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Committee on the Environment, Public Health and Food Safety

2019/2816(RSP)

12.11.2019

DRAFT MOTION FOR A RESOLUTION

further to Question for Oral Answer B9-0000/2019

pursuant to Rule 136(5) of the Rules of Procedure

Strategic approach to pharmaceuticals in the environment (2019/2816(RSP))

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on behalf of the Committee on the Environment, Public Health and Food Safety

B9-0000/2019

European Parliament resolution on Strategic approach to pharmaceuticals in the environment
(2019/2816(RSP))

The European Parliament,

– having regard to Article 168 of the Treaty on the Functioning of the European Union,

– having regard to the Commission Communication of 11 March 2019 entitled 'European Union Strategic Approach to Pharmaceuticals in the Environment' (COM(2019)128),

– having regard to the Political Declaration of the high-level meeting of the United Nations General Assembly of 21 September 2016 on antimicrobial resistance,

– having regard to Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products[1],

– having regard to Regulation (EU) 2019/4 of the European Parliament and of the Council of 11 December 2018 on the manufacture, placing on the market and use of medicated feed[2],

– having regard to Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement[3],

– having regard to Directive 2013/39/EU of the European Parliament and of the Council of 12 August 2013 as regards priority substances in the field of water policy[4],

– having regard to Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use[5],

– having regard to Directive 2000/60/EC of 23 October 2000 establishing a framework for Community action in the field of water policy[6],

– having regard to the Commission proposal for a Directive of the European Parliament and of the Council on the quality of water intended for human consumption (recast) (COM(2017)753),

– having regard to the Commission proposal for a regulation on minimum requirements for water reuse (COM(2018) 337),

[1] OJ L 4, 7.1.2019, p. 43–167.
[2] OJ L 4, 7.1.2019, p. 1–23.
[3] OJ L 094 28.3.2014, p. 65.
[4] OJ L 226, 24.8.2013, p. 1–17.
[5] OJ L 311 , 28/11/2001 P. 0067 - 0128.
[6] OJ L 327, 22.12.2000, p. 1–73

– having regard to the Council conclusions of 26 June 2019 entitled ‘Towards a Sustainable Chemicals Policy Strategy of the Union’,

– having regard to the Commission Communication of 7 November 2018 entitled ’Towards a comprehensive European Union framework on endocrine disruptors’ (COM(2018)734),

– having regard to the Commission communication of 29 June 2017 entitled ‘A European One Health Action Plan against Antimicrobial Resistance’ (COM(2017)339),

– having regard to the Commission Communication of 15 November 2011 entitled ‘Action Plan Against the Rising Threats from Antimicrobial Resistance’ (COM(2011)748),

– having regard to Commission Communication of 10 December 2008 entitled ‘Safe, Innovative and Accessible Medicines: a Renewed Vision for the Pharmaceutical Sector’ (COM(2008)666),

– having regard to its resolution of 13 September 2018 on a European One Health Action Plan against Antimicrobial Resistance (AMR) (2017/2254(INI)),

– having regard to the UN Drinking Water Parameter Cooperation Project,

– having regard to the World Bank report of March 2017 entitled ‘Drug-Resistant Infections: A Threat to Our Economic Future’,

– having regard to the EMA and EFSA Joint Scientific Opinion of 1 December 2016 on measures to reduce the need to use antimicrobial agents in animal husbandry in the European Union, and the resulting impacts on food safety (RONAFA opinion);

– having regard to the Commission’s Science for Environment Policy - Future brief of May 2015 (Issue 11) entitled ‘Sustainable Aquaculture’,

– having regard to the study of July 2018 on options for a strategic approach to pharmaceuticals in the environment[7],

– having regard to the study of December 2013 on the environmental risks of medicinal products[8],

– having regard to the questions to the Commission and the Council on Strategic approach to pharmaceuticals in the environment (O-000000/2019 – B9-0000/2019),

– having regard to Rules 136(5) and 132(2) of its Rules of Procedure,

– having regard to the motion for a resolution of the Committee on the Environment, Public Health and Food Safety,

[7] https://op.europa.eu/en/publication-detail/-/publication/5371e7bd-25db-11e9-8d04-01aa75ed71a1
[8] https://ec.europa.eu/health/sites/health/files/files/environment/study_environment.pdf

A. whereas pharmaceuticals play an essential role in ensuring a high level of public health; whereas there are currently more than 3000 active pharmaceutical ingredients on the European market;

B. whereas the wide use of pharmaceuticals in human and veterinary medicines, including antimicrobial agents, has increased their concentrations in many environmental reservoirs such as soils, sediments and waterbodies in the past 20 years; whereas the largest source of pharmaceuticals entering the environment is their use and disposal;

C. whereas pharmaceuticals reach the environment through the discharge of effluent from urban wastewater treatment plants, the spreading of animal manure and aquaculture, discharge of effluent from manufacturing plants, the spreading of sewage sludge, grazing livestock, the treatment of pets, improper disposal into landfill of unused pharmaceuticals and contaminated waste;

D. whereas the excessive and incorrect use of antibiotics, particularly in livestock farming, and more generally poor practices in both human and veterinary medicine, have progressively rendered antimicrobial resistance a massive threat to human and animal health;

E. whereas pharmaceuticals put on the market before 2006 were not subject to an environmental risk assessment as part of the authorisation process and might therefore still lack such an assessment;

F. whereas an environmental risk assessment is taken into account in the benefit-risk assessment for veterinary medicinal products but not for human medicinal products;

G. whereas there is sufficient evidence that action should be taken to reduce the risk from pharmaceuticals in the environment;

H. whereas the environmental impact of pharmaceuticals has been recognised as an issue of concern by a large number of international organisations, third countries, European institutions, industry associations and Non-Governmental Organisations;

I. whereas the Commission had committed to propose measures to reduce the potentially harmful impacts of pharmaceuticals on the environment in 2008[9];

J. whereas according to Article 8c of Directive 2013/39, the Commission was obliged to develop a strategic approach to pollution of water by pharmaceutical substances by 13 September 2015 and to propose measures by 14 September 2017;

K. whereas in its conclusions of June 2019, the Council called upon the Commission “to assess and define the most effective measures, including legislative measures, to mitigate the effects of pharmaceuticals in the environment and to combat the development of antimicrobial resistance and to reinforce the link with the health sector in this regard”;

L. whereas there is self-regulation to limit the negative impact of pharmaceuticals in the

[9] Commission Communication of 10 December 2008 entitled ‘Safe, Innovative and Accessible Medicines: a Renewed Vision for the Pharmaceutical Sector’ (COM(2008)666)

environment, such as iPiE (Intelligent Assessment of Pharmaceuticals in the Environment);

General considerations

1. Welcomes that the Commission finally adopted its communication of 11 March 2019; regrets that there has been a serious delay in presenting the strategic approach and the proposed actions;

2. Agrees with the four main objectives of the strategic approach as presented by the Commission;

3. Notes however with concern the very soft nature of the measures included in the communication; considers that legislative measures are needed in addition to non-legislative measures to properly tackle pharmaceutical pollution;

4. Recalls that any future initiatives in the field of the environmental impact of pharmaceuticals should be science and target driven, as well as technology neutral, making sure that safety and efficacy still remain key priority features for access for patients to pharmaceutical treatments;

5. Considers that a holistic approach is needed to tackle pharmaceutical pollution, taking into account the entire life cycle of drugs; stresses that regulatory actions have to be taken in line with the precautionary principle; highlights that the polluter pays principle should apply, primarily covering the manufacturing process, but also incentivising better prescription practices and consumer behaviour;

6. Highlights that emissions of pharmaceuticals into the environment may not only harm ecosystems, but may also undermine the effectiveness of these same pharmaceuticals, as they can cause the emergence of antibiotic resistance;

7. Recalls that studies have shown that pharmaceutical products are especially present in water bodies, and that they are ineffectively filtered by wastewater treatment plants;

8. Notes that due to generally low concentrations, risks are more related to possible cumulative effects of long-term low-dose exposure than to acute or immediate health effects; is particularly concerned by the endocrine disrupting properties of many pharmaceuticals ending up in the environment;

9. Points to the need to regulate pharmaceuticals under water legislation; recalls that interinstitutional negotiations are on-going on a review of the Directive on the quality of water intended for human consumption and on a regulation on minimum requirements for water reuse;

10. Asks for a special focus to be put on emission hot spots, such as hospitals and pharmaceutical production plants;

11. Calls on the Commission to facilitate the exchange of existing best practices;

Increase awareness and promote prudent use of pharmaceuticals

12. Calls on the Member States to share best practices in the preventive use of antibiotics and to reinforce the 'One Health Action Plan Against Antimicrobial Resistance'; reaffirms the positions expressed in its resolution of 13 September 2018 on a European One Health Action Plan against Antimicrobial Resistance;

13. Calls on the Member States and on the Commission to promote awareness-raising campaigns among veterinaries and physicians on the prudent use of pharmaceuticals, particularly of antimicrobials; calls on actors in the pharmaceutical supply chain to contribute to providing to patients with sufficient information on how incorrectly disposed medicines may negatively impact the environment; calls for on-pack labelling in the form of an appropriate pictogramme to inform consumers how to properly dispose of unused medicines;

Support the development of pharmaceuticals intrinsically less harmful for the environment and promote greener manufacturing

14. Highlights the importance of the design, development and manufacturing phases to minimise the environmental impact of pharmaceuticals;

15. Calls on Member States and the Commission to support the development of pharmaceuticals intrinsically less harmful for the environment ('greener pharmaceuticals'), which degrade more readily, into harmless substances, in wastewater treatment plants and the environment;

16. Considers that the environmental impacts of pharmaceuticals could be included into the benefit-risk assessment of human medicines, as is already the case for veterinary medicines;

17. Calls the Commission to take into account, where appropriate, ongoing existing efforts by stakeholders for future initiatives to reduce environmental risks and promote environmentally responsible practices;

18. Calls for monitoring data from the Water Framework Directive to be used for post-market evaluation;

19. Calls on the Commission to ensure that the emission of pharmaceuticals to water is considered as a possible Key Environmental Issue when reviewing Best Available Techniques Reference Documents under the Industrial Emissions Directive for relevant sectors;

20. Points to the important role of procurement policy in promoting greener pharmaceuticals; calls on the Commission to develop clear guidance on this issue;

21. Calls on the Commission to take all necessary action to ensure that the production of imported medicines meets the same high environmental standards as applicable to medicines produced in the Union;

Improve environmental risk assessment and its review

22. Considers that a clear road map for completing environmental risk assessments is

needed, where those are not available;

23. Calls on Member States and the European Medicines Agency to make sure that applicants submit a completed assessment by the time of the authorisation for marketing human medicinal products, so that adequate risk management measures can be established and published;

24. Considers it appropriate that pharmaceutical companies submit a joint environmental risk assessment per active substance so as to have coherent information, avoid duplication of work and reduce animal testing;

25. Points to the need to implement fully the veterinary medicines and medicated feed regulation, in order to reduce the use of antibiotics, including by evaluating the feasibility of setting up of an EU-wide active substance-based review system and other potential alternatives for the environmental risk assessment;

Reduce wastage and improve the management of waste

26. Stresses that measures must be based on scientific evidence and calls on all relevant players to ensure that actions taken do not jeopardise access to safe and effective pharmaceutical treatments for human patients and animals; in this regard, supports the Commission's intention to reduce waste by allowing that medicines be dispensed in quantities better matching needs, including by optimising the package size, and to explore the possibility to extend expiry dates for medicines to avoid that medicines that can still be safely used are unnecessarily thrown away;

27. Considers that the overall per capita drug consumption should be reduced, without jeopardising patients' health; is of the opinion that the overall per animal veterinary medicines consumption should also decrease;

28. Considers that a review of Directive 86/278/EEC on sewage sludge is long overdue; calls on the Commission to make a legislative proposal to review and update Directive 86/278/EEC no later than by the end of 2020, not least so as to avoid that pharmaceutical residues are spread onto fields;

29. Considers that pharmaceutical production plants should pre-treat their wastewater;

30. Calls for full enforcement of the existing provisions with regard to take-back schemes for unused medicines;

31. Calls on the Commission to coordinate cooperation on schemes aiming at avoiding improper discard of pharmaceuticals;

Expand environmental monitoring

32. Is concerned that monitoring of pharmaceuticals in the environment is still very limited; stresses the need to strengthen post-marketing control mechanisms into comprehensive monitoring, also with regard to environmental effects, as the current surveillance system (pharmacovigilance) is not adequately and systematically covering the environmental data deficit;

33. Calls on the Commission to address the possible impact of pharmaceuticals on the watchlist pursuant to the Water Framework Directive and to assess whether the list should be updated;

34. Highlights that comprehensive monitoring of antibiotics has been developed in farming; calls on the Commission to also develop a monitoring system in relation to human antibiotics;

Fill other knowledge gaps

35. Emphasises the need to support further research, particularly under the next multi-annual financial framework, on the direct impact on human health of exposure to pharmaceuticals and their residues in the environment and on better understanding how pharmaceuticals enter and persist in the environment;

36. Considers that the methods of analysis to quantify the presence of pharmaceuticals in the environment should be improved;

Increase transparency

37. Recalls that pharmaceutical environmental information plays a key role for risk management and that this type of information should be made available to relevant stakeholders;

38. Believes that a strong legislative framework should be established to increase transparency throughout the entire supply chain, as this would allow proper scrutiny and ensure companies are held to account for the environmental release of pharmaceuticals;

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39. Instructs its President to forward this resolution to the Council and the Commission.