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REVIEW ARTICLE

# Drug disposal and environmental concern

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**ABSTRACT**

Drugs have become an integral part of our lives. It is a boon for the humanity for prevention, diagnosis, treatment and cure of disease. Besides beneficial effects drugs do have some adverse environmental effects. The disposal methods create a lot of dilemma in the minds of drug users and caregivers. This has given birth to the descipline of Ecopharmacovigilance. There are various countries, especially European and American with regulatory requirements which governs ERA of pharmaceuticals. Most drugs can be thrown in the household trash, but consumers should take certain precautious before tossing them out according to the Food and drug administration (FDA). A few drugs should be flushed down the toilet, besides, take back programs at the level of community offer safe disposable alternative. Despite the safety reason for flushing drugs, some people are questioning the practice because of trace levels of drugs and residues are found in surface water, such as river , lakes and in some community, drinking water supplies. Exposure of human beings and animals to drugs through the environment affect them directly or indirectly. Measures like safe disposable methods, education about judicious and rational use of drugs and development of biodegradable products may go a long way in achieving or minimising environmental pollution by drug.

**Key works-** Ecopharmacovigilance, drug disposal ERA, FDA

## 1. INTRODUCTION:

Drugs have become an integral part of our lives. It is a boon for the humanity for prevention, diagnosis, treatment and cure of disease. Besides beneficial effects drugs do have some adverse environmental effects[1]. This has drawn attention to save our environment from undesirable effects of these very useful chemicals. A measure, like safe disposable method is a big question posed by the society and is a big responsibility of pharmaceutical companies, regulatory authorities and medical personals .The disposal methods creates a lot of dilemma in the minds of drug users and caregivers. This has given birth to the descipline of Ecopharmacovigilance which can be defined as science and activities concerning detection, assessment, understanding and prevention of adverse effects or other problems related to the presence of pharmaceuticals in the environment which affect human and other animal species. In recent years great concern has been expressed over the potential impact of pharmaceuticals in the environment. Human pharmaceuticals from various therapeutic classes have increasingly being detected in the environment, typically at ng/L to as low as ug/L in Surface water [2-17]. This has led to the emergence of Ecopharmacovigilance (EPV) which was first coined by Velo [18]. There are a number of other analogous terms like ecopharmacology, pharmacovigilance, pharmacoenvironmentology.

## 2. What is Ecopharmacovigilance:

This science is still in the inceptional stage and hence it is very unclear what exactly it means. EPV aims to monitor the adverse effects of pharmaceuticals on the humans through nontherapeutic environmental exposure. Some background is necessary about the Pharmaceuticals in the environment and Environmental risk assessment of pharmaceuticals[19]. Environmental risk Assessment (ERA) is now a regulatory requirement prior to launch of any new drug.

### 2.1 Pharmaceuticals in Environment (PIE) - Sources of Entry:

The potential routes of environmental entry are

(i) Patient excretion of the drugs or its metabolities via the Sewage System.

(ii) Direct release from waste water system from manufacturing units.



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(iii) Hospital or self disposal of unused, unwanted, expired drugs via trash or flushing.
(iv) Terrestrial deposition, for examples via sluge application to land, leaching from Solid waste landfills or irrigation with treated or untreated waste water [4,13,16,20,21]

Pharmaceuticals enter the environment, usually from excretion of drugs after human and veterinary therapeutic use , also by the effluent discharges from the manufacturing units and disposal of unused drugs. Disposal of unused drugs can be managed effectively by providing guidance to patients about take back schemes and disposal practices[22]. Pharmaceutical residues in the environment as a result of human use is an unavoidable consequence of patient drug use and it is much more difficult to prevent. It can be tackled by effective sewage treatment which may prevent significant environmental contamination. But still this is not a zero error solution and some residues do gain entry in the environment. So the doubt remains whether such residues present any significant risk and to what extent. This pertinent question is addressed for new drugs by understanding an environmental risk assessment as apart of regulatory approval to market a new drug.

**2.2 ERA of pharmaceuticals:**

There are various countries, especially European and American with regulatory requirements which governs ERA of pharmaceuticals. It assesses the environmental fate and effects produced by these pharmaceuticals. Environmental Risk Assessment (ERA) has become mandatory before seeking marketing[1] authorization of the drugs in European union (EU). Countries like United kingdom have witnessed the impact of stringent regulation. The American Senate has also passed a legislation to monitor the drugs in environment. But, India, with several folds more environmental contamination as compared to developed countries is still striving to safeguard the environment. So it's very important for scientific society and regulatory authorities to work together and address this very relevant and vital issue. In recent years concerns have been expressed over the potential impact of pharmaceuticals on the environment. It is assessed by risk quotient which is the ratio of the predicted environmental concentration (PEC) to the predicted no- effect concentration (PNEC) [PEC:PNEC][19]. The PEC provides an estimate of the maximum concentration anticipated to be detected in the environment and PENC is derived from ecotoxicological tests, normally carried out in algae, daphnids and fish. If PEC :PNEC is < 1 no further information is required but if it is > 1 then additional tests are required and appropriate risk management is needed. This ERA is mandatory in EU before a new drug approval. There is no such regulation in our country.

**3. How to dispose expired drugs or medications:**

Most drugs can be thrown in the household trash, but consumers should take certain precautious before tossing them out according to the Food and drug administration (FDA). A few drugs should be flushed down the toilet, besides, take back programs at the level of community offer safe disposable alternative.

**3.1 FDA Guidelines for drug disposal are:**

Follow specific disposal instructions on the drug label or patient information brochure that accompanies the medication. Do not flush prescription drugs down the toilet unless this information specially instructs to do so[23].

Take advantage of community drug take back programs that allow the public to bring unused drugs to a central location for proper disposal. This take back programs for disposal are a good way to remove expired, unwanted or unused medicines from home and reduce the chances of accidental exposure.

If no instructions are given on the drug label and no take back program available, throw the drugs in the household trash.

Mix medicine (do not crush labels or capsules) with an unpalatable substance like tea, coffee ground, kitty littre etc., place it in a sealed container like plastic bags to prevent it leaking from breakages of garbage and then throw the bags container in your household trash. To make the instructions unreadable scratch the information on the prescription label[23].



 

**List of drugs:**

| List of Drugs | Route |
|---|---|
| Fentanyl | Tablets (sublingual) |
| Fentanyl Cireate | Oral transmucosal lozenge |
| Morphine Sulfate | Capsules (Extended release) |
| Buprenorphine Hydrochloride | Tablets (Sublingual) |
| Buprenorphine, Hydrochloride, Naloxone, Hydrochloride | Tablets (sublingual) |
| Buprenorphine | Transdermal patch system |
| Methylphenidate | Transdermal patch system |
| Meperidine Hydrochloride | Tablets |
| Meperidine Hydrochloride | Oral solution |
| Diazepam | Rectal gel |
| Hydromorphone Hydrochloride | Dilaudid, Tablets |
| Hydromorphone Hydrochloride | Oral liquid |
| Methadone Hydrochloride | Tablets |
| Fentanyl | Patch (extended release) |
| Morphine Sulfate; Naltrexone Hydrochloride | Capsules (extended release) |
| Hydromorphone Hydrochloride | Tablets (extended release) |
| Fentanyl Citrate | Tablets (buccal) |
| Morphine Sulfate | Capsules (extended release) |
| Methadone Hydrochloride | Oral solution |
| Methadone Hydrochloride | Tablets |
| Morphine Sulfate | Tablets (immediate release) |
| Morphine Sulfate | Oral Solution |
| Morphine Sulfate | Tablets (extended release) |
| Tapentadol | Tablets (extended release) |
| Fentanyl Citrate | Soluble film (buccal) |
| Oxymorphone Hydrochloride | Tablets (immediate release) |
| Oxymorphone Hydrochloride | Tablets (extended release) |
| Oxycodone Hydrochloride | Tablets (immediate release) |
| Oxycodone Hydrochloride | Capsules |
| Oxycodone Hydrochloride | Oral solution |
| Oxycodone Hydrochloride | Tablets (extended release) |
| Acetaminophen; Oxycodone Hydrochloride | Tablets |
| Aspirin; Oxycodone Hydrochloride | Tablets |
| Buprenorphine Hydrochloride; Naloxone Hydrochloride | Sublingual |
| Sodium Oxybate | Oral solution |
| Buprenorphine Hydrochloride; Naloxone Hydrochloride | Tablets (sublingual) |

FDA continually evaluates medicines for safety risks and will update the list as needed.

**Table 1: Medicines recommended for disposal by flushing:**

**List revised: November 2013**[23]

**3.2 Flushing of certain Medication:**

There are a number of medicines they may be specially harmful and even fatal with just one dose if used by a person who in not meant to take it. Therefore to prevent accidental ingestion by children, pets or anyone else, few medicine have specific disposal instructions, indicating they should be flushed down the sink or toilet as soon as they are no longer needed, especially when they cannot be disposed of through a medicine take back program. For example, fentanyl patches for pain, after their use or



 

unrequired patches, should immediately be flushed down the toilet to prevent use by others intentionally or accidently. Unwarrented fentanyl use can cause severe breathing problems and lead to death in babies, children, pets and even adults. Even after the patch is used a lot of drug remains in the patch.

**4. Environmental concern:**

Despite the safety reason for flushing drugs, some people are questioning the practice because of trace levels of drugs and residues are found in surface water, such as river, lakes and in some community, drinking water supplies. Exposure of human beings and animals to drugs through the environment affect them directly or indirectly. However, the main route by which the drug residues enter the water system, is by people taking medication and then naturally passing them through their bodies. Most drugs are not completely metabolized by the body and enter the environment after passing through waste water treatment plants.

For FDA approval , the manufacturer of the drug must submit an application package to the agency. FDA requires the assessment of the effect of the drug on the environment. For most drugs there have been no indication of environmental effects due to flushing. In addition according to the environmental protection agency, they have found no evidence of adverse drug health effects from pharmaceutical residue in the environment.

According to one estimate 100,000 tons of antimicrobial are consumed every year[24] More than 30 billion doses of nonsteroidal antiinflammatary drugs(NSAIDS) are consumed annually in the United States only[25]. Drugs are usually water soluble and therefore find their way easily into the sewage system. Industrial waste of the pharmaceutical industry also contributes towards the entry of drugs into the environment. Cocaine,oral contraceptive. carbamazepine and iodine contrast agents are some examples[26,27,28]. Cocaine has been detected in Po river in italy[29]. In Niagra river, antidepressant drugs,statins, carbamazepine and other antiepileptics were detected[30]

**5. Consequences of environmental pollution by pharmaceuticals:**

Due to environmental exposure human beings and animals are affected directly or indirectly especially pregnant woman, children, geriatric population and hepatic and renal disease patient. They have altered pharmacokinetics and are at greater risk to such exposure causing toxic effects [31].

Some examples of impact of drug through environment on human being and animals can be seen from the decline in number of vultures in Indian Subcontinent, secondary to their indirect exposure to diclofenac. A study from Pakistan revealed that due to the use of diclofenac in treatment of live stock and consumption of their dead bodies by vultures, led to the kidney failure of these vultures [32]. This has led to decline in number of vultures and consequently declared as endangered species.

Government of India has banned diclofenac for vetinary use [33].

Sterility of frogs due to traces of Oral contraceptive pills in water became the cause of decrease in number of frogs[34]. Presence of sex hormones in aquatic environment has also feminised the male fish. Whether it has a long term population level impact is still uncertain and is dependent on the severity of feminized males [35,36]. Another key challenge for EPV is that in the environment there are many different species that may be potentially exposed and it is simply not possible to monitor all of them.

Aserious environmental concern is with the metered dose inhalers used by people who have asthama or other breathing problems such as COPD. Traditionally many inhalers contained chloroflurocarbons (CFC's), as a propellant, that damages the protective ozone layer. The CFC inhalers are being phased out and replaced with more environmentally friendly ones. Inhalers and aerosol products may be thrown into household trash or recyclables or may be considered hazardous waste and require special handling. Some inhalers should not be punctured or thrown into fire or incinerator. To ensure safe disposal we should follow instructions on the label[23].

**CONCLUSION:**

Drugs have become an integral part of our lives. They are neither immortal nor faultless. So efforts should be made to save the planet earth from the undesirable effects of these very useful chemicals Measures like safe disposable methods, education about judicious and rational use of drugs and development of biodegradable products may go a long way in achieving or minimising environmental pollution by drug.[37].

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