



Q&A – Strategic approach to pharmaceuticals in the environment

Brussels, 11 March 2019

1. Why do we need a strategic approach on pharmaceuticals in the environment?

Pharmaceuticals are used in human or veterinary medicine, either as treatments or diagnostic agents. Until recently, little was known about their presence in the environment. However, there is growing evidence that the levels of some pharmaceuticals found in the soil and water pose a risk to wildlife, partly because they are designed to act at low concentrations. In addition, there are concerns that the release of antimicrobials into the environment may also be contributing to the development and spread of antimicrobial resistance, an issue of global importance. The aim of the "[Strategic Approach to Pharmaceuticals in the Environment](#)" is to draw attention to those risks and to identify six areas where action is needed. The areas cover the lifecycle of pharmaceuticals, from design and production to disposal and waste management.

2. Do all pharmaceuticals pose a problem to the environment?

Not all pharmaceuticals are a problem for the environment. Product packages contain an information leaflet which often indicates whether the product poses a risk to the aquatic environment. This is a useful piece of information about how to dispose unused medicines correctly, which in many countries means taking the product to a pharmacy. In Sweden, for instance, medical professionals have access to a list which facilitates comparison on environmental grounds. Environmental risk assessment for pharmaceuticals is a work in progress, since for many pharmaceuticals such an assessment does not exist yet. The Commission has been working closely with stakeholders in order to improve the situation.

3. Are pharmaceuticals a big source of emissions to the environment?

In the European Union, the largest source of pharmaceuticals discharge in the environment is the excretion of pharmaceuticals by humans and animals, estimated to be about 90% of total emissions. These emissions enter the environment mainly via urban wastewater, sewage sludge, and manure. Emissions from manufacturing are the next largest source, followed by emissions from the disposal of unused pharmaceuticals.

4. Are there risks for human health?

Some pharmaceuticals have been found at very low concentrations in drinking water. According to the World Health Organisation ([WHO](#)) these are unlikely to pose a risk based on current evidence. However, there is a clear need to study the possible effects of long-term and combined exposure on vulnerable populations. The more obvious risk to human health comes from the possible role of antimicrobials in the environment in supporting the development and spread of [antimicrobial resistance](#). Several actions in the strategic approach are intended to contribute to the objectives of the [European One-Health Action Plan against Antimicrobial Resistance \(AMR\)](#).

5. Who will benefit from the actions outlined in the Strategic Approach?

The overall objective of the actions set in the Communication is to help lowering the concentrations of pharmaceuticals in the environment. This will have multiple benefits. It will help to slow down the spread of antimicrobial resistance, which constitutes a potential health threat. When it comes to the environment, it will boost the protection of fish by reducing their exposure to harm from pharmaceuticals in rivers and lakes, and this should in turn benefit the birds and mammals that prey on fish. It will also reduce the risk of harming a range of insects, on which fish or bird species prey, or that are essential for improving soils.

6. Which are the next steps?

The Commission is already starting to pursue some of the actions in the Communication, and will take each of them forward according to the best possible timeline. Certain limitations will need to be taken into consideration, in particular as regards the timing of legislative actions or research funding initiatives, the need for additional studies, and the availability of resources.

The [Communication](#) also refers to ongoing and future evaluations of relevant legislation. Those evaluations could be followed by proposals for legislative revision, if considered necessary. To come

forward with legislative proposals, the Commission is required to carry out an impact assessment addressing the potential social, economic and environmental impacts, taking into account public health needs and the cost-effectiveness of the measures proposed.

In the lead-up to the adoption of the Strategic Approach, the Commission already stepped up its action to address the issue of pharmaceuticals in the environment. A [new EU Regulation on veterinary medicinal products](#) was adopted recently and will apply as of 28 January 2022. It consolidates the requirements for environmental risk assessment, in particular as regards antimicrobials, and strengthens competent authority powers where such risks persist or have not been sufficiently addressed during the authorisation or post-marketing stages. In addition, it lays down a wide range of concrete measures to fight antimicrobial resistance and promote prudent and responsible use of antimicrobials in animals.

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