AmCham EU
SPEAKING FOR AMERICAN BUSINESS IN EUROPE

Consultation response

Public Consultation on Pharmaceuticals in the Environment

AmCham EU speaks for American companies committed to Europe on trade, investment and competitiveness issues. It aims to ensure a growth-orientated business and investment climate in Europe. AmCham EU facilitates the resolution of transatlantic issues that impact business and plays a role in creating better understanding of EU and US positions on business matters. Aggregate US investment in Europe totalled more than €2 trillion in 2016, directly supports more than 4.5 million jobs in Europe, and generates billions of euros annually in income, trade and research and development.

American Chamber of Commerce to the European Union
Speaking for American business in Europe

Avenue des Arts/Kunstlaan 53, 1000 Brussels, Belgium • **T** +32 2 513 68 92
info@amchameu.eu • amchameu.eu • European Transparency Register: 5265780509-97

1. Please indicate your preference as regards publication of your contribution

X 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

Comment:

2. Are you replying as:

◯ An individual

◯ An EU institution

◯ A national/regional/local public authority

◯ A company

X A business or workers' organisation

◯ An NGO, environmental or consumer group

◯ A research organisation

◯ Other

Comment: American Chamber of Commerce to the EU

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 Please provide your email address *(Please note that your email address will not be published regardless of the option chosen in question 1)*

fgl@amchameu.eu

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

Comment: AmCham EU represents companies in several sectors including pharmaceuticals, chemicals, water management, human and animal health

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

Comment:

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
- X Work
- ☐ Information from pharmacist/doctor/dentist/hospital/vet
- ☐ Talking with friends/family
- ◯ Other

Comment:

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
- X Other

Comment: Response is on behalf of industry and business.

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.)

- X Yes
- ◯ No
- ☐ Not sure

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

500 character(s) maximum

Most APIs end up in the environment via natural excretion, but a significant proportion is caused by incorrect disposal of unused or expired medicines. We encourage governments, healthcare professionals, patient organizations and all relevant stakeholders to increase public awareness around PIE. An important step in the right direction is the pharmaceutical industry's #Medsdisposal campaign (http://medsdisposal.eu/). Strengthening national collection systems must also remain a priority.

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

X Urgent

◯ No opinion

Comment:

B) For veterinary pharmaceuticals

◯ Not necessary

◯ Necessary but not urgent

◯ Urgent

X No opinion

Comment:

If you wish to, please explain your answer:

1500 character(s) maximum::

We encourage an urgent, open and constructive dialogue on PIE with all relevant stakeholders, taking into account both environmental and public health needs. If risks are identified, prioritized and verified, risk management measures should be adopted in a targeted and proportionate way. As our scientific understanding improves, we will find new ways of detecting trace amounts of pharmaceuticals in the environment and better understand their impact. The pharmaceutical industry is striving to improve our processes and develop novel means of creating treatments that not only save lives, but that are also mindful of the environment. This includes improved stewardship across the medicine life-cycle, while continuing to respond to patients' needs and ensuring access to medicines.

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	X	○	○	○	○	○
*2. "Greener" design of pharmaceuticals, e.g. to make them more biodegradable	○	○	○	○	X	○
*3. More stringent conditions for putting a pharmaceutical on the market	○	○	○	○	☐	X
*4. Cleaner manufacturing	○	○	X	○	○	○
*5. Better risk mitigation, e.g. not allowing over-the-counter sale of pharmaceuticals that pose an environmental risk	○	○	○	○	X	○
*6. Better/more thorough post-market monitoring of pharmaceuticals in the	X	○	○	○	○	○

environment and feedback to the regulatory process						
*7. (a) Better training for medical professionals, e.g. about pharmaceuticals that are less harmful for the environment		X				
*7. (b) Better information for the public, e.g. about how to dispose of unused medicines			X			
*7. (c) Smaller packaging sizes, to reduce unnecessary waste/disposal					X	
*8. Improved handling of waste pharmaceuticals			X			
*9. (a) Improved sewage and wastewater treatment		X				
*9. (b) Improvements in livestock farming to reduce the use/emission of pharmaceuticals					X	

Comment:

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

1500 character(s) maximum:

Comment:

1 & 2 - More research is needed to understand potential risks and evaluate if/which measures should be undertaken. Instead of developing greener medicines, focus should be in developing better tools to predict toxicity earlier in development.

3 - ERA should not be part of benefit/risk assessment as this would undermine access to effective treatments for patients. We support better post-authorization management of environmental risks of APIs.

4 - Manufacturers should take actions where relevant, comply with current legislation and strive for best practices in manufacturing effluent management. However we oppose environmental aspects as part of EU GMP because 1) it would divert the focus away from product quality and patient safety; 2) it would create trade barriers and jeopardize EU's MRAs with third countries, e.g. the US.

5- Not allowing OTC sale of pharmaceuticals neglects why legal status of OTC has been granted: to allow easier access to treatments and ease burden on overall healthcare systems and costs.

7 - Pack sizes are part of the assessment process of the EMA. To ensure the products remain available on the market, individualizing pack-sizes for each treatment may not be feasible from a cost/practical point of view.

8 - All Member States should implement the existing EU legislation to ensure its effective enforcement.

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

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 support the Commission in filling the knowledge gaps and exploring how to protect the environment while safeguarding patient access to medicines. We are in favor of adopting a comprehensive, life-cycle approach and agree that all stakeholders have a shared responsibility to tackle PIE, by acting in the areas under their control/responsibility. We strongly oppose environment to become part of benefit/risk analysis in the marketing authorization process, as well as environmental criteria in GMP for the reasons highlighted

above. We support a flexible framework where monitoring of PIE continues after marketing authorization, environmental risk and mitigation measures are assessed in a science-/risk-based way, and re-adapted as our knowledge improves.

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

***Comment**:*

If you wish to submit additional documentation (up to three pages), please upload your file here.
The maximum file size is 1 MB