PHARMACEUTICALS IN THE ENVIRONMENT

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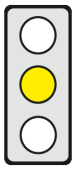
KEY ISSUES

Objective of the Communication: The EU Commission has submitted a "Strategic Approach" aimed at reducing pharmaceutical residues and their impact on the environment.

Affected parties: Patients, manufacturers of human and veterinary medicinal products, farmers, operators of sewage treatment plants.



Pro: (1) It is appropriate to reduce pharmaceutical residues because they can speed up the development of antimicrobial resistance (AMR) and have a detrimental effect on the hormone system.

(2) Restricting the use of antibiotics in livestock farming is an important contribution to the reduction of pharmaceutical residues in the environment.

Contra: (1) Solutions should primarily address the causes. The Strategic Approach lacks this emphasis.

(2) The use of antibiotics can also be reduced by tests that indicate the type of infection – bacterial or viral – a fact which the Commission wrongly ignores.

The most important passages in the text are indicated by a line in the margin.

CONTENT

Title

Communication COM(2019) 128 from the Commission of 11 March 2019: **European Union Strategic Approach to Pharmaceuticals in the Environment**

Brief Summary

► **Background**

– The EU Commission was to issue a "Strategic Approach" to the pollution of water bodies caused by pharmaceutical substances "as far as possible" by the end of 2015 [Art. 8c Environmental Quality Standards Directive (EC) 2008/105].
– Pharmaceutical residues have been found in animal tissue, soils and surface and ground water [p. 2]. These included antimicrobial pharmaceuticals (e.g. antibiotics) [p. 4].
– Pharmaceutical residues in the environment arise primarily from the following sources [p. 2 et seq.]:
  - wastewater from sewage treatment plants containing excreted as well as unused pharmaceuticals as the ability of sewage treatment to remove pharmaceutical residues varies significantly.
  - animal manure.
  - the dispensing of pharmaceuticals in animal feed in aquaculture.
– A further source of pharmaceutical residues, particularly in third countries, is the discharge of effluent from manufacturing plants [p. 3].
– Residues from antimicrobial pharmaceuticals may play a role in accelerating the development, maintenance and spread of resistant bacteria and fungi (antimicrobial resistance – AMR) [p. 4].
– The effects of certain chemical substances on the hormone system (endocrine disrupters) also represent a potential risk [p. 3].

► **Objectives and "action areas"**

– The EU Commission has submitted a "Strategic Approach" aimed at reducing pharmaceutical residues and their impact on the environment. For this it sets out four "main objectives" [p. 5 et seq.]:
  - Identify actions to address the potential risks from pharmaceutical residues in the environment, i.a. to combat antimicrobial resistance (AMR).
  - Encourage innovation as a way of addressing the risks and to promote the circular economy by facilitating the recycling of water, sewage sludge and manure.
  - Identify remaining knowledge gaps and develop solutions.
  - Ensure safe and effective pharmaceutical treatments for humans and animals.
– The EU Commission envisages six "action areas" [p. 7–12]:
  - Promote the prudent use of pharmaceuticals,
  - Support the development and manufacture of more environmentally friendly pharmaceuticals,

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- Improve environmental risk assessment of pharmaceuticals and its review,
- Reduce wastage and ensure proper disposal of pharmaceuticals,
- Expand environmental monitoring,
- Fill other knowledge gaps.

– To "spread the efforts evenly" the EU Commission is proposing measures which [p. 7]
- "not only include end-of-pipe controls" (e.g. improved wastewater treatment),
- "but also address the original sources of emissions" (e.g. production and use [of pharmaceuticals]).

► **Action area 1: Promote the prudent use of pharmaceuticals**

– The EU Commission wants inter alia to [p. 7-8]
- limit the preventive use of veterinary antimicrobials;
- foster exchange between Member States on how environmental considerations can be better taken into account such as in the prescription of medicinal products and the choice of therapy;
- promote the development of guidelines and training for healthcare professionals.

► **Action area 2: Support the development and manufacture of more environmentally friendly pharmaceuticals**

– The pharmaceutical industry is to take account of "the environment" in the design and manufacturing stages already [p. 8].

– The EU Commission wants inter alia to [p. 8 et seq.]
- fund research to support the development of "greener" pharmaceuticals that degrade more readily to harmless substances;
- discuss with Member States how far public procurement policy can be used to encourage more environmentally friendly pharmaceutical design and manufacturing;
- engage with the pharmaceutical industry on its contribution to meeting the objectives of the Strategic Approach, e.g. how producer responsibility could be extended to improve the efficacy of water treatment;
- encourage action in third countries in order to reduce the global spread of antimicrobial resistance.

► **Action area 3: Improve environmental risk assessment (ERA) of pharmaceuticals and its review**

– The risk assessment of pharmaceuticals and the development of guidelines for the ERA of pharmaceuticals should be coordinated. Retrospective ERAs for veterinary medicinal products already on the market should provide data allowing better evaluation. [p. 9]

– The EU Commission wants inter alia [p. 9 et seq.]
- on the basis of the Regulation on veterinary medicinal products [(EU) 2019/6]
  - to initiate a "catching-up procedure" for veterinary medicinal products that are on the market without an ERA;
  - to assess the feasibility of an EU-wide review system based on active pharmaceutical ingredients to support the ERA of veterinary medicinal products;
- in collaboration with the European Medicines Agency and the Member States
  - to consider developing guidelines for the ERA of medicinal products used in aquaculture and, where appropriate, issue recommendations;
  - to examine how to improve public access to the main ERA results and relevant toxicological thresholds for medicinal products.

► **Action area 4: Reduce wastage and ensure proper disposal of pharmaceuticals**

– There is to be less wastage and an improvement in the proper disposal of pharmaceuticals in order to reduce the risks posed by pharmaceutical residues [p. 10].

– The EU- Commission wants inter alia to [p. 10 et seq.]
- explore the possibility of reducing unnecessary waste by optimising the package size of pharmaceuticals and by safely extending use-by and/or expiry dates;
- invest in technologies to improve the efficiency of urban wastewater treatment in removing pharmaceuticals and antimicrobial resistance genes;
- investigate whether urban wastewater treatment plants can be upgraded with more advanced treatment technologies;
- assess the implementation of collection schemes for unused pharmaceuticals;
- examine how to increase public awareness of collection schemes;
- examine how an extended producer responsibility could play a role in appropriate disposal.

► **Action area 5: Expand environmental monitoring**

– Monitoring of certain parts of the environment should be extended. This will improve knowledge about the concentrations of pharmaceuticals and thus also ERAs. [p. 11]

– The EU Commission wants inter alia to [p. 11]
- support research on monitoring substances in waters, soils, sediments, and wildlife;
- gather data on effluents and develop online monitoring to analyse potential exposure with stakeholders.

► **Action area 6: Fill other knowledge gaps**
– The EU Commission considers supporting additional research inter alia in the following areas [p. 11 et seq.]:
- the eco-toxicity and environmental fate of pharmaceuticals, in particular those not yet subject to environmental risk assessment;
- the links between antimicrobials in the environment and the development and spread of antimicrobial resistance;
- effects on humans of low levels of pharmaceuticals in the environment.

Policy Context

With this Communication, the EU Commission is complying with its obligation to issue a Strategic Approach to the pollution of water bodies caused by pharmaceutical substances. The approach now being proposed is supposed to contribute to the European Action Plan to combat antimicrobial resistance [see cep**PolicyBrief** 01/2018] whose implementation is also one of the tasks of the new EU Commission [s. cep**Adhoc** A Healthy Europe]. In reaction to the Strategic Approach both the Council and the European Parliament are calling on the Commission to specify the most effective measures – including statutory measures – to contain the environmental impact of pharmaceuticals and combat the development of resistance to antimicrobials. In parallel, the negotiations on the Drinking Water Directive and the proposal for a Regulation on minimum requirements for water reuse, indicate that there will be further regulation of pharmaceuticals regarding water management.

Options for Influencing the Political Process

Directorates General:	DG Environment (leading)
Committees of the European Parliament:	Environment, Public Health and Food Safety (leading)

ASSESSMENT

Economic Impact Assessment

The consumption of pharmaceuticals in the EU is going to increase further particularly also due to the ageing society and resulting increase in demand. The basic problem is the fact that the use of pharmaceuticals for humans and animals – in addition to the desired effects – also has an unintended impact on the environment and thus also negative consequences for humans.

It is appropriate to reduce pharmaceutical residues because they can speed up the development of antimicrobial resistance (AMR) **and**, due to certain chemical substances (endocrine disruptors), **have a detrimental effect on the hormone system.** Both uniform EU measures and measures in third countries are required as AMR is spread across borders by freight and passenger transport.

Solutions should primarily address the causes of pharmaceutical residues. **The Strategic Approach lacks this emphasis.** Source-directed measures are appropriate – such as more environmentally friendly pharmaceutical design and manufacturing processes – and at the same time, use-oriented measures to optimise the use of pharmaceuticals for patients. End-of-pipe controls to remove residues should only be supplemental because even modern end-of-pipe controls cannot completely remove pharmaceutical residues.

Restricting the use of antibiotics in livestock farming – as envisaged by the Communication – **is another important contribution to the reduction of pharmaceutical residues in the environment.** In Germany, the dispensation of antibiotics as veterinary medicinal products was already reduced by more than 50% between 2011 and 2016. As the reduction in the use of antibiotics requires improvements in animal husbandry and hygiene, additional costs may arise, possibly resulting in price increases for the consumer. In the long term, however, these additional costs do not outweigh others, such as those threatened by AMR.

The planned support for an exchange between Member States, with the aim of taking account of the environmental impact when prescribing pharmaceuticals, is misguided because this will only be possible where there are two medically equivalent alternatives. Doctors will generally prescribe the medicine which promises the best chance of a successful treatment and not the one with least impact on the environment.

The use of antibiotics can also be reduced by tests already available on the market **which can indicate the type of infection – bacterial or viral – a fact which the Commission wrongly ignores.** This may prevent prescription simply based on suspicion.

Supporting the development of "greener" pharmaceuticals is appropriate as long as this is based on fundamental research. The planned **support for** exchange between Member States on the possibility of **"greener" pharmaceuticals via public procurement is too selective.** Other **incentive systems** with a long-term impact such as **allowing the aspect of "greener" design and manufacture to be incorporated into pricing** of new pharmaceuticals **and into** national pharmaceutical **reimbursement schemes are more appropriate.**

Pharmaceutical manufacturers bear some responsibility for pharmaceutical residues in the environment. It is therefore appropriate to include them when it comes to removal of the residues. This could take place, e.g. by way of a fund

through which end-of-pipe controls and research on "greener" pharmaceuticals can be financed. Participation in the fund should be ensured as far as reasonably possible according to the polluter-pays principle by way of a specially created environmental classification system for pharmaceuticals. This system should be based on the results of assessments of the manufacturers regarding (1) environmental risk, i.e. the concentration below which no adverse effects on the environment are expected (so called PNEC factor), (2) environmental relevance, i.e. persistence, bio-accumulation and toxicity and (3) the defined daily dose.

In order to ensure that the pharmaceutical manufacturing process is less harmful to the environment, environmental risk must be integrated into the EU guidelines on "good manufacturing practice" ("GMP"). As the EU GMPs must be observed irrespective of the production location, this may also provide an incentive to produce "greener" pharmaceuticals in third countries. Thus, the local population would be less exposed to the dangers of pharmaceutical residues in the environment. Consequently, however, this may lead to an increase in pharmaceutical prices and thus to a corresponding financial burden on health systems.

The proposed extension of the expiry date of medicinal products – i.e. their use – and the fastest possible biodegradability cannot be achieved simultaneously. Therefore, this is not an efficient way to achieve the actual objective of reducing pharmaceutical residues in the environment.

The proposed end-of-pipe controls, e.g. improved purification technologies in water treatment plants, should be regarded as supplemental as they do not tackle the actual causes of pharmaceutical residues and also give rise to additional costs. Pharmaceuticals can generally – depending on regional particularities – be disposed of in residual waste if the active pharmaceutical ingredients are destroyed by waste incineration plants. Where this is not the case, pollutant collection points are appropriate. Use of such collection points could be based on a deposit return scheme.

Better information for patients on the correct method of disposal is also important. **The packaging of medicinal products should display clear instructions for the consumer** on the best method of disposal **and indicate that medicinal products must under no circumstances be discharged into the sewerage system**.

Legal Assessment

Legislative Competency

In 2013, the EU Commission was obliged by law to develop, as far as possible by the end of 2015, a Strategic Approach to the pollution of water by pharmaceutical substances [Art. 8c Environmental Quality Standards Directive 2008/105/EC]; this Communication is issued in compliance with that obligation.

The measures announced in the Strategic Approach are within EU competence because, as far as foreseeable, they will principally serve to encourage cooperation between Member States [Art. 168 (2) para. 1 TFEU] and promote coordination between Member States [Art. 168 (2) para. 2 TFEU].

Subsidiarity

Unproblematic. The risks of pharmaceutical residues can have cross-border impact irrespective of their place of origin.

Proportionality with respect to Member States

Dependent on the design of the actual measures.

Conclusion

As pharmaceutical residues speed up the development of antimicrobial resistance (AMR) and can have a detrimental effect on the hormone system, it is appropriate to reduce them. Solutions should primarily address the causes. The Strategic Approach lacks this emphasis. Restricting the use of antibiotics in livestock farming is an important contribution to the reduction of pharmaceutical residues in the environment. The use of antibiotics can also be reduced by tests to indicate the type of infection – bacterial or viral – a fact which the Commission wrongly ignores. Promoting "greener" pharmaceuticals via public procurement is too selective. Incentive systems, incorporating the aspect of "greener" design and manufacture into pricing and reimbursement schemes are more appropriate. The packaging of medicinal products should display clear instructions for the consumer that such products must under no circumstances be discharged into the sewerage system.