

Thursday 17 September 2020

P9\_TA(2020)0226

**Strategic approach to pharmaceuticals in the environment****European Parliament resolution of 17 September 2020 on a strategic approach to pharmaceuticals in the environment (2019/2816(RSP))**

(2021/C 385/07)

*The European Parliament,*

- having regard to the Treaty on the Functioning of the European Union (TFEU), and in particular Articles 11, 168 and 191(2) thereof,
- having regard to Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products <sup>(1)</sup>,
- 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 <sup>(2)</sup>,
- having regard to Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement <sup>(3)</sup>,
- 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 <sup>(4)</sup>,
- 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 <sup>(5)</sup>,
- having regard to Directive 2000/60/EC of 23 October 2000 establishing a framework for Community action in the field of water policy <sup>(6)</sup>,
- having regard to Directive 2008/56/EC of the European Parliament and of the Council of 17 June 2008 establishing a framework for community action in the field of marine environmental policy (Marine Strategy Framework Directive) <sup>(7)</sup>,
- having regard to Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (the 'REACH Regulation') <sup>(8)</sup>,
- having regard to Decision No 1386/2013/EU of the European Parliament and of the Council of 20 November 2013 on a General Union Environment Action Programme to 2020 'Living well, within the limits of our planet' (the '7th EAP') <sup>(9)</sup>,
- 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)0753),

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<sup>(1)</sup> OJ L 4, 7.1.2019, p. 43.

<sup>(2)</sup> OJ L 4, 7.1.2019, p. 1.

<sup>(3)</sup> OJ L 94, 28.3.2014, p. 65.

<sup>(4)</sup> OJ L 226, 24.8.2013, p. 1.

<sup>(5)</sup> OJ L 311, 28.11.2001, p. 67.

<sup>(6)</sup> OJ L 327, 22.12.2000, p. 1.

<sup>(7)</sup> OJ L 164, 25.6.2008, p. 19.

<sup>(8)</sup> OJ L 396, 30.12.2006, p. 1.

<sup>(9)</sup> OJ L 354, 28.12.2013, p. 171.

Thursday 17 September 2020

- having regard to the Commission proposal for a regulation on minimum requirements for water reuse (COM(2018)0337),
- having regard to the Council conclusions of 25 June 2019 on the next steps towards making the EU a best practice region in combating antimicrobial resistance,
- 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 11 March 2019 entitled ‘European Union Strategic Approach to Pharmaceuticals in the Environment’ (COM(2019)0128),
- having regard to the Commission Communication of 7 November 2018 entitled ‘Towards a comprehensive European Union framework on endocrine disruptors’ (COM(2018)0734),
- having regard to the Commission communication of 29 June 2017 entitled ‘A European One Health Action Plan against Antimicrobial Resistance’ (COM(2017)0339),
- having regard to the Commission communication of 15 November 2011 entitled ‘Action plan against the rising threats from Antimicrobial Resistance’ (COM(2011)0748),
- having regard to the Commission communication of 10 December 2008 entitled ‘Safe, Innovative and Accessible Medicines: a Renewed Vision for the Pharmaceutical Sector’ (COM(2008)0666),
- having regard to the Commission communication of 11 December 2019 entitled ‘The European Green Deal’ (COM(2019)0640),
- having regard to its resolution of 13 September 2018 on a European One Health Action Plan against Antimicrobial Resistance (AMR) <sup>(10)</sup>,
- having regard to its resolution of 15 January 2020 on the European Green Deal <sup>(11)</sup>,
- having regard to several Member States’ programmes to reduce pharmaceutical residues in water,
- having regard to the European Medicines Agency (EMA) and European Food Safety Authority (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 successive annual European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) reports (since 2011),
- having regard to the Commission publication Science for Environment Policy — Future Brief of May 2015 (Issue 11) entitled ‘Sustainable Aquaculture’,
- having regard to the Commission reflection paper of 30 January 2019 entitled ‘Towards a Sustainable Europe by 2030’ (COM(2019)0022),
- having regard to the Organisation for Economic Co-operation and Development (OECD) study of 13 November 2019 entitled ‘Pharmaceutical Residues in Freshwater — Hazards and Policy Responses’,
- having regard to the political declaration of the high-level meeting of the UN General Assembly of 22 September 2016 on antimicrobial resistance,

<sup>(10)</sup> OJ C 433, 23.12.2019, p. 153.

<sup>(11)</sup> Texts adopted, P9\_TA(2020)0005.

Thursday 17 September 2020

- 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 Commission report of July 2018 on options for a strategic approach to pharmaceuticals in the environment,
  - having regard to the report of the Executive Agency for Health and Consumers of 12 December 2013 on the environmental risks of medicinal products,
  - having regard to the questions to the Council and the Commission on a strategic approach to pharmaceuticals in the environment (O-000040/2020 — B9-0015/2020 and O-000041/2020 — B9-0016/2020),
  - 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,
- A. whereas pharmaceuticals play an essential role in ensuring a high level of human and animal health; whereas there are currently more than 3 000 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 environmental concentrations are likely to increase further as the population grows and ages; whereas climate change will furthermore affect both the quantity and the quality of water resources, as at times of drought concentrations will be higher, which also has a knock-on effect on water treatment; whereas there is a need for widespread gathering of data to measure this problem around the world; 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, and the improper disposal into landfill of unused pharmaceuticals and contaminated waste;
- D. whereas the inappropriate use of antibiotics, particularly in livestock farming, and poor practices in both human and veterinary medicine more generally, have progressively rendered antimicrobial resistance a massive threat to human and animal health;
- E. whereas the OECD in its latest report on pharmaceutical residues in freshwater found that 'current policy approaches to manage pharmaceutical residues are inadequate for the protection of water quality and freshwater ecosystems upon which healthy lives depend';
- F. whereas the chemical and/or metabolic stability of certain pharmaceuticals means that up to 90 % of their active substances are released into the environment in their original form after use;
- G. whereas pharmaceuticals authorised for human use and 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;
- H. whereas an environmental risk assessment is taken into account in the benefit-risk assessment for veterinary medicinal products but not for human medicinal products;
- I. whereas, in its communication of 11 March 2019, the Commission itself acknowledges the knowledge gaps in terms of concentrations of certain pharmaceuticals in the environment and the resulting levels of risk;

Thursday 17 September 2020

- J. whereas there is sufficient evidence that action should be taken to reduce the environmental impact from pharmaceutical substances, which can pose a risk to the environment, especially for the protection of waters used for the abstraction of drinking water;
- K. 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; whereas some EU Member States such as the Netherlands, Germany and Sweden have already taken action to address the growing presence of pharmaceuticals in the environment;
- L. whereas the Commission had committed in 2008 to propose measures to reduce the potentially harmful impacts of pharmaceuticals on the environment <sup>(12)</sup>;
- M. whereas in accordance with Article 8c of Directive 2013/39/EU, 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;
- N. whereas in its conclusions of June 2019, the Council called on 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'; whereas the Council acknowledged that further research is required to better understand the extent of the emerging human health and environmental impact of pharmaceuticals and their residues;
- O. whereas the AMR Industry Alliance has developed industry-driven principles under the Common Antibiotic Manufacturing Framework and determined targets for antibiotic discharge concentration in order to protect ecological resources and lower the potential risk of AMR development in the environment;
- P. whereas human and animal health players and professionals, patients, industry, waste management and water treatment operators, etc., have a role to play in reducing the impact of pharmaceutical products on the environment;
- Q. whereas the OECD advocates four proactive strategies with a focus on preventive options early in a pharmaceutical product's life cycle to cost-effectively manage pharmaceuticals in the environment and to deliver the most long-term and large-scale environmental benefits;
- R. whereas a campaign was launched by several stakeholders to raise awareness on how to dispose of unused or expired medicines appropriately in Europe as part of the MedsDisposal initiative;
- S. whereas any measure regarding the environmental impact of drugs must consider as the prevailing principle the right of patients to swift access to drugs deemed safe and effective with respect to the current risk-benefit assessment criteria;

### **General considerations**

- 1. Welcomes the fact that the Commission finally adopted its communication of 11 March 2019; considers it regrettable 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 with concern, however, the soft nature of the measures included in the communication; considers that effective measures are needed to mitigate the negative impacts of pharmaceuticals in the environment;

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<sup>(12)</sup> Commission communication of 10 December 2008 entitled 'Safe, Innovative and Accessible Medicines: a Renewed Vision for the Pharmaceutical Sector' (COM(2008)0666).

Thursday 17 September 2020

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 priorities for patients' access to pharmaceutical treatments;
5. Considers that a holistic approach, including all stakeholders concerned, is needed to tackle pharmaceutical pollution, taking into account the entire life cycle of drugs; stresses that, in order to ensure the effectiveness of regulatory actions, it is crucial that they are taken in line with the precautionary principle and the principle that environmental damage should as a priority be rectified at source; highlights that the polluter pays principle should apply, primarily covering the manufacturing process, but also incentivising better prescription practices and responsible consumer behaviour; notes with concern the role that pharmaceuticals play in contributing to antimicrobial resistance when released into the environment via the discharge of animal manure, water pollution or improper disposal; calls on the Commission to consider the use of extended producer responsibility to decrease the negative impacts of pharmaceuticals on the environment;
6. Considers it necessary to organise, in collaboration with the Member States, campaigns to inform and educate the public about the dangers of over-consumption of non-prescribed medicines; draws attention to the increase in the number of supermarket and online sales of medicines without medical recommendation, and to the danger of media advertising for such points of sale outside of pharmacies or suitably accredited establishments;
7. Highlights the fact that the discharge of pharmaceuticals into the environment may not only harm ecosystems and wildlife, but may also undermine the effectiveness of these same pharmaceuticals, especially in the case of antibiotics, as they can cause the emergence of antibiotic resistance;
8. Recalls that pharmaceuticals have diverse impacts on aquatic and marine ecosystems but also wildlife, including behavioural changes, fecundity reduction, size modification or development of sexual and reproductive abnormalities; calls on the Commission, therefore, to integrate concrete measures taking into account the cumulative effects of pharmaceutical products' contamination on aquatic and marine species;
9. Recalls that studies have shown that pharmaceutical products and residues are especially present in waterbodies, and that they are not completely removed by conventional wastewater treatment plants, which currently cannot effectively filter out all pharmaceutical products; highlights that contamination of freshwater and river basins leads to contamination of the oceans;
10. Notes that due to generally low concentrations, risks to human health 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 certain pharmaceuticals ending up in the environment;
11. Points to the need to regulate the level of pharmaceutical residues under water legislation;
12. Asks for a special focus to be put on discharge hotspots, such as pharmaceutical production plants, hospitals and wastewater treatment plants;
13. Calls on the Commission to also consider the impact of pharmaceuticals in the context of the zero-pollution action plan for air, water and soil announced by the Commission for 2021;
14. Calls on the Commission to facilitate the exchange of existing best practices among Member States and stakeholders with a view to reducing the environmental impacts of the manufacture, use and disposal of pharmaceuticals;
15. Believes that existing and self-regulated initiatives should be analysed and, where appropriate, considered in future EU initiatives on pharmaceuticals in the environment;

Thursday 17 September 2020

***Increasing awareness and promoting prevention measures and prudent use of pharmaceuticals***

16. Calls on the Member States to share best practices in the preventive use of antibiotics and to fully implement and, if necessary, 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;

17. Calls on the Member States and the Commission to promote training for healthcare professionals, including veterinarians, physicians and pharmacists, and awareness-raising campaigns for patients, on the prudent use of pharmaceuticals, such as antimicrobials, antidepressants and contrast fluids; calls on actors in the pharmaceutical supply chain to contribute to providing patients and stockbreeders with clear and sufficient information on how medicines, when disposed of incorrectly, may negatively impact the environment; calls for on-pack labelling in the form of an appropriate pictogram to inform consumers how to properly dispose of unused medicines;

18. Stresses that health professionals must be kept continuously up to date regarding the latest developments in research and good practices when it comes to preventing the spread of AMR;

19. Calls on the Member States to include the issue of pharmaceuticals in the environment in their cross-border cooperation in river basins, and to coordinate measures where they are deemed useful;

20. Calls on the Commission and the Member States to promote vaccination as a disease prevention measure, so as to minimise the need for pharmaceuticals;

***Supporting the development of pharmaceuticals that are intrinsically less harmful for the environment and promoting greener manufacturing***

21. Highlights the importance of faster, more ambitious and targeted action to reduce the environmental risks posed by pharmaceuticals, while acknowledging the need for further research for a better understanding of the extent of the current impact of pharmaceuticals on human health and the environment, and that the price of pharmaceutical products should not increase as a result;

22. Notes that, in relation to the healthcare sector, addressing any excessive workforce pressures on physicians is a necessary condition for healthcare professionals to ensure that antimicrobials are prescribed appropriately; further notes that healthcare professionals could be further assisted via the provision of clear, evidence-based prescribing guidance that provides consistent advice across different clinical indications;

23. Calls on the Member States and the Commission to support research, development and innovation in the field of pharmaceuticals that are equally effective for patients and intrinsically less harmful for the environment, given that 'greener pharmaceuticals' are not toxic for the environment, do not bioaccumulate, and degrade more readily, into harmless substances, in wastewater treatment plants and the environment, while taking into account that greater biodegradability could potentially impair the efficacy;

24. Calls on the Member States and all stakeholders concerned to make use of EU programmes to invest in technology aimed at improving the effectiveness of the disposal of pharmaceutical products and antimicrobial-resistant genes while ensuring that such products are just as effective in terms of meeting patients' needs;

25. Considers that the environmental impacts of pharmaceuticals should be included in the benefit-risk assessment of human medicines, as is already the case for veterinary medicines, provided that marketing authorisations are not delayed nor refused solely on the grounds of adverse environmental impacts;

26. Considers that the environmental assessment of pharmaceuticals should encompass their degradation products and metabolites;

Thursday 17 September 2020

27. Calls on the Commission to take into account, where appropriate, ongoing efforts by stakeholders to develop future initiatives to reduce environmental risks, and to promote environmentally responsible practices and appropriate use and return of pharmaceuticals;
28. Calls for monitoring data from the Water Framework Directive to be used for post-market evaluation;
29. Calls on the Commission to ensure that the discharge of pharmaceuticals into water is considered as a possible Key Environmental Issue when reviewing Best Available Techniques Reference Documents under the Industrial Emissions Directive for relevant sectors;
30. Points to the important role of procurement policy in promoting greener pharmaceuticals; calls on the Commission to develop clear guidance on this issue;
31. Calls on the Commission to take all necessary action to ensure that the production of imported medicines meets the same high environmental standards as those applicable to medicines produced in the Union;
32. Calls on the European Medicines Agency (EMA) to facilitate joint inspections of manufacturing discharges at overseas pharmaceutical factories supplying the EU;

***Improving environmental risk assessment and its review***

33. Considers that a clear road map for completing environmental risk assessments is needed, where they are not available;
34. Calls on the Member States and the EMA 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;
35. 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;
36. Points to the need to implement in full the regulations on veterinary medicines and medicated feed with a view to reducing the use of antibiotics, including by evaluating the feasibility of setting up an EU-wide active substance-based review system by 28 January 2022 and other potential alternatives for the environmental risk assessment;
37. Calls on the Commission to support research on the assessment of mixture effects, chronic low-dose exposure and antimicrobial resistance development, especially in relation to vulnerable groups;

***Reducing wastage and improving the management of waste***

38. Stresses that measures must be based on scientific evidence and calls on all relevant stakeholders to ensure that no action taken jeopardises 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 medicines to be dispensed in quantities better matching patients' needs, while ensuring compliance with current traceability legislation, including by optimising package sizes, and to explore the possibility of extending expiry dates for medicines so that medicines that can still be used safely are not unnecessarily thrown away;
39. Calls for an update of the requirements with regard to the environmental risk assessment to ensure a proper assessment of persistent, bioaccumulative and toxic substances and of mixture effects, and to take into account the risk of antimicrobial resistance developing in the environment;



**Thursday 17 September 2020**

40. Considers that overall per capita drug consumption should be reduced, without causing difficulties in access to medicines and without reducing the effectiveness of treatments; is of the opinion that overall per animal consumption of veterinary medicines should also decrease, without compromising animal health and welfare, and that better alternatives should be found;

41. Considers that a review of Directive 86/278/EEC on sewage sludge is long overdue; calls on the Commission to present a legislative proposal to review and update Directive 86/278/EEC by no later than the end of 2021, in order to update quality standards in accordance with the latest scientific evidence and to promote a circular economy which does not harm human health and the environment;

42. Considers that pharmaceutical production plants should pre-treat their wastewater using the best techniques available;

43. Calls on the Member States to establish, widely promote and fully enforce provisions for take-back schemes for unused medicines;

44. Calls on the Commission to coordinate cooperation on schemes aimed at avoiding improper disposal of pharmaceuticals;

45. Calls on the Commission and the Member States to support research, innovation and development vis-à-vis more advanced wastewater treatment technologies that can detect and improve the removal of pharmaceutical residues;

#### ***Expanding environmental monitoring***

46. Is concerned that monitoring of pharmaceuticals in the environment, including in soil, is still very limited; stresses the need to strengthen post-marketing surveillance mechanisms, also with regard to environmental effects, so as to adequately and systematically cover the environmental data deficit;

47. Calls on the Commission to address the possible impact of pharmaceuticals on the watch list under the Water Framework Directive and to assess whether the list should be updated;

48. Calls on the Commission to include pharmaceuticals that pose a significant risk to the environment in the list of priority substances under the Water Framework Directive and to set environmental quality standards and concentration limits under the Environmental Quality Standards (EQS) Directive;

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

#### ***Filling other knowledge gaps***

50. Emphasises the need to support further research, particularly under the next multiannual financial framework, on the direct impact of exposure to pharmaceuticals and their residues in the environment on human health and ecology and on better understanding how pharmaceuticals enter and persist in the environment, including in aquatic and marine ecosystems;

51. Considers that the methods of analysis to quantify the presence of pharmaceuticals in the environment and their development should be improved, and that analytical detection methods should be made publicly available;

#### ***Increasing transparency***

52. Recalls that pharmaceutical environmental information such as the impact on water, environmental behaviour, degradability and possible cocktail effects plays a key role in risk management and that this type of information should be transparent and made available to relevant stakeholders; therefore calls on the Commission and the relevant authorities to set up a secure, centralised database enabling all stakeholders concerned to have access to the results of the environmental risk assessments of products;



Thursday 17 September 2020

53. 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 that companies are held to account for the environmental release of pharmaceuticals;

54. Calls on the pharmaceutical industry to provide more transparency in supply chains by disclosing the origin of drugs and active pharmaceutical ingredients (API) at raw material production stage, to ensure total traceability of all pharmaceutical products;

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

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