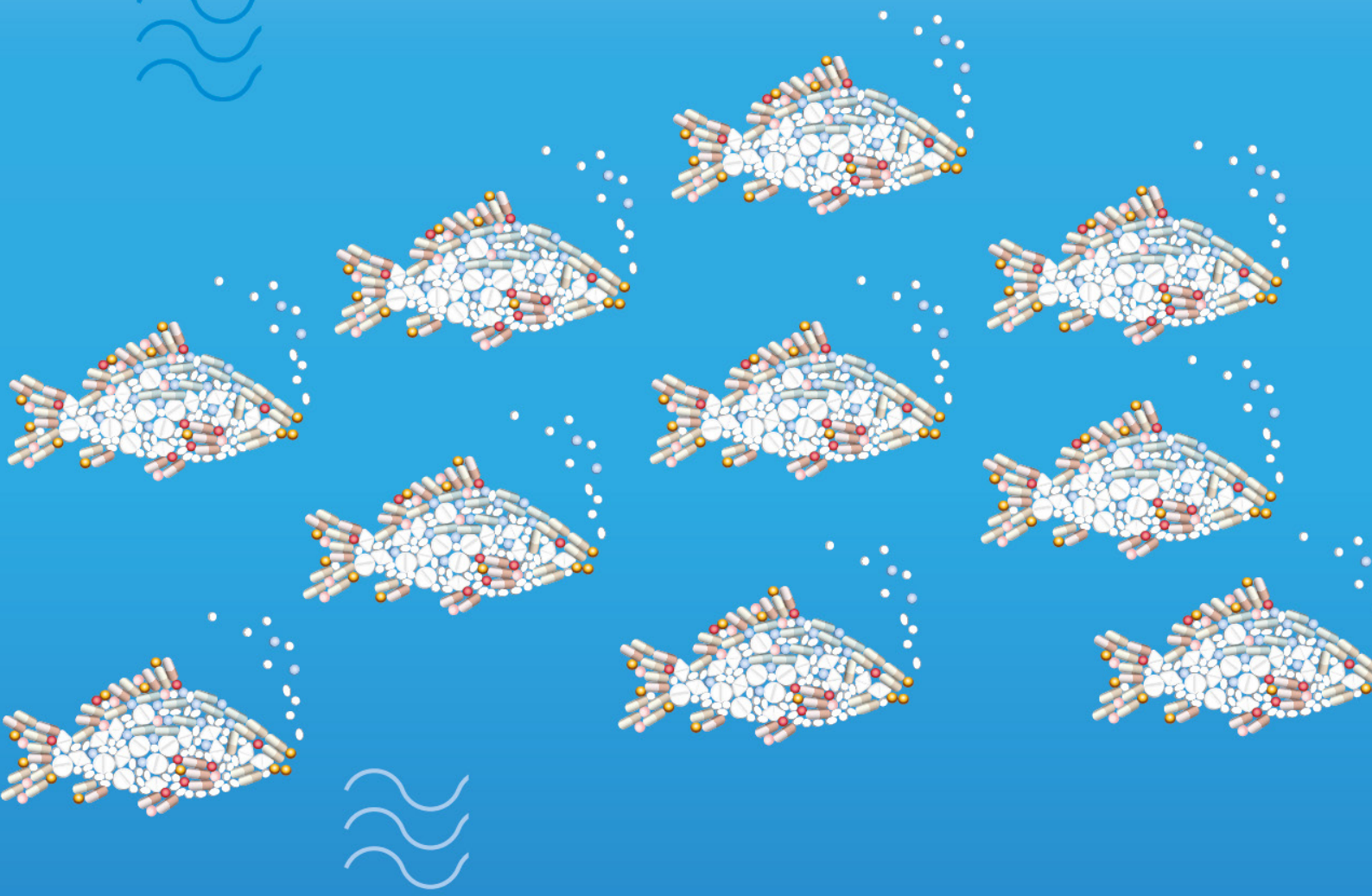
European Commission

# Update on Progress and Implementation

## European Union Strategic Approach to Pharmaceuticals in the Environment



Environment

Luxembourg: Publications Office of the European Union,2020



Print ISBN 978-92-79-25106-4 doi:10. 2779/037747 KH-03-20-727-EN-N

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# Update on Progress and Implementation

## European Union Strategic Approach to Pharmaceuticals in the Environment

## 1. INTRODUCTION

In March 2019, the Commission adopted the European Union Strategic Approach to Pharmaceuticals in the Environment (PiE)[1] which focuses on actions to address the environmental implications of all phases of the lifecycle of (both human and veterinary) pharmaceuticals, from design and production through use to disposal. In the context of the European Green Deal and the COVID-19 pandemic, the topic is now even more relevant (see also Chapter 2). The EU Strategic Approach to PiE received strong backing from Council and Parliament, as well as from stakeholders. Complementary to the Pharmaceutical Strategy, which also includes an environmental sustainability angle, it is time to reflect on what has been so far achieved in implementing the March 2019 EU Strategic Approach to PiE.

In June 2019, the Environment Council discussed the issue of pharmaceuticals in the environment, concluding that concrete and ambitious actions are necessary to reduce the risk from pharmaceuticals and their residues to the environment[2] and from antimicrobial resistance in particular[3]. During its plenary session in September 2020, the European Parliament adopted a resolution[4] on the EU Strategic Approach to PiE, which highlights the importance of a holistic approach with both legislative and non-legislative measures and is aimed at counteracting the risks posed by pharmaceutical residues in the environment.

This document aims to show the overall progress made on the actions of the EU Strategic Approach to PiE so far (Chapter 3), assesses progress per action (Chapter 4) and proposes further follow-up.

1 European Union Strategic Approach to Pharmaceuticals in the Environment
2 Towards a Sustainable Chemicals Policy Strategy of the Union - Council conclusions
3 Conclusions on the next steps towards making the EU a best practice region in combatting antimicrobial resistance
4 European Parliament resolution of 17 September 2020 on a strategic approach to pharmaceuticals in the environment

## 2. WIDER PICTURE

There is overwhelming evidence that traces of pharmaceuticals in the environment, in particular in water and soil, could have an adverse impact on wildlife such as fish, birds, and insects and knock-on effects on wider ecosystems, including antimicrobial resistance. Pharmaceutical residues are now found across Europe's soils and surface waters and have even reached the drinking water, although not in quantities that cause immediate concern. Access to safe, qualitative and effective pharmaceutical treatments must remain fully available to citizens and animals. This comes to light during the ongoing COVID-19 pandemic probably more than ever, including the need for sustainable supply chains and consumption patterns. At the same time, it must be avoided that there is an undue impact of pharmaceutical residues on the environment. Indeed, as highlighted by the pandemic, our health and well-being strongly depend on a healthy environment.

The Zero Pollution ambition for a toxic-free environment, as expressed in the European Green Deal[5], aims to protect both public health and ecosystems through avoiding negative effects of chemical substances, including certain pharmaceutical residues, on air, soil and water. The recently adopted Farm to Fork Strategy[6] includes the target to reduce overall EU sales of antimicrobials for farmed animals and in aquaculture by 50% by 2030, thus reducing this source of environmental contamination. Other initiatives, including the 8th Environment Action Programme[7], the Circular Economy Action Plan[8], the Chemicals Strategy for Sustainability[9] and the Biodiversity Strategy[10], set a framework for generating an overall shift to a production and consumption of resources, materials and chemicals, which is safe and sustainable by design and creates the lowest possible impact on the environment, including considering pollutants of emerging concern. Work is ongoing on a variety of interlinked topics, from i.a. greener manufacturing and pollution abatement over a reduced use of veterinary pharmaceuticals to enhanced wastewater treatment.

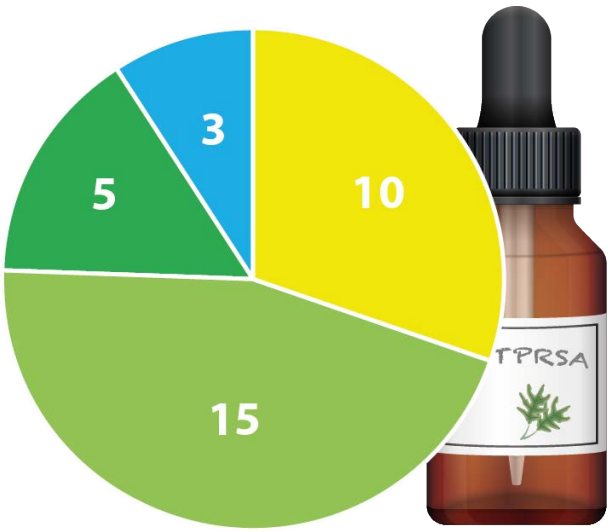
The Pharmaceutical Strategy for Europe focuses on availability, affordability, sustainability and security of supply of pharmaceuticals, as well as enabling innovation. It also includes actions referring to the environmental aspects of production, use and disposal of medicines and establishes links with the actions of the EU Strategic Approach to PiE where applicable.

5 The European Green Deal
6 A Farm to Fork Strategy for a fair, healthy and environmentally-friendly food system
7 General Union Environment Action Programme to 2030
8 Circular Economy Action Plan for a cleaner and more competitive Europe
9 Chemicals Strategy for Sustainability - Towards a Toxic-Free Environment
10 EU Biodiversity Strategy for 2030 - Bringing nature back into our lives

## 3. OVERALL PROGRESS

Good progress has been made in implementing the different actions. While at least some progress has been made on all of the actions, the majority has either 'started' or is 'ongoing'. Some are already well advanced and a couple are completed.

This chart shows the "steps of progress" achieved so far, with the steps and colours representing the progress categories 'started' (yellow), 'ongoing' (light green), 'good progress' (dark green) and 'implemented/ achieved' (blue).




Amongst those actions to highlight specifically, already quite advanced is the analysis of pharmaceutical concentrations and antimicrobial genes in soil (action 5.5.4).

Any legislative follow-up depends on the planned revision of the concerned legislation. Additional pharmaceuticals were included in the revised Surface Water Watch List under the Water Framework Directive[11] adopted in August this year[12], which functions as an early warning system for pollutants in surface waters (action 5.5.1). For veterinary medicinal products, implementing and delegated acts are currently being drafted under the Regulation on veterinary medicinal products (action 5.1.3). Their aim is to promote a more prudent use of antimicrobials in animals and implement a wide range of concrete measures to fight antimicrobial resistance. A study 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 EU level has also been launched (action 5.3.2) The REACH Regulation[13] already reduces emissions of chemical substances that may be used in the manufacturing of medicinal products through authorisation of used substances. Furthermore, as part of the impact assessment for the potential revision of the Urban Waste Water Treatment Directive,

11 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

12 Commission Implementing Decision (EU) 2020/1161 of 4 August 2020 establishing a watch list of substances for Union-wide monitoring in the field of water policy

13 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)

ways will be explored to tackle micro-pollutants, including pharmaceuticals, more effectively (action 5.4.3.b).

An effective reduction of the impact of pharmaceuticals on the environment cannot be achieved at EU level without strong engagement also at the level of national health authorities, pharmaceutical industry and health professionals. In the medicines area, work has started with Member States' health ministries, for instance to make sure health professionals consider also environmental impacts of medication. In addition, the ad-hoc Working Group focused on PiE set up under the Pharmaceuticals Committee already endorsed an action plan for the implementation of various measures in the pharmaceuticals sector. Initiatives taken in some Nordic countries to use public procurement as a tool to promote pharmaceuticals that are produced in a 'green' manner are encouraged. The European Medicines Agency is updating guidelines on Environmental Risk Assessment for human medicinal products (action 5.3.1.a).

In the waste sector, new guidelines will be developed on collecting schemes for unused medicines (action 5.4.2). In the area of research, the ongoing Horizon 2020 programme is co-funding solution-oriented research, as illustrated for example by a wide-ranging study on contaminants of emerging concern, pathogens and antimicrobial resistance in the water cycle[14] (action area 5.6). Inevitably, many of research-oriented actions to be considered in the coming funding period are categorised as 'started' as they will be based on the new Horizon Europe programme[15] or other research funding that is still under development, this includes for example support for the manufacturing of greener pharmaceuticals (action 5.2.1).

[14] AquaticPollutants, grant # 869178
[15] Horizon Europe - the next EU research and innovation framework programme

## 4. PROGRESS BY ACTION

### 4.1. Increase awareness and promote prudent use of pharmaceuticals

***Action 5.1.1*** ***Promote the development of guidelines for healthcare professionals on the prudent use of pharmaceuticals posing a risk to or via the environment.***

Progress: ongoing

Follow-up until autumn 2020: The ad-hoc working group focused on PiE under the Pharmaceutical Committee for human medicines has agreed on an action plan with concrete actions to be further developed, including recommendations and/or the promotion of guidelines for healthcare professionals on the prudent use of pharmaceuticals posing a risk to or via the environment.

Planned further follow-up: The Pharmaceuticals Strategy promotes the prudent use of pharmaceuticals and strengthening communication with healthcare professionals and the public to raise their awareness on antimicrobial resistance.

***Action 5.1.2*** ***Explore, in cooperation with relevant stakeholders, how environmental aspects could become part of medical training and professional development programmes.***

Progress: ongoing

Follow-up until autumn 2020: The ad-hoc working group focused on PiE under the Pharmaceutical Committee for human medicines has agreed on an action plan with concrete actions to be further developed, including recommendations to explore in cooperation with the relevant stakeholders how to include the environmental aspects into medical training and professional development programmes.

Planned further follow-up: The Pharmaceuticals Strategy promotes the prudent use of pharmaceuticals and strengthening communication with healthcare professionals and the public to raise their awareness on antimicrobial resistance. These aspects are aimed to be included into the vocational and educational medical training at the level of the Member States.

***Action 5.1.3*** ***Aim to limit the preventive use of veterinary antimicrobials by ensuring correct implementation of the newly adopted Regulation on veterinary medicinal products.***

Progress: good progress

Follow-up until autumn 2020: Regulation (EU) 2019/6 on veterinary medicinal products will become applicable on 28 January 2022. Commission Services based on scientific input of the European

Medicines Agency are developing corresponding tertiary legislation.

Planned further follow-up: Follow-up on the implementation after 28 January 2022 and foster Member States' best-practice exchange.

***Action 5.1.4 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.***

Progress: ongoing

Follow-up until autumn 2020: The ad-hoc working group focused on PiE under the Pharmaceutical Committee for human medicines has agreed on an action plan with concrete actions to be further developed, including recommendations from the Member States on advertising and prescription. The Working Group Chemicals under the Common Implementation Strategy of the Water Framework Directive also facilitates best practice exchange between Member States.

Planned further follow-up: Implementation of the recommendations and/or guidelines by the Member States and including main messages into awareness raising campaigns, considering also the use of over-the-counter medicines.

***Action 5.1.5 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.***

Progress: ongoing

Follow-up until autumn 2020: Discussions about pollutants of emerging concern, including pharmaceuticals and especially antimicrobials, are ongoing in the international cooperation between the EU and international organisations, including WHO, UNEP (United Nations Environment Programme)[16] and the OECD[17], leading to increasing global exchange and consensus on the need to tackle the threat of pharmaceuticals in the environment[18]. An international event was organised by the EU in New York in support of

[16] On the basis of a proposal from the EU and its Member States, the UN Environment Assembly (UNEA) adopted resolution 3/4 on Environment and Health[16], which inter alia addresses AMR and is the basis for a report on AMR and the environment for the fifth session of the UN Environmental Assembly (UNEA5) in 2021. PiE and, more generally, AMR have also become regular subjects of cooperation between the World Health Organisation and the European Commission. As a result, for example, the WHO cooperated with the EC in a water conference organised in late 2019 in Zaragoza (Spain).

[17] Pharmaceutical Residues in Freshwater - Hazards and Policy Responses

[18] Under the Strategic Approach to International Chemicals Management (SAICM) a resolution was adopted in 2015 to declare environmentally persistent pharmaceutical pollutants as an emerging policy issue

a One Health approach, which is key to addressing pharmaceuticals in the environment.

Planned further follow-up: Two projects under the EU Partnership Instrument are addressing antimicrobial resistance, one in Asia and one in Latin America. An expected UNEP report on Antimicrobial Resistance will offer further ground for international engagement.

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

***Action 5.2.1 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.***

Progress: ongoing

Follow-up until autumn 2020: Sustainability is part of the governance framework under the European Green Deal and the Recovery and Resilience Facility[19]. The Chemicals Strategy sets the framework for generating an overall shift towards chemicals, including pharmaceuticals, which are safer and more sustainable by design and create the lowest possible impact on the environment. The evaluation of the Urban Waste Water Treatment Directive[20] identified i.a. pharmaceuticals as an important area to be tackled in the context of the ongoing revision. Programmes for EU funding under Horizon Europe and other research programmes are still under development, but will offer scope for relevant proposals[21].

Planned further follow-up: Follow up on the actions in the different strategies and the potential revision of the Urban Waste Water Treatment Directive. Ensure that proposed funding programmes/partnerships result in projects addressing pharmaceuticals in the environment[22].

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19 Recovery and Resilience Facility: Helping EU Countries to Come Out of the Coronavirus Crisis Stronger

20 Evaluation of the Urban Waste Water Treatment Directive

21 The proposed PREMIER project - Prioritisation and Risk Evaluation of Medicines In the EnviRonment - aims to evaluate the development of greener pharmaceuticals. The predecessor project IMI1 included two important research projects: iPie (Intelligent Assessment of Pharmaceuticals in the Environment) and CHEM21 (Chemical manufacturing methods for the 21st century pharmaceutical industries).

22 For example, in 2021 the topic 'Contained biomass solutions for sustainable and zero-ILUC (Indirect land use change) production systems for high value application' is planned, including production of engineered proteins and metabolites for i.a. vaccines, pharmaceuticals and veterinary product.

***Action 5.2.2*** ***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.***

Progress: ongoing

Follow-up until autumn 2020: Meetings with relevant stakeholders have taken place where industry engagement, such as their Eco-Pharmaco-Stewardship[23] or AMR Industry Alliance[24], were discussed; also meetings with other stakeholders took place, e.g. to discuss the European River Memorandum for Quality Assurance of Drinking Water Production[25]. A feasibility study on extended producer responsibility, including in the pharmaceuticals sector, is planned as part of the impact assessment on the potential revision of the Urban Waste Water Treatment Directive[26].

Planned further follow-up: Continue the ongoing dialogue with relevant stakeholders to press for greater uptake of environmentally responsible practices and consider applying extended producer responsibility.

***Action 5.2.3*** ***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 with Member States on environmental quality standards for pharmaceuticals posing a risk at national level.***

Progress: good progress

Follow-up until autumn 2020: Pharmaceuticals are being considered in the ongoing revision process of the Priority Substances List under the Water Framework Directive and well as the lists of substances annexed to the Groundwater Directive.

Planned further follow-up: Engage the European Medicines Agency expert networks more actively in the prioritisation work and consider effect-based grouping of (pharmaceutical) substances.

23 Care for People, Care four Our Environment
24 AMR Industry Alliance
25 European River Memorandum for Quality Assurance of Drinking Water Production
26 Roadmap for the potential revision of the Urban Waste Water Treament Directive.

***Action 5.2.4*** ***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.***

Progress: ongoing

Follow-up until autumn 2020: Data collection was unsuccessfully proposed in the review of the Best Available Techniques Reference Document for Slaughterhouses and Animal By-Products. Techniques used by the pharmaceutical industry are in general covered by the Best Available Techniques Reference Document on 'Organic Fine Chemicals' within the context of the Industrial Emissions Directive[27].

Planned further follow-up: The Industrial Emissions Directive has been evaluated and an impact assessment has been launched in view of its revision[28]. In this context, also a possible review of the Best Available Techniques Reference Documents relevant to the discharge of pharmaceuticals into the environment will be considered.

***Action 5.2.5*** ***Discuss, with the relevant Member State authorities, the possibility of using procurement policy to encourage greener pharmaceutical design and manufacturing.***

Progress: started

Follow-up until autumn 2020: Discussions started with the Member States. Some Nordic countries already use public procurement as a tool to promote pharmaceuticals produced in a 'green' manner and best practice on this has been exchanged.

Planned further follow-up: The Pharmaceuticals Strategy includes public procurement as one important area to achieve i.a. "green production" conditions. Best practice exchange between Member States will be continued and the possibility of an EU wide approach explored.

***Action 5.2.6*** ***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.***

Progress: ongoing

Follow-up until autumn 2020: Part of the international cooperation with WHO is on antimicrobial resistance (see also action 5.1.5 above), under which action in third countries is also fostered on the basis of multilateral cooperation and exchanges that

[27] Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control)

[28] Revision of the Industrial Emissions Directive: Inception Impact Assessment

are subsequently implemented at country level, e.g. under the Strategic Approach to International Chemicals Management. Existing cooperation mechanisms with the main producing third countries exist and can be used to raise concerns (e.g. bilateral dialogues with India and China).

Planned further follow-up: The Partnership Instrument projects will continue to support projects on antimicrobial resistance in different regions of the world. The Pharmaceutical Strategy also has the international dimension where i.a. the EU Strategic Approach to PiE will continue to be followed including bilateral dialogues.

### 4.3. Improve environmental risk assessment and its review

***Action 5.3.1a 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.***

Progress: ongoing

Follow-up until autumn 2020: Revision of the Guidelines on Environmental Risk Assessment for human medicinal products is ongoing. The ad-hoc working group focused on PiE under the Pharmaceutical Committee for human medicines has agreed on an action plan with concrete actions to be further developed together with the European Medicines Agency, including recommendations for this action.

Planned further follow-up: Follow-up on the revised guidelines for implementation and encourage the promotion of exchanges between experts on Environmental Risk Assessment, whenever needed and appropriate.

***Action 5.3.1b In collaboration with the European Medicines Agency and Member States: Consider developing guidance on the environmental risk assessment of medicinal products for use in aquaculture including, where appropriate, recommendations for risk management measures.***

Progress: started

Follow-up until autumn 2020: The European Medicines Agency's Committee for Medicinal Products for Veterinary Use and their Working Group on Environmental Risk Assessment will initiate this work in 2021. The Farm to Fork Strategy includes the target to reduce the overall EU sales of antimicrobials for farmed animals and in aquaculture by 50% by 2030. This target will be supported by the effective implementation

of the Regulations on veterinary medicinal products[29] and on medicated feed[30], applicable as of 2022. These provide for an array of measures to fight antimicrobial resistance and promote a more prudent and responsible use of antimicrobials in animals.

Planned further follow-up: Follow-up on the initiative and the implementation of the Farm to Fork target.

***Action 5.3.1c In collaboration with the European Medicines Agency and Member States: 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.***

Progress: ongoing

Follow-up until autumn 2020: The ad-hoc working group focused on PiE under the Pharmaceutical Committee for human medicines has agreed on an action plan with concrete actions to be further developed together with the European Medicines Agency, including recommendations for this action. Ongoing voluntary Horizon 2020 research projects develop publicly accessible databases on environmental aspects of pharmaceuticals [31].

Planned further follow-up: The Chemicals Strategy proposes several actions as regards the 'one substance, one assessment' approach as introduced by the European Green Deal, which include the development of a common open data platform to be implemented for chemicals[32].

***Action 5.3.1d In collaboration with the European Medicines Agency and Member States: 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.***

Progress: ongoing

Follow-up until autumn 2020: The ad-hoc working group focused on PiE under the Pharmaceuticals Committee for human medicines has agreed on an action plan with concrete actions to be further developed together with the European Medicines Agency, including recommendations for this action. For

[29] 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

[30] 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, amending Regulation (EC) No 183/2005 of the European Parliament and of the Council and repealing Council

[31] The PREMIER project (Prioritisation and Risk Evaluation of Medicines In the EnviRonment) aims to develop a publicly available database. The IMI1 project iPie (Intelligent Assessment of Pharmaceuticals in the Environment) published databases on environmental risks of pharmaceuticals.

[32] This will be without prejudice to the product specific legislation requirements.

centralised applications, applicants are reminded of obligations at marketing authorisation application, pre-submission meetings and/or scientific advice procedures if appropriate.

Planned further follow-up: Follow-up on the implementation of the revised Guidelines on Environmental Risk Assessment. Encourage the promotion of exchanges between experts whenever needed and appropriate

***Action 5.3.2*** ***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.***

Progress: started

Follow-up until autumn 2020: A feasibility study of an active-substance-based review system ('monographs') and other potential alternatives for the Environmental Risk Assessment of veterinary medicinal products was launched in early October.

Planned further follow-up: Follow-up on the study results.

***Action 5.3.3*** ***Initiate a systematic catching-up procedure for veterinary medicinal products without an (adequate) environmental risk assessment, as provided for in the Regulation on veterinary medicinal products, and take stock of the results of research under the Innovative Medicines Initiative in relation to human medicinal products.***

Progress: Ongoing

Follow-up until autumn 2020: The catching-up activity should be launched as of 28 January 2022, when Regulation (EU) 2019/6 on veterinary medicinal products becomes applicable; orientation analyses have started at competent authority level. Research projects[33] resulted in published databases on environmental risks of pharmaceuticals and developed new manufacturing processes for the pharmaceuticals industry to reduce the use of expensive and toxic materials. The ad-hoc working group focused on PiE under the Pharmaceuticals Committee for human medicines has agreed on an action plan with concrete actions to be further developed, including recommendations for medicinal products for human use.

Planned further follow-up: Follow-up on the implementation of Regulation (EU) 2019/6 after 28 January 2022 as well as on the research projects and recommendations.

[33] IMI1 iPie (Intelligent Assessment of Pharmaceuticals in the Environment) and CHEM21 (Chemical manufacturing methods for the 21st century pharmaceutical industries);

***Action 5.3.4*** ***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.***

Progress: implemented/achieved

Follow-up until autumn 2020: Follow-up is assumed through the Chemicals Strategy (one substance, one assessment), and in the evaluation of the Endocrine Disruptors Strategy.

Planned further follow-up: Follow-up on the actions included in the Chemicals Strategy.

### 4.4. Reduce wastage and improve the management of waste

***Action 5.4.1a*** ***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.***

Progress: ongoing

Follow-up until autumn 2020: The ad-hoc working group focused on PiE under the Pharmaceutical Committee for human medicines has agreed on an action plan with concrete actions to be further developed, including best practices and recommendations for this action under the pharmaceuticals framework. Furthermore, under the environmental legislation the packaging and packaging waste legislation[34] is under review focusing – among others – on reducing (over)packaging and reinforcement of essential requirements for all packaging in general, accommodating however sector specific requirements, such as the requirements for pharmaceutical packaging.

Planned further follow-up: Follow-up on the recommendations and review.

***Action 5.4.1b*** ***In collaboration with Member States and the European Medicines Agency: 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.***

Progress: ongoing

Follow-up until autumn 2020: The ad-hoc working group focused on PIE under the Pharmaceutical Committee for human medicines has agreed on an action plan with concrete actions to be

[34] European Parliament and Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste

further developed, including best practices and recommendations for this action under the pharmaceuticals framework.

Planned further follow-up: Share best practices and develop recommendations so as to facilitate Member State action.

***Action 5.4.2*** ***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.***

Progress: good progress

Follow-up until autumn 2020: Under the environmental legislation, a study on separate collection of various waste streams published in April 2020[35] was used to develop guidelines on the separate collection of household hazardous waste, which have been published on 6 November 2020[36]. Under the pharmaceuticals framework, the ad-hoc working group focused on PiE under the Pharmaceuticals Committee for human medicines has agreed on an action plan with concrete actions to be further developed, including best practices and recommendations for this action. Stakeholdes and Member States[37] engaged in awareness raising campaigns.

Planned further follow-up: Facilitate best-practice exchange within and between Member States.

35 Guidance for separate collection of municipal waste

36 Commission Notice - Separate Collection of Household Hazardous Waste (2020/C 375/01)

37 See e.g. #medsdisposal Campaign or Member States Campaigns such as the German "No pharmaceuticals down the toilet or sink!"

***Action 5.4.3a*** ***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).***

Progress: started

Follow-up until autumn 2020: Several LIFE projects helped developed and promote methods to address pharmaceuticals and other emerging contaminants in Waste Water Treatment Plants. EU funding is also used to upgrade urban wastewater collection and treatment throughout the Member States. For Example Member States have allocated funding from the cohesion policy funds to investments in the water sector, as well as to innovation and cooperation in water-related activities.

Planned further follow-up: This is and will be one of the priority topics for water under current and future LIFE and will also be addressed through Horizon Europe and other research programmes. Cohesion policy support will continue in the 2021-2027 period. The possible revision of the Urban Waste Water Treatment Directive will also deal with pharmaceuticals and other micropollutants, aiming at securing a better uptake of latest technological developments in wastewater treatment.

***Action 5.4.3b*** ***In relation to urban waste water treatment: 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.***

Progress: implemented/achieved

Follow-up until autumn 2020: The evaluation of the Urban Waste Water Treatment Directive identified i.a. pharmaceuticals as an issue[38]. The Commission is now considering appropriate follow-up to these findings.

Planned further follow-up: Follow up on this issue i.a. in the impact assessment and possible revision of the Urban Waste Water Treatment Directive[39].

***Action 5.4.4*** ***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.***

Progress: started

Follow-up until autumn 2020: The Farm to Fork Strategy includes the target to reduce the overall EU sales of antimicrobials for farmed animals

38 Evaluation of the Urban Waste Water Treatment Directive.

39 Roadmap for the potential revision of the Urban Waste Water Treatment Directive.

and in aquaculture by 50% by 2030. Work on monitoring antimicrobial residues in manure, water and soil started[40].

Planned further follow-up: Follow-up on the Farm to Fork target and work at technical level to develop the Codes of Good Agricultural Practices and the analysis of the feasibility of the practices.

***Action 5.4.5 When the Industrial Emissions Directive is next evaluated, assess whether it should address intensive dairy farming.***

Progress: good progress

Follow-up until autumn 2020: The Industrial Emissions Directive has been evaluated and an impact assessment is starting[41]. One aspect being considered is expanding the scope and possibly include how to address intensive dairy farming. This will be explored in the impact assessment.

Planned further follow-up: Follow-up through the Industrial Emissions Directive revision, scheduled for 4th quarter 2021.

### 4.5. Expand environmental monitoring

***Action 5.5.1 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.***

Progress: good progress

Follow-up until autumn 2020: Several pharmaceuticals were included in the revised Watch List for surface water pollutants under the Water Framework Directive, adopted in August 2020[42], and others will be considered for inclusion at the next update planned for 2022. The Working Group Chemicals under the Water Framework Directive is discussing a way forward for monitoring antimicrobial resistance genes and organisms as well as on AMR in water in general[43].

Planned further follow-up: Consider expanding the list further to include the types of pharmaceuticals mentioned in the action. Substances for which enough information is available could be included in the Priority Substances List under the Water Framework Directive (possible revision proposal 2022).

40 JRC Technical Report - Residues of antimicrobial agents and related compounds of emerging concern in manure, water and soil

41 Revision of the Industrial Emissions Directive: Inception Impact Assessment

42 Commission Implementing Decision (EU) 2020/1161 of 4 August 2020 establishing a watch list of substances for Union-wide monitoring in the field of water policy

43 JRC Technical Report - State of the Art on the Contribution of Water to Antimicrobial Resistance

The Chemicals Strategy also includes actions to promote and provide financial support for EU-wide bio-monitoring of substances in humans and the environment, and their uptake for regular purposes, complementing ecosystem monitoring initiatives.

***Action 5.5.2*** ***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.***

Progress: ongoing

Follow-up until autumn 2020: Addressed in research funded by Horizon 2020.

Planned further follow-up: Follow up to ensure that proposed funding programmes/partnerships result in projects addressing pharmaceuticals in the environment and take up the results in the consideration of pollutants in water legislation. For example, three research topics planned for 2021-2022 will be dealing with inland water quality and pollution[44].

***Action 5.5.3*** ***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, to inform analyses of sources and potential exposure.***

Progress: started

Follow-up until autumn 2020: Monitoring results for water activities are already stored on this platform.The Chemicals Strategy includes actions on data collection and sharing, e.g. to develop a common open data platform on chemicals and provide financial support for EU wide monitoring capacities. The evaluation of the Urban Waste Water Treatment Directive identified i.a. pharmaceuticals as an issue. The Commission is now considering appropriate follow-up to these findings.

Planned further follow-up: The forthcoming Zero Pollution Action Plan will also set up an integrated Monitoring and Outlook framework on pollution prevention and control, focused on key pollutants. The Industrial Emissions Directive has been evaluated and an impact assessment has been launched in view of its revision[45]. In this context, also a possible review of the Best Available Techniques Reference Documents relevant to the discharge of pharmaceuticals

[44] This includes a) innovative monitoring strategies and integration of IT tools/platforms and advanced modelling; b) innovative concepts, cost effective technologies and advanced sensors and monitoring approaches for sustainable waste water collection and urban drainage systems; and c) advanced, integrated and cost-effective water quality sensors and analytical methods.

[45] Revision of the Industrial Emissions Directive: Inception Impact Assessment

into the environment will be considered. Follow up through i.a. the impact assessment and possible revision of the Urban Waste Water Treatment Directive and engage as part of the stakeholder consultation activities for the impact assessment with experts and the wastewater sector in general on how to improve the Directive, also as regards chemical pollution[46].

***Action 5.5.4*** ***Include antimicrobials and possibly antimicrobial resistance genes in the next phase of the European Commission's LUCAS soil survey.***

Progress: implemented/achieved

Follow-up until autumn 2020: Pharmaceutical concentrations and antimicrobial genes are analysed in samples of agricultural soils and mixed land use, respectively, collected during the LUCAS 2018 soil survey[47].

Planned further follow-up: Follow-up on results (envisaged for 2022) and keep including these in the next surveys. The Zero Pollution Action Plan for air, water and soil will propose ways to improve the monitoring and data availability also on soil contamination.

### 4.6. Fill other knowledge gaps

***Action 5.6.1*** ***The eco-toxicity and environmental fate of pharmaceuticals, in particular those not yet subject to environmental risk assessment.***

Progress: started

Follow-up until autumn 2020: Programmes for EU funding under Horizon Europe are still under development but will have scope for including relevant research.

Planned further follow-up: Follow up to ensure that proposed Horizon Europe programmes/partnerships result in projects addressing pharmaceuticals in the environment.

***Action 5.6.2*** ***The links between the presence of antimicrobials in the environment (if possible also the entry and natural presence of antimicrobial resistance genes) and the development and spread of antimicrobial resistance.***

Progress: started

Follow-up until autumn 2020: Programmes for EU funding under Horizon Europe and other research programmes are still under development but will have scope for relevant research. The initiative

46 Consultation Strategy for the potential revision of the Urban Waste Water Treatment Directive

47 LUCAS: Land Use and Coverage Area frame Survey

AquaticPollutants[48], co-funded by Member States, got huge interest for proposals and will start shortly.

Planned further follow-up: Follow up to ensure that proposed funding programmes/partnerships result in projects addressing pharmaceuticals in the environment.

***Action 5.6.3 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.***

Progress: started

Follow-up until autumn 2020: The Chemicals Strategy includes actions to promote research on chemicals and their impact on health and the environment, and announced a comprehensive research agenda for chemicals, including in relation to mixtures. Programmes for EU funding under Horizon Europe and other research programmes are still under development but will offer scope for relevant proposals. As part of the special Green Deal call of Horizon 2020 the topic 'Fostering regulatory science to address combined exposures to industrial chemicals and pharmaceuticals: from science to evidence-based policies' has been published.

Planned further follow-up: Follow up to ensure that proposed funding programmes/partnerships result in projects addressing pharmaceuticals in the environment as well as follow-up on actions of the Chemicals Strategy. Projects resulting from the Green Deal call will be monitored to see how their results can best feed into the activities of this strategy.

***Action 5.6.4 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.***

Progress: started

Follow-up until autumn 2020: Programmes for EU funding under Horizon Europe and other research programmes are still under development but will offer relevant opportunities. The evaluation of the

[48] AquaticPollutants, grant # 869178
Themes include a) Measuring – Environmental behaviour of contaminants of emerging concern (CECs), pathogens and antimicrobial resistant bacteria in aquatic ecosystems; b) Evaluating – Risk assessment and management of CECs, pathogens and antimicrobial resistant bacteria from aquatic ecosystems (inland, coastal and marine) to human health and environment; and c) Taking Actions – Strategies to reduce CECs, pathogens and antimicrobial resistant bacteria in aquatic ecosystems (inland, coastal and marine).

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| | Sewage Sludge Directive[49] is ongoing in parallel with the impact assessment process for the potential revision of the Urban Waste Water Treatment Directive, with a view, amongst others, to enhance resource efficiency and reduce toxicity for re-use. |
| Planned further follow-up: | Follow up on the evaluation of the Sewage Sludge Directive and ensure that proposed funding programmes/partnerships result in projects addressing pharmaceuticals in the environment. |

[49] Council Directive 86/178/EEC of 12 June 1986 on the protection of the environment, and in particular of the soil, when sewage sludge is used in agriculture

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