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The Significance of Ecopharmacovigilance in the Current Environmental Situations

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ABSTRACT

Drug abuse, personal health care use, and gross domestic product abuse are all on the rise among humans and animals. These trends create disposal and waste issues, which have an impact on the environment. The majority of active principles are actually intricately synthesised organic molecules that interact with human or animal bodies through specific biochemical processes. These reactions are never 100% efficient and occasionally result in residues that are more toxic than the initial compounds. It is simple to state that no drug can be regarded as healthy, making its use a significant source of pollution, just by reading the warning sheet that comes with any drug. Many researchers were able to approach this relatively new environmental issue from one decade various angles thanks to the widespread awareness of it. The sources of these substances in the environment, their effects on human health as well as on flora and fauna species, their recalcitrance and potential methods of degradation, and analytical techniques that can identify them and their metabolites even at low concentrations and in complex matrices are all being considered by current studies. As a pharmacist, I must say that pharmacy is profession which benefits to the world. But certain area in pharmacy are consistently points the pharmacist as towards negative aspects. Hence it's a pharmacist's duty to focus on wrong practices to make a profession as boon for world.

INTRODUCTION

The term 'Environmental pharmacology' was coined by Halling Sorensen in the year 1998.

Environmental pharmacology is defined as the effect of pharmaceuticals and house care products on the environment and the ecosystem. Drug abuse, personal health care, and gross domestic product consumption are all on the rise among humans and animals. These trends create disposal and waste issues, which have an impact on the environment. If they are not properly disposed of, unused or expired medications could endanger both public safety and the environment. This is because many medications have dual lives: one in the body of an animal or human and another in the environment. Prescription and over-the-counter drugs are among the unsafe products.[1]

Sources of Pharmaceuticals' Entry into the Environment

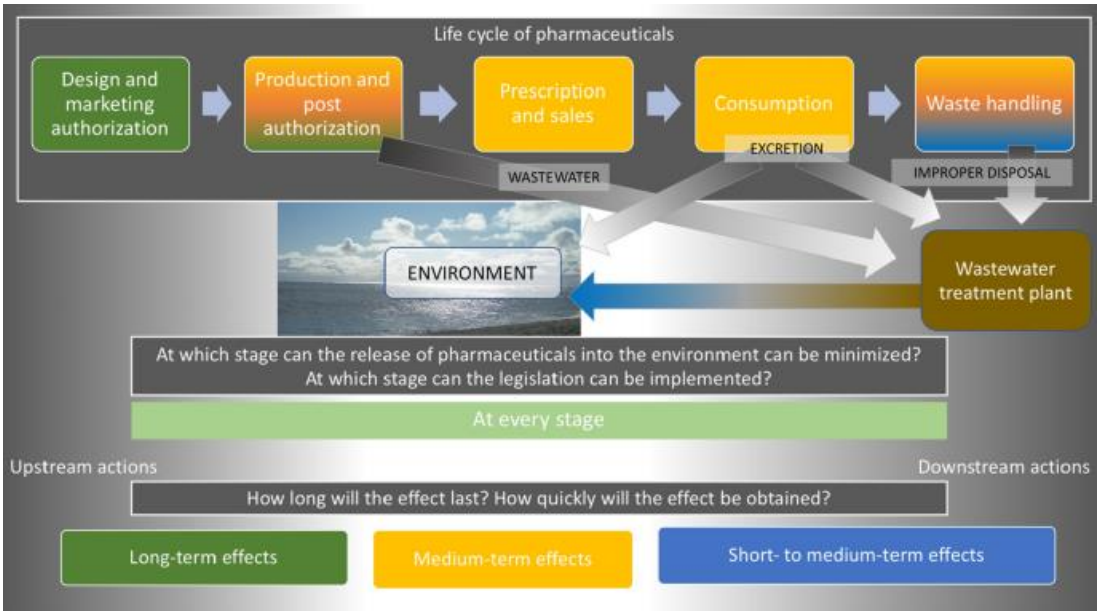
Worldwide annual pharmaceutical product consumption exceeds 100,000 tonnes, with 24% of that occurring in Europe. Biotransformed pharmaceutical products may persist in the environment and may actively accumulate in the food chain, Long-term presence of antidepressants and other pharmaceuticals have been traced in rivers and lakes, Excreted or discarded pharmaceutical product enters the urban wastewaters and finally goes into wastewater treatment plants.[2] Active pharmaceutical ingredients (APIs) and other chemical components are released into the environment during their production, use, and disposal. With an estimated annual death toll from drug-resistant illnesses of approximately 58,000 newborns,[3] India is one of the nation's most severely impacted by antimicrobial resistance.[4]

Drug use in both the human and veterinary population is escalating day by day. According to one estimate 100,000 tons of antimicrobials are consumed every year.[5]

More than 30 billion doses of non-steroidal anti-inflammatory drugs (NSAIDs) are consumed annually in the United States only [6] The Handbook of Environmental Chemistry has provided sound and solid knowledge about environmental topics from a chemical perspective. Presenting a wide spectrum of viewpoints and approaches, the series now covers topics such as local and global changes of natural environment and climate.[7]

Unused medications should be returned to pharmacists so that they can send them to businesses where they can be recycled and used again. According to a study by the Indian

Institute of Technology, the Musi River has 1000 times more antibiotic concentrations than rivers in wealthy nations. Villagers claim that the manufacturing sector degrades their access to land, water, and food, but medicine corporations reject any responsibility for environmental degradation, claiming there is no proof.[8]



Environmental Effects of Pharmaceutical Pollution

The increasing human and animal use and abuse of drugs as well as of personal health care and gross domestic products, involve disposal and waste problems and, as a consequence, affect the environmental condition. Environmental Pharmacology involves study of:-

1. Gene-environment interaction.

2. Drug-environment interaction.

3. Toxin-environment interaction

Pharmacoenvironmentology Eco pharmacology it seeks to deal with the environmental impact of drugs given to humans and animals at therapeutic doses. It is described as entry of chemicals or drugs into the environment through any route and at any concentration disturbing the balance of ecosystem. It deals specifically with pharmacological agents and their impact on the environment, after elimination from humans and animals as post-therapy. It is a broad term that includes studies of “Pharmaceuticals and Personal Care Products (PPCPs)" irrespective of doses and route of entry into environment. It may be a component of

Pharmacovigilance if extended to environment which can monitor adverse effects of drugs on environment at therapeutic doses. Eco pharmacology should be a part of the regulatory requirement prior to the launch of any new drug.

SOURCE OF PHARMACEUTICALS: The potential routes of entry of pharmaceutical and house hold care products in the environment include:-

1. Patients' and animals' excretion either as a parent compound or metabolites.

2. Direct release from manufacturing, hospitals or disposed via toilets and sinks.

3. Terrestrial depositions via sludge application to land, leaching from solid waste landfills.

4. Drugs destined for plant health like insecticides and pesticides.

5. Overflow of agricultural runoff may contain herbicides, pesticides and fertilizers.

6. Herbal preparations like aristolochic acid commonly found in Aristolochiacea family of plants used in Chinese herbal medicine.

7. Non pharmaceutical industrial sources, for example plastic products-Bisphenol A, household products like phthalates. The adverse effect of medicinal wastes on environment is yet to be understood in detail and addressed seriously in India, since India stands as one of the country with highest pharmaceutical activity. In this study, an assessment is done on India's contribution towards ecopharmacovigilance, the impact of pharmaceuticals on the environment and the seriousness of this issue which inquires for a need to implement ecopharmacovigilance in Indian government policy.[8]

Polluted river Thames Effect on aquatic organisms

Table showing the effect of pharmaceuticals on wild life

Drug	**Animal**	**Impact**
Diclofenac	Gyps vultures	Abdominal gout and acute kidney failure leading to death.[9]
	Fish	Histological changes in the liver, kidney, and gills of fish.[10]
Oral contraceptives	Frogs	Sterility[11]
Ivermectin	Dung Beetle	Death[12]
Sex hormones	Male fish	Feminization[13]

Need for EPV in India

Though it is impossible to eliminate pharmaceutical entry into environment through human and animal excretion, it is possible to reduce the entry through hospital wastes, improper disposal of unused drugs and wastes emerging from manufacturing industries.[14] Considering the established facts of detrimental effects caused by pharmaceuticals entering the environment, there is a need for setting up of a strong law concerning ecopharmacovigilance.[15] In recent years, an approach termed eco-directed sustainable prescribing (EDSP), which was proposed to prevent the adverse effects of APIs in the environment resulting from medical prescriptions, has been well-accepted as an indispensable part during EPV implementation. Ecopharmacovigilance, as a kind of pharmacovigilance for the environmental, aims to monitor the adverse effects of pharmaceuticals both on the environment and on humans through indirect non-therapeutic exposure. Conclusion: India is struggling to balance economic development and environmental protection. EPV provides useful reference for the disposal of environmental issues associated with pharmaceuticals in the environment in a timely way. Compared to the west, EPV in india is in infancy. We have to build some perfect laws and regulation system on EPV, defining the evaluation index for EPV, continuing the clinical rational medication, and the pharmaceutical takeback programs popularizing the concept of EPV and strengthening the policy-guided and scientific researches of EPV in pharmaceutical firms and academia.

Medical Expert Systems have reached good performance, as "MYCIN, for diagnosing of bacterial infections"; "deDombal`s Leeds Abdominal Pain System"; "Help System, developed at LDS Hospital in Salt Lake City", and we believe this software system stable and quite complex to support all the active pharmaceutical ingredients existing, produced or delivered in Europe.9 EU regulations in the shape of the Good Manufacturing Practice framework (GMP) require that medicinal products are of consistent high quality, are appropriate for their intended use, and meet the requirements of the market authorization or clinical trial authorization (EMA). These requirements focus on drug safety, but do not oblige companies to put in place environmental safeguards when producing their drugs, despite the alarming and well-known risks.

In the report, Swedwatch and Swedish Society for Nature Conservation call on pharmaceutical companies and authorities in importing countries to introduce and enforce strict environmental standards in drug manufacturing. They also call on authorities in Sweden

and the EU to enable the public release of supply chain information and environmental risk assessments for all pharmaceutical products available on their markets.

CONCLUSION:-

Ecopharmacovigilance is defined by the World Health Organization (WHO) as the science and activities concerned with the detection, assessment, understanding, and prevention of adverse events or other related problems caused by pharmaceuticals in the environment that affect people and other animal species. This review is an attempt to compile information on Ecopharmacovilance, with an emphasis on the Indian perspective. Necessity of Ecopharmacovigilance is absolute in India after considering the immense pharmaceutical activity. There is a need for individual and collaborative research between industry, academia and government acting in a proactive manner to improve the scientific understanding of EPV.[16] Research is needed to improve scientific understanding of pharmaceuticals in the environment and Environmental Risk Assessment. A government based individual program or as a part of existing programs such as Pharmacovigilance Program of India [PvPI] is essential to identify, solve and avoid the mishaps occurring in the environment due to the entry of pharmaceuticals.[17,18]

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