Pharmaceutical Residues in Freshwater

Hazards and Policy Responses

POLICY HIGHLIGHTS

OECD

BETTER POLICIES FOR BETTER LIVES

Pharmaceutical Residues in Freshwater

Hazards and Policy Responses

"A combination of promoting hygiene practices to reduce the incidence of infection and disease, encouraging sustainable pharmaceutical design and production, spreading awareness of responsible pharmaceutical use and disposal, and improving environmental monitoring and risk assessment of pharmaceuticals, are critical steps to achieving the dual sustainable development goals of improving health and protecting the environment."

Rodolfo Lacy
Director of the Environment Directorate, OECD

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BETTER POLICIES FOR BETTER LIVES

The OECD (2019) report *Pharmaceutical Residues in Freshwater: Hazards and Policy Responses* calls for a better understanding of the effects of pharmaceutical residues in the environment, greater international collaboration and accountability distribution, and policy actions to prevent and remedy emerging concerns. Laboratory and field tests show traces of oral contraceptives causing the feminisation of fish and amphibians, and residues of psychiatric drugs altering fish behaviour. Antimicrobial resistance, linked to the overuse of antibiotics, has rapidly escalated into a global health crisis.

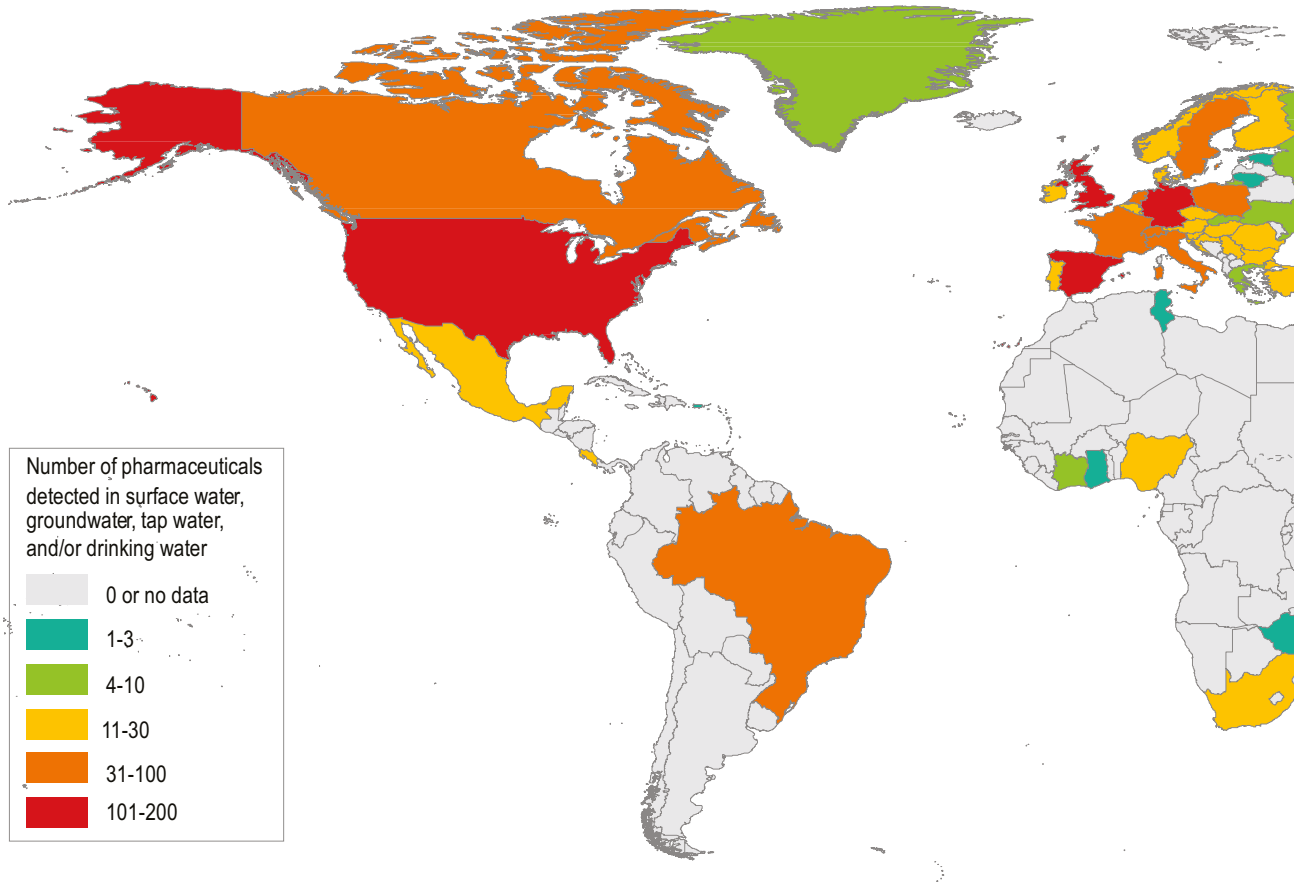
Unless adequate measures are taken to manage the risks, pharmaceutical residues will increasingly be released into the environment as ageing populations, advances in healthcare, and intensification of meat and fish production spur the demand for pharmaceuticals worldwide. The report outlines a collective, life-cycle approach to managing pharmaceuticals in the environment. A policy mix of source-directed, use-orientated and end-of-pipe measures, involving several policy sectors, can help to improve health and protect the environment.

1 The challenge of managing pharmaceuticals in water

Pharmaceuticals are an important element of medical and veterinary practice, and their beneficial effects on human and animal health, food production and economic welfare are widely acknowledged. However, an area where we lack a common understanding is what happens when these pharmaceuticals are constantly discharged into the environment, through pharmaceutical manufacturing, consumption and excretion, and improper disposal of unused or expired products.

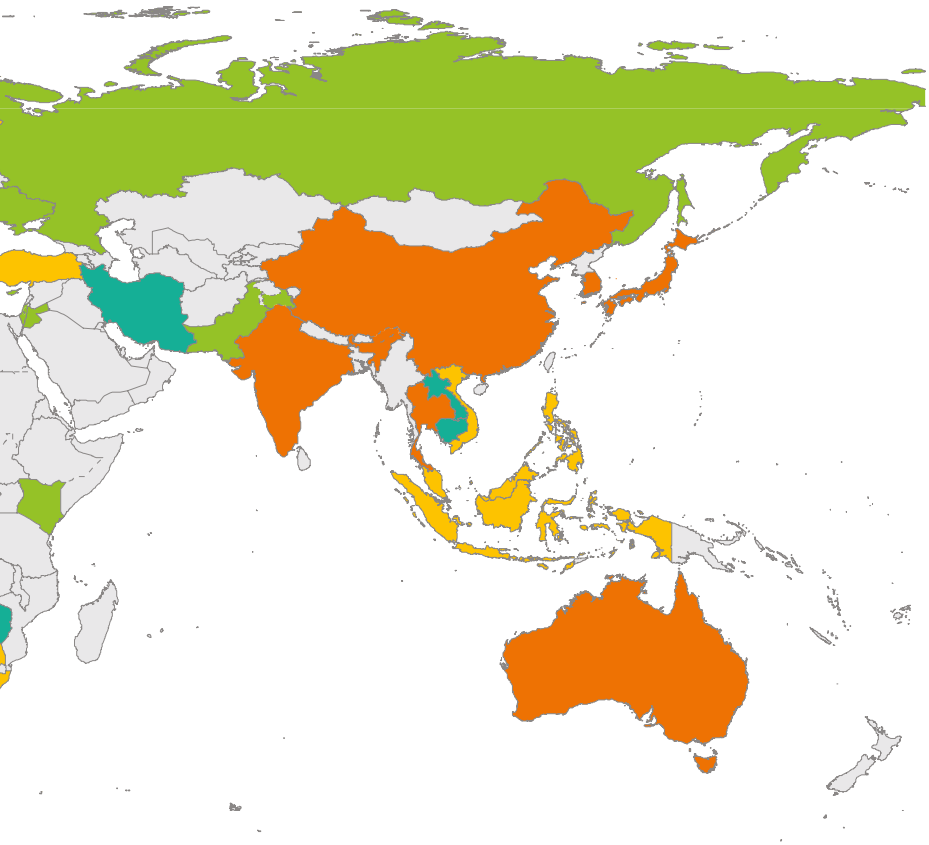
Pharmaceuticals in the environment are a challenge to manage for the following reasons:

- Pharmaceuticals are designed to interact with a living system and produce a pharmacological response at low doses, which makes them of environmental concern even at low concentrations. When exposed to non-target organisms in the environment, unintentional harmful impacts may occur.
- Pharmaceuticals are designed to be stable in order to reach and interact with target molecules. This means that either they are very slow to degrade or their constant use leads to continuous release into the environment at rates exceeding degradation rates.



Source: (aus der Beek et al., 2016).

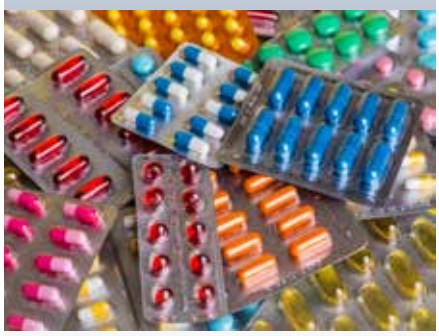
- Conventional wastewater treatment plants are not designed to, nor do they fully, remove pharmaceuticals from wastewater. Furthermore, veterinary pharmaceuticals used in agriculture and aquaculture can enter water bodies directly or via surface runoff (diffuse pollution).
- For most wildlife, exposure to pharmaceuticals in the environment could be long-term, potentially occurring via multiple exposure routes, and involving mixtures of substances.



2000

ACTIVE PHARMACEUTICAL INGREDIENTS

About 2,000 active pharmaceutical ingredients are being administered worldwide in prescription medicines, over-the-counter therapeutic drugs and veterinary drugs (Burns et al., 2018).



30-90%

ORAL DOSES EXCRETED AS ACTIVE SUBSTANCES

Pharmaceuticals administrated to humans or animals are excreted via urine and faeces, with 30 to 90% of oral doses generally excreted as active substances (BIO Intelligence Service, 2013).

HIGH ENVIRONMENTAL CONCENTRATIONS OF PHARMACEUTICALS DETECTED

Extremely high pharmaceutical concentrations (in the order of mg/l), have been detected in industrial effluents and recipient streams in China, India, Israel, Korea and the USA (Larsson, 2014).

2 Sources and trends of pharmaceuticals in the environment

1/3

OF PRESCRIPTION ITEMS BECOME WASTE IN THE UNITED STATES

In the United States, it is estimated that about one-third of the four billion prescription items annually become waste (Product Stewardship Council, 2018).

6.5 %

PHARMACEUTICAL INDUSTRY ANNUAL GROWTH RATE

Projected growth rate of the pharmaceutical industry: 6.5% per year by 2022 (UN Environment, 2019).

CLIMATE CHANGE TO INCREASE RISK OF DISEASE

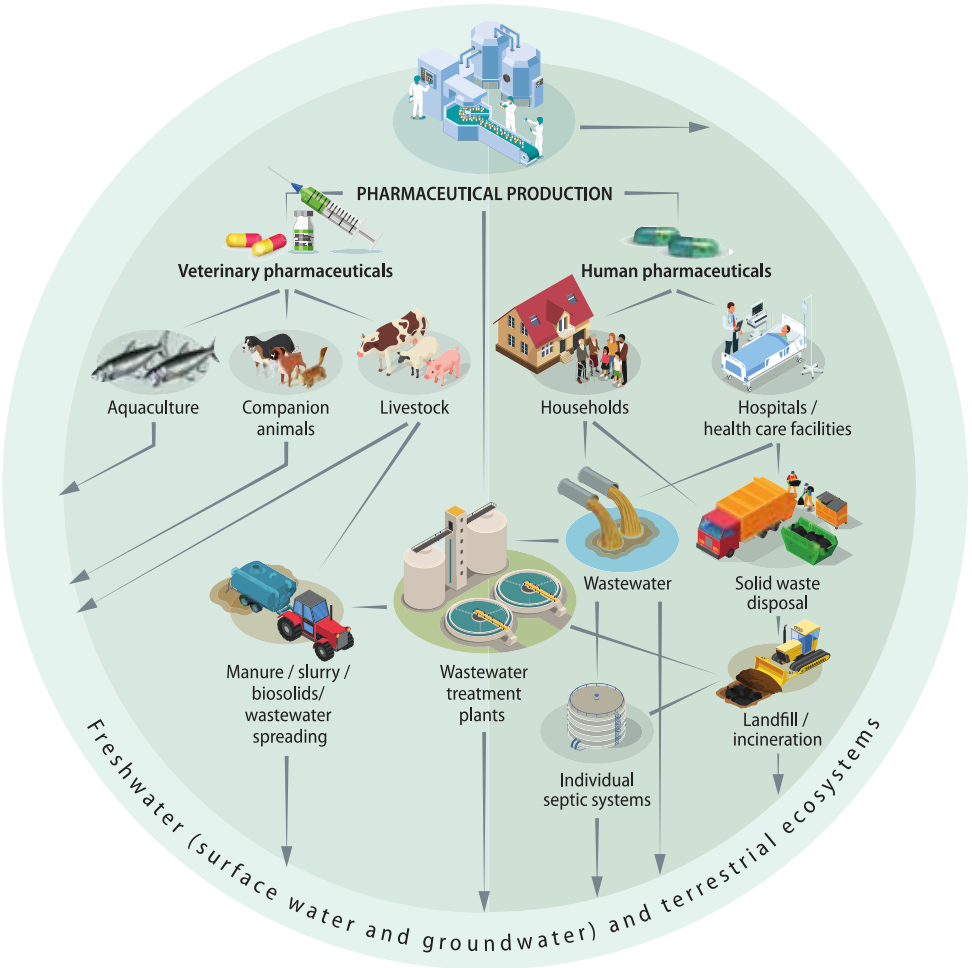
Millions of people are predicted to be newly at risk to mosquito-borne and tick-borne diseases under climate change. (Cavicchioli et al., 2019).

Pharmaceuticals are present in the environment as a consequence of pharmaceutical production and formulation, patient use, use in food production and improper disposal of unused or expired products (Figure 1).

The presence of pharmaceuticals in freshwater and terrestrial ecosystems can result in the uptake of pharmaceuticals into wildlife, and have the potential to bioaccumulate. Humans can subsequently be exposed through drinking water, and ingestion of pharmaceutical residues in plant crops, fish, dairy products and meat.

The concentrations and impacts of pharmaceuticals in the environment depend on a combination of variables, including their use and the toxicity, degradation, persistence and mobility properties of the pharmaceutical; source and timing of pollution; wastewater treatment plant technology, operation and removal efficiency; agriculture and veterinary practices; and the sensitivity of the receiving environment and exposure history (Figure 2).

Figure 1. **Major pathways of release of human and veterinary pharmaceuticals into the environment**



Pharmaceuticals in the environment are expected to rise with an increase in pharmaceutical consumption. The use of pharmaceuticals will increase as:

- populations age and life-spans increase;
- economies grow - particularly in emerging economies - and with it, an increasing ability and expectation to treat ageing-related and chronic diseases;
- clinical practices evolve - recommendations of earlier treatement, higher dosages or prolonged treatment;
- livestock and aquaculture practices are intensified;
- new pharmaceuticals are engineered;
- climate change exacerbates existing diseases. Non-communicable diseases (e.g. cardiovascular disease and mental illness) and respiratory, water-borne, vector-borne and food-borne toxicants and infections are expected to become more common as climate change intensifies.

67%

PROJECTED INCREASE IN LIVESTOCK ANTIBIOTICS WORLDWIDE BY 2030

Projected increase in antibiotics administered to livestock animals in feed: 67% worldwide by 2030 (from 2015 levels) (Van Boeckel et al., 2015). Much of this increase will come in emerging economies.

43-67%

INCREASE IN PHARMACEUTICAL USAGE, GERMANY

In Germany, pharmaceutical usage is projected to increase by 43-67% by the year 2045 (from a baseline of 2015). An ageing population is thought to be the main driver (Civity, 2017).

Figure 2. **A typology for pharmaceuticals in the environment**

Sources	Pathways	Concentration patterns	Pharmaceutical properties	Receiving environment type (sinks)	Concentration, context-dependent factors
• Pharmaceutical manufacturing plants • WWTPs - Municipal - Hospitals - Industry • Agriculture (particularly intensive livestock farming) • Aquaculture • Septic tanks • Waste management facilities (landfills).	• **Point source** (WWTP discharge) • **Diffuse source** (i.e. agricultural runoff, leaching of septic tanks to groundwater).	• **Continuous** (e.g. WWTPs) • **Seasonal** (linked with farming practices and with seasonal influenza and allergies, water flow and temperature) • **Intermittent** (linked with rainfall events, stormwater overflow, irrigation patterns and pandemics).	• **Persistence** - Half life - Solubility - Metabolites - Transformation products • **Bioaccumulation** • **Toxicity** - Individual effects - Population effects - Additive effects - Mixture effects • **Mobility**	• Rivers • Lakes • Groundwater • Soil • Sediment • Coastal zones Oceans	• Medical, agriculture and veterinary practices • Illicit drug use • Consumption rates • Pharmaceutical properties • Disposal and waste management practices • WWTP technology, operation and removal efficiency • Receiving environment type • Climate • Drainage characteristics • Water flow variations • Sunlight, temperature • Presence of other pollutants • Exposure history • Disturbance regime • Food web structure

Note: WWTPs: wastewater treatment plants.

3 Impacts of pharmaceuticals in the environment on human and freshwater ecosystem health

The presence of pharmaceuticals in the environment has raised concerns among drinking water regulators, governments, water suppliers and the public. Certain pharmaceuticals have been proven in laboratory experiments to cause unintended, undesired adverse effects on aquatic organisms, including mortality, as well as changes to physiology, behaviour and reproduction. Of greatest concern are: hormones, antibiotics, analgesics, antidepressants and anticancer pharmaceuticals used for human health; and hormones, antibiotics and parasiticides used as veterinary pharmaceuticals.

For example, active substances in oral contraceptives have caused the feminisation of fish and amphibians; psychiatric drugs, such as fluoxetine have altered fish behaviour making them less risk-averse and vulnerable to predators, and the over-use and discharge of antibiotics to water bodies exacerbates the problem of antimicrobial resistance. A summary of ecosystem health impacts of pharmaceuticals in the environment are presented in Table 1.

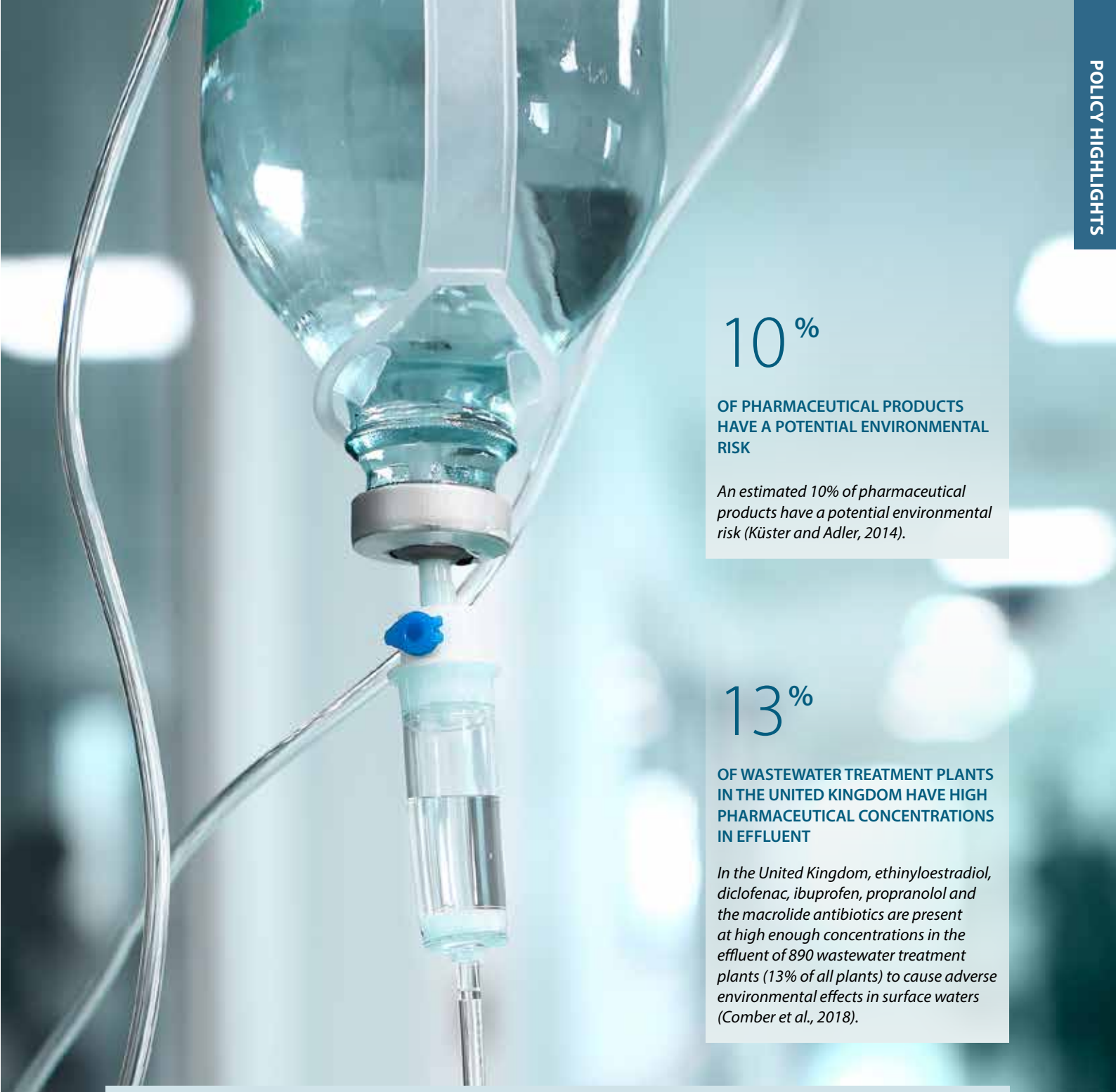
The impacts of other pharmaceuticals in the environment are less well-known; the vast majority of pharmaceuticals have not been evaluated for their long-term toxicity, occurrence or fate in the environment, and it is therefore difficult to generalise the risk they may give rise to.

In real life, substances are not isolated in the environment; instead they occur mixed together and in combination with other contaminants. There is growing evidence that mixtures of pharmaceuticals possess a joint toxicity greater (i.e. additive effects) than individual toxicities.

Table 1. **Examples of measured effects of certain pharmaceutical residues on aquatic organisms in laboratory studies**

Therapeutic group	Examples of Pharmaceutical	Impact and effected organisms
Analgesics	Diclofenac, Ibuprofen	Organ damage, reduced hatching success (fish) Genotoxicity, neurotoxicity and oxidative stress (mollusk) Disruption with hormones (frog)
Antibiotics	-	Reduced growth (environmental bacteria, algae and aquatic plants)
Anti-cancer	Cyclophosphamide[1], Mitomycin C, Fluorouracil	Genotoxicity
Antidiabetics	Metformin	Potential endocrine-disrupting effects (fish)
Anti- convulsants	Carbamazepine, Phenytoin, valproic acid	Reproduction toxicity (invertebrates), development delay (fish)
Antifungals	Ketoconazole, Clotrimazole Triclosan	Reduced growth (algae, fish), reduced algae community growth
Antihistamines	Hydroxyzine, Fexofenadine, Diphenhydramine	Behaviour changes, growth and feeding rate (fish) Behaviour changes and reproduction toxicity (invertebrates)
Antiparasitics	Ivermectin	Growth and reduced reproduction (invertebrates)
Beta blockers	Propranolol	Reproduction behaviour (fish), reproduction toxicity (invertebrates)
Endocrine disrupting pharmaceuticals	E2, EE2, Levonorgestrel	Disruption with hormones causing reproduction toxicity (fish, frogs)
Psychiatric dugs	Fluoxetine, Sertraline, Oxazepam, Citalopram, Chlorpromazine	Behaviour changes - feeding, boldness, activity, sociality (fish) Disruption with hormones (fish) Behaviour changes - swimming and cryptic (invertebrates) Reproduction toxicity and disruption with hormones (invertebrates)

Note: [1] Transformation of Cyclophosphamide and Ifosfamide; E2: 17β- estradiol (natural steroidal oestrogen); EE2: 17α- ethinylestradiol (synthetic oestrogen).



10 %

OF PHARMACEUTICAL PRODUCTS HAVE A POTENTIAL ENVIRONMENTAL RISK

An estimated 10% of pharmaceutical products have a potential environmental risk (Küster and Adler, 2014).

13 %

OF WASTEWATER TREATMENT PLANTS IN THE UNITED KINGDOM HAVE HIGH PHARMACEUTICAL CONCENTRATIONS IN EFFLUENT

In the United Kingdom, ethinyloestradiol, diclofenac, ibuprofen, propranolol and the macrolide antibiotics are present at high enough concentrations in the effluent of 890 wastewater treatment plants (13% of all plants) to cause adverse environmental effects in surface waters (Comber et al., 2018).

Box 1. **Antimicrobial resistance: an urgent, global health crisis**

Antimicrobial resistance (AMR) is a global health crisis with the potential for enormous health, food security and economic consequences. AMR is the ability of a microbe to resist the effects of medication that could once successfully destroy or inhibit the microbe.

Drug resistant infections already cause an estimated 700,000 deaths each year globally. If no action is taken, this is projected to increase to 10 million per year by 2050 – that is more than the number of people dying from cancer. A continued rise in AMR is projected to lead to a reduction of 2-3.5% in GDP globally, with a cumulative cost of up to USD 100 trillion.

The mis- and over-use of antibiotics is an important contributing factor of AMR; up to 50% of the antibiotics prescribed for human use are considered unnecessary. The number is even greater in the agriculture and aquaculture sectors, where they are mainly administered as a growth promoter and as a substitute for good hygiene. The environment becomes a reservoir for resistant genes, as well as an arena for the development and spread of resistance to pathogens.

Sources: (IACG, 2018), (OECD, 2018), (Review on Antimicrobial Resistance, 2015).

4 Policy instruments to control pharmaceuticals in the environment

88%

OF HUMAN PHARMACEUTICALS ARE WITHOUT ENVIRONMENTAL TOXICITY DATA

88% of human pharmaceuticals do not have comprehensive environmental toxicity data. Whilst pharmaceuticals are stringently regulated for efficacy and patient safety, the negative effects they may have in the natural environment have not yet been sufficiently studied and are not covered by an international agreement or arrangement.

OVER-PRESCRIPTION, SELF-MEDICATION & MIS-DIAGNOSIS INCREASE PHARMACEUTICALS IN THE ENVIRONMENT

Over-prescription, self-medication (over-the-counter pharmaceuticals) and misdiagnosis of symptoms can increase the amount of pharmaceuticals in the environment.

There are several mitigation options for water quality improvement in the pharmaceutical life cycle, including improvements in the design, authorisation, production, use, solid waste and wastewater treatment. A focus on preventive options early in the pharmaceutical life cycle, may deliver the most long-term, cost-effective and large-scale benefits.

A selection of key mitigation policy options across the pharmaceutical life cycle are presented in Table 2. France, Germany, the Netherlands, Sweden and the United Kingdom have started a multi-sector dialogue to tackle the problem. At the EU level, a "Strategic Approach to Pharmaceuticals in the Environment" identifies actions for stakeholders throughout the pharmaceutical life cycle with an emphasis on sharing good practices, on cooperating at international level, and on improving understanding of the risks.

Figure 3. **The pharmaceutical life cycle**

Table 2. **Selection of key mitigation policy options across the pharmaceutical life cycle**

Step in pharmaceutical life cycle	Relevant stakeholders	Mitigation options
Cross-cutting	Government, Industry, Research organisations	Targeted monitoring and prioritisation of high-risk pharmaceutical ingredients. Harness new innovations in water quality monitoring, modelling, scenario development and risk assessment. Environmental quality norms / water quality standards.
Design	Industry	Innovation in green pharmacy, biological therapies, personalised or precision medicines.
Authorisation	Government, Industry	Legislation and standardised methodology for environmental risk assessment and incorporation into pharmaceutical authorisation process. More stringent conditions for putting a pharmaceutical on the market that is of high-risk to the environment (e.g. increased risk intervention and mitigation options, eco-labelling, prescription only, post-approval monitoring).
Production	Industry, Government, Intergovernmental Organisations	Green public procurement with environmental criteria. Environmental criteria for Good Manufacturing Practices, effluent discharge limits and disclosure of pharmaceutical wastewater discharge from supply chains.
Consumption (professional use)	Agriculture, Health sector, Government	Emission prevention through disease prevention and sustainable use: • improved human and animal health and well-being • improved diagnostics, avoided prescriptions • improved hygienic standards in health facilities, stable management and livestock handling • personalised medicines, vaccinations, targeted delivery mechanisms • prescription of environmentally-friendly pharmaceutical alternatives[1] • restrictions or bans of unnecessary high-risk pharmaceuticals (e.g. veterinary use of antibiotics for preventative measures and hormones as growth promoters in livestock)
Consumption (over-the-counter purchases/ self-prescription)	Health sector, Industry, Consumers	Eco-labelling on pharmaceutical products to improve consumer choice selection and awareness
Collection and disposal	Solid waste utilities, Industry	Education campaigns to avoid disposal of pharmaceuticals via sink or toilet Public pharmaceutical collection schemes for unused drugs Extended producers responsibility schemes Improved manure management by passive storage or anaerobic fermentation in biogas plants
Wastewater treatment	Wastewater utilities	Upgrade of wastewater treatment plants
Drinking water treatment	Drinking water utilities	Upgrade of drinking water treatment plants Water safety planning

Note: [1] Requires that a substitute pharmaceutical is available with lower environmental risk. An alternative assessment would be required to confirm this, in order to prevent pollution-swapping.

THE REMOVAL OF PHARMACEUTICALS IS LIMITED BY WASTEWATER TREATMENT PLANT UPGRADES

Upgrading wastewater treatment with new technologies will not solely solve the problem of pharmaceuticals in water. They are limited by their removal efficiencies, high capital investment and operation costs and increased energy consumption. They do not capture diffuse sources of pharmaceutical pollution (e.g. from agriculture and aquaculture).

A selection of policy instruments to control pharmaceuticals in the environment in OECD countries


Sweden has a 'Wise List' of recommended pharmaceuticals for the treatment of common diseases that takes into account environmental impacts when comparing medications that are equally safe and equally suitable for the medical purpose.
The Swedish government has proposed a revised public procurement system in which pollution control during manufacturing is considered when pharmaceutical companies complete to obtain product subsidies for state healthcare.
Korea uses suspect and non-target screening to identify and prioritise pharmaceuticals for water quality monitoring.
Switzerland has a nationwide tax to fund the upgrade of 100 wastewater treatment plants with new technologies to reduce pharmaceuticals in water bodies.
Australia has a national pharmaceutical collection and disposal programme, with retail pharmacies commonly acting as collection sites.

5 OECD Policy recommendations

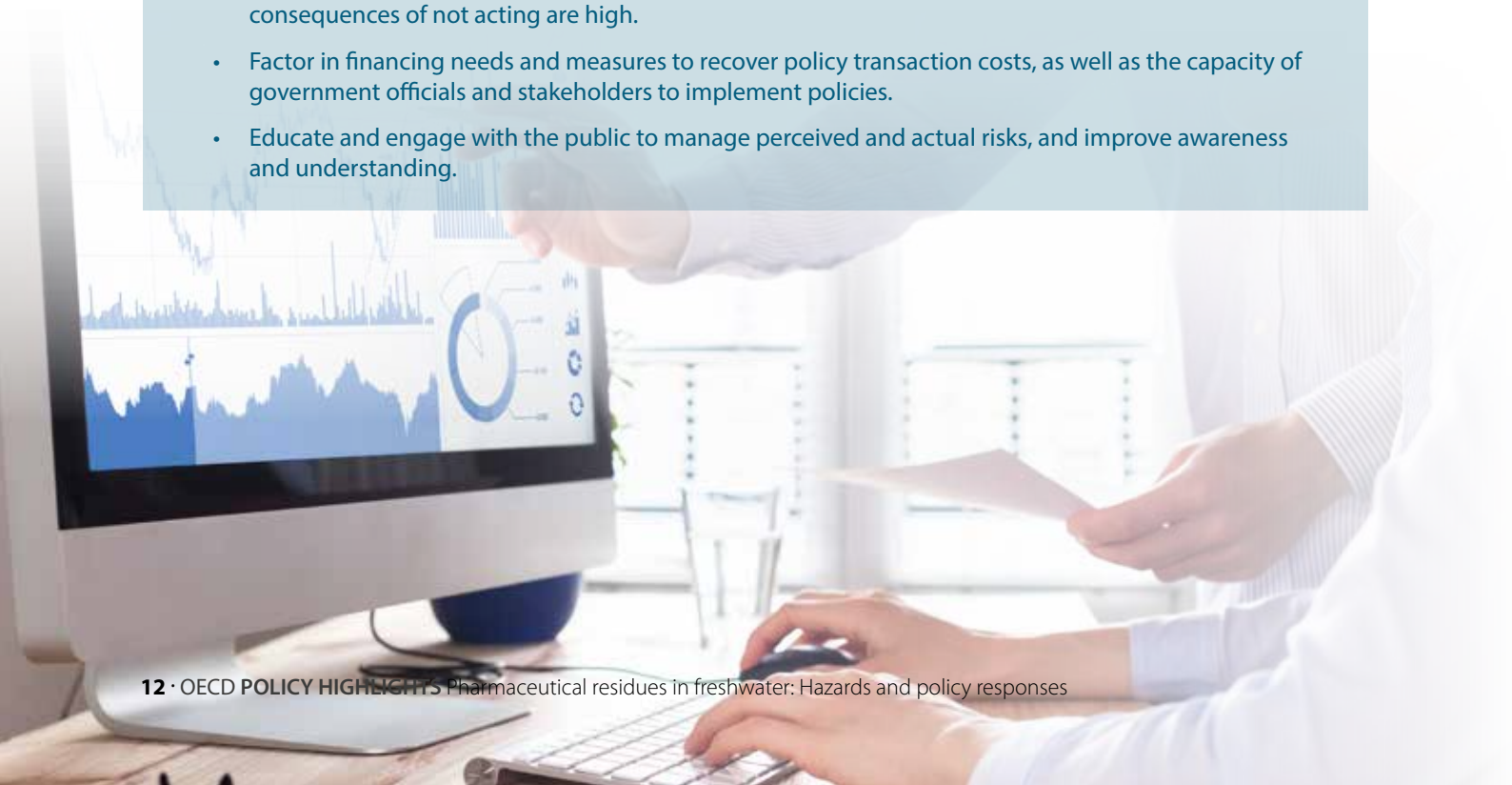
The OECD recommends government's take a collective, life cycle approach to managing pharmaceuticals in the environment. This means: i) designing and implementing a policy mix of source-directed, use-orientated and end-of-pipe measures; ii) targeting stakeholders throughout the life cycle of pharmaceuticals; and iii) using a combination of voluntary, economic and regulatory instruments. A national pharmaceutical strategy and action plan to manage environmental risks should be developed in collaboration with relevant government departments, local authorities and other stakeholders, and be supported by a strategic financing strategy to ensure effective implementation.

Policies that cost-effectively manage pharmaceuticals for the protection of water quality and freshwater ecosystems rest on five strategies:

1. Improvement of knowledge, understanding and reporting on the occurrence, fate, toxicity, and human health and ecological risks of pharmaceutical residues in water bodies in order to lay the ground for future pollution reduction measures.

OECD recommendations on improving knowledge, understanding and reporting

- Identify potential environmental risks of existing and new active pharmaceutical ingredients through intelligent and targeted assessment strategies. Reduce unknowns on relationships between pharmaceuticals, and human and environmental health. The relative risk of active pharmaceuticals ingredients should also be compared with other pollutants (e.g. heavy metals, persistent organic pollutants and other contaminants of emerging concern) to achieve improvements in water quality and ecosystems in the most cost effective way.
- Encourage the uptake of new monitoring methods, modelling and decision-support tools to better understand and predict the risks. Prioritise substances and water bodies of highest concern.
- Increase access to data and information, and institutional coordination, to reduce knowledge gaps.
- Adopt precautionary measures when scientific evidence is uncertain, and when the possible consequences of not acting are high.
- Factor in financing needs and measures to recover policy transaction costs, as well as the capacity of government officials and stakeholders to implement policies.
- Educate and engage with the public to manage perceived and actual risks, and improve awareness and understanding.



2. Source-directed approaches to impose, incentivise or encourage measures in order to prevent the release of pharmaceuticals into water bodies. They are primarily targeted towards pharmaceutical companies and manufacturing facilities.

OECD recommendations on source-directed approaches. Pharmaceutical life cycle stages: design, marketing authorisation, manufacturing, post-authorisation

- Develop clear and shared environmental criteria (and performance indicators) for sustainable 'green' procurement of pharmaceuticals.
- Consider expansion of the regulatory framework for good manufacturing practice to include mandatory environmental criteria.
- Develop drinking water safety plans, monitoring programmes of pharmaceuticals and incidence reporting to identify and prevent contamination, and adapt policy to new science.
- Ensure Environmental Risk Assessment (ERA) robustness, consistency and transparency. Establish a centralised database with independent regulatory oversight to share ERAs of pharmaceuticals and prevent duplication efforts.
- Consider environmental risks in the risk-benefit authorisation of human pharmaceuticals in order to manage and mitigate risks.
- Provide incentive structures to advance green pharmacy, and personalised and precision medicines. A return on public investments in new pharmaceuticals should be considered when assessing support for the private sector in pharmaceutical development.
- Address any potential economic impacts to avoid loss of pharmaceuticals or supply chain interruptions, and to limit increased costs to healthcare providers against static budgets.
- Establish new business models for pharmaceuticals that balance access needs, appropriate use and adequate return. This is particularly important for new antibiotics and tackling AMR; current business models link profit (sales) with volume (consumption).

3. Use-orientated approaches to impose, incentivise or encourage reductions in the inappropriate and excessive consumption of pharmaceuticals. They are designed to inform and change the behaviours and practices of physicians, veterinarians, pharmacists, patients and farmers.

OECD recommendations on use-orientated approaches. Pharmaceutical life cycle stages: prescription and use

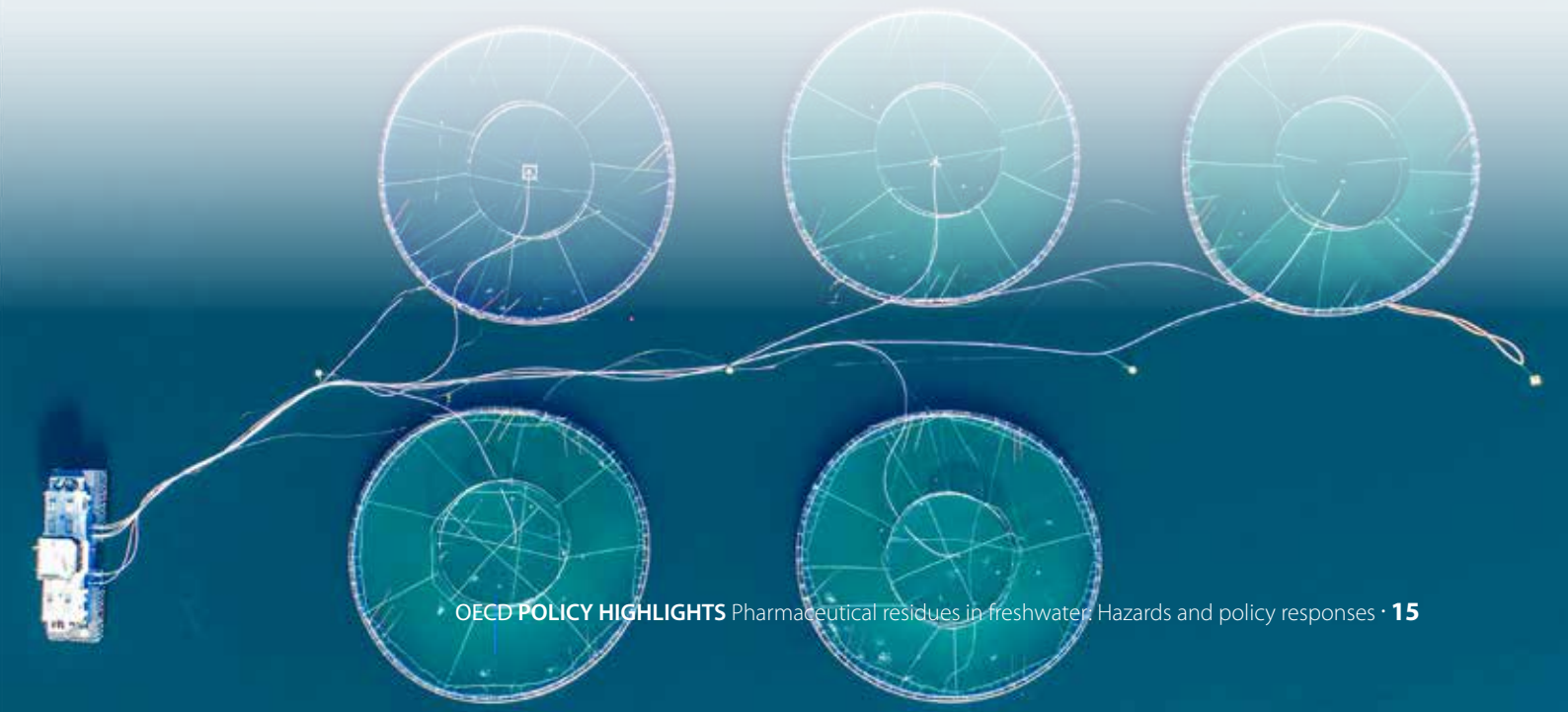
- Reduce the incidence of infection and disease. Improved access to safe water supply, sanitation and hygiene is particularly important. Other important measures include improved stable and livestock handling, practitioner training, education campaigns and vaccinations.
- Reduce unnecessary use and release of pharmaceuticals. Improve diagnostics and delay prescription of pharmaceuticals when they are not immediately required. If not already in place, consider bans or restrictions on antibiotics for preventative use, and hormones as growth promoters, in the livestock and aquaculture sectors.
- Optimise the use of pharmaceuticals with effective diagnosis, dosing, personalised medicines and targeted delivery systems.
- Reduce self-prescription of pharmaceuticals with high-risk (e.g. antibiotics and pharmaceuticals that target the endocrine system) and illegal sales of pharmaceuticals.
- Promote best practices on the storage and use of livestock manure and slurry from livestock treated with pharmaceuticals.

4. End-of-pipe measures – as a compliment to strategies 1-3 – that impose, incentivise or encourage improved waste and wastewater treatment to remove pharmaceutical residues after their use or release into the aquatic environment.

OECD recommendations on end-of-pipe measures. Pharmaceutical life cycle stages: collection and disposal, and wastewater treatment and reuse

- End-of-pipe measures should only be used in complementary to source-directed and use-orientated measures. An over-emphasis on upgrading wastewater treatment plant (WWTP) infrastructure is not a sustainable, optimal use of limited resources.
- Ensure value-for-money in investments in WWTP upgrades through evaluation and prioritisation, including achieving economies of scale. Consider potential trade-offs (e.g. incomplete removal of pharmaceutical residues to varying degrees; generation of potentially toxic transformation products and sludge; increased energy, chemicals and carbon emissions).
- Factor in financing needs and cost-recovery mechanisms for capital, and operation and maintenance costs of WWTP upgrades, including potential affordability issues with sanitation tariffs.
- Ensure appropriate collection and disposal of waste pharmaceuticals. Educate and engage with health professionals, veterinarians, consumers and farmers to raise awareness about inappropriate disposal of unused medications. Consider extended producer responsibility schemes to recover costs.
- Promote best practices on the use and disposal of biosolids (which may include toxic transformation products) following wastewater treatment.

5. Collaboration and a life cycle approach, combining the four strategies above and involving several policy sectors. Action on pharmaceuticals in the environment is much more likely to be extended and sustained if it is mainstreamed into broader health, agricultural and environmental policies and projects.



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