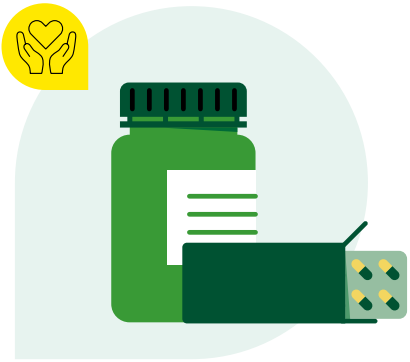


Sustainable drug supply for a healthy society: Study on ecological sustainability in antibiotic supply

As of November 2025

The political and public debate on drug supply is dominated primarily by a debate on higher drug prices. Serious long-term developments, such as increasing antibiotic resistance, poor local production conditions and the negative effects on people and the environment, are largely ignored. There is no question that a solid supply of pharmaceuticals requires stable supply chains and sustainable, fair and viable price reimbursement models. Dependencies on global, non-European markets must also be minimised to reduce the risks of unstable supply chains and strengthen the resilience of the supply of pharmaceuticals.

However, the supply of pharmaceuticals can only be stabilised in the long term if it is made sustainable in all three dimensions – economic, social and ecological. This is a responsibility that we as a society, both nationally and across Europe, must shoulder.

Antimicrobial resistance (AMR) jeopardises the effective prevention and medical treatment of a steadily growing number of infections and leads to a high number of premature deaths worldwide. Both the European Commission and the WHO consider AMR to be one of the greatest threats to health. **As the most powerful weapon in the fight against infectious diseases, antibiotics are increasingly losing their effectiveness due to the development of resistance. A major cause of this is the unhindered discharge of contaminated production wastewater into the immediate environment, and its global spread thereafter.**

Study: Measurement results show danger to local population and risk of global spread of antimicrobial resistance

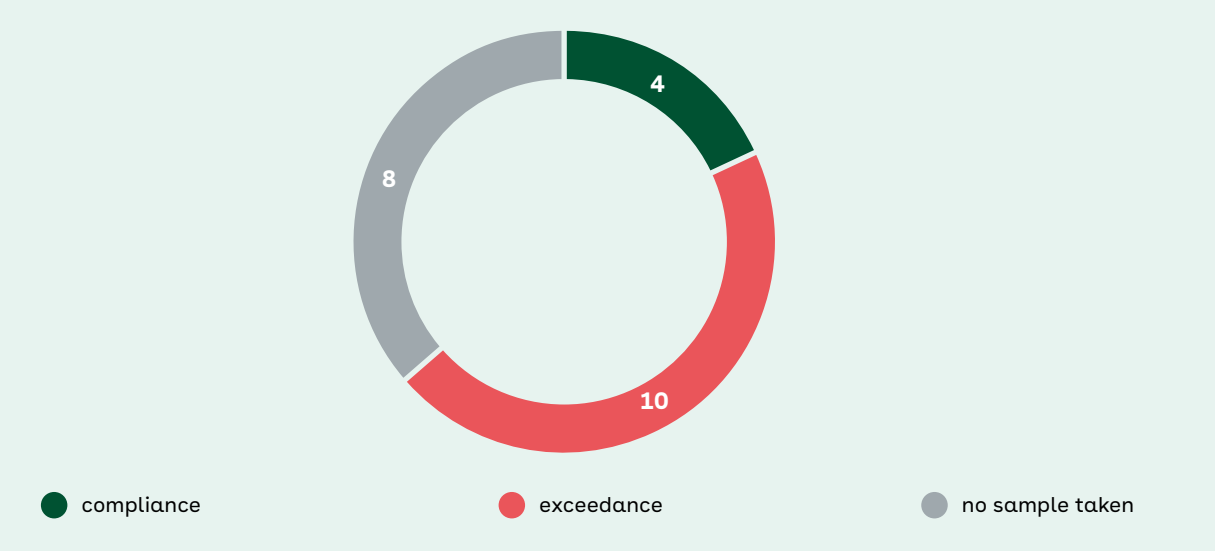
Under the leadership of AOK Baden-Württemberg, the AOK community, together with the Water Research Institute (IWW) and with the support of the Federal Environment Agency (UBA), was the first health insurance company in Germany to initiate and conduct a pilot study on ecological sustainability in antibiotic supply in 2020. The aim of the study is to create incentives for the environmentally friendly production of antibiotics through a voluntary bonus criterion in the context of awarding discount contracts for pharmaceutical companies. The companies guarantee compliance with effect-based maximum concentrations ('Predicted No Effect Concentration', PNEC) in the production wastewater and runoff of the active ingredient production facility and allow independent on-site verification.

Since September 2021, a total of over 50 inspections has been carried out at 22 sites in China, India and Europe. The results paint an alarming picture: at eleven production sites to date, sometimes massive exceedances of threshold values have been detected for nine of the antibiotics covered by the contract.

The highest concentration was measured in the **production wastewater** for Levofloxacin. The measured value of >600 µg/l exceeded the contractually agreed threshold value by more than 2,500 times. Other exceedances in production wastewater were also in some cases several thousand times higher than the threshold values.

In total, the inspectors detected 26 different antibiotics in **environmental samples.** At just under half of the sites investigated, exceedances of the PNEC as the ecotoxicologically relevant threshold value for at least one antibiotic were detected in the environmental samples. Of the total of 14 water bodies sampled, only four showed no antibiotic concentrations of concern *(Figure 1)*. It was not possible to take environmental samples at all locations.

Figure 1: Antibiotics in environmental samples.



Number of locations with PNEC exceedances or compliance in environmental samples.
A maximum of one exceedance was recorded per location.

The highest exceedance in all samples to date was found in a **surface runoff** of a production facility for the antibiotic Clindamycin. The independent inspectors found a concentration of ~180,000 µg/l. The concentration exceeded the specified PNEC of 0.4 µg/l **by more than 4,500,000 times (!).** The highest **environmental concentration** next to a production facility was detected for Ciprofloxacin with a measured value of >3.000 µg/l, exceeding the PNEC by more than **33,000 times.**

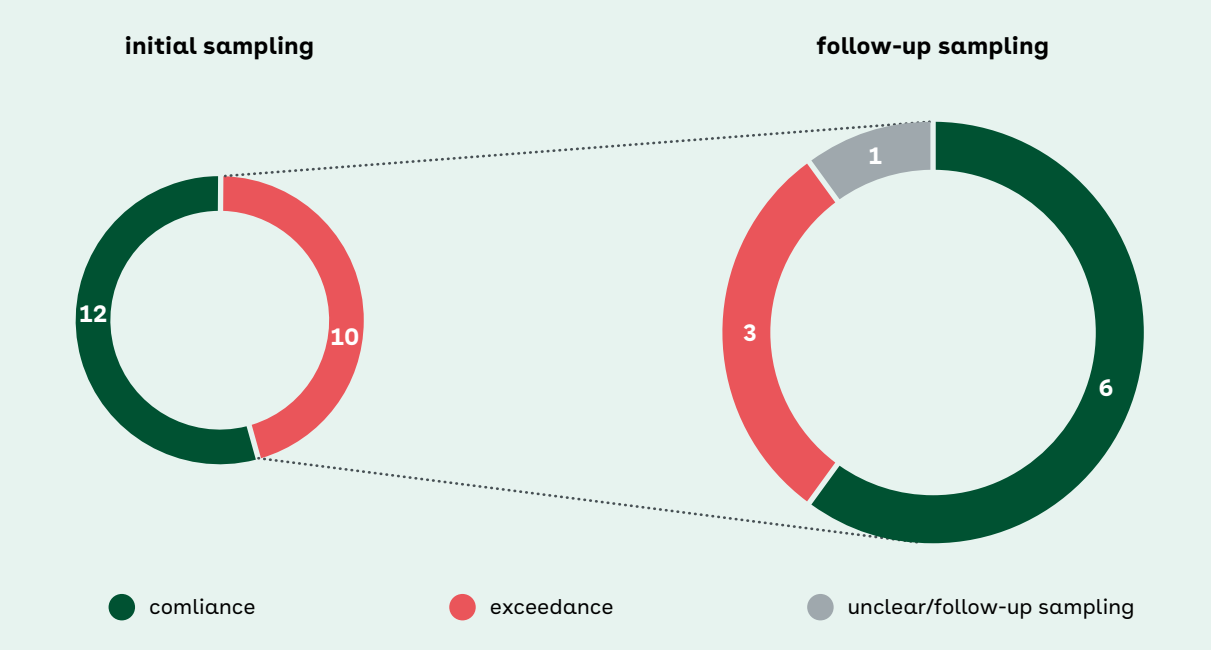
The detection of high concentrations of antibiotics in water bodies affected by production facilities – including surface runoff from rainwater that flows directly into the environment – is extremely worrying. In several cases, the sampled water bodies flow through heavily used pastureland and inhabited settlements.

However, the five-year study period has also revealed positive effects of the investigations. Sampling and direct exchange with IWW representatives on site have demonstrably increased knowledge about the environmentally critical and health-threatening effects of production.

Raising awareness of this issue has already led to local improvements in the treatment of production wastewater and rainwater management. In addition, it has become apparent that production facilities are increasingly communicating with each other and sharing knowledge, which has demonstrably led to an improvement in production conditions at other plants.

Overall, all studies show that in most cases, a significant improvement in production conditions could be demonstrated in the follow-up sampling at production facilities, which initially featured PNEC exceedances *(Figure 2)*.

Figure 2: Exceedance in initial and follow-up sampling



Compliance with and exceedances of the agreed threshold values in production wastewater, environmental samples and surface runoff at the individual sites in initial sampling and follow-up investigations in the period from September 2021 to May 2025.

Need for action

The results of the study highlight the urgent need for action at national and, above all, European level. Especially, as the study partners have so far only been able to examine a small part of drug production, the study results can be considered as the tip of the iceberg. If the international community wants to get the problem of antibiotic resistance under control and reduce the associated negative consequences for the environment and health in order to effectively avert negative consequences for the environment and health, regulatory frameworks must address the root causes.

An effective minimisation of the risks to the environment and health requires a European approach. This requires Germany to take a united and strong stance in the European context. It is therefore important to use the current revision of EU pharmaceutical legislation, including the Critical Medicines Act, in a targeted manner to strengthen the sustainable supply of medicines.

Specific policy demands

Inclusion of binding environmental criteria for active substance production in EU pharmaceutical legislation:

- **Scientifically derived upper limits for active substance emissions into the environment** (all active substance inputs from production into water, soil and other environmental compartments) at the production site
- **Binding environmental criteria for the authorisation and ongoing production** of selected medicinal products, in particular antibiotics
- In the course of the current **amendment of EU pharmaceutical legislation (including the Critical Medicines Act),** environmental criteria for production must be specified

Uniform control systems to verify compliance during authorisation and ongoing production:

- **Introduction of uniform control systems** for approval and ongoing production to verify compliance with these environmental criteria for all entry pathways
- **Obligation of pharmaceutical companies** to submit corresponding **audit and certification protocols when awarding public contracts and creation of the corresponding legal basis, especially in EU pharmaceutical law but also in EU public procurement law**
- Designation of specific control institutes in EU pharmaceutical law and their scope of action, e.g. **unannounced inspections**

Knowledge transfer through partner projects, particularly in Asia:

- Strengthening the development of control systems and technical equipment on site to improve the production process
- Establishment of **partnership projects, particularly with Asia**

Stabilisation of supply chains by amending EU law:

- Preference for European production in tenders for medicinal products
- This requires comprehensive transparency regarding all production sites in the EU and the active ingredients produced there.
- In addition, supplementary and accompanying **economic policy measures** are needed **to promote business locations within the EU,** as well as mandatory use of active ingredients from European production in a defined minimum quota.
- If EU member states do not issue tenders in the patent-free pharmaceutical market, other measures to shorten and diversify supply chains should become mandatory.

Expanding the early warning system for identifying impending supply shortages of pharmaceuticals and strengthening stockpiling:

- A comprehensive early warning system for all pharmaceuticals billable to the statutory health insurance system along the entire value chain is imperative and must be implemented stringently at national level and for social insurance carriers in the European area
- Extend the six-month stockpiling requirement under the ALBVVG to non-discounted pharmaceuticals

Imprint

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