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Inhumane inaction on pharmaceutical pollution

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Opinion Plus

The release of pharmaceuticals into the environment has significant detrimental effects on human health, write Sirpa Kärenlampi and Angelica Lindsey-Clark.

Photo credit: Fotolia

The release of pharmaceuticals into the environment has significant detrimental effects on human health, yet is one of the most frequently overlooked causes of antimicrobial resistance (AMR).

Despite at least 700,000 people dying globally from drug-resistant infections each year, the European Commission has failed to support its own DG Environment to push through swift and enforceable action to prevent the excessive and irresponsible dumping of active pharmaceutical ingredients (APIs) and finished dose drugs into the environment during the manufacture of antimicrobials.

Evidently, the loss of human life appears not to be a sufficient motivator to introduce legislation that

could result in incurred costs for the pharmaceutical industry.

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A recent AMR event in the European Parliament addressed the fact that as well as entering the environment from excreted human and animal waste, huge amounts of pharmaceutical effluent are released during drug manufacturing.

Most of the world's antibiotic drugs are manufactured in China and India, where manufacturing costs are substantially lower than in Europe. While 80-90 per cent of the antibiotic APIs are produced in China, India leads the production of 'finished dose' antibiotic products using APIs predominantly imported from China.

These APIs and finished dose drugs are then sold in bulk to European pharmaceutical companies, cutting their drug production costs. Unfortunately, there is mounting evidence that some drug manufacturers do not adequately treat the waste products, resulting in the release of pharmaceutical waste into the local environment.

The dissemination of APIs and finished dose antibiotics into the environment can pollute soils, crops and water sources, encouraging the development of drug resistance among the bacteria present.

Thus, the pharmaceutical companies who should be working to cure diseases are in fact contributing to the spread of multidrug-resistant infections which are predicted to kill 10 million people per year by 2050.

To highlight the severity of the problem, tests on effluent from a treatment plant in Hyderabad receiving wastewater from around 90 manufacturing plants showed that the concentration of the commonly used antibiotic Ciprofloxacin was far higher than the concentration of the antibiotic that would routinely be found in the blood of a patient taking the drug.

> "the European Commission has failed to support its own DG Environment to push through swift and enforceable action to prevent the excessive and irresponsible dumping of active pharmaceutical ingredients (APIs) and finished dose drugs into the environment during the manufacture of antimicrobials"

The estimated total release of Ciprofloxacin for one day was sufficient to treat 44,000 people. These excessive concentrations of antibiotics provide a catalyst for the emergence of antibiotic resistance.

Alarmingly, over 86 per cent of bacterial strains in samples from an Indian waste water treatment plant were resistant to 20 or more antibiotics.

This has devastating consequences for the health of the people living near manufacturing sites who are exposed to the polluted water. In India, more than 58,000 new-borns died in 2013 as a result of drug-resistant infections.

The link between pharmaceutical pollution of the environment and AMR has been cemented by a recent study which demonstrated that exposure to an environmental source of antimicrobial drugs appears to be placing poor pregnant women in Hyderabad at a higher risk of community-acquired AMR than their wealthier peers.

For years, there have been calls for the introduction of effective legislation on this issue including the incorporation of environmental criteria to Good Manufacturing Practices (GMP).

In the final report of the Review on AMR, the UK Government recommended the establishment of targets for maximum levels of antimicrobial API discharge associated with the manufacture of pharmaceutical products and urged pharmaceutical companies to improve monitoring of API emissions from manufacturing facilities along with third party suppliers.

Article 8c of Directive 2008/105/EC (as amended by Directive 2013/39/EU) obliged the European Commission to develop a strategic approach to water pollution from pharmaceutical substances by September 2015.

> "The report of the European Parliament on the European One Health Action Plan against AMR, which will be voted on in the plenary session next week, has extensively highlighted this important issue"

However, despite numerous calls by the water industry, major investors and European environmental and public health NGOs urging the Commission to take immediate action, the strategic approach has been significantly delayed.

Even Environment Ministers – arguably the 'boss' of the European Commission – from ten countries have expressed their concern, co-signing a letter demanding the publication of the strategic approach within the term of the current Commission. This failure of the Commission to act is ultimately endangering the lives of global citizens.

Not only has the strategic approach been severely delayed, specific legislative proposals to tackle pharmaceutical pollution have been removed, as exposed by The Guardian newspaper.

Leaked documents have revealed that plans to include environmental criteria in Good Manufacturing Practices (GMP) have been discarded. This highly sought after legislation would have allowed EU inspectors to visit factories in Asia, sanctioning them if evidence of pharmaceutical pollution was found.

An additional dropped proposal would have ensured that pharmaceutical firms collect, monitor and share data on the discharge of their microbials into effluent.

As highlighted in the Access to Medicine Foundation's Antimicrobial Resistance Benchmark 2018, there is a shocking lack of transparency among pharmaceutical companies. Of 18 companies evaluated, GSK was the only company which set limits for third-party suppliers and waste-treatment

plants whilst none disclosed their actual discharge levels.

In addition, only one company disclosed the identity of all third-party manufacturers. Without transparency, there is no pressure for pharmaceutical companies to ensure third-party suppliers are properly disposing of antibiotic waste.

The report of the European Parliament on the European One Health Action Plan against AMR, which will be voted on in the plenary session next week, has extensively highlighted this important issue.

The report specifically states that the Parliament “Deplores the fact, in this context, that the Commission did not propose a strategic approach to the pollution of water with pharmaceuticals sooner [and] urges the Commission and the Member States, therefore, to draw up an EU strategy for tackling drug residues in water and the environment without delay”.

Ultimately, the rapid implementation of effective EU legislation is needed to ensure that thousands of people living in drug-producing countries, namely India and China, stop paying the price for the supply of cheap antibiotics to Europe.

About the author

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