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Targeted consultation on options for a strategic approach to pharmaceuticals in the environment

Fields marked with * are mandatory.

1. About this consultation

This targeted consultation, aimed at stakeholders with specific relevant expertise, complements an open public consultation taking place as 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 to full impact assessment. Experts are free to respond to both questionnaires, but are requested not to submit the same additional information twice over.

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 targeted consultation aims to collect feedback and further information from stakeholders on 30 possible policy options identified on the basis of a review of the recent literature and preliminary consultation of stakeholders.

A background paper, provided with this questionnaire, describes the options. We advise you to read the paper or the summary of it before answering the questions. The full titles of the 30 policy options are presented in the introduction to the background document under the 10 action areas presented in that document and its summary. The full titles are also listed in this questionnaire but used in shortened form in the individual questions. In section 5.1, questions are posed in relation to effectiveness and timescale, Sections 5.2 and 5.3 ask about the costs and ease of implementing each option. Section 6 allows you to propose additional options.

Your responses will help the European Commission (EC) to identify and to narrow down options for further consideration. Thank you in advance.

2. 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 attached.

3. 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)**

Ministry of Health, the Netherlands

***3b. Please provide an email address.** *Please note that your email adress will not be published, even if you accepted that your name and country are published.*

[redacted]

***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

***If other, please specify:**

250 character(s) maximum

All of the above.

*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

4. Numbered list of options - full titles

The full titles of the 30 policy options are presented below under the 10 action areas presented in the background document (and summary). In section 5.1, questions are posed in relation to effectiveness and timescale, Sections 5.2 and 5.3 ask about the costs and ease of implementing each option. Section 6 allows you to propose additional options. Please refer to the full title of each option when answering the questions.

Whole life-cycle - knowledge base: options for improving the understanding of risks from pharmaceuticals to the environment.

1 Provide further EU funding for, and encourage Member States and industry to fund, research regarding the fate, behaviour and impacts of pharmaceuticals in the environment

2 Provide EU funding for, and encourage Member States and industry to fund, research on the role of antimicrobials/resistant microorganisms in the environment on the emergence and spread of antimicrobial resistance (AMR) and its link with human and animal health

Design: option for designing greener substances.

3 Develop information resources and EU/industry co-funding initiatives to promote the design of active pharmaceutical ingredients (APIs) that pose lower risks to the environment.

Authorisation: options for ensuring the scientific robustness, consistency and transparency of risk assessments:

4 Strengthen the environmental expertise of the European Medicines Agency (EMA, its scientific committees) and the national competent authorities.

5 Ensure that all environmentally relevant toxicological thresholds for pharmaceuticals placed on the market are systematically made publicly available in a standardised format

6 Develop a system for sharing comprehensive active-substance-based Environmental Risk Assessments (ERAs) at EU level

7 Ensure that ERA results are systematically considered in the overall benefit/risk analysis for the authorisation of HMPs

8 Ensure that ERAs adequately consider Persistent Bio-accumulative and Toxic substances (PBT) and endocrine properties for the APIs, as well as the toxicity and other properties of major metabolites, degradation products and excipients: a) for human pharmaceuticals, b) for veterinary pharmaceuticals.

Manufacturing: options for promoting greener manufacturing processes:

9 Under the Industrial Emissions Directive, review and revise Best Available Techniques Reference (BREF) documents relevant to emissions from the manufacturing of pharmaceuticals

10 Prepare a sectoral reference document under the European Eco-Management and Audit Scheme (EMAS) to promote increased adoption by pharmaceutical companies, and by their global suppliers, of good environmental manufacturing standards

11 Ensure that EU Good Manufacturing Practices (GMP) address discharges of active pharmaceutical ingredients (APIs), degradation products and excipients into the environment

Post-authorisation: options for ensuring environmental risks are adequately taken into account and dealt with by mitigation actions where relevant

12 Instigate an Environmental Risk Assessment (ERA) catching-up procedure for relevant pharmaceuticals for which there is still no or only an incomplete ERA

13 Require from the marketing authorisation holder (MAH) the update/revision of ERAs based on post-marketing monitoring data or newly published information

14 Link the need for a prescription to supply/obtain human pharmaceuticals (HMPs) to the results of ERAs, and provide guidelines for the enforcement of existing similar provisions for veterinary pharmaceuticals (VMPs)

15 Require Member States to designate the authority/authorities responsible at national level for the follow-up and reporting obligations linked to implementation of risk mitigation measures

Use: options for:

- Ensuring environmental risks and impacts observed post-marketing are identified and reported

16 Establish routine dialogue and information exchange between relevant Member State agencies and authorities to help ensure that API levels in the environment are safe for the environment and human and animal health

17 Ensure that environmental issues are a) introduced into the pharmacovigilance system for human pharmaceuticals (HMPs) and b) strengthened for veterinary pharmaceuticals (VMPs), particularly in relation to AMR

18 Include pharmaceuticals as relevant in the watch lists for monitoring surface and groundwater under the Water Framework Directive (WFD) a) along with AMR in relevant microorganisms when antimicrobials are included; b) without requiring monitoring of AMR

- Promoting sustainable use of pharmaceuticals

19 Encourage Member States to increase the consideration of environmental aspects during medical /veterinary education and advanced training of healthcare professionals including healthcare managers

20 Ensure the provision of information to the general public that encourages the sustainable use of pharmaceuticals, in particular antimicrobials

21 Develop recommendations or requirements regarding the size and form of packaging for pharmaceuticals to facilitate their efficient use

Waste collection and disposal: options for ensuring appropriate collection and disposal of unused pharmaceuticals and pharmaceutical waste:

22 Promote better enforcement of EU legislation with regard to the implementation of waste collection schemes for human and veterinary pharmaceuticals, including through extended producer responsibility

23 Ensure that the CLP Regulation does not exclude pharmaceuticals in medicinal products, and that its provisions are consistent with the Waste Framework Directive

Waste treatment and reuse: options for promoting more effective treatment of waste water, manure and sludge.

24 Establish EU guidelines for appropriate wastewater management in hospitals and healthcare centres

25 Require monitoring of antimicrobials and AMR microorganisms in the effluent and organic waste from potential "hotspots" such as large waste water treatment plants, hospitals, pharmaceutical manufacturing sites and intensive livestock farms

26 Develop EU funding opportunities for research, development and implementation of advanced water treatment technologies to ensure that levels of pharmaceuticals, including antibiotics, and of AMR microorganisms, are reduced

27 Encourage Member States to establish innovative mechanisms for investing in advanced (waste and drinking) water treatment

28 Take additional measures, e.g. set quality standards or risk assessment requirements, to ensure that the concentrations of relevant pharmaceuticals and AMR microorganisms in manure, sewage sludge, and irrigation water are safe before it can be spread on agricultural fields

29 Encourage Member States to revise their Codes of Good Agricultural Practice and revise relevant best available techniques under the IED at EU level to include provisions for the handling of manure containing pharmaceuticals/AMR microorganisms

Whole life-cycle – overall management: option for promoting better overall management of pharmaceutical emissions into soils and the aquatic environment

30 Prepare guidance under the Common Implementation Strategy (CIS) for the Water Framework Directive (WFD) to support better Member State action against pharmaceuticals in the aquatic environment

5. Detailed questions on possible options

5.1 Effectiveness of options

10. How effective do you think the options listed above (in section 4) and in the background document would be in terms of mitigating risks from pharmaceuticals in the environment, in particular by way of reducing the presence of pharmaceuticals in the environment that could have harmful effects on or via the environment?

	Very effective	Moderately effective	Slightly effective	Not effective	Don't know
1 Research on pharmaceuticals in the environment	○	◉	○	○	○
2 Research on pharmaceuticals and AMR	◉	○	○	○	○
3 Promote greener pharmaceuticals design	○	○	◉	○	○
4 Strengthen environmental expertise of EMA and national authorities	○	◉	○	○	○
5 Toxicological thresholds for pharmaceuticals publicly available in standardised format	◉	○	○	○	○
6 System for sharing substance-based ERAs at EU level	◉	○	○	○	○
7 Benefit/risk analysis of ERA results in HMP authorisation	○	○	○	◉	○
8a ERA adequately considers PBT, endocrine properties, metabolites, degradation products and excipients: HMPs	○	○	◉	○	○
8b ERA adequately considers PBT, endocrine properties, metabolites, degradation products and excipients: VMPs	○	○	◉	○	○
9 Review and revise BREF documents	○	○	◉	○	○
10 Prepare EMAS ref. document	○	◉	○	○	○
11 Ensure GMP addresses discharges	◉	○	○	○	○
12 ERA catching up procedure	○	◉	○	○	○
13 Update/revision of ERAs	○	○	◉	○	○
14 Link need for prescription to supply HMPs to the results of ERAs	◉	○	○	○	○

15 National authorities for follow-up and reporting obligations	○	○	◉	○	○
16 Routine dialogue and information exchange on API levels	◉	○	○	○	○
17a Introduce environmental issues in pharmacovigilance for HMPs	○	○	○	◉	○
17b Strengthen environmental issues in pharmacovigilance for VMPs	○	○	◉	○	○
18a Relevant pharmaceuticals in WFD watch lists: with AMR microorganisms	○	○	◉	○	○
18b Relevant pharmaceuticals in WFD watch lists: without AMR	○	○	◉	○	○
19 Increased consideration of environmental aspects in education and training	○	◉	○	○	○
20 Information to encourage sustainable use of pharmaceuticals	◉	○	○	○	○
21 Packaging pharmaceuticals for efficient use	○	○	◉	○	○
22 Enforcement of waste collection schemes, including through EPR	○	◉	○	○	○
23 CLP includes pharmaceuticals in products, in line with Waste FD	○	○	○	◉	○
24 EU guidelines on waste water from hospitals	○	○	◉	○	○
25 Monitoring of antimicrobials and AMR microorganisms at discharge “hotspots”	◉	○	○	○	○
26 EU funding for advanced water treatment technologies	◉	○	○	○	○
27 Innovative MS mechanisms for investment in advanced water treatment	◉	○	○	○	○
28 Safe concentrations of pharmaceuticals and AMR microorganisms in waste(water) for agricultural use	○	○	◉	○	○
29 Revised Codes of Good Agricultural Practice and BAT under IED	○	◉	○	○	○
30 Guidance under CIS for WFD	◉	○	○	○	○

11. If you considered an option as slightly, moderately or very effective, over what timescale(s) would you see it having an effect? (Please select all timescales that apply if, e.g. there is more than one effect.)

	Soon, i.e. within 6 months	More than 6 months away, but less than 2 years	After 2 years or more
1 Research on pharmaceuticals in the environment	○	○	◉
2 Research on pharmaceuticals and AMR	○	○	◉
3 Promote greener pharmaceuticals design	○	○	◉
4 Strengthen environmental expertise of EMA and national authorities	○	○	◉
5 Toxicological thresholds for pharmaceuticals publicly available in standardised format	○	○	◉
6 System for sharing substance-based ERAs at EU level	○	○	◉
7 Benefit/risk analysis of ERA results in HMP authorisation	○	○	◉
8a ERA adequately considers PBT, endocrine properties, metabolites, degradation products and excipients: HMPs	○	○	◉
8b ERA adequately considers PBT, endocrine properties, metabolites, degradation products and excipients: VMPs	○	○	◉
9 Review and revise BREF documents	○	○	◉
10 Prepare EMAS ref. document	○	○	◉
11 Ensure GMP addresses discharges	○	○	◉
12 ERA catching up procedure	○	○	◉
13 Update/revision of ERAs	○	○	◉
14 Link need for prescription to supply HMPs to the results of ERAs	○	○	◉
15 National authorities for follow-up and reporting obligations	○	○	◉
16 Routine dialogue and information exchange on API levels	○	○	◉
17a Introduce environmental issues in pharmacovigilance for HMPs	○	○	◉

17b Strengthen environmental issues in pharmacovigilance for VMPs	○	○	◉
18a Relevant pharmaceuticals in WFD watch lists: with AMR microorganisms	○	○	◉
18b Relevant pharmaceuticals in WFD watch lists: without AMR	○	○	◉
19 Increased consideration of environmental aspects in education and training	○	○	◉
20 Information to encourage sustainable use of pharmaceuticals	○	○	◉
21 Packaging pharmaceuticals for efficient use	○	○	◉
22 Enforcement of waste collection schemes, including through EPR	○	○	◉
23 CLP includes pharmaceuticals in products, in line with Waste FD	○	○	◉
24 EU guidelines on waste water from hospitals	○	○	◉
25 Monitoring of antimicrobials and AMR microorganisms at discharge “hotspots”	○	○	◉
26 EU funding for advanced water treatment technologies	○	○	◉
27 Innovative MS mechanisms for investment in advanced water treatment	○	○	◉
28 Safe concentrations of pharmaceuticals and AMR microorganisms in waste(water) for agricultural use	○	○	◉
29 Revised Codes of Good Agricultural Practice and BAT under IED	○	○	◉
30 Guidance under CIS for WFD	○	○	◉

12. Please provide a brief explanation for your answers on the options, including any proposals for modifying them. Please also explain why you selected certain timescales. When responding, please indicate the number of the option you refer to.

1500 character(s) maximum

To start, we would like to note that this is the combined contribution of the Dutch ministries of Health (VWS), Environment (I&W), and Agriculture (LNV).
We feel that the wording of the options as listed in the consultation does not always reflect the scope and extent of the measures sufficiently. Also, the evaluation of an number of options is very difficult because the measures have different impacts and effects on human medicines, veterinary medicines, and the reduction of AMR. However, there was no option to specify our answer to one area. Please note that therefore, we had to evaluate the options taking into account all three areas. We would have scored differently if the

questionnaire would have been more specific.
For more detailed comments on the options presented above, we refer to the attached document, which can be seen as our main contribution.
Regarding the timescales, most proposed measures will have effects after two years of more.

5.2 Costs of implementing options

13. What do you consider the costs of implementing these options would be? Please consider only the direct costs to relevant stakeholder(s) who have to take the relevant measure(s), not "knock-on" costs to other stakeholders that might follow implementation. Please consider the costs in relation to the likely overall budget of the stakeholder; the last line allows you to consider the costs to all stakeholders instead of by stakeholder group (or in addition). The term "Public authorities" includes regulators and public healthcare providers.

1 Research on pharmaceuticals in the environment

	High costs	Moderate costs	Low costs	No costs	Don't know
Public authorities	○	○	○	○	○
Pharmaceutical and healthcare industry	○	○	○	○	○
Water and waste treatment industries	○	○	○	○	○
Individual citizens	○	○	○	○	○
All stakeholders	○	○	○	○	○

2 Research on pharmaceuticals and AMR

	High costs	Moderate costs	Low costs	No costs	Don't know
Public authorities	○	○	○	○	○
Pharmaceutical and healthcare industry	○	○	○	○	○
Water and waste treatment industries	○	○	○	○	○
Individual citizens	○	○	○	○	○
All stakeholders	○	○	○	○	○

3 Promote greener pharmaceuticals design

	High costs	Moderate costs	Low costs	No costs	Don't know

Public authorities					
Pharmaceutical and healthcare industry					
Water and waste treatment industries					
Individual citizens					
All stakeholders					

4 Strengthen environmental expertise of EMA and national authorities

	High costs	Moderate costs	Low costs	No costs	Don't know
Public authorities					
Pharmaceutical and healthcare industry					
Water and waste treatment industries					
Individual citizens					
All stakeholders					

5 Toxicological thresholds for pharmaceuticals publicly available in standardised format

	High costs	Moderate costs	Low costs	No costs	Don't know
Public authorities					
Pharmaceutical and healthcare industry					
Water and waste treatment industries					
Individual citizens					
All stakeholders					

6 System for sharing substance-based ERAs at EU level

	High costs	Moderate costs	Low costs	No costs	Don't know
Public authorities					
Pharmaceutical and healthcare industry					

Water and waste treatment industries					
Individual citizens					
All stakeholders					

7 Benefit/risk analysis of ERA results in HMP authorisation

	High costs	Moderate costs	Low costs	No costs	Don't know
Public authorities					
Pharmaceutical and healthcare industry					
Water and waste treatment industries					
Individual citizens					
All stakeholders					

8a ERA adequately considers PBT, endocrine properties, metabolites, degradation products and excipients: HMPs

	High costs	Moderate costs	Low costs	No costs	Don't know
Public authorities					
Pharmaceutical and healthcare industry					
Water and waste treatment industries					
Individual citizens					
All stakeholders					

8b ERA adequately considers PBT, endocrine properties, metabolites, degradation products and excipients: VMPs

	High costs	Moderate costs	Low costs	No costs	Don't know
Public authorities					
Pharmaceutical and healthcare industry					
Water and waste treatment industries					

Individual citizens					
All stakeholders					

9 Review and revise BREF documents

	High costs	Moderate costs	Low costs	No costs	Don't know
Public authorities					
Pharmaceutical and healthcare industry					
Water and waste treatment industries					
Individual citizens					
All stakeholders					

10 Prepare EMAS ref. document

	High costs	Moderate costs	Low costs	No costs	Don't know
Public authorities					
Pharmaceutical and healthcare industry					
Water and waste treatment industries					
Individual citizens					
All stakeholders					

11 Ensure GMP addresses discharges

	High costs	Moderate costs	Low costs	No costs	Don't know
Public authorities					
Pharmaceutical and healthcare industry					
Water and waste treatment industries					
Individual citizens					
All stakeholders					

12 ERA catching up procedure

	High costs	Moderate costs	Low costs	No costs	Don't know
Public authorities	○	○	○	○	○
Pharmaceutical and healthcare industry	○	○	○	○	○
Water and waste treatment industries	○	○	○	○	○
Individual citizens	○	○	○	○	○
All stakeholders	○	○	○	○	○

13 Update/revision of ERAs

	High costs	Moderate costs	Low costs	No costs	Don't know
Public authorities	○	○	○	○	○
Pharmaceutical and healthcare industry	○	○	○	○	○
Water and waste treatment industries	○	○	○	○	○
Individual citizens	○	○	○	○	○
All stakeholders	○	○	○	○	○

14 Link need for prescription to supply HMPs to the results of ERAs

	High costs	Moderate costs	Low costs	No costs	Don't know
Public authorities	○	○	○	○	○
Pharmaceutical and healthcare industry	○	○	○	○	○
Water and waste treatment industries	○	○	○	○	○
Individual citizens	○	○	○	○	○
All stakeholders	○	○	○	○	○

15 National authorities for follow-up and reporting obligations

	High costs	Moderate costs	Low costs	No costs	Don't know
Public authorities	○	○	○	○	○

Pharmaceutical and healthcare industry					
Water and waste treatment industries					
Individual citizens					
All stakeholders					

16 Routine dialogue and information exchange on API levels

	High costs	Moderate costs	Low costs	No costs	Don't know
Public authorities					
Pharmaceutical and healthcare industry					
Water and waste treatment industries					
Individual citizens					
All stakeholders					

17a Introduce environmental issues in pharmacovigilance for HMPs

	High costs	Moderate costs	Low costs	No costs	Don't know
Public authorities					
Pharmaceutical and healthcare industry					
Water and waste treatment industries					
Individual citizens					
All stakeholders					

17b Strengthen environmental issues in pharmacovigilance for VMPs

	High costs	Moderate costs	Low costs	No costs	Don't know
Public authorities					
Pharmaceutical and healthcare industry					

Water and waste treatment industries					
Individual citizens					
All stakeholders					

18a Relevant pharmaceuticals in WFD watch lists: with AMR microorganisms

	High costs	Moderate costs	Low costs	No costs	Don't know
Public authorities					
Pharmaceutical and healthcare industry					
Water and waste treatment industries					
Individual citizens					
All stakeholders					

18b Relevant pharmaceuticals in WFD watch lists: without AMR

	High costs	Moderate costs	Low costs	No costs	Don't know
Public authorities					
Pharmaceutical and healthcare industry					
Water and waste treatment industries					
Individual citizens					
All stakeholders					

19 Increased consideration of environmental aspects in education and training

	High costs	Moderate costs	Low costs	No costs	Don't know
Public authorities					
Pharmaceutical and healthcare industry					
Water and waste treatment industries					
Individual citizens					

All stakeholders	○	○	○	○	○

20 Information to encourage sustainable use of pharmaceuticals

	High costs	Moderate costs	Low costs	No costs	Don't know
Public authorities	○	○	○	○	○
Pharmaceutical and healthcare industry	○	○	○	○	○
Water and waste treatment industries	○	○	○	○	○
Individual citizens	○	○	○	○	○
All stakeholders	○	○	○	○	○

21 Packaging pharmaceuticals for efficient use

	High costs	Moderate costs	Low costs	No costs	Don't know
Public authorities	○	○	○	○	○
Pharmaceutical and healthcare industry	○	○	○	○	○
Water and waste treatment industries	○	○	○	○	○
Individual citizens	○	○	○	○	○
All stakeholders	○	○	○	○	○

22 Enforcement of waste collection schemes, including through EPR

	High costs	Moderate costs	Low costs	No costs	Don't know
Public authorities	○	○	○	○	○
Pharmaceutical and healthcare industry	○	○	○	○	○
Water and waste treatment industries	○	○	○	○	○
Individual citizens	○	○	○	○	○
All stakeholders	○	○	○	○	○

23 CLP includes pharmaceuticals in products, in line with Waste FD

	High costs	Moderate costs	Low costs	No costs	Don't know
Public authorities					
Pharmaceutical and healthcare industry					
Water and waste treatment industries					
Individual citizens					
All stakeholders					

24 EU guidelines on waste water from hospitals

	High costs	Moderate costs	Low costs	No costs	Don't know
Public authorities					
Pharmaceutical and healthcare industry					
Water and waste treatment industries					
Individual citizens					
All stakeholders					

25 Monitoring of antimicrobials and AMR microorganisms at discharge "hotspots"

	High costs	Moderate costs	Low costs	No costs	Don't know
Public authorities					
Pharmaceutical and healthcare industry					
Water and waste treatment industries					
Individual citizens					
All stakeholders					

26 EU funding for advanced water treatment technologies

	High costs	Moderate costs	Low costs	No costs	Don't know
Public authorities					

Pharmaceutical and healthcare industry					
Water and waste treatment industries					
Individual citizens					
All stakeholders					

27 Innovative MS mechanisms for investment in advanced water treatment

	High costs	Moderate costs	Low costs	No costs	Don't know
Public authorities					
Pharmaceutical and healthcare industry					
Water and waste treatment industries					
Individual citizens					
All stakeholders					

28 Safe concentrations of pharmaceuticals and AMR microorganisms in waste(water) for agricultural use

	High costs	Moderate costs	Low costs	No costs	Don't know
Public authorities					
Pharmaceutical and healthcare industry					
Water and waste treatment industries					
Individual citizens					
All stakeholders					

29 Revised Codes of Good Agricultural Practice and BAT under IED

	High costs	Moderate costs	Low costs	No costs	Don't know
Public authorities					
Pharmaceutical and healthcare industry					

Water and waste treatment industries					
Individual citizens					
All stakeholders					

30 Guidance under CIS for WFD

	High costs	Moderate costs	Low costs	No costs	Don't know
Public authorities					
Pharmaceutical and healthcare industry					
Water and waste treatment industries					
Individual citizens					
All stakeholders					

14. Please provide a brief explanation for your answers on the costs of the options. Please also specify how you think costs should be distributed among stakeholders. When responding, please indicate the number of the option you refer to.

1500 character(s) maximum

We chose to not answer the questions about costs, because the costs fully depend on how measures will be implemented and executed. Also, it was unclear what is considered to be high/moderate/low costs. Furthermore, we cannot estimate the costs for other organizations as we do not know how the measures are perceived by them. A general note: remarkably almost none of the options imply direct costs to waste water treatment or drinking water treatment; in the Netherlands it was concluded that measures both at the front end (in the health sector) as well as on the back end (modernization of sewage treatment) of the chain are necessary (see also Q18).

5.3 Ease of implementing options

15. How easily do you think these options could be implemented? Please consider the relevant aspects of feasibility; leave blank any aspect you consider not relevant. Capacity-related is intended to cover resource availability and logistical aspects.

1 Research on pharmaceuticals in the environment

	Very easily	Moderately easily	Not easily	Don't know
Legal				
Technical				
Capacity-related				

Social acceptability				

2 Research on pharmaceuticals and AMR

	Very easily	Moderately easily	Not easily	Don't know
Legal				
Technical				
Capacity-related				
Social acceptability				

3 Promote greener pharmaceuticals design

	Very easily	Moderately easily	Not easily	Don't know
Legal				
Technical				
Capacity-related				
Social acceptability				

4 Strengthen environmental expertise of EMA and national authorities

	Very easily	Moderately easily	Not easily	Don't know
Legal				
Technical				
Capacity-related				
Social acceptability				

5 Toxicological thresholds for pharmaceuticals publicly available in standardised format

	Very easily	Moderately easily	Not easily	Don't know
Legal				
Technical				
Capacity-related				

Social acceptability				

6 System for sharing substance-based ERAs at EU level

	Very easily	Moderately easily	Not easily	Don't know
Legal				
Technical				
Capacity-related				
Social acceptability				

7 Benefit/risk analysis of ERA results in HMP authorisation

	Very easily	Moderately easily	Not easily	Don't know
Legal				
Technical				
Capacity-related				
Social acceptability				

8a ERA adequately considers PBT, endocrine properties, metabolites, degradation products and excipients: HMPs

	Very easily	Moderately easily	Not easily	Don't know
Legal				
Technical				
Capacity-related				
Social acceptability				

8b ERA adequately considers PBT, endocrine properties, metabolites, degradation products and excipients: VMPs

	Very easily	Moderately easily	Not easily	Don't know
Legal				
Technical				

Capacity-related				
Social acceptability				

9 Review and revise BREF documents

	Very easily	Moderately easily	Not easily	Don't know
Legal				
Technical				
Capacity-related				
Social acceptability				

10 Prepare EMAS ref. document

	Very easily	Moderately easily	Not easily	Don't know
Legal				
Technical				
Capacity-related				
Social acceptability				

11 Ensure GMP addresses discharges

	Very easily	Moderately easily	Not easily	Don't know
Legal				
Technical				
Capacity-related				
Social acceptability				

12 ERA catching up procedure

	Very easily	Moderately easily	Not easily	Don't know
Legal				
Technical				

Capacity-related				
Social acceptability				

13 Update/revision of ERAs

	Very easily	Moderately easily	Not easily	Don't know
Legal				
Technical				
Capacity-related				
Social acceptability				

14 Link need for prescription to supply HMPs to the results of ERAs

	Very easily	Moderately easily	Not easily	Don't know
Legal				
Technical				
Capacity-related				
Social acceptability				

15 National authorities for follow-up and reporting obligations

	Very easily	Moderately easily	Not easily	Don't know
Legal				
Technical				
Capacity-related				
Social acceptability				

16 Routine dialogue and information exchange on API levels

	Very easily	Moderately easily	Not easily	Don't know
Legal				
Technical				

Capacity-related				
Social acceptability				

17a Introduce environmental issues in pharmacovigilance for HMPs

	Very easily	Moderately easily	Not easily	Don't know
Legal				
Technical				
Capacity-related				
Social acceptability				

17b Strengthen environmental issues in pharmacovigilance for VMPs

	Very easily	Moderately easily	Not easily	Don't know
Legal				
Technical				
Capacity-related				
Social acceptability				

18a Relevant pharmaceuticals in WFD watch lists: with AMR microorganisms

	Very easily	Moderately easily	Not easily	Don't know
Legal				
Technical				
Capacity-related				
Social acceptability				

18b Relevant pharmaceuticals in WFD watch lists: without AMR

	Very easily	Moderately easily	Not easily	Don't know
Legal				
Technical				

Capacity-related				
Social acceptability				

19 Increased consideration of environmental aspects in education and training

	Very easily	Moderately easily	Not easily	Don't know
Legal				
Technical				
Capacity-related				
Social acceptability				

20 Information to encourage sustainable use of pharmaceuticals

	Very easily	Moderately easily	Not easily	Don't know
Legal				
Technical				
Capacity-related				
Social acceptability				

21 Packaging pharmaceuticals for efficient use

	Very easily	Moderately easily	Not easily	Don't know
Legal				
Technical				
Capacity-related				
Social acceptability				

22 Enforcement of waste collection schemes, including through EPR

	Very easily	Moderately easily	Not easily	Don't know
Legal				
Technical				

Capacity-related	○	○	○	○
Social acceptability	○	○	○	○

23 CLP includes pharmaceuticals in products, in line with Waste FD

	Very easily	Moderately easily	Not easily	Don't know
Legal	○	○	○	○
Technical	○	○	○	○
Capacity-related	○	○	○	○
Social acceptability	○	○	○	○

24 EU guidelines on waste water from hospitals

	Very easily	Moderately easily	Not easily	Don't know
Legal	○	○	○	○
Technical	○	○	○	○
Capacity-related	○	○	○	○
Social acceptability	○	○	○	○

25 Monitoring of antimicrobials and AMR microorganisms at discharge "hotspots"

	Very easily	Moderately easily	Not easily	Don't know
Legal	○	○	○	○
Technical	○	○	○	○
Capacity-related	○	○	○	○
Social acceptability	○	○	○	○

26 EU funding for advanced water treatment technologies

	Very easily	Moderately easily	Not easily	Don't know
Legal	○	○	○	○
Technical	○	○	○	○

Capacity-related				
Social acceptability				

27 Innovative MS mechanisms for investment in advanced water treatment

	Very easily	Moderately easily	Not easily	Don't know
Legal				
Technical				
Capacity-related				
Social acceptability				

28 Safe concentrations of pharmaceuticals and AMR microorganisms in waste(water) for agricultural use

	Very easily	Moderately easily	Not easily	Don't know
Legal				
Technical				
Capacity-related				
Social acceptability				

29 Revised Codes of Good Agricultural Practice and BAT under IED

	Very easily	Moderately easily	Not easily	Don't know
Legal				
Technical				
Capacity-related				
Social acceptability				

30 Guidance under CIS for WFD

	Very easily	Moderately easily	Not easily	Don't know
Legal				

Technical	○	○	○	○
Capacity-related	○	○	○	○
Social acceptability	○	○	○	○

16. Please provide a brief explanation for your answers on the implementation of the options. When responding, please indicate the number of the option you refer to.

1500 character(s) maximum

We chose to not answer the above questions, because the ease of implementation fully depends on how measures will be implemented and excecuted. Also, the term 'social acceptability' is quite vague and it is therefore difficult to answer these questions.

6. Further information

If you are responding to both this and the open public consultation, please do not provide the same additional information twice over.

17. What 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.

18. If you are aware of any options already being implemented in your own country, please mention them and provide details.

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 life-cycle 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.
We would also like to refer to the Dutch policy to combat antimicrobial resistance, which is based on a holistic and one health approach. The environment is one of the key domains in the national policy. You can find the English translation of the Dutch AMR policy here: https://www.government.nl/topics/antibiotic-resistance/documents/parliamentary-documents/2015/06/24/letter-to-parliament-about-the-approach-to-antibiotic-resistance

19. Please feel free to suggest further options, in addition to those included in this questionnaire or mentioned in your answer to Q.18, to address the impacts of pharmaceuticals in the environment. Please indicate the phase of the lifecycle of the option(s) and likely effectiveness, costs and degree of feasibility.

1500 character(s) maximum

See attachment for details about the Dutch approach

20. 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

The Dutch National Institute for Public Health and Environment (RIVM) has performed (and is currently performing) many research projects related to this issue.
Research on AMR: http://www.rivm.nl/en/Documents_and_publications/Scientific/Reports/2017/juli/Sources_of_antibiotic_resistance_in_the_environment_and_intervention_measures
Overview report on pharmaceuticals in the Netherlands: http://www.rivm.nl/en/Documents_and_publications/Scientific/Reports/2016/oktober/Pharmaceuticals_and_water_quality
Report on environmental considerations when choosing pharmaceuticals: http://www.rivm.nl/Documenten_en_publicaties/Wetenschappelijk/Rapporten/2017/Maart/Milieuafwegingen_in_de_geneesmiddelvoorziening
Report on antiparasiticides: http://www.rivm.nl/en/Documents_and_publications/Scientific/Reports/2017/juli/Risks_of_antiparasitic_veterinary_products_for_groundwater_and_surface_water
Report on measures: http://www.rivm.nl/Documenten_en_publicaties/Wetenschappelijk/Rapporten/2016/mei/Towards_balancing_the_benefits_of_pharmaceutical_care_and_minimizing_its_environmental_harm_Identification_of_potential_levers_in_the_medicinal_product_chain

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

The maximum file size is 1 MB

4814297e-1aa5-48cb-b91d-6e45f99f1a1d/bijlage_targeted_consultatie.docx
0d8b6bc5-ba02-4d30-bb82-aa1d0bd6f383/Dutch_approach_to_pharmaceutical_residues_-_v0.1.pdf

Background Documents

Background_Paper.pdf (/eusurvey/files/41a5e4c1-9091-4f11-adf1-e6b92bc1fe05)

Study report (/eusurvey/files/472cd6f7-1c2b-470d-8b6f-582d3a6bcd0b)

Summary_Background_Paper.pdf (/eusurvey/files/f520d2e2-fd04-4651-a5d2-1600fe178f90)

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