
PHARMACOVIGILANCE IN SELF-MEDICATION: A FOCUS ON OVER-THE-COUNTER DRUGS

**Mr. Gundare Santosh Rajendra, Dr. Prasad Katare, Mr. Wasim Deshmukh, Mr. Pritam
Gadekar*

India.

Article Received: 29 February 2026 *Corresponding Author: Mr. Gundare Santosh Rajendra

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ABSTRACT

Self-medication with over-the-counter (OTC) drugs is a common practice worldwide due to the convenience, accessibility, and affordability of these medicines. OTC drugs are generally considered safe when used appropriately; however, misuse, overdose, drug interactions, and inappropriate self-diagnosis may lead to adverse drug reactions (ADRs) and serious health complications. Pharmacovigilance plays a crucial role in monitoring the safety of drugs after their marketing and identifying adverse effects associated with their use. With the increasing availability of OTC medicines, monitoring their safety through pharmacovigilance systems has become essential to protect public health. This review highlights the role of pharmacovigilance in self-medication practices, particularly focusing on OTC drugs, their benefits, risks, misuse patterns, and the importance of effective safety monitoring systems. The article also discusses challenges in pharmacovigilance reporting, the role of healthcare professionals, and future perspectives for improving OTC drug safety.

KEYWORDS: Pharmacovigilance, Self-medication, OTC drugs, Adverse drug reactions, Drug safety, Community pharmacy.

1. INTRODUCTION

Self-medication is defined as the selection and use of medicines by individuals to treat self-recognized illnesses or symptoms without consulting a healthcare professional. The practice has increased significantly worldwide due to factors such as easy availability of medicines, lack of healthcare access, time constraints, and rising healthcare costs. Over-the-counter

drugs play a major role in self-medication as they can be purchased without a physician's prescription.

OTC medicines are widely used to treat common health conditions such as fever, headache, cough, cold, pain, allergies, indigestion, and minor infections. These medications are generally considered safe when used according to instructions on the label or as recommended by healthcare professionals.

However, the widespread use of OTC medicines can also pose potential risks when used improperly. Incorrect dosing, prolonged use, drug interactions, and inappropriate self-diagnosis may lead to serious adverse drug reactions (ADRs). Pharmacovigilance is therefore essential to ensure the safe use of medicines, including OTC drugs. Pharmacovigilance refers to the science and activities related to detecting, assessing, understanding, and preventing adverse effects or any other drug-related problems.

The increasing trend of self-medication and OTC drug use has highlighted the need for stronger pharmacovigilance systems to monitor drug safety and reduce medication-related harm.

2. Pharmacovigilance: Concept and Importance

Pharmacovigilance is an essential component of public health systems that ensures the safe use of medicines after they are approved for marketing. It focuses on identifying adverse drug reactions, evaluating drug safety, and implementing regulatory actions when necessary.

The main objectives of pharmacovigilance include:

- Detection of adverse drug reactions
- Monitoring drug safety after marketing
- Identification of risk factors associated with drug use
- Prevention of medication errors
- Improvement of patient safety

Pharmacovigilance activities are conducted through various systems such as spontaneous reporting systems, electronic health records, clinical studies, and pharmacovigilance databases. These systems collect information about adverse drug reactions and help regulatory authorities identify safety signals related to medicines.

Global pharmacovigilance programs are coordinated by organizations such as the World Health Organization (WHO), which operates international drug monitoring systems to detect drug safety issues worldwide.

3. Over-the-Counter Drugs

Over-the-counter drugs are medications that can be sold directly to consumers without a prescription from a healthcare professional. These drugs are considered safe and effective for use by the general public when used according to labeled instructions.

Common categories of OTC drugs include:

- Analgesics (paracetamol, ibuprofen)
- Antihistamines
- Antacids
- Cough and cold medications
- Laxatives
- Topical antifungal agents

OTC drugs play an important role in healthcare systems by enabling individuals to manage minor illnesses without visiting healthcare facilities. This reduces the burden on healthcare providers and improves access to treatment.

However, despite their benefits, OTC drugs may cause adverse effects if used improperly. Incorrect dosing or prolonged use of OTC medications such as analgesics can lead to serious complications such as liver damage, gastrointestinal bleeding, or kidney injury.

4. Self-Medication Practices with OTC Drugs

Self-medication refers to the use of medicines without professional medical advice to treat minor illnesses or symptoms. OTC drugs are the most commonly used medicines in self-medication practices.

The prevalence of self-medication varies across countries but is generally higher in developing regions due to limited healthcare access and economic constraints.

Common reasons for self-medication include:

- Convenience and time saving
- Cost of medical consultation
- Previous experience with the same illness
- Easy availability of OTC medicines
- Influence of advertisements and media

Many individuals believe that OTC drugs are completely safe because they are available without prescription. However, this misconception may lead to inappropriate use and increased risk of adverse drug reactions.

5. Risks Associated with OTC Drug Self-Medication

Although OTC medicines are generally safe, several risks are associated with their misuse.

5.1 Adverse Drug Reactions

Adverse drug reactions are unwanted or harmful effects that occur after drug administration. OTC drugs such as analgesics, antihistamines, and cough suppressants can cause ADRs if used in excessive doses or for prolonged periods.

5.2 Drug Interactions

Self-medication with multiple OTC drugs may lead to drug interactions. For example, combining certain OTC analgesics with prescription medications may increase the risk of toxicity.

5.3 Misuse and Abuse

Studies have shown that OTC medicines may be misused or abused, particularly among adolescents and young adults. Certain drugs such as cough suppressants and sedative antihistamines have potential for misuse and dependence.

5.4 Incorrect Self-Diagnosis

Patients may misinterpret symptoms and use OTC medicines for conditions that require professional medical treatment.

5.5 Overdose

Overdose is another major concern with OTC medicines. For example, excessive use of paracetamol may cause severe liver damage.

6. Pharmacovigilance of OTC Drugs

Pharmacovigilance plays an essential role in ensuring the safe use of OTC medicines by monitoring adverse drug reactions and identifying potential safety signals.

Key pharmacovigilance methods include:

6.1 Spontaneous Reporting Systems

Spontaneous reporting systems allow healthcare professionals and patients to report adverse drug reactions. These reports are collected in national pharmacovigilance databases and analyzed for safety signals.

6.2 Post-Marketing Surveillance

Post-marketing surveillance studies monitor drug safety after approval and help identify rare or long-term adverse effects.

6.3 Pharmacoepidemiological Studies

These studies evaluate the patterns of drug use and associated adverse effects in large populations.

7. Role of Community Pharmacists

Community pharmacists play a vital role in ensuring the safe use of OTC medicines. They are often the first healthcare professionals consulted by patients seeking treatment for minor illnesses.

Pharmacists contribute to pharmacovigilance by:

- Providing counseling on safe drug use
- Identifying potential drug interactions
- Educating patients about correct dosing
- Reporting adverse drug reactions

However, pharmacists often face challenges such as patient pressure, lack of time, and limited awareness among consumers regarding medication safety.

8. Challenges in Pharmacovigilance of OTC Drugs

Despite the importance of pharmacovigilance, several challenges exist in monitoring OTC drug safety.

8.1 Underreporting of ADRs

Many adverse reactions associated with OTC medicines are not reported because patients may not recognize them or may not know how to report them.

8.2 Lack of Awareness

Public awareness regarding safe drug use and pharmacovigilance reporting is often limited.

8.3 Regulatory Challenges

In some countries, regulatory frameworks for OTC drugs are still developing, making it difficult to monitor drug safety effectively.

8.4 Limited Data

Most pharmacovigilance studies focus on prescription medicines rather than OTC drugs, resulting in limited safety data.

9. Strategies to Improve Pharmacovigilance of OTC Drugs

Several strategies can help improve pharmacovigilance for OTC medicines:

9.1 Patient Education

Educating patients about safe medication use, dosage, and potential side effects can reduce drug-related problems.

9.2 Strengthening Reporting Systems

Simplifying adverse drug reaction reporting systems can encourage more healthcare professionals and patients to report drug safety issues.

9.3 Digital Pharmacovigilance

Mobile applications and online reporting platforms can improve ADR monitoring and data collection.

9.4 Pharmacist Involvement

Community pharmacists should be actively involved in pharmacovigilance programs and patient education initiatives.

9.5 Regulatory Policies

Governments should strengthen regulatory frameworks for OTC drugs to ensure safe use.

10. Future Perspectives

The future of pharmacovigilance involves integrating advanced technologies such as artificial intelligence, electronic health records, and big data analytics to improve drug safety monitoring.

Digital pharmacovigilance systems can help identify safety signals faster and improve the efficiency of adverse event detection.

Public health programs should also focus on increasing awareness about responsible self-medication practices.

11. CONCLUSION

Self-medication with OTC drugs has become a common practice worldwide. Although these medicines provide convenient access to treatment for minor ailments, improper use may lead to adverse drug reactions and serious health complications. Pharmacovigilance plays a crucial role in ensuring the safety of OTC drugs by monitoring adverse reactions and identifying potential risks associated with their use.

Strengthening pharmacovigilance systems, improving patient education, and promoting responsible self-medication practices are essential for reducing drug-related harm. Healthcare professionals, regulatory authorities, and patients must work together to ensure the safe use of OTC medicines.

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