while reducing their environmental and health impact throughout their life cycle. We also aim to foster innovations for green products. We currently lead the only EU-wide campaign dealing with the presence of pharmaceuticals in the environment - Safer Pharma (<http://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?**

500 character(s) maximum

- Companies do not disclose the origin of their drugs back to the factories that produced the raw materials
- There are no monitoring requirements or emission limits for the release of APIs from manufacturing plants
- Information regarding the environmental impact of APIs is not publicly available
- There are no concentration limits for pharmaceuticals in drinking, surface and wastewater
- There is no obligation for MS 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, we consider that 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.

We consider that 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.**

*1500 character(s) maximum*

We consider all of the measures we rated very effective as very important, and should be addressed in the Strategic Approach. They address the whole 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 posed by the presence of pharmaceuticals in the environment.

We have carefully considered the available research on issues relating to pharmaceuticals in the environment and AMR and we believe that at present there is enough scientific data and 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.**

*1500 character(s) maximum*

In 2013 HCWH Europe published a report (<https://noharm-europe.org/sites/default/files/documents-files/4646/2013-12%20Unused%20pharmaceuticals.pdf>) about the disposal of unused medicines in selected EU countries to help assess the efficiency of pharmaceutical collection schemes. One of the main conclusions of this report was that detailed information regarding the implementation and efficiency of collection schemes in Europe is highly scattered and often lacking, therefore useful comparisons between countries and type of schemes implemented cannot be made. Moreover, it is not clear whether all EU countries have met their obligations with regards to collection schemes.

At present, HCWH Europe is working to develop a database that aims to provide an overview of current and past initiatives by local, regional, and national NGOs, European projects, and national/regional authorities of EU Member States to tackle pharmaceuticals in the environment and pharmaceutical waste (including in wastewater). We expect that this database will be available online by the end of 2018.

**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.**

*1500 character(s) maximum*

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 in the supply chain. This will improve both production practices and patient safety.
4. Set Environmental Quality Standards (EQS) for pharmaceuticals in groundwater and surface water.
5. Ensure that ERAs adequately consider the combination effects of mixtures.
6. Ensure that pharmaceutical substances added to the Water Framework Directive's Priority Hazardous Substances List are automatically classified as hazardous waste under the Waste Framework Directive and Commission Decision 2000/532/EC establishing the List of Wastes.
7. Include active pharmaceutical ingredients in the list of main pollutants within the Water Framework Directive (Annex VIII).
8. Amend the Sewage Sludge Directive to enforce monitoring for selected pharmaceutical substances.
9. Set concentration limits for APIs in different environmental compartments.

**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.**

*1500 character(s) maximum*

- 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? (12/2013): <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>

- Pharmaceuticals in the environment: scientific evidence of risks and its regulation: <http://rstb.royalsocietypublishing.org/content/369/1656/20130587>

- Re-Designing of Existing Pharmaceuticals for Environmental Biodegradability: A Tiered Approach with  $\beta$ -Blocker Propranolol as an Example: <http://pubs.acs.org/doi/abs/10.1021/acs.est.5b03051>

If you wish to submit additional documentation (up to three pages), please upload your file here.

The maximum file size is 1 MB

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## Contact

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