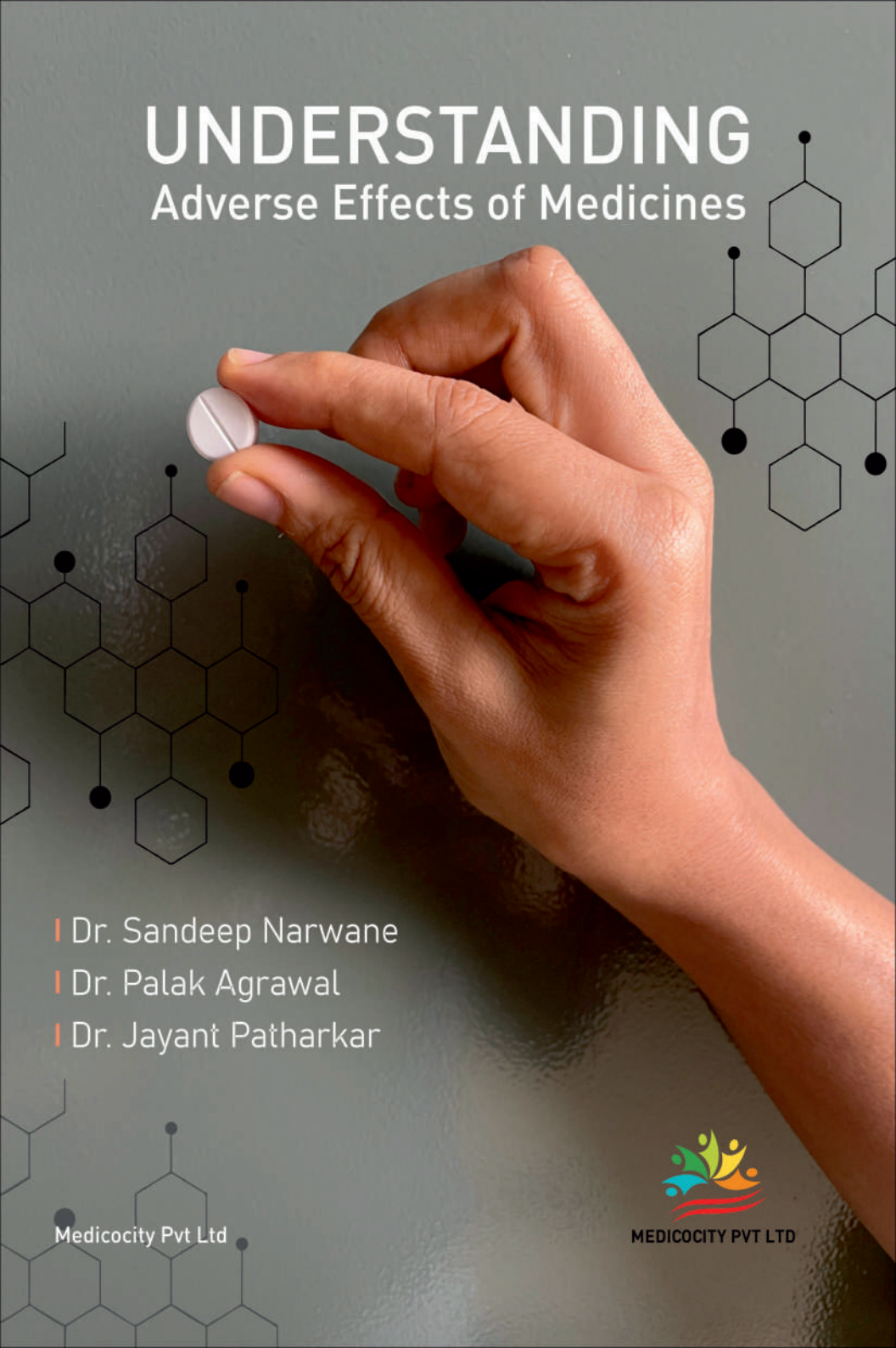
UNDERSTANDING
Adverse Effects of Medicines



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Understanding Adverse Effects of Medicines

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About the Author

Dr. Sandeep Narwane is serving as a Professor in the Department of Pharmacology, Dr. Balasaheb Vikhe Patil Rural Medical College, Pravara Institute of Medical Sciences (DU), Loni, Ahmednagar.

Dr. Sandeep Narwane is a distinguished pharmacologist with an extensive academic and professional background. After completing SSC at Khaki Baba Memorial English High School and HSC at Adarsh College, both in Hingoli, he pursued an MBBS degree from Government Medical College, Aurangabad (Sambhajinagar). He further specialized in Pharmacology & Therapeutics with an MD from the prestigious Seth GS Medical College, Mumbai.

With a passion for teaching, Dr. Narwane has become a respected faculty member, imparting knowledge in various fields such as pharmacology, research methodology, and clinical practice. Dr. Narwane teaches undergraduate students in MBBS, BDS, Nursing, and Physiotherapy programs, and also serves as a postgraduate teacher, mentoring future medical professionals.

Dr. Narwane has published over 30 peer-reviewed articles and contributed a chapter to the renowned "Textbook of Pharmacology" by Dr. Prasan R. Bhandari. In addition to academic teaching, Dr. Narwane has experience in pharmacovigilance and animal house management.

About the Author

Dr. Palak Agrawal is a distinguished expert in pharmacology with a robust background in medical education and research. She earned her MBBS degree from MIMER Medical College in Talegaon, Pune and subsequently completed her MD in Pharmacology from SBKS Medical Institute & Research Centre in Baroda.

Currently, Dr. Agrawal serves as a Professor in the Department of Pharmacology, Dr. Balasaheb Vikhe Patil Rural Medical College, Pravara Institute of Medical Sciences (DU), Loni, Ahmednagar.

With nine years of teaching experience, she has imparted her knowledge to a diverse range of students, including those in MBBS, dental, physiotherapy and nursing programs. Her commitment to education is further exemplified by her role as a postgraduate guide for MD and MSc students.

Dr. Agrawal is also actively involved in the Pharmacovigilance and ADR (adverse drug reactions) Monitoring centre at her institution, where she plays a key role in ensuring the safety and efficacy of medications. Her extensive research contributions, including numerous case reports and publications on adverse drug reactions in both national and international journals, underscore her expertise and dedication to advancing the field of pharmacology.

Her ongoing work to the field ensures that she remains at the forefront of developments in pharmacology, making her a valuable asset to the medical community.

About the Author

Dr. Jayant Patharkar currently serves as an Associate Professor in the Department of Pharmacology at Smt. B. K. Shah Medical Institute & Research Centre, Sumandeep Vidyapeeth Deemed to be University, Piparia, Vadodara, Gujarat. In addition to his academic responsibilities, Dr. Patharkar plays a pivotal role as the Deputy Coordinator of the Adverse Drug Reaction Monitoring Centre, a key unit under the Pharmacovigilance Programme of India, where he contributes significantly to enhancing drug safety and monitoring.

Dr. Patharkar's journey in medicine began with an MBBS degree from B.J. Medical College, Pune, followed by an MD in Pharmacology from Smt. B. K. Shah Medical Institute & Research Centre, Sumandeep Vidyapeeth. His career includes 14 years of dedicated service as Chief Medical Officer at the Smt. Uttara Devi Charitable Trust in Hyderabad, where his leadership and clinical expertise made a lasting impact on the community.

His recent accomplishment of completing the Yog Teachers Training Course (YTTC) from Yoganiketan, Sir Sayajirao Institute of Research in Yoga, Ayurveda, Naturopathy, Music & Allied Sciences, highlights his holistic approach to health and wellness, blending modern medicine with traditional practices.

Foreword

It gives me great pleasure to introduce this insightful and timely book, “Understanding Adverse Effects of Medicine”, authored by Dr. Sandeep Narwane and Dr. Palak Agrawal, both esteemed professors in the Department of Pharmacology at our institute. As the Dean, I am proud to witness the culmination of their years of dedication, research, and academic excellence in this comprehensive work.

In today’s rapidly advancing medical landscape, understanding adverse drug effects has become paramount to safeguarding patient health. The side effects of medications, though often underestimated, can have significant impacts on individuals and public health systems alike. This book serves as a crucial guide to demystifying the complexities surrounding drug safety, providing readers with a clear understanding of the mechanisms behind adverse drug reactions, and the importance of reporting such effects through pharmacovigilance practices.

Dr. Narwane and Dr. Agrawal have delved deeply into the pharmacological aspects of drug safety, explaining not only how adverse effects arise but also how they can be recognized and managed effectively. Their expertise shines through as they address the vital role of consumers and healthcare professionals in reporting and mitigating these effects.

Pharmacovigilance, the science and activities relating to the detection, assessment, understanding, and prevention of adverse drug effects, is covered with clarity and depth. The authors emphasize how this discipline has become an essential part of healthcare systems, ensuring safer medication practices worldwide. Through this book, healthcare practitioners, students, and consumers alike are given the tools to engage more actively and responsibly in safeguarding patient health.

As our institute continues to uphold its mission of advancing medical knowledge and improving patient care, I am confident that this book will become an invaluable resource for medical professionals, pharmacists, and patients alike. It will contribute to raising awareness of the critical importance of drug safety and adverse effect reporting, thereby fostering a more informed and vigilant healthcare community. I extend my congratulations to Dr. Narwane and Dr. Agrawal for their remarkable work and am confident that "Understanding Adverse Effects of Medicines" will serve as a significant contribution to the field of pharmacology.

Air Vice Marshal (Retd) Dr. Rajvir Bhalwar
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Foreword

It is with immense pride and admiration that I introduce “Understanding Adverse Effects of Medicines”, authored by my esteemed colleagues Dr. Sandeep Narwane and Dr. Palak Agrawal, both distinguished professors in the Department of Pharmacology. As the Head of the Department, I have had the privilege of working closely with both authors, and I can confidently say that this book represents a milestone in their commitment to advancing the field of pharmacology.

In recent years, the importance of understanding drug safety has become increasingly recognized within the medical community. Adverse drug effects are not only a concern for healthcare professionals but also for patients and consumers, who play a pivotal role in recognizing and reporting these effects. This book thoroughly addresses these concerns, offering a well-rounded approach to understanding, managing, and reporting adverse effects, making it an essential resource for both healthcare professionals and consumers alike.

Dr. Narwane and Dr. Agrawal have done a commendable job of simplifying complex pharmacological concepts, making them accessible to a wider audience. Their deep understanding of pharmacovigilance—the science of detecting, assessing, and preventing adverse effects of medications—is evident in every chapter. The book provides a comprehensive framework for recognizing the risks associated with medications and emphasizes the crucial role of reporting adverse effects through established pharmacovigilance systems.

This publication also highlights the indispensable contribution of consumers in reporting their experiences with medications. It sheds light on the proactive role that patients can play in enhancing drug safety by reporting side effects, thereby contributing to a safer healthcare environment.

As a department, we are deeply committed to the advancement of knowledge in pharmacology, and this book is a testament to that mission. It serves not only as an academic reference but also as a practical guide for everyday clinical practice, ensuring that drug safety remains a top priority in patient care.

I am confident that *Understanding Adverse Effects of Medicines* will be an invaluable asset to students, clinicians, pharmacists, and consumers, inspiring a more informed and responsible approach to medication safety.

I congratulate Dr. Narwane and Dr. Agrawal for their remarkable effort in producing this significant work, and I look forward to seeing the positive impact it will have on the field of pharmacology and healthcare at large.

Dr. Rahul Kunkulol,
Professor & Head,
Department of Pharmacology,
Dr. Balasaheb Vikhe Patil Rural Medical College, Loni.

Foreword

Many people remain unaware of the potential adverse effects of the medications they take. This lack of knowledge often leads to the misuse of drugs, the failure to recognize adverse drug reactions (ADRs), and delays in seeking medical intervention. For example, the overuse of antibiotics, stemming from ignorance of their potential side effects, has contributed significantly to the global rise of antibiotic resistance. Similarly, frequent use of non-prescription painkillers such as ibuprofen, aspirin, and acetaminophen (paracetamol) can lead to serious health problems, including peptic ulcers, hypertension, and chronic kidney disease. Many individuals self-treat pain with over-the-counter (OTC) analgesics without addressing the underlying cause, resulting in delayed diagnoses and treatment of potentially serious medical conditions.

Drugs may also behave differently in various populations or interact with other medications. For instance, taking multiple drugs containing the same active ingredients—such as combining cold medicine and painkillers that both contain acetaminophen—can result in accidental overdose. Moreover, not adhering to recommended dosages, with the belief that taking more pills will bring quicker relief, further increases the risk of harm.

ADRs can vary from insignificant common discomfort to life-threatening conditions. Monitoring these reactions is critical for minimizing risks and safeguarding patients. For example, although rare, anaphylaxis from penicillin is a potentially fatal ADR, underscoring the importance of pharmacovigilance. Pharmacovigilance allows for the collection of real-world data to

improve our understanding of how drugs work across diverse populations, and it plays a crucial role in recognizing personalized treatment approaches. For instance, genetic variations affecting drug metabolism, such as in the case of warfarin, can increase the risk of bleeding, necessitating customized dosing strategies.

The COVID-19 pandemic highlighted the importance of pharmacovigilance on a global scale. The rapid development and distribution of vaccines and treatments required close monitoring of ADRs to ensure their safety. Public ignorance regarding the need for such monitoring contributed to vaccine hesitancy, slowing efforts to control the pandemic. This ignorance of pharmacovigilance is a worldwide matter affecting both developed and developing nations. The World Health Organization (WHO) has emphasized the need for greater awareness of pharmacovigilance to ensure safer medication use, particularly in regions with limited healthcare infrastructure. In countries where unregulated or counterfeit drugs are more common, the risk of ADRs is higher, making public knowledge of drug safety even more critical.

The current book on understanding adverse effects of medicines, written by Dr Narwane and Dr Agrawal, experts in the field, thoroughly addresses key concepts such as ADRs, the necessity of drug safety monitoring, and the importance of accessible reporting systems that allow the public to be aware, take appropriate safety measures and report side effects. By promoting public engagement in pharmacovigilance, the book encourages individuals to play an active role in improving drug safety.

A significant gap in public awareness has led to increased morbidity and mortality from the inappropriate or excessive use of life-saving medications intended to improve quality of life. This book aims to bridge that gap by offering valuable insights and practical guidance,

ultimately contributing to better patient outcomes and greater safety in drug therapies.

Dr. Shubhangi R. Parkar,
Former Dean,
Seth GS Medical College & KEM Hospital, Parel, Mumbai,
Dean,
Vedantaa Institute of Medical Science, Palghar.

Preface

Our journey as part of the Pharmacovigilance Programme of India (PvPI) and the Department of Pharmacology has been a rewarding one, giving us the inspiration to write this book, "Understanding Adverse Effects of Medicines". The idea behind this book stems from our experiences in the field, where we witnessed firsthand the importance of drug safety and the need for increased awareness about the adverse effects of medications.

This book is written with the goal of helping everyone—patients, healthcare professionals, and the general public—understand the magnitude of the effects that medicines can have, and the precautions that must be taken to ensure safety. We've made every effort to use simple language and have further simplified the concepts through real-life examples and short stories, making the book accessible to all readers, regardless of their background in healthcare or pharmacology.

The book begins with an introduction to adverse effects of drugs, exploring the various types and classifications. From there, we delve into the vital field of pharmacovigilance, explaining how it functions and why it is essential for ensuring safe medication practices. Importantly, we also guide readers on how they themselves can report adverse effects of medicines through available channels.

We believe that education is key to preventing and managing adverse drug reactions, which is why this book is being distributed as a free eBook. By doing so, we hope to maximize its reach and impact, ensuring that this valuable information is available to as many people as possible.

It is with great pleasure that we publish this book on the occasion of Pharmacovigilance Week, celebrated each year from 17th to 23rd September. This week is a reminder of the critical role pharmacovigilance plays in protecting public health, and we hope this

book contributes to the ongoing efforts to promote drug safety in our society.

Dr. Sandeep Narwane
Dr. Palak Agrawal
Dr. Jayant Patharkar

Acknowledgement

We would like to express our deepest gratitude to all the individuals and institutions whose contributions and support made this book, "Understanding Adverse Effects of Medicines", possible.

First and foremost, our deepest thanks go to Pravara Institute of Medical Sciences, Loni and Sumandeep Vidyapeeth, Vadodara for their unwavering institutional support, without which this project would not have come to fruition.

We would also like to acknowledge the continuous encouragement provided by AVM (Retd) Dr. Rajvir Bhalwar, Dean, and Dr. Rahul Kunkulol, Professor and Head of the Department of Pharmacology, Dr. Balasaheb Vikhe Patil Rural Medical College, Loni, whose faith in this project has been a constant source of motivation.

We extend our sincere thanks to the Indian Pharmacopoeia Commission, Ministry of Health and Family Welfare (MOHFW), which runs the Pharmacovigilance Programme of India (PvPI). Their work has been instrumental in shaping this book, and we are particularly grateful for the use of the Adverse Drug Reaction (ADR) reporting form for consumers, as well as other valuable information provided through their website.

We are also deeply appreciative of the contribution made by the students of Dr. Balasaheb Vikhe Patil Rural Medical College— Ms. Netal Atul Nyati, Ms. Gauri Ravindra Laddhad, Mr. Arya Magesh Bakshi, Ms. Harshada Gautam Lodha, Mr. Tanmay Dileep Sardesai and Mr. Devesh Pavan Surekha—for their dedication in enacting the roles of characters in the photographs that accompany the stories in this book.

We are equally grateful to Mr. Parth Dhundiraj Deo, Mr. Pushkar Prashant Deshpande, Mr. Aadesh Patil, Mr. Gaurav Kate and Mr. Shreyash Rupnawar, the students of Dr. Balasaheb Vikhe Patil Rural

Medical College for their inspiration, particularly in encouraging us to write stories on the topics of medicine toxicity and oral contraceptive pills. Their curiosity and enthusiasm fuelled our efforts to make this book both informative and engaging.

Our heartfelt thanks go to Dr. Motilal Tayade, Professor and Head of the Department of Physiology, Dr. Balasaheb Vikhe Patil Rural Medical College, Loni for his invaluable technical assistance for the creation of this book.

A special note of appreciation goes to Mr. Minanath Rokade, for his constant moral support and for pushing us to see this project through to completion.

Lastly, and most importantly, we express our profound gratitude to our family members—whose unwavering emotional support, patience, and understanding allowed us to dedicate ourselves fully to the writing and completion of this book.

Finally, we thank **God** for providing us with the strength, guidance, and perseverance to bring this work to life.

If anyone who has been a part of this journey has inadvertently been left out, please know that your contributions are sincerely appreciated and have not gone unnoticed.

Dr. Sandeep Narwane
Dr. Palak Agrawal
Dr. Jayant Patharkar

Understanding Adverse Effects of Medicines

Dedicated to,
All Citizens, especially the patients and their relatives.

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A Lesson Remembered

Rajesh and Sushma anxiously walked into the hospital with their daughter, Ravina. The young girl had been running a fever and complaining of abdominal pain since the previous night. Her usually vibrant face was flushed with discomfort.

Worry etched on their faces, they approached the reception, and soon they were ushered into Dr. Sumeet's office.

Dr. Sumeet, a kind and experienced pediatrician, greeted them with a reassuring smile. After a thorough examination of Ravina, he prescribed medicine to address the fever and pain. The parents, relieved to have a course of action, took the prescription and left the hospital, hopeful that their daughter would feel better soon.

However, the next morning, their relief turned to alarm. Ravina had developed a rash all over her body. The once faint spots had now spread, causing her to itch uncontrollably. Concerned, Rajesh and Sushma rushed back to the hospital with Ravina in tow.

Dr. Sumeet listened intently as they described the new symptoms. After examining Ravina again, he explained, "This looks like an adverse reaction to the medicine I prescribed. It's important to stop that medicine immediately." He then prescribed a new medication to treat the rash and an alternative to manage the fever.

The doctor sat the worried parents down and spoke to them calmly, “Sometimes, these reactions can happen. It’s important that you remember this event. Whenever Ravina needs treatment in the future, always inform the doctor about this reaction. This way, we can avoid medicines that might cause her harm.”

Rajesh and Sushma nodded, absorbing the seriousness of the situation. Grateful for the care they had received, they left the hospital, determined to remember Dr. Sumeet’s advice. Six months passed, and life returned to its usual rhythm. Ravina was back to her playful self, filling the house with laughter and mischief.

But as the seasons changed, so did Ravina's health. One evening, she began coughing and soon developed a fever. Rajesh and Sushma decided to take her to the hospital the next morning.

As they sat in Dr. Rajat's office, Sushma's mind flashed back to the incident from six months ago. She quickly recounted the allergic reaction Ravina had experienced, ensuring that Dr. Rajat was fully informed.

Dr. Rajat listened carefully and nodded approvingly. "You've done the right thing by telling me this," he said with a smile. "It's very important for us to know about past reactions so we can choose the safest treatment."

He then prescribed medicines that would be effective without risking another allergic reaction. Rajesh and Sushma felt a wave of relief. They realized the importance of their vigilance and the difference it made in ensuring Ravina's safety.

As they left the hospital, Sushma held Ravina's hand a little tighter, feeling a sense of pride in having protected her daughter. Rajesh gave her a reassuring nod, knowing that they had learned a valuable lesson in caring for their child. The experience had taught them the importance of communication and attentiveness in healthcare, and they were determined never to forget it.

From that day on, whenever they visited a doctor, they made sure to mention Ravina's previous reaction, safeguarding her against any potential harm. It was a lesson learned through experience, one that would keep their daughter safe in the years to come.

Message from the story

Always inform healthcare providers about any past adverse reactions or allergies you/your family member has experienced. This crucial information helps doctors choose the safest and most effective treatments, preventing potential harm. Clear communication and vigilance are key to ensuring your health and safety during medical care.

Knowing Adverse effects of drugs

1. What are Medicines/Drugs?

Medicines, commonly referred to as drugs in medical fraternity, are substances prescribed by a physician to a person for treatment or prevention of disease.

In this book, the terms 'drugs', 'medications' and 'medicines' will be used interchangeably. Before we embark upon the ill effects of medicines, we must understand the purpose of taking medicines.

2. Why do we need Medicines?

Medicines are used for

i. Symptomatic relief for e.g. headache, joint pain.
ii. Treatment of an infection e.g. Typhoid, Pneumonia.
iii. Treatment of chronic disease which apparently has no cure e.g. Hypertension, Diabetes.
iv. Prophylaxis (prevention)of disease e.g. Tuberculosis, polio, tetanus, wound, dog bite.
v. Treatment of Cancer.

3. Who gives Medicines?

Treatment is prescribed by a qualified physician for the above purposes. Along with the name of medicine, the dosage form (syrup, tablet etc.), dose (amount), frequency (number of

times in a day), duration (for how many days), precautions (before meals, avoid driving after taking medications, drink more water etc.) are advised for optimum effect of medicines.

It is not necessary that doctor will prescribe medicines to each and every patient. Most of the times, advise (change in eating behaviour, exercise, proper posture, sleep hygiene) and counselling (making aware of the situation and bringing about change in thought process that has a positive effect in the long run) are all that is required. A medicine may be an assistant for instant relief of symptoms or curing of infection.

4. What are the shortcomings of Medicines?

There is an important message here. Medicines are made for well-being and easing of hard times during suffering from a disease condition, but have their own shortcomings. Medicines, if not taken as prescribed may have undesirable consequences. Taking medicines on your own may also lead to deleterious effects. Moreover, these effects may also be seen (less frequently that those taken on our own or instructions not properly followed) when the medicines are not taken as prescribed.

5. What are Adverse effects of Medicines?

The undesirable effects of medicine/drug seen as a consequence of its use are termed as Adverse effect of drug. Adverse effect may be seen in around 10 to 25% of people consuming medicines. This is not a small number. An adverse effect of a drug is a very broad term and includes very mild to severe, even fatal effects.

At times, it may be difficult to point at the drug administered for the untoward effect seen. The term 'adverse drug event' (ADE) encompasses adverse effects that may or may not have any relationship with the drug consumed. Therefore, ADE is the term used until the relationship between the drug consumed and effect seen is established. Hence, Adverse effect is a subset of ADE.

When the adverse effects occur at normal doses of a drug and requires modification in treatment, it is known as adverse drug reaction (ADR). Adverse effects that are known & mild or that which occur due to overdose/poisoning are not included under ADR.

Now one may think that if a drug has one or the other harmful effect, then why take drugs? Each time a drug is taken is equivalent to a risk taken. It is like the risk taken while crossing

a road. However, one must understand that the benefit and risk of a drug are always weighed when a drug is prescribed. For example, a drug taken for headache of migraine is justified even if it leads to abdominal discomfort, if the headache is decapitating and abdominal discomfort is more tolerable that the headache itself.

6. How do you classify adverse effects based on its severity?

Adverse effects can be graded as:

i. Mild or minor- the adverse effect does not require any active treatment.
ii. Moderate- requires modification in existing treatment or causes prolonged stay in hospital.
iii. Severe- potentially lethal or causes permanent damage or requires hospitalisation in intensive care.
iv. Lethal- it directly or indirectly leads to death.

7. What are the types of Adverse effects?

Let us dive into types of adverse effects and differences between them. Knowing about adverse effects consciously gives better control over its management. Adverse effects can

be categorized on the basis of time taken for the effect to occur after consumption of a medicine. Some adverse effects may be observed within minutes, while others may take days to present. They can also be categorized on the basis of severity, reason as well as presentation of adverse effect.

The most common used classification includes predictable and unpredictable adverse drug reactions.

8. What are predictable adverse drug reactions?

Most of the times, adverse effect of a medicine can be traced back to its known actions on the body. For example, a drug that lowers blood sugar level used in patients with diabetes, may cause fainting/dizziness if he/she has taken the medicine and skipped the meals. Normally, blood sugar levels increase after meals as sugar is absorbed from intestine. In this case, the medicine has lowered blood sugar level more than required due to skipping of meals. Low blood sugar levels cause dizziness/fainting. This type of adverse effect is known as predictable and includes side effects, toxic effects and effects due to withdrawal of drug. Predictable adverse effects occur commonly.

The severity of adverse effect is pronounced with increasing dose because of its relationship with action of drugs. In the

above example, the blood sugar lowering effect will be more severe with higher dose of medications for diabetes. Therefore, dizziness/fainting in the above can be treated by asking the patient to take any sweets like candy to increase the blood sugar level instantly.

Predictable adverse drug reactions are generally avoidable and reversible. In the above example, the adverse effect could have been avoided by taking meals after the medication.

Whenever such incidence occur, the first thing one needs to do is to report the adverse effect to the treating physician. The physician may either alter the dose of medication, stop the medication or advice changes in life style and dietary habits that are sustainable with the drug.

9. What are unpredictable adverse effects of a drug?

In contrast to predictable adverse effects, unpredictable adverse effects are not related to the known actions of drug. It has more to do with the individual than with the drug. Unique genetic or phenotypic attributes make some individuals susceptible to these adverse effects. These adverse effects include allergic and idiosyncratic reactions. No relation is seen between dose and severity of adverse effects. Exposure to even a very small dose can trigger the reaction. Fortunately,

these adverse effects are less common. However, these reactions are more serious than predictable adverse effects and require immediate stoppage of drugs. A few of these reactions based on genetic makeup of a patient are preventable. For example, before prescribing primaquine (a drug used for treatment of malaria), a blood test is done to know whether the patient would be able to tolerate the drug.

Allergic reactions can also be prevented by allergen test. Before giving penicillin (an antibiotic) by injection, allergen test is done by injecting very small dose under the skin of forearm. If a person tests positive, the drug is not used. Other drugs are prescribed instead. There are drugs that are chemically similar, so that, if one drug is causing allergic reaction, other such drugs need to be avoided in that patient. Allergic reactions, however, are not 100% preventable. After all precautions taken, there are chances (although rare) that allergic reactions do occur.

10. What are Side effects?

Side effects are the adverse effects that are seen on consumption of normal dose of a drug. These are quite common but mostly non-serious. For example, nitrates (drug used to lower blood pressure) used for increased blood pressure (hypertension) causes headache. The blood pressure lowering

effect and headache are both related to the same action of the drug on the body, i.e. expansion of arteries. Expansion of arteries in systemic circulation lowers blood pressure while the same effect in the head causes headache. It means that if a person is experiencing headache, his medicine is working well and having blood pressure lowering effect as well. Simply put, medicines have multiple effects, one of which may be useful while the other maybe disturbing. One way of dealing with side effects is reducing dose of the medication with proper medical consultation.

11. What are Secondary effects?

These effects are part of a cascade occurring due to indirect action of drugs. For example, steroids used for asthma through inhalation pump helps in preventing and treatment of its symptoms. Steroids suppress immunity. This is how they work in supressing asthma. The same effect may increase the risk of fungal infection in the oral cavity. Therefore, the patient needs gargle using saline to wash away steroids that gets deposited in mouth during inhalation. This example underscores one of the reasons why the instructions given by physicians should be meticulously followed.

When More Became Too Much

Shankar had always been a healthy man, seldom needing to visit the doctor. However, over the past week, he had developed a persistent cough that left him breathless. Each time he tried to take a deep breath, it felt like his lungs were resisting,

tightening up with every attempt.

One day, after a particularly rough night of coughing and wheezing, Shankar decided it was time to seek help. He visited a local clinic, where Dr. Maruti examined him and prescribed a

bottle of terbutaline syrup, a medicine that would help open up his airways and ease his breathing.

"Take these three times a day, just one teaspoon each time," Dr. Maruti instructed, handing Shankar the bottle of syrup.

Shankar nodded, grateful for the doctor's help. He rushed home and took his first dose, feeling a sense of relief as the syrup began to work. His breathing eased, and for the first time in days, he felt like he could take a full, deep breath without struggling.

But as the day wore on, Shankar grew impatient. He wanted to get better as quickly as possible. The idea of suffering through another night of coughs and shortness of breath was

unbearable. So, instead of waiting for his next dose, he decided to take another teaspoon. Then another. And another.

Before he knew it, the bottle was empty.

At first, Shankar felt a rush of energy, a sense of euphoria even, as if he could take on the world. But soon, his heart began to race uncontrollably, pounding against his chest like a drum. His hands trembled, and a wave of restlessness swept over him. He felt jittery, unable to sit still or focus on anything. As the hours passed, the feeling only worsened.

Concerned, Shankar called his friend, Sunil, and explained what he had done.

"You took the whole bottle? Shankar, that's dangerous! You need to see a doctor right away," Sunil urged, his voice filled with worry.

Reluctantly, Shankar returned to the clinic. As soon as Dr. Maruti saw him, he knew something was wrong. Shankar's face was flushed, and he was visibly shaking.

"What happened?" Dr. Maruti asked, though he had a sinking feeling he already knew the answer.

"I took the whole bottle of the cough syrup you gave me," Shankar admitted, his voice shaky. "I just wanted to get better quickly."

Dr. Maruti's expression darkened. "Shankar, medicines are not to be taken lightly. You were only supposed to take a teaspoon,

three times a day. Taking the whole bottle was extremely dangerous."

"But I felt better after the first dose," Shankar protested. "I thought if I took more, I'd get better faster."

"That's not how it works," Dr. Maruti said sternly. "You've

overloaded your system with terbutaline, which is why you're experiencing these symptoms—restlessness, palpitations, and even the tremors you're feeling now."

Shankar hung his head in shame, realizing the gravity of his mistake.

"I'm sorry, Doctor," he said quietly. "I didn't think it would be this serious."

Dr. Maruti sighed, his tone softening. “I understand you wanted to feel better, Shankar, but you must always follow the instructions given by your doctor. Taking more of a medicine doesn’t mean you’ll get better faster. In fact, it can lead to serious side effects, just like what you’re experiencing now.”

After giving Shankar the necessary treatment to manage the

overdose, Dr. Maruti gave him a stern warning. “Next time, follow the prescription exactly as directed. Medicines are powerful tools, but they must be used correctly to be safe.”

Shankar nodded, the lesson sinking in deeply.

As he left the clinic, he couldn’t help but think about how a simple mistake had nearly caused him serious harm. He knew

one thing for sure: he would never again take more medicine than prescribed, no matter how desperate he felt.

Message from the story: Always take medications as prescribed by your doctor. More is not always better, and taking too much can be dangerous.

> **Message from the story**
>
> **Always take medications as prescribed by your doctor. More is not always better, and taking too much can be dangerous.**

1. What are toxic effects?

"All things are poison, and nothing is without poison; the dosage alone makes it so a thing is not a poison." – Paracelsus

When the effect of a drug is pronounced owing to overdosage or its prolonged use, the adverse effect is termed as toxic effect. These effects when occur due to overdose may be accidental or intentional (suicidal or homicidal). Let us take

paracetamol as an example. Paracetamol causes damage to kidney either at large doses or when used for a long time.

The toxic dose of paracetamol is just the 10 times dose of normal dose. Therefore, you may have observed that the paracetamol syrup is dispensed in small bottles to prevent toxicity due to accidental consumption of the bottle by children.

Similarly, when paracetamol is consumed for very long period by a person who habitually (paracetamol tablet is an over the counter drug, meaning prescription is not required for buying it from chemist shop) takes this medicine for joint pain, it may cause damage to kidney. Therefore, any drug should not be consumed for long period in absence of physician's consultation.

2. What is Intolerance?

Some individuals show the known toxic effects of drugs at normal prescribed doses. This is due to increased sensitivity in these individuals to the effects of drugs.

3. What is idiosyncrasy?

It is a very rare type of adverse effect. Individuals with certain genetic traits show susceptibility to certain drugs. For

example, barbiturates (drugs that were used in past for treatment of insomnia) cause sedation, but may cause excitement in some individuals. If such adverse effects are seen in an individual, the drug is not indicated (contraindicated) in future.

4. What is drug allergy?

This is an immunological reaction to administrated drug. This is a type of unpredictable adverse effect akin to idiosyncrasy. Any organ system may get involved in drug allergy. Skin rash, oedema, kidney damage (nephropathy), massive rupture of red blood cells (haemolysis), breathlessness (asthma or anaphylaxis) are few examples of drug allergy. The dose of drug administered is irrelevant.

In allergic reaction, a prior sensitization of the immune system is required. The prior exposure of drug may go unnoticed. Allergic reactions can be well understood by the example of a vaccine. Vaccines contain information of the bacteria/virus in the form of its part (antigen) or whole of the organism. This information is enough for recognition of the organism if it comes in contact with the individual who is vaccinated (like a pamphlet circulated with photo of a "Wanted" criminal). The first dose of a vaccine triggers immunological response

(formation of antibodies or activation of white blood cells that stand as soldiers against the antigen to which they are sensitised) and thus prevents infection from occurring.

The only difference between immunological response to vaccine and an allergen is that the immunity protects for the vaccinated organism in case of a vaccine, while an allergen induces an immunological response against cells of the body itself.

5. How to identify drug allergy?

Here are a few observations that can alert you about an allergic reaction.

- ✓ Allergic reaction to a drug is not related to drug dose. Even a small dose may induce the reaction.
- ✓ The reaction is similar to allergic diseases due to allergy to substances like fish, gluten, peanuts etc.
- ✓ These reactions are rare. Only a few consuming the drug will show allergic reactions.
- ✓ Allergic reactions are not related to the known pharmacological actions of administered drug on the body.

- ✓ Most of the times, there is history of earlier use of the medication.
- ✓ Usually, the reaction stops on stopping the drug and reappears on restarting it.

The example presented in the comic is that of penicillin. Penicillin can cause allergic reaction known as anaphylaxis in one in 10000 individuals. This allergic reaction occurs within 10 to 15 minutes after injection of drug.

6. What are other types of adverse effect seen after prolonged use of drugs?

Apart from the toxic effect of a drug observed after it's prolonged use, there are other adverse effects, which include drug dependence, withdrawal reaction, teratogenicity and cancer.

7. What is Drug dependence?

A person who drinks alcohol under peer pressure for the first time experiences a high at a very small dose. If he continuous to drink, he develops tolerance to alcohol, i.e., larger and larger dosages are required to experience the same high that he had at initial small dose. Tolerance occurs due to

adaptation of the body at metabolic and receptor (site where the drugs act in the body) levels. On abstinence of alcohol, physical as well as behavioural changes can be seen. The behavioural change includes craving for alcohol to an extent to have hostile behaviour for seeking alcohol and detrimental effect on his obligations and responsibilities. Similarly, deprivation of alcohol causes physical symptoms, like tremors, sweating, palpitation, insomnia, etc. These changes are called as withdrawal effects.

Similar effect can also be observed with continued use of some drugs. This phenomenon is termed as drug dependence. In simple terms, the body is habituated to the use of medicine.

Dependence is of two types; physical and psychological.

Physical dependence is identified by withdrawal reactions. Let us assume that a person has insomnia (sleeplessness). A drug (benzodiazepine) is prescribed to him to induce sleep. After continued use of this drug, he is dependent on the drug to fall asleep. Now his body has developed dependence to the drug. If he forgets to take the medication or his supply of medicine is exhausted, his body will show the physical signs of deprivation of the drug. These signs of drug deprivation, named as withdrawal effects, are opposite to the action of the drug.

Therefore, these drugs that induce sleep will lead to insomnia as withdrawal effect. Moreover, the withdrawal symptoms are exaggerated.

Another classic example is that of beta blockers. Beta blockers cause decrease in overall activity of heart. These drugs are prescribed for elevated blood pressure and prevention of heart attack. Sudden stoppage of beta blockers causes exaggerated activity of heart. This presents as palpitation, increased blood pressure, chest pain and even heart attack.

That is why once you start medication and have been advised to take them for prolonged period, make sure that you do not stop the medication abruptly and maintain stock of medicines. Also take advise of your doctor before stopping the treatment.

Psychological dependence occurs when an individual feels emotionally distressed in absence of the drug. Absence of these drugs develop craving leading to drug seeking behaviour. Marijuana (although not used as medicine) develops psychological drug dependence.

A drug may develop physical dependence or psychological dependence or both. One must be vigilant of such drugs and contact physician in case of withdrawal symptoms due to

physical dependence or craving due to psychological dependence. There is high risk of overdose in those having drug dependence which may lead to poisoning.

8. What is Teratogenicity?

Pregnant women are given priority in our culture. Utmost care is taken for the well-being of mother and unborn child. Therefore, mothers are apprehensive to take medication during pregnancy. The reason behind this apprehension is not over estimated. It is well known that consumption of tobacco or alcohol during pregnancy causes deficient growth of foetus and at times may lead to miscarriage. The same holds true for some drugs. These drugs can lead to abnormal or anomalous growth of baby known as Teratogenicity.

A drug named thalidomide was used for morning sickness among pregnant women in West Germany. This drug was not tested for its ill effects (teratogenic effects) on the foetus. As a consequence, the babies were born with under developed hands and legs (seal like limbs) known as phocomelia.

Now-a-days, drugs are first tested in controlled environment on animals first and its effect on foetus is tested. Later, if indicated for use during pregnancy, the drug is first tested in

selected pregnant women to rule out its teratogenic effect. Drugs that are found safe are only prescribed during pregnancy. Therefore, even for a single dose of drug for consumption during pregnancy, consultation of physician is must.

There are situations where drugs may cause harm to the foetus but at the same time stopping treatment may cause more harm than the harmful effect of the drug. In such situations, drugs having more benefit then harm is continued. Precautions are taken to minimise the risk to the baby.

9. Can drugs cause cancer?

Some drugs can cause abnormal growth of cells in the body. This growth can be harmless or lethal. Examples of such drugs include anti-cancer drugs (drugs used for treatment of cancer themselves), estrogen and radioactive drugs.

10. What are iatrogenic diseases?

Iatrogenic diseases, also known as drug induced diseases, are caused by consumption of drugs. Most common example is that of chronic use of pain killers causing peptic ulcer disease.

The Overlooked Truth

Mrs. Sheela was a vibrant woman in her early thirties, happily married and living a contented life with her husband, Rajesh. They had been married for five years and were planning to start a family soon, but for now, they had decided to delay pregnancy. Sheela was on oral contraceptive (OC) pills, which she took diligently every day without fail.

One morning, about a month ago, Sheela noticed a slight fever accompanied by a persistent cough and occasional breathlessness. At first, she dismissed it as a common cold, but as the days turned into weeks, her symptoms refused to subside. Rajesh, noticing her fatigue and frequent coughing, grew concerned and insisted that she see a doctor.

They visited Dr. Amit, a seasoned physician known for his thoroughness. After examining Sheela and conducting a few tests, Dr. Amit delivered the diagnosis: tuberculosis. It was a

shocking revelation, but Sheela was relieved to finally know what was wrong.

"Mrs. Sheela," Dr. Amit began, "we need to start you on anti-tuberculosis medications right away. But first, are you currently taking any other medications?"

Sheela hesitated for a moment, but then shook her head. "No, doctor, I'm not on any other medication."

Dr. Amit nodded and prescribed the standard regimen for TB, a combination of drugs that would help her fight the infection. Rajesh thanked the doctor, and they both left the clinic with a sense of hope that Sheela would soon be on the path to recovery.

Over the next two months, Sheela's health improved significantly. The fever subsided, her cough became less frequent, and the breathlessness gradually disappeared. She

was thrilled with the progress and looked forward to her follow-up appointment with Dr. Amit.

However, there was one thing that troubled her: she had missed her periods. At first, she thought it might just be stress or a side effect of the illness, but as the days passed, she couldn't shake the feeling that something wasn't right.

When she returned to Dr. Amit for her follow-up, she mentioned her missed periods.

Dr. Amit frowned and asked, "Mrs. Sheela, are you absolutely sure you weren't taking any other medications when we started the TB treatment?"

Sheela hesitated again, her heart sinking as she remembered the OC pills she had been taking all along. She had forgotten to mention them during her first visit. "Actually, doctor... I was on birth control pills," she admitted, her voice barely above a whisper.

Dr. Amit's expression darkened. "Mrs. Sheela, why didn't you tell me this earlier? The medications I prescribed for TB can interact with oral contraceptives, making them less effective. This is likely why you've missed your periods. You could be pregnant."

Sheela's eyes widened in shock. She hadn't considered the possibility that her TB medication could interfere with her birth control.

Dr. Amit continued, his tone firm but concerned. “It’s crucial that you always tell your doctor about any medications you’re taking, no matter how unrelated they might seem. Drug interactions can have serious consequences, and in your case, it’s possible that the effectiveness of your OC pills was reduced because of the TB treatment.”

Tears welled up in Sheela’s eyes as the gravity of the situation hit her. She had been so focused on getting better that she hadn’t even thought about the potential interactions between her medications.

Dr. Amit softened his tone, seeing her distress. “We’ll do a pregnancy test to confirm, but please, remember this lesson. Always be upfront with your doctor about any and all medications you’re taking. It helps us make the best decisions for your treatment.”

A pregnancy test was conducted, and as Dr. Amit had suspected, it came back positive. While the news was unexpected, Sheela and Rajesh accepted it with mixed emotions. They were overjoyed at the thought of starting a family, but also anxious about the unplanned nature of the pregnancy.

As they left the clinic, Sheela couldn't help but reflect on how a simple oversight had led to such a significant turn in their lives. She promised herself that she would never withhold information from her doctor again, no matter how trivial it seemed.

Message from the story

Always give a complete history of any medications you are taking to your doctor. This ensures they can make informed decisions about your treatment and prevent harmful drug interactions.

1. How can we prevent harmful effects of drug?

Although it is not possible to totally get rid of adverse effects, this can be minimised by taking following precautions:

i. Do not take medicines on your own. Seek help of a doctor before doing so.

ii. Meticulously take the medicines as prescribed by your doctor. Do not alter the dose or frequency, even if you feel better. There is a good scientific reason behind the dosing schedule prescribed.

iii. Always tell your doctor about your history of adverse reactions and drugs responsible for it. Similarly, communicate to your doctor about any allergic disorders which may increase the risk of allergic reactions to drugs.

iv. Be careful when you are taking multiple drugs. Tell your doctor about drugs that you are taking on regular basis. Some drugs when taken together may show interactions causing either diminished effect of drugs or increased chances of harmful effects.

v. Get yourself investigated as advised by your doctor to monitor the effects of drugs on your body.

Summary

- Drugs are not failproof. They can cause harmful effects on the body ranging from very mild to very severe forms.
- Any new symptom or aggravation of existing symptom after consumption of a drug should be suspected as an adverse effect.
- Most of the adverse effects of drugs can be avoided by following proper instructions.
- Seeking help in case of an event of adverse drug effect and telling history of adverse effect to the doctor prevents potential repetition of such events.

Monitoring of adverse effects of drugs

1. How does a drug gets approved for its use in general population?

When a drug/molecule is found to have potential of being used for a disease, it is rigorously tested for its safety before being marketed for its intended use. The stages of this testing include:

i. Laboratory and animal testing:

These potential drugs/molecules are tested on animals in the lab to know their safety and efficacy (effectiveness)

ii. Clinical trials:

Studies done for testing of drugs in humans are known as clinical trials. These are done in various phases viz., Phase I, II, III and IV clinical trials. These studies are performed under controlled environment on human volunteers with utmost care to avoid any potential harm of the molecule tested. When found safe and effective in each step of clinical trial (till Phase III), the reports of studies performed are evaluated by regulatory authority. If the regulatory authority is satisfied with the evidences, they grant the approval for the drug to be marketed and sold. Central Drugs Standard Control Organization (CDSCO) is regulatory authority in India.

2. How do we come to know about adverse effects of drugs?

Data of adverse effects of drugs is generated from the preclinical studies and clinical trials. After regulatory approval, the drug is marketed for its use in general population. The monitoring of adverse effect continues in the marketing phase (Phase IV clinical trial) known as Post marketing surveillance. This is an important phase because, more information is gathered about rare adverse effects, long term effects of the drug and also its benefit in the broader population. This continuous monitoring for adverse effects and effectiveness of drugs done in the real-world settings among the larger population is known as Pharmacovigilance.

3. How do you define Pharmacovigilance?

The term pharmacovigilance is derived from pharmakon (drugs) and vigilance (watchful). As per WHO, Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects related to any medicine/vaccine.

4. What is journey of pharmacovigilance in India?

The initiation of Pharmacovigilance related activity started under supervision of the drug controller of India in 1986. Thus,

the adverse drug reaction (ADR) monitoring system was established. India joined hands with World Health Organization (WHO) Programme for International Drug Monitoring in 1998. This move for sharing drug safety data at global level was however a failure. The Pharmacovigilance related activity was revived by launching the National Programme of Pharmacovigilance in 2005. This programme was later replaced by Pharmacovigilance Programme of India (PvPI) under the Ministry of Health and Family Welfare in 2010.

Currently, Indian Pharmacopoeia Commission (IPC), Ghaziabad runs the PvPI as the National Coordination Centre (NCC). It also heads the Materiovigilance Programme of India (MvPI).

5. What is purpose of establishment of PvPI?

All medicines, irrespective of their source (Allopathy, Siddha, Unani, Ayurvedic, Homeopathy etc.) are monitored to safeguard the health of Indian population. The websites of CDSCO (www.cdsco.nic.in) and NCC (www.ipc.gov.in) provide all the communication to the **general public** regarding any information about PvPI.

The purpose is to improve patient safety and welfare of Indian population by monitoring safety of medicines, thereby reducing the risk associated with their use.

6. What is Adverse Drug Reaction Monitoring Centre?

Adverse Drug Reaction Monitoring Centre (AMC) is the basic unit of PvPI. Over 895 AMCs are spread across the country that gather ADRs reported by health care professional. This reporting is done through a software (VigiFlow) to the NCC, Ghaziabad, which in turn is connected to WHO's Uppsala Monitoring Centre (UMC), Sweden. WHO-UMC is the global centre for Pharmacovigilance.

All the AMCs celebrate National Pharmacovigilance week on 17th -23rd September, every year with a theme given by the NCC-IPC, Ghaziabad. The objective of the week is to create awareness on reporting of adverse drug reactions for general public.

7. What is Haemovigilance?

The term hemovigilance is derived from the word hema (blood) and vigilans (watchful). Similar to Pharmacovigilance, Haemovigilance focuses on reactions occurring during blood transfusion. Haemovigilance Programme of India was launched in 2012 across the country to improve safe blood transfusion practice. Information related to Haemovigilance

Programme of India can be accessed on the official website haemovigilance@nib.gov.in

8. What is Materiovigilance?

Medical device is any instrument used during treatment of a disease, for example disposable syringes, IV cannula (for injecting drugs and saline), N-95 masks, pulse oximeter, cardiac stents (used during angioplasty), orthopaedic implants (for joint replacement), lenses (for cataract surgery).

Materiovigilance encompasses reporting of adverse effects related to medical devices. The Materiovigilance Programme of India (MvPI) was launched at IPC, Ghaziabad by the Drugs Controller General India (DCGI) in 2015.

Official website for the Materiovigilance Programme of India is http://www.ipc.gov.in/mandates/pvpi/materiovigilance-programme-of-india-mvpi.html

9. Why it is important to report adverse reactions?

Reporting of adverse reactions on a large scale provides a background data of which can be processed to identify common and uncommon adverse effects of drugs. This helps the regulatory agencies to make necessary changes in the continuation/discontinuation of drug use in market. It also gives un update of newer adverse effects as well as other

potential uses of drugs (adverse effect in one person may be a beneficial effect in another person). This helps the health care professionals for future treatment of patients in the light of new knowledge gained. This is important for building trust among patients and better treatment results.

Summary

Pharmacovigilance plays a vital role in safeguarding public health by ensuring that the benefits of medicines outweighs the risks and by promoting safe and effective use of drugs. Likewise, Hemovigilance and Materiovigilance are crucial flagbearers for monitoring adverse effects related to blood transfusion and medical devices, respectively.

Reporting adverse drug reaction is of utmost importance for the monitoring of the medicines as well for the safety of patients. India runs the PvPI, MvPI and Hemovigilance programme of India for the same cause.

Reporting of Adverse effects of drugs

1. Who can report Adverse effects/Adverse drug reaction?

Generally, the health care professionals report Adverse drug reactions through a proper channel. These include doctors, nurses, pharmacists and other paramedical staff. Moreover, Adverse drug reactions can also be reported by patients, their relatives or anyone who is taking care of the patient.

2. How can you report an Adverse drug reaction?

Options available for reporting adverse effects of drugs are:

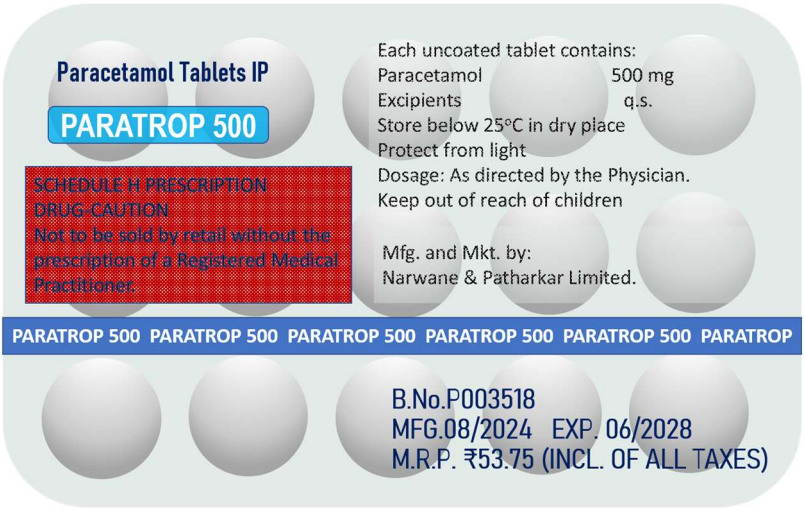
i. Reporting it to your care taker/Health care professional. He/she shall take care of your adverse effect and report it further.
ii. Reporting adverse effects using ADR reporting form for consumers available online at https://www.ipc.gov.in/PvPI/adr.html
iii. The toll-free number for reporting adverse drug reactions (ADRs) in India is 1800-180-3024. This number is available Monday to Friday from 9 AM to 5:30 PM.
iv. Reporting it using the PVPI ADR application on smartphones. This will soon be available.

Before you report an adverse effect of Medicine/drug, you must be aware of the Name of the medicine, its drug dosage form and its expiry date.

Drug dosage form is the physical form of a Medicine that is used for its use. For e.g., Solid dosage form (Tablet, Capsule, Powder), semi solid dosage form (Paste, Lotion, Cream), Liquid dosage form (Syrup, Elixir), gaseous (inhaler).

The names of Medicine are broadly of two types: Generic and Brand. Generic name is the chemical name of the drug while brand drug is the specific name given by the company that manufactures it. A generic drug may be sold in the name of multiple brand names.

The Batch number, Manufacture date as well as Expiry dates are provided on the label of medicine.



For example, dosage form of the medicine above is Tablet. Also, the Generic drug in the above dosage form is Paracetamol while Paratrop-500 is the brand name. The dose of the drug in 500mg. While reporting a medicine, its Generic name/Brand name may be written. The expiry date and date of manufacture are also available on the label.

Reporting your adverse effect using ADR reporting form for consumers

Version 1.0

MEDICINES SIDE EFFECT REPORTING FORM (FOR CONSUMERS)

Indian Pharmacopoeia Commission, National Coordination Centre- Pharmacovigilance Programme of India, Ministry of Health & Family Welfare, Government of India.

This reporting is voluntary, has no legal implication and aims to improve patient safety. Your active participation is valuable.

1.Patient Details

Patient Initials: ☐☐	Gender (√): Male ☐ Female ☐ Other ☐	Age (Year or Month) :

2. Health Information

a. Reason(s) for taking medicine(s)(Disease/Symptoms):

b. Medicines Advised by (√): Doctor ☐ Pharmacist ☐ Friends/Relatives ☐ Self (Past disease experienced/No past disease experienced) ☐

3. Details of Person Reporting the Side Effect

Name (Optional):

Address:

Telephone No:	Email:

4. Details of Medicine Taking/Taken

Name of Medicines	Quantity of Medicines taken (e.g. 250 mg, Two times a day)	Expiry Date of Medicines	Date of Start of Medicines	Date of Stop of Medicines
			dd/mm/yy	dd/mm/yy
			dd/mm/yy	dd/mm/yy
			dd/mm/yy	dd/mm/yy

Dosage form (√) : Tablet ☐ Capsule ☐ Injection ☐ Oral Liquids ☐ If Others (Please Specify.....)

5. About the Side Effect

When did the side effect started? dd/mm/yy

Side Effect Continuing (Yes/No): ☐

When did the side effect stopped? dd/mm/yy

6.How bad was the Side Effect? (Please √ the boxes that Apply)

☐ Did not affect daily activities	☐ Affect daily activities
☐ Admitted to hospital	☐ Death
☐ Others	

7.Describe the Side Effect (What did you do to manage the side effect?)

The information provided in this form will be forwarded to ADR Monitoring Centre for follow-up. You are requested to cooperate with the programme officials when they contact you for more details. Please do report if you do not have all the information.

Please turn the page to read the instructions

The details of filling the form and sending it to the Pharmacovigilance Programme of India is given on the second page of the form (shown in the following page).

Send your report by mail or Fax to	
Pharmacovigilance Programme of India National Coordination Centre, Indian Pharmacopoeia Commission, Ministry of Health & Family Welfare, Govt. of India Sector-23,Rajnagar,Ghaziabad-201002.Uttar Pradesh Tel.:0120-2783400, 2783401, 2783392 FAX: 0120-2783311 Email: **pvpi.compat@gmail.com** For more information visit us at **www.ipc.gov.in**	 **Call us on Helpline** **1800180-3024** (Toll Free) **(9:00 AM to 5:30 PM, weekdays)**

Confidentiality: The patient's identity is held in strict confidence and protected to the fullest extent. Programme staff is not expected to and will not disclose the reporter's identity in response to a request from the public.

Instructions to Complete the Form

Section 1 - Patient Details

- ✓ In patient Initial, write first letter of the name and first letter of the surname (e.g. Pradeep Sharma-PS).
- ✓ Provide personal information (Gender, Age).

Section -2 Health Information

- ✓ Provide reason(s) for taking medicines and medicines advised by (Doctor, Pharmacists, Friends/ Relatives and Self).

Section 3 - Details of Person Reporting the Side Effect

- ✓ Provide the name (optional), address; telephone no. and email are necessary to assess the report.

Section 4 - Details of the Medicines Taking/Taken

- ✓ Give all details about the Medicines (Name of Medicines, Quantity of Medicines taken, Expiry Date, start and stop date of Medicines) that have caused side effect.
- ✓ Please provide Dosage form (Tablets, Capsule, injections, Oral liquid) and if others please specify.

Section 5 - About the Side Effect

- ✓ Provide Side effect start and stop dates and also specify whether the side effect continuing.

Section 6 - How bad was the Side Effect

- ✓ Please tick marks the appropriate boxes that apply.

Section 7- Describe the Side Effect

- ✓ Please describe the deatils of side effect and what treatment taken to manage side effect.

Thank you for taking the time to complete this form

Remarks:

This reporting is voluntary, has no legal implication and aims to improve patient safety. Your active participation is valuable.

The information provided in this form will be forwarded to ADR Monitoring Centre for follow-up. You are requested to cooperate with the programme officials when they contact you for more details. Please do report if you do not have all the information.

Confidentiality: The patient's identity is held in strict confidence and protected to the fullest extent. Programme staff is not expected to and will not disclose the reporter's identity in response to a request from the public. The Name of patients is optional, although initials of the name should be mentioned.

MEDICOCITY PVT LTD

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