

# 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)**

CHEM Trust

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 Please provide your email address (*Please note that your email address will not be published regardless of the option chosen in question 1*)**

ninja.reineke@chemtrust.org

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

CHEM Trust is a registered charity under UK law and not a membership organisation

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

- Yes  
 No

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

27053044762-72

**\* 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

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

*250 character(s) maximum*

EU chemicals policy: Improving EU laws to better protect wildlife and people from harmful chemicals, including pharmaceuticals, pesticides, biocides, industrial chemicals

**\* 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):**

EU

## 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*

Research publications and scientific conferences

**\* 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*

CHEM Trust published reports on the science and provided policy recommendations to inform the public and decisionmakers on the need for more protective regulatory oversight

**\* 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

The issue of pharmaceuticals in the environment is a neglected policy area and stricter regulatory action is long overdue. CHEM Trust is particularly concerned about the threat to wildlife from endocrine disrupting pharmaceuticals and the mixture effects, see CHEM Trust reports from 2008 (Effects of pollutants on the reproductive health of male vertebrate wildlife - Males under threat) and 2014 (Pharmaceuticals in the environment: A growing threat to our tap water and wildlife).

## 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 pollution of the environment resulting from the increasing use of human and veterinary pharmaceuticals poses a threat to wildlife and also humans via drinking water supplies. However, monitoring and controlling the presence of pharmaceuticals in the environment is difficult and currently inadequate. The types of pharmaceutical products raising concern from the perspective of their potential effects on wildlife include (but are not limited to): antibiotics; anti-cancer drugs; antidepressants; anti-parasitics; non-steroidal anti-inflammatory drugs; betablockers; lipid regulators; oral contraceptives and hormone replacement therapies and analgesics.

Human exposure can arise from tap water or from food chain contamination. Crops can take up some pharmaceuticals from soil fertilised with manure or sewage sludge. With regard to harmful effects on human health from environmental exposure to pharmaceuticals, it has been suggested that antibiotics, anti-parasitics, anti-fungals and anticancer medicines might prove to be the most important, because these are designed to kill organisms or cells. Furthermore, there is also concern that antibiotics in the environment may contribute to the increasing problem of antibiotic resistance in bacteria.

Some pharmaceuticals are persistent, while others seem to be continuously present in the environment because of their ubiquitous use. They are all designed to be biologically active and many can affect wildlife at low doses.

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 checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
* 2. "Greener" design of pharmaceuticals, e.g. to make them more biodegradable	<input type="radio"/>	<input type="radio"/>	<input checked="" 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*

Reducing wastage and ensuring the least environmentally damaging pharmaceuticals are used should be part of effective strategies to protect the environment. The EU and governments should act to reduce usage of veterinary medicines in agriculture and aquaculture. However, given that some pharmaceuticals will inevitably be required, improved sewage treatment is a necessity. Regulation has to improve sewage treatment works so that they remove pharmaceutical pollution from waste waters. The challenge ahead is not only to ensure adequate data provision and effective regulation, but also to raise awareness and educate doctors, veterinarians, pharmacists and the public on the important role that they must play. Furthermore, the public should be encouraged to reduce unnecessary consumption and take-back unwanted drugs so that they can be disposed of properly. For the latter point it will be important to (re-)install effective national take back schemes.

**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*

see information on UK in CHEM Trust report, 2014: Pharmaceuticals in the environment: a growing threat to our tap water and wildlife. The report can be downloaded here:  
<http://www.chemtrust.org/medicines-in-the-environment-a-growing-threat-to-wildlife-and-drinking-water/>

**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*

CHEM Trust provided several recommendations in our 2014 report: Pharmaceuticals in the environment: a growing threat to our tap water and wildlife. They included the following points, among others. (For more details, check chapters 7 and 8):

- It will be of utmost importance to strengthen the environmental aspects of the EU system for authorising medicines, including better testing and more consideration of environmental impacts (linked to option 3 above.) - Implement an environmental classification scheme for pharmaceuticals, with environmental authorities having full access to safety data on new medicines. A full PBT assessment should be required for all pharmaceuticals (including veterinary medicines), similar to that required under REACH.
- Develop a phased approach for establishing and addressing the environmental risks of older pharmaceuticals.
- Strengthen standards for, and monitoring of, pharmaceuticals in (i) drinking water, (ii) sewage sludge, (iii) food and (iv) the environment.

Moreover, pharmaceutical companies have to accept their responsibility for comprehensive environmental stewardship of their products from cradle to grave. This means under the polluter pays principle that companies should be obliged to contribute to pay for pollution control measures and monitoring.

**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*

CHEM Trust report 2014: <http://www.chemtrust.org/medicines-in-the-environment-a-growing-threat-to-wildlife-and-drinking-water/>

CHEM Trust report 2008: <http://www.chemtrust.org/wp-content/uploads/Male-Wildlife-Under-Threat-2008-full-report.pdf>

UBA database: <https://www.umweltbundesamt.de/en/database-pharmaceuticals-in-the-environment-0>

Bio IS, 2013: Study on the environmental risks of medicinal products [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)

EEA (European Environment Agency) (2010). Pharmaceuticals in the Environment: Results of an EEA Workshop. EEA Technical report No1/2010, ISSN 1725-2237.

Report from Health Care Without Harm: <https://noharm-europe.org/documents/unused-pharmaceuticals-where-do-they-end-snapshot-europeancollection-schemes>

Wennmalm A. (2008). Experience with the Swedish Environmental Classification Scheme, 1st International Conference, Sustainable Pharmacy, April 24th-25th Osnabruck. <https://www.dbu.de/media/130508051837a525.pdf>

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

The maximum file size is 1 MB

## Contact

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