International Journal of Scientific Research in Science and Technology
Print ISSN: 2395-6011 | Online ISSN: 2395-602X (www.ijsrst.com)
doi : https://doi.org/10.32628/IJSRST

A Review on Ecopharmacovigilance and their Major Impact on Bio-Diversity

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Article Info
Volume 9, Issue 3
Page Number : 687-691

Publication Issue
May-June-2022

Article History
Accepted : 10 June 2022
Published : 25 June 2022

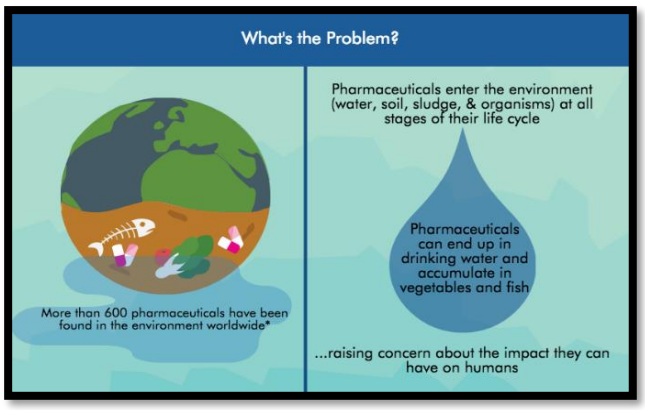
ABSTRACT

Ecopharmacovigilance (EPV) included science and activities associated with the detection, evaluation, understanding, and prevention of adverse effects of pharmaceuticals in the environment. These drugs enter the environment in a variety of ways, creating negative impacts. Vultures dying after eating the carcasses of animals treated with Diclofenac sodium, Ethinyl oestradiol negatively affecting fish through "feminization" of males, Ivermectin negatively affecting dung beetle growth, Fluoxetine causing behavioural changes in shrimps, and bacterial resistance are just a few examples of drugs that have harmful effects on the environment. Some corrective methods that can be expected to reduce the number of pharmaceuticals entering the environment include lowering pharmaceutical waste, enhancing the efficiency of sewage treatment plants, green pharmacy, and developing better medication disposal systems. Regulatory agencies have tried a variety of approaches to mitigate the environmental impact of pharmaceuticals, including Environmental Risk Assessment (ERA) of drugs, Resource Conservation and Recovery Act (RCRA), and Risk Mitigation Measures. Drug effects must be monitored not only for medical reasons, but also to protect the environment.

Keywords - Ecopharmacovigilance, pharmaceuticals, environment, green pharmacy.

I. INTRODUCTION

Pharmaceutical compounds, as well as heavy metals, insecticides, and emissions from gasoline engines, contaminate the environment. Vulture population decreases in the Indian subcontinent have alarmed environmental scientists and campaigners. At this point, the focus has shifted to the influence of pharmaceuticals on the environment, giving rise to the concept of Ecopharmacovigilance.



Pharmaceutical contamination is now a severe hazard to the environment all around the world. In a study conducted in Spain, 19 of the 27 human medications evaluated were discovered in the aquatic environment. In flow proportional 24 h composite samples of wastewater effluent collected from the Norwegian cities of Oslo and Troms, metabolites of carbamazepine (carbamazepine epoxide), diclofenac (4'- and 5-hydroxy diclofenac), and atorvastatin (o- and p-hydroxy atorvastatin) were detected at higher concentrations than the parent pharmaceuticals. Thus, the science of Ecopharmacovigilance can be discussed under following heads:

II. PHARMACEUTICALS IN THE ENVIRONMENT

Drug use in both the human and veterinary population is escalating day by day. According to one estimate100,000 tons of antimicrobials are consumed every year. More than 30 billion doses of non-steroidal anti-inflammatory drugs (NSAIDs) are consumed annually in the United States only. The potential routes of environmental entry of pharmaceuticals have been extensively reviewed and these include:

- Excretion of pharmaceutical ingredients from patients
- Release from the skin
- Leftover medicines
- Manufacturing units and hospitals
- Discharges from drug formulations
- Animal carcass

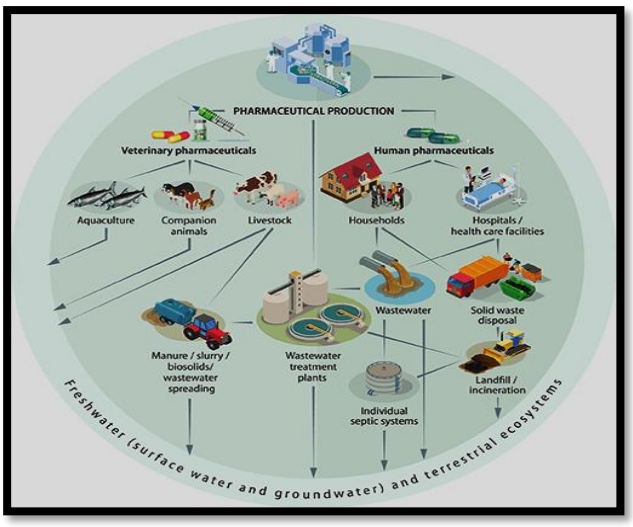


Fig 1 – Routes of Pharmaceutical Exposure to the Environment

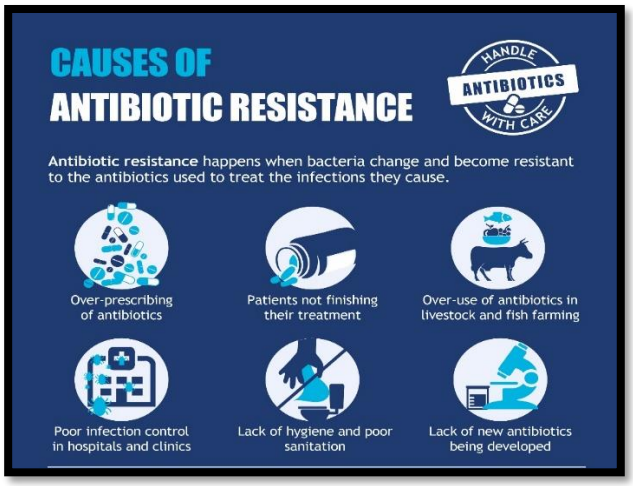
Consequences of Environmental Pollution by Pharmaceuticals

Medicines play a significant role in the treatment and prevention of disease in both humans and animals. However, due to the nature of medicines, they may have unforeseen consequences for animals and microbes in the environment.

Table 1 - Table showing the effect of pharmaceuticals on wild life

Drug	Animal	Impact
Diclofenac	Gyps Vulture	Abdominal gout and acute kidney failure leading to death
	Fish	Histological changes in the liver, kidney and gills of fish
Oral contraceptive	Frog	Sterility
Ivermectin	Dung Beetle	Death
Sex hormones	Male fish	Feminization
Fluoxetine	Fish	Adversely affect reproduction, growth and behaviour
	Shrimps	Behavioural changes leading to death

Antibiotic resistance



III. APPROACHES TO REDUCE NUMBER OF PHARMACEUTICALS RELEASED TO THE ENVIRONMENT

Some remedial measures can be projected to reduce the number of drugs entering the environment –

- **To reduce generation of pharmaceutical waste –**

Rather than dealing with pharmaceutical waste after it has been generated, the primary aim should be to limit the amount of pharmaceutical waste generated. Reducing pharmaceutical waste not only examines the underlying source of the problem, but it also lowers overall health-care costs.

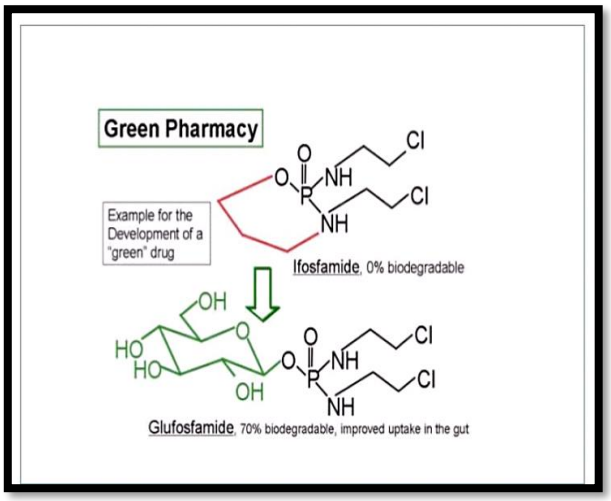
- **To increase efficiency of sewage treatment plants**

In most cases, sewage treatment plants are not prepared to remove medications on a regular basis. As a result, steps should be taken to improve the efficiency of these sewage treatment plants, allowing pharmaceuticals to be removed from sewage before it reaches local waterways.

- **Use of Green pharmacy -**

The design of medications and procedures that decrease or eliminate the usage and generation of hazardous substances is known as green pharmacy.

For example –



- **Developing better drug disposal programs –**

Fig - Household disposal drug

- **WHAT DOES INDUSTRY NEED TO DO TO REDUCE ECOPHARMACOVIGILANCE ?**

➢ **Minimize Environmental exposure –**

✓ Ensure discharges of pharmaceuticals from manufacturing are controlled.

✓ Optimise drug use by patients

✓ Actively promote and facilitate the safe disposal of life expired & unused pharmaceuticals.

➢ **Improve Understanding of Environmental Impact -**

✓ Publish ERAs for all existing pharmaceuticals.

✓ Establish active ecopharmacovigilance programmes.

- ✓ Continue to support research into the ecotoxicological effects of chronic exposure to pharmaceuticals.

IV. ECOPHARMACOVIGILANCE AND DRUG REGULATIONS

Environmental Risk Assesment ERA of drugs

- When new drug is purpose for market, FDA reguires the manufacturer to conduct a risk assesment that estimates the concentration that will be found in the environment.
- If the risk assesment concludes that the concentration will be less than one part per billon,the drug is assumed to pose acceptable risks

Resource conservation and Recovery Act (RCRA)

- The RCRA was passed in 1976 as an amendment to the solid waste disposal act. Amendments were added to expand the program in 1984. The program set three goal.
- To protect human health and the environment.
- To reduce waste and conserve energy and natural resources.
- To reduce or eliminate the generation of hazardous waste as enpeditiously as possible.

Risk Mitigation Measurement (RMM)

- If the ERA of a veterinary medicinal product (VMP) indicates an unacceptable risk to the environment benefit balance is negative i.e., the therapeutic benefit is overweighted by risk to the environment, safety or efficasy, the authorizatition can be refused.
- RMMs can be applied to improve the prevention of exposure and the protection of the environment.

V. CONCLUSION

Drug use has become an unavoidable part of our lives but it is not imperative to compromise with the balance of ecosystem on any grounds. Biopharmaceuticals may be an alternative but we still lack scientific evidence to accept them as a complete substitute of drugs in practice. If we don't begin to address the environmental damage we are causing, it will be at the far greater cost of accelerated species extinction and disruption of the food chain. The research community, EPA, FDA and pharmaceutical manufacturers should work together to design educational programs to better inform investigators, healthcare providers and patients about the potential environmental impacts of pharmaceutical use and appropriate disposal methods.

VI. ACKNOWLEDGEMENT

We excess my thanks and gratitude to Trustee of Samarth Rural Educational Institute's and Samarth Institute of Pharmacy, Belhe with their valuable guidance and support.

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Cite this article as :

Miss. Rakshe Payal, Mr. Tambe Abhijit, Miss. Kumbhar Jagruti, Miss. Uchale Pratiksha, Prof. Datkhile Sachin, "A Review on Ecopharmacovigilance and their Major Impact on Bio-Diversity", International Journal of Scientific Research in Science and Technology (IJSRST), Online ISSN : 2395-602X, Print ISSN : 2395-6011, Volume 9 Issue 3, pp. 687-691, May-June 2022. Available at doi : https://doi.org/10.32628/IJSRST2293122
Journal URL : https://ijsrst.com/IJSRST2293122