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# COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL AND THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE

## European Union Strategic Approach to Pharmaceuticals in the Environment



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# COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL AND THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE

## European Union Strategic Approach to Pharmaceuticals in the Environment

## 1. INTRODUCTION

The treatment of many diseases in humans and animals relies on access to effective pharmaceuticals[1]. At the same time, pollution caused by some pharmaceuticals is an emerging problem[2,3,4], with well-documented evidence of risks to the environment and, particularly in relation to antimicrobial resistance, to human health. Residues of pharmaceutical products may enter the environment during their manufacture, use and disposal.

Article 8c of the Priority Substances Directive (2008/105/EC[5] as amended by Directive 2013/39/EU[6]) requires the European Commission to propose a strategic approach to the pollution of water by pharmaceutical substances. With the present Communication, the Commission is delivering on that legal obligation, as well as on a call referred to in the pharmacovigilance legislation to examine the scale of the problem of pollution of water and soils with pharmaceutical residues[7]. The approach supports the Commission's aim of delivering a Europe that protects[8], and fits well with its intention to work towards a sustainable Europe by 2030, guided by the Sustainable Development Goals[9]. It delivers on a commitment made by the Commission at the 3rd session of the United Nations Environment Assembly in 2017. It will contribute in particular to achieving Sustainable Development Goal 6 on clean water and sanitation. Furthermore, as a component of the Union's One-Health Action Plan against Antimicrobial Resistance[10], it can be seen as part-implementation of the

[1] The term "pharmaceuticals" is used here to refer to human or veterinary medicinal products. Usually, the active pharmaceutical ingredients (APIs) are the substances of concern, but also their metabolites and degradation products may be relevant, as well as some ingredients (excipients) other than the active substance and the packaging material.

[2] COM (2008) 666 Final: Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on Safe, Innovative and Accessible Medicines: A Renewed Vision for the Pharmaceutical Sector.

[3] Regulation (EU) No 1235/2010 of the European Parliament and of the Council of 15 December 2010 amending, as regards pharmacovigilance of medicinal products for human use, Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, and Regulation (EC) No 1394/2007 on advanced therapy medicinal products, OJ L 348, 31.12.2010, p. 1; Directive 2010/84/EU of the European Parliament and of the Council of 15 December 2010 amending, as regards pharmacovigilance, Directive 2001/83/EC on the Community code relating to medicinal products for human use, OJ L 348, 31.12.2010, p. 74

[4] https://ec.europa.eu/health/sites/health/files/scientific_committees/scheer/docs/scheer_s_002.pdf

[5] Directive 2008/105/EC, OJ L348, 24.12.2008, p.84

[6] Directive 2013/39/EU, OJ L 226, 24.8.2013, p.1

[7] Recital 6 of Directive 2010/84/EU, OJ L 348, 31.12.2010, p.74

[8] http://europa.eu/rapid/press-release_IP-16-3500_en.htm

[9] https://ec.europa.eu/commission/publications/reflection-paper-towards-sustainable-europe-2030_en

[10] COM/2017/0339 final: Communication from the Commission to the Council and the European Parliament: A European One Health Action Plan against Antimicrobial Resistance (AMR) https://eur-lex.europa.eu/legal-content/GA/TXT/?uri=CELEX:52017DC0339



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commitment taken in the context of the G7/G20 and World Health Organisation regarding antimicrobial resistance.

The approach has been informed by a number of studies and reports[11], and by the results of public and targeted stakeholder consultations launched in 2017[12]. It takes account of the international dimension to the problem and circular economy considerations.

The pharmaceutical sector is a vibrant industry, with a drive to innovate. Such innovation could support "green design", for example the development of products that pose a lower environmental risk or facilitate the recycling of waste water, and promote the use of greener manufacturing methods. Innovation in water and manure treatment may also be possible. In these respects, the approach will contribute to the Commission's first political priority of promoting jobs, growth and investment.

## 2. PROBLEM DEFINITION

### 2.1 Concentrations of pharmaceuticals in the environment

Residues of several pharmaceuticals have been found in surface and ground waters, soils and animal tissues across the Union at concentrations depending upon the pharmaceutical and the nature and proximity of sources. Certain painkillers, antimicrobials, antidepressants, contraceptives and antiparasitics are commonly found[13]. Traces of some pharmaceuticals have also been found in drinking water[14].

### 2.2 Sources of pharmaceuticals in the environment

The largest source of pharmaceuticals entering the environment is use; the route will likely differ depending upon whether human or veterinary use is involved. The chemical and/or metabolic stability of some pharmaceuticals means that up to 90% of the active ingredient is excreted (or washed off) in its original form. Wastewater treatment varies in its ability to eliminate pharmaceutical residues[15], depending upon the substance and the level of treatment; in some cases, substantial amounts are removed, in others, only a small percentage; but even the best, most expensive, current treatments are not 100% effective. The release of veterinary medicines to the environment tends to come from untreated diffuse sources such as the spreading of manure.

Pharmaceuticals mainly reach the environment through:

- the discharge of effluent from urban waste water (sewage) treatment plants – containing excreted pharmaceuticals as well as unused pharmaceuticals thrown away into sinks and toilets, despite the existence of collection schemes;

[11] BIO Intelligence Service 2013 Study on the environmental risks of medicinal products. https://ec.europa.eu/health/sites/health/files/files/environment/study_environment.pdf; Report of the 2014 Commission workshop on pharmaceuticals in the environment https://circabc.europa.eu/w/browse/5d532921-1e1f-48f5-b0e0-3057798423ca and http://ec.europa.eu/environment/water/water-dangersub/index.htm#strategic

[12] http://ec.europa.eu/environment/water/water-dangersub/index.htm#strategic

[13] http://ec.europa.eu/environment/water/water-dangersub/index.htm#strategic

[14] http://ec.europa.eu/environment/water/water-drink/pdf/20171215_EC_project_report_final_corrected.pdf

[15] Metabolites (conversion products) may have lower biological activity (see case studies in http://ec.europa.eu/health/human-use/environment-medicines/index_en.htm) but may, e.g. if conjugated, be converted back to the parent pharmaceutical during sewage treatment, or have similar biological activity.



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- the spreading of animal manure; and
- aquaculture, in which pharmaceuticals are often dispensed with the animal feed.

Other sources are:

- the discharge of effluent from manufacturing plants (especially those outside the Union);
- the spreading of sewage sludge, i.e. containing pharmaceuticals removed from waste water;
- grazing livestock;
- the treatment of pets;
- improper disposal into landfill of unused pharmaceuticals and contaminated waste.

## 2.3 Effects on the environment

Most pharmaceuticals are designed to act at low concentrations so that they can be tolerated by the human or animal body, and to last long enough to have their intended effect. Pharmaceuticals that persist in the environment and spread through water and soil or accumulate in plants or wildlife, as well as pharmaceuticals whose environmental concentrations are steady because of constant release, may pose a risk because of their toxicity or similar properties. Studies have shown direct effects on wildlife from some pharmaceuticals at or even below the low concentrations found in water and soil[16]. For example, male fish exposed to such concentrations of the main ingredient in the contraceptive pill may become feminised as a result of its effects on the endocrine system, thus affecting the capacity of the population to reproduce[17]. In other studies, fish exposed to low concentrations of certain antidepressants have been found to change their behaviour in ways that could affect their survival[18]. The painkiller diclofenac has been found in fish and otters[19]. Alarm was raised several years ago over the unexpectedly lethal effect of this pharmaceutical on vultures in Asia, which were exposed to it via the carcasses of cattle treated with it[20]. A decline in populations of dung beetles is thought to be at least partly attributable to the use of anti-parasitic pharmaceuticals, including ivermectin[21] in livestock. This has consequences for nutrient cycling, and other indirect effects on ecosystems including rare bat and bird species may also be significant[22].

## 2.4 Effects *via* the environment, including antimicrobial resistance

As yet, no clear link has been established between pharmaceuticals present in the environment and direct impacts on human health. The World Health Organisation reports[23] that the weight of evidence from several recent studies points to it being very unlikely that

[16] Niemuth NJ and Klaper RD 2015. Chemosphere 135: 38-45; Fent K 2015. Environ Int 84:115-30; Matthiessen P and Sumpter JP 1998. EXS. 86:319-35
[17] Kidd KA et al 2007. PNAS 104(21): 8897-8901
[18] Dzieweczynski, TL et al. 2016. J Exp Biol. 219: 797-804
[19] Richards NL et al. 2011. Eur J Wild Res 57(5): 1107-1114
[20] Naidoo V et al. 2009. Regul Toxicol Pharmacol 53(3): 205-8
[21] Verdú JR et al. 2015. Scientific Reports 5: 13912
[22] LIFE11 NAT/BE/001060,http://www.lifeprairiesbocageres.eu/fileadmin/Life/Prairies_bocageres/brochure_LPB_antiparasitaires_final.pdf
[23] http://ec.europa.eu/environment/water/water-drink/pdf/20171215_EC_project_report_final_corrected.pdf



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pharmaceuticals in drinking water pose a threat to human health at the low concentrations[24] found. However, it notes that the issue of pharmaceutical residues cannot be ignored, and refers to its earlier report[25] which mentions the possible effects of long-term exposure on vulnerable populations, hence the need for a precautionary approach, consistent with the Commission's proposal to introduce a relevant parameter into the Drinking Water Directive[26].

Several antimicrobial (antibiotic and antifungal) pharmaceuticals from the treatment of humans and animals have been found in water and soil: their presence may play a role in accelerating the development, maintenance and spread of resistant bacteria and fungi. The Commission's 2011 Communication on an Action Plan against the rising threats from Antimicrobial Resistance (AMR)[27] recognised this. Evidence has grown[28], as reflected in the revised Action Plan published in 2017[29]. The One Health approach in the Action Plan, which had previously already taken account of the interconnection between human and animal health, now also encompasses the environmental dimension, recognising it as another link between diseases in humans and animals and as a potential source of new resistant microorganisms. As well as referring to this Strategic Approach, the Action Plan includes some additional measures to better address the role of the environment in AMR.

Of particular concern are the indications that emissions from some antimicrobial manufacturing plants in third countries[30], some of which supply products for consumption also in the Union, could be contributing to the development and spread of antimicrobial resistance at global level.

## 2.5 Knowledge gaps

The growing body of evidence regarding pharmaceuticals in the environment includes the results of several Union-funded projects[31]. More information is still needed to understand and evaluate certain pharmaceuticals as regards their environmental concentrations and the resulting levels of risk. One reason is that many pharmaceuticals put on the market several years ago were not subject to an environmental risk assessment as part of the authorisation process. Another reason is that monitoring of pharmaceuticals in the environment is very limited, although selected substances are monitored in surface and ground-waters under the Water Framework Directive[32,33,34].

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[24] Concentrations typically several orders of magnitude lower than the minimum therapeutic dose

[25] http://apps.who.int/iris/bitstream/10665/44630/1/9789241502085_eng.pdf?ua=1

[26] COM (2017) 753 final: Proposal for a Directive of the European Parliament and of the Council on the quality of water intended for human consumption (recast)

[27] COM (2011) 748 final: Communication from the Commission to the European Parliament and the Council on an Action Plan Against the Rising Threats from Antimicrobial Resistance

[28] e.g. ECDC/EFSA/EMA, 2015. EFSA Journal 2015;13(1):4006, 114 pp. doi:10.2903/j.efsa.2015.4006; Finley RL et al. 2013. Clinical Infectious Diseases 57(5): 704-710

[29] See footnote 10

[30] Lubbert C et al. 2018. Scientific Reports 45: 479

[31] Knappe, Poseidon, Endetech, Pharmas, Cytothreat, Radar, Demeau, DePharm, Pharm AD, Solutions https://cordis.europa.eu/projects/home_en.html

[32] Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy, OJ L327, 22.12.2000, p.1

[33] Commission Implementing Decision (EU) 2018/840 of 5 June 2018 establishing a watch list of substances for Union-wide monitoring in the field of water policy pursuant to Directive 2008/105/EC of the European Parliament and of the Council and repealing Commission Implementing Decision (EU) 2015/495, OJ L141, 7.6.2018, p.9



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There is also limited monitoring of "hotspot" locations, such as those affected by hospital effluents. Even less is known about concentrations in soils, and about the presence of antimicrobial resistant micro-organisms and antimicrobial resistance genes. In addition, possible "cocktail" effects from the combined presence of many pharmaceuticals and other chemicals in the environment are not well understood.

It is important to identify the pharmaceuticals that pose a risk through their individual presence in the environment so that risk management efforts can be targeted. For pharmaceuticals already on the market without an environmental risk assessment, an industry-led attempt is being made to predict which should be assessed first[35].

Progress has been made, as an environmental risk assessment must now be carried out for all pharmaceuticals. However, more timely availability of a complete assessment for human medicinal products could facilitate the timely introduction of appropriate risk management measures.

### 2.6 Outlook

The quantities of pharmaceuticals sold on the European market have grown quickly over the past three decades, both in terms of volumes of sales and numbers of active pharmaceutical ingredients. More than 3000 active pharmaceutical ingredients are currently on the market.

According to figures from the pharmaceutical industry[36], the value of sales of human medicinal products in the Union has risen very substantially since 1990. Although due in large part to increases in the price of products, this rise also reflects a steady increase in consumption per head of the population[37]. Environmental concentrations are likely to increase as the population ages and grows.

As regards sales of veterinary medicinal products, data-gathering has focussed on antimicrobials used in livestock farming[38] because of concerns about antimicrobial resistance. Reports for nine countries from 2005 to 2009[39], and for 30 countries from 2010 to 2016[40], suggest that, overall, the quantity of antimicrobials used has decreased, although not in all countries. Total tonnage could increase if livestock numbers grow significantly, even if use per livestock unit decreases. The figures do not cover other veterinary medicinal products.

## 3. THE OBJECTIVES OF THE STRATEGIC APPROACH

The main objectives are to:

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[34] Groundwater Watch List: Pharmaceuticals Pilot Study 2016. https://circabc.europa.eu/w/browse/a1e23792-6ecd-4b34-b86c-dcb6f1c7ad1c

[35] http://i-pie.org/

[36] https://www.phar-in.eu/wp-content/uploads/2014/05/Figures_2014_Final.pdf; https://www.efpia.eu/media/361960/efpia-pharmafigures2018_v07-hq.pdf

[37] OECD (2019), "Pharmaceutical market", *OECD Health Statistics* (base de données), https://doi.org/10.1787/data-00545-en (données extraites le 07 January 2019)

[38] https://www.ema.europa.eu/en/veterinary-regulatory/overview/antimicrobial-resistance-veterinary-medicine

[39] https://www.ema.europa.eu/documents/report/trends-sales-veterinary-antimicrobial-agents-nine-european-countries_en.pdf

[40] https://www.ema.europa.eu/documents/report/sales-veterinary-antimicrobial-agents-30-european-countries-2016-trends-2010-2016-eighth-esvac_en.pdf



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- identify **actions to be taken or further investigated** to address the potential risks from pharmaceutical residues in the environment, not least to contribute to the Union's action on combatting antimicrobial resistance;
- encourage **innovation** where it can help to address the risks, and promote the circular economy by facilitating the recycling of resources such as water, sewage sludge and manure;
- identify remaining **knowledge gaps**, and present possible solutions for filling them;
- ensure that actions to address the risk do not jeopardise **access to safe and effective pharmaceutical treatments** for human patients and animals.

## 4. CURRENT SITUATION: RELEVANT UNION POLICY AND WIDER INITIATIVES

### 4.1 Union policy

European Union legislation on medicinal products[41] is the primary means for ensuring the quality, safety and efficacy of pharmaceuticals for use in humans and animals, and their safety for the environment. An environmental risk assessment is now mandatory for all applications for a marketing authorisation for human and veterinary medicinal products; it is taken into account in the benefit-risk assessment for the latter[42]. Various other pieces of Union legislation are directly or indirectly relevant to the production, use or disposal of pharmaceuticals and their environmental safety[43]. However, despite the legislation, and partly because some of it is only recent, risks to and via the environment remain.

The Strategic Approach is complementary to the recently adopted Strategy on Endocrine Disruptors[44], and linked to a number of other current and recent initiatives, including evaluations of the Urban Waste Water Treatment Directive and other key pieces of Union water law, the proposals for a Regulation on water reuse and for a recast of the Drinking Water Directive, and evaluations of the chemicals legislation.

It should be noted that pharmaceuticals as products are exempt from most of the provisions under the Union's general chemicals legislation[45], though not from restriction provisions[46]. Substances used in the manufacture of pharmaceutical products are also exempt if they are present in the final product. Those used but not present are subject to registration and

[41] Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC, OJ L 4, 7.1.2019, p.43, and 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, OJ L 311, 28.11.2001, p.67, as amended.

[42] Regulation (EU) 2019/6 as in previous footnote

[43] BIO Intelligence Service 2013 Study (see footnote 11): Chapter 8

[44] COM(2018) 734 final: Communication from the Commission to the European Parliament, the Council, the European Economic And Social Committee and the Committee of the Regions: "Towards a comprehensive European Union framework on endocrine disruptors"

[45] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006, OJ L 353, 31.12.2008, p.1; 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, OJ L 396, 30.12.2006, p.1

[46] Restriction provisions in REACH are those which allow the manufacture, use or placing on the market of substances to be made subject to conditions or be prohibited to address identified risks not adequately controlled; in practice, these provisions have not been applied in relation to medicinal products.



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evaluation provisions under REACH, and can be subject to authorisations and restrictions[47]. A study[48] has raised questions about the links between the chemicals and medicinal products legislation in relation to environmental protection.

### 4.2 Other initiatives

Several Member States (e.g. The Netherlands[49], Sweden[50]), the European Parliament[51], third countries (e.g. Switzerland[52]), international organisations (e.g. the United Nations[53], HELCOM[54], Organisation for Economic Cooperation and Development[55]), industry associations[56] and Non-Governmental Organisations have expressed concerns and taken action to address the growing presence of pharmaceuticals in the environment. At international level, both the United Nations Agenda 2030, in particular Sustainable Development Goal 6, and the 2017 United Nations Environment Assembly ministerial declaration, represent commitments to act in this area, and action on antimicrobial resistance has been agreed by the G7/G20 and World Health Organisation.

## 5 ACTIONS

As required by Article 8c of the Priority Substances Directive, this strategic approach should be followed, where appropriate, by proposals for measures to be taken at Union and/or Member State level to address the possible environmental impacts of pharmaceutical substances, with a view to reducing discharges, emissions and losses of such substances into the aquatic environment, taking into account public health needs and the cost-effectiveness of the measures proposed. To be effective and spread the efforts evenly, measures should not only include end-of-pipe controls (e.g. improved waste water treatment) but also address the original sources of emissions (e.g. production and use), and consider the terrestrial as well as the aquatic environment. This Communication sets out six areas for action, and several specific actions relating to possible measures.

### 5.1 Increase awareness and promote prudent use of pharmaceuticals

Promoting the prudent use of medicinal products which pose a risk to or via the environment, including antimicrobials, could significantly reduce the problem at source. Member States and medical professionals have a key role to play in this context, but the Commission can play a role by bringing together relevant professionals, contributing to the funding of certain training programmes, ensuring that relevant legislation is adopted, implemented and enforced, and partnering with international organisations.

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[47] Some authorisations have been granted.

[48] http://ec.europa.eu/environment/chemicals/reach/pdf/studies_review2012/report_study8.pdf

[49] The Netherlands Chain approach to reduce pharmaceutical residues in water. 2018. Abstract for OECD workshop on contaminants.

[50] https://www.fass.se/LIF/

[51] E.g. EP Intergroup CCBSD event 29 November 2017 http://ebcd.org/event/pharmaceuticals-in-the-environment/

[52] https://www.parlament.ch/centers/eparl/curia/2012/20123090/Bericht%20BR%20D.pdf

[53] SAICM http://www.saicm.org/EmergingPolicyIssues/Pharmaceuticalnbsp;Pollutants/tabid/5477/language/en-US/Default.aspx

[54] The Baltic Marine Environment Protection Commission: http://www.helcom.fi/news/Pages/Pharmaceuticals-in-Baltic-waters--new-status-report-by-UNESCO-and-HELCOM.aspx

[55] http://www.oecd.org/water/oecdworkshoponmanagingcontaminantsofemergingconcerninsurfacewaters.htm

[56] Eco-pharmaco-stewardship https://www.efpia.eu/media/25628/eps-a-holistic-environmental-risk-management-program.pdf and https://www.efpia.eu/media/288586/pie-brochure.pdf



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The Commission will:

- **Promote the development of guidelines for healthcare professionals on the prudent use of pharmaceuticals posing a risk to or via the environment;**
- **Explore, in cooperation with relevant stakeholders, how environmental aspects could become part of medical training and professional development programmes;**
- **Aim to limit the preventive use of veterinary antimicrobials by ensuring correct implementation of the newly adopted Regulation on veterinary medicinal products[57];**
- **Foster best-practice exchanges between Member States on how environmental considerations are taken into account in the advertising and prescription of medicinal products and the choice of therapy more generally, where appropriate;**
- **Strengthen cooperation with the World Health Organisation and other key international organisations on activities to raise awareness of the issue and find solutions, including by the sharing of best practices.**

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

The pharmaceutical industry needs to be encouraged to take the environment, from a lifecycle perspective, more into account through the design and manufacturing stages. Since the industry acts at global level and its actions can have global reach, it makes sense for the Union to ensure a level playing field as regards environmental and health protection across the Union, and to stimulate responsible behaviour also outside the Union.

The Commission will:

- **Subject to adequate availability of funds following final agreement with the co-legislators on the next Multi-annual Financial Framework, fund research and innovation to support the development of "greener" pharmaceuticals that degrade more readily, to harmless substances, in waste water treatment plants and the environment;**
- **Engage directly with the pharmaceutical industry on its potential contribution to meeting the objectives of the approach, among other things to explore how extended producer responsibility could play a role in supporting action to improve the efficacy of water treatment;**
- **Under the Water Framework Directive, consider specific pharmaceuticals, and groups of pharmaceuticals with similar effects, in the work supporting the regular review of the list of substances posing a risk at Union level, and work**

[57] Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC, OJ L 4, 7.1.2019, p.43



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**with Member States on environmental quality standards for pharmaceuticals posing a risk at national level;**

- **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;**
- **Discuss, with the relevant Member State authorities, the possibility of using procurement policy to encourage greener pharmaceutical design and manufacturing;**
- **Encourage, through dialogue and cooperation, as part of the Union's external policies, action in third countries where pharmaceutical emissions from manufacturing and other sources are suspected of contributing to the global spread of AMR.**

### 5.3 Improve environmental risk assessment and its review

It's important that risk assessment and guidance development are coordinated and involve all relevant expertise. Data sharing and improved access to data could facilitate better risk management, as could retrospective environmental risk assessment for several products already on the market, and earlier availability of the risk assessment data for human medicinal products. The initiative in all these areas can best be taken at Union level.

The Commission will:

- **In collaboration with the European Medicines Agency and Member States:**
  - **Seek to improve the level of environmental expertise in the Committees and networks involved in the environmental risk assessment of medicinal products;**
  - **Consider developing guidance on the environmental risk assessment of medicinal products for use in aquaculture including, where appropriate, recommendations for risk management measures;**
  - **Examine how to improve public access to the main environmental risk assessment results and relevant toxicological thresholds for medicinal products while respecting data-protection rules;**
  - **Emphasise to applicants the importance of submitting 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;**
- **Pursuant to the newly adopted Regulation on veterinary medicinal products, report on the feasibility of setting up an EU-wide review system based on active pharmaceutical ingredients, or similar, to support the environmental risk assessment of veterinary medicinal products at Union level;**
- **Initiate a systematic catching-up procedure for veterinary medicinal products without an (adequate) environmental risk assessment, as provided for in the**



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**Regulation on veterinary medicinal products, and take stock of the results of research under the Innovative Medicines Initiative[58] in relation to human medicinal products;**

- **Consider the findings of recent REACH evaluations and the ongoing Fitness Check of other Union chemicals legislation as regards links with the medicinal products legislation in relation to environmental protection.**

### 5.4 Reduce wastage and improve the management of waste

Less wastage of pharmaceuticals and proper disposal would reduce the risk to the environment. More advanced waste water treatment technology may be appropriate at some locations. Source control of the diffuse emissions from livestock farming appears particularly necessary.

The Commission will:

- **In collaboration with Member States and the European Medicines Agency:**
  - **explore the possibility of reducing waste by optimising the package size of pharmaceuticals so that medicines can be dispensed in quantities better matching needs, and by safely extending use-by (expiry) dates so that fewer medicines that are still usable have to be thrown away;**
  - **facilitate the exchange of best practices among healthcare professionals on the environmentally safe disposal of medicinal products and clinical waste, and the collection of pharmaceutical residues as appropriate ;**
- **Assess the implementation of collection schemes for unused pharmaceuticals and consider how their availability and functioning could be improved, how to increase public awareness of the importance of using them, and how extended producer responsibility could play a role in reducing inappropriate disposal;**
- **In relation to urban waste water treatment:**
  - **Use Union programmes to invest in technologies to improve the efficiency of removal of pharmaceuticals (and antimicrobial resistance genes);**
  - **As part of the study supporting the evaluation of the existing urban waste water treatment legislation, assess whether it sufficiently controls pharmaceutical emissions and investigate the feasibility of upgrading selected urban waste water treatment plants to more advanced treatment technologies;**
- **Assess the possibility of working with Member States on improving their Codes of Good Agricultural Practice to cover also the management of contaminants including pharmaceuticals in livestock manure;**
- **When the Industrial Emissions Directive is next evaluated, assess whether it**

[58] For example as regards the potential application of relevant prioritisation principles identified in the ongoing Innovative Medicines Initiative project on Intelligence-led Assessment of Pharmaceuticals in the Environment (http://i-pie.org/), due to be completed by the end of 2019.



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**should address intensive dairy farming[59].**

### 5.5 Expand environmental monitoring

The collection and management of environmental data is to a large extent based on Union legislation and/or supported by Union funding. Knowing more about the concentrations of pharmaceuticals in the environment would allow environmental risk assessments to be improved and measures to be more focused, especially if monitoring could be extended to better cover certain parts of the environment, where necessary involving cooperation with stakeholders.

The Commission will:

- **Consider additional potentially relevant pharmaceuticals, such as cytotoxic pharmaceuticals and X-ray contrast media, in the work supporting the review of the surface water Watch List under the Water Framework Directive, as well as the feasibility of monitoring antimicrobial resistant microorganisms and antimicrobial resistance genes;**
- **Support research on monitoring individual substances and mixtures of substances in fresh and marine waters, soils, sediments, and wildlife, using conventional analytical and complementary techniques;**
- **Explore with stakeholders, including water treatment companies/authorities, the gathering of relevant data in effluents from potential hotspots; the development of online monitoring, and the sharing of data via the Information Platform for Chemical Monitoring[60], to inform analyses of sources and potential exposure;**
- **Include antimicrobials and possibly antimicrobial resistance genes in the next phase of the European Commission's LUCAS soil survey[61].**

### 5.6 Fill other knowledge gaps

While the above actions include some research, our ability to manage the risk could benefit from research in other areas.

The Commission will thus consider supporting further research, also under the Union's next Multi-annual Financial Framework, into:

- **The eco-toxicity and environmental fate of pharmaceuticals, in particular those not yet subject to environmental risk assessment;**
- **The links between the presence of antimicrobials in the environment (if possible also the entry and natural presence of antimicrobial resistance genes) and the**

[59] At present, only intensive pig and poultry farming are covered (http://eippcb.jrc.ec.europa.eu/reference/irpp.html).
[60] https://ipchem.jrc.ec.europa.eu/RDSIdiscovery/ipchem/index.html
[61] https://esdac.jrc.ec.europa.eu/projects/lucas



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**development and spread of antimicrobial resistance;**

- **The possible effects on humans of (chronic) exposure to low levels of pharmaceuticals via the environment, taking account of the potential for combined effects from multiple substances, and of vulnerable sub-populations;**
- **Cost-effective methods for reducing the presence of pharmaceuticals including antimicrobials in slurry, manure and sewage sludge to enable their use in the circular economy.**

## 6 CONCLUSIONS

This Communication sets out a strategic approach to the risks from pharmaceuticals in the environment, and thus meets a legal obligation to propose an approach addressing the pollution of water by pharmaceuticals. It also contributes to tackling the problem of antimicrobial resistance and honours commitments made at international level, where, as a strong global actor, the Union can encourage wide cooperation.

Although it is clear that treating many diseases in animals and humans relies on effective pharmaceuticals, and that some substantial knowledge gaps remain to be filled, there is sufficient evidence that action should be taken to reduce the risk from pharmaceuticals in the environment. This requires the involvement of all relevant stakeholders along the entire life cycle, including Member State competent authorities, the pharmaceutical industry, medical and veterinary professionals, patients, farmers and the water industry, with the shared goal of building a more sustainable, resource-efficient and circular economy.

While leading on actions within its area of competence, the Commission will also encourage others to lead, including by facilitating the exchange of best practices.

The Communication focuses on actions that are starting, will be initiated and, in some cases, completed by 2020.

The Commission will then take stock of progress made and decide on further steps, taking into account the outcomes of ongoing evaluations of the water legislation and relevant research.



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