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Public consultation on pharmaceuticals in the environment

Fields marked with * are mandatory.

About this consultation

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

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 |
| *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) |
| The Netherlands - Ministries of Health (VWS), Environment (I&W), and Agriculture (LNV) |
| regardless of the option chosen in question 1) |
| *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 |
| All of the above: this is a joint submission by three ministries |
| |
| *9. What is your main country of residence or activities? (published) |
| Austria |
| Belgium |
| Bulgaria |
| Croatia |

| | Cyprus |
|--------------------------------------|--|
| 0 | Czech Republic |
| 0 | Denmark |
| 0 | Estonia |
| 0 | Finland |
| 0 | France |
| | Germany |
| | Greece |
| | Hungary |
| | Ireland |
| | Italy |
| | Latvia |
| | Lithuania |
| | Luxembourg |
| | Malta |
| o | Netherlands |
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| Other |
|--|
| *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 |
| *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 *Not sure |
| 14. What (other) aspect of the issue (of pharmaceuticals in the environment) concerns you most? 500 character(s) maximum |
| We wish to stress that all measures must include an assessment of the impact on the sustainable availability of medicines for patients that need them. We are concerned about: (1) development and spreading of antibiotic resistance, we recommend to take actions now and not fully depend on the results of further research (2) Effects on ecology (3) effects on drinking water, regarding quality of sources of drinking water, public perception and the costs for water treatment. |
| *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

4

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

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

1500 character(s) maximum

As a general comment, we would like to highlight that de the consultation hardly provides any differentiation between human and veterinary medicinal products. The prioritization of measures for human vs veterinary pharmaceuticals is different in certain situations. Our response regards human pharmaceuticals.

Also, the above 12 possible actions are very simplified and do not reflect the complexity of the issue.

We have specific comments on Q2: 'Greener' design of pharmaceuticals does not reflect the complexity of the development of a pharmaceutical nor the efficacy and/or stability. Better degradable pharmaceuticals will also breakdown in the human or animal body which is not desirable from a therapeutic point of view. Besides it could lead to a high dosage which is not desirable for the environment. Cleaner manufacturing, design, targeted delivery methods and personalized medication is supported. However, 'greener' design is not considered feasible.

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

Please see the submission on the targeted consultation for more details.

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

We would like to refer to the recently published paper on the Dutch 'chain approach' to reduce pharmaceutical residues in water (attached to this submission). In this national approach, all actors in the lifecycle of pharmaceuticals are involved and active. Each actor is responsible for certain concrete actions within their part of the 'chain'. The approach adds value by bringing different expertise and interests together and facilitates communication. We are now working on a concrete plan of action for the coming years. We will be happy to share with you the conducted and planned actions once the action plan is finished.

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

Please see the submission on the targeted consultation for more details.

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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