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A Review on Pharmacovigilance

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Abstract: Pharmacovigilance is not just about reporting side effects when they happen. It's also about carefully studying how medicines work after they are released to the public. Understanding a drug's real value and safety often takes years, as more people around the world use it and more data becomes available.Pharmacovigilance used to be a small part of drug regulation, but now it plays a much bigger role. Collecting and studying information about a drug's benefits and risks is mainly a scientific task. However, it also involves challenges related to ethics, laws, money, business interests, and how things are managed.To make sure the information is useful and trustworthy, good practices in pharmacovigilance must be followed. This means gathering and using data in the right way, for the right reasons. Pharmacovigilance promotes the safe and appropriate use of medications. Spontaneous reporting of adverse drug reactions (ADRs) is a crucial aspect of pharmacovigilance. However, significant under-reporting of ADRs persists. In developing countries, adverse drug reactions have become a serious concern. Enhancing knowledge of pharmacovigilance could serve as the foundation for strategies aimed at improving reporting rates and reducing the occurrence of ADRs.

I. INTRODUCTION

Medicines have changed how we treat diseases**.**Even though drug treatment has many benefits, it can also cause side effects, known as adverse drug reactions (ADRs**)**. These side effects are a well-known risk of using medicines. ADRs are common and, in many cases, can be prevented. They can lead to illness, disability, or even death.An ADR is defined as a harmful or unpleasant reaction to a medicine, which may happen even when the drug is used correctly. Such a reaction may suggest that the drug could cause harm if used again. As a result, it may be necessary to prevent the reaction, change the dose, or stop using the drug altogether.Pharmacovigilance is the science and activities involved in detecting**,** understanding, and preventing side effects or other problems related to medicines. It is an important part of drug safety, public health programs, and good medical practice. Medicines have changed how we treat diseases**.**Even though drug treatment has many benefits, it can also cause side effects, known as adverse drug reactions (ADRs**)**. These side effects are a well-known risk of using medicines. ADRs are common and, in many cases, can be prevented. They can lead to illness, disability, or even death.An ADR is defined as a harmful or unpleasant reaction to a medicine, which may happen even when the drug is used correctly. Such a reaction may suggest that the drug could cause harm if used again. As a result, it may be necessary to prevent the reaction, change the dose, or stop using the drug altogether.Pharmacovigilance is the science and activities involved in detecting, understanding, and preventing side effects or other problems related to medicines. It is an important part of drug safety, public health programs, and good medical practice. Drug safety has been getting a lot of attention recently.Almost every week, newspapers and scientific journals report on medicines that cause unexpected side effects, also known as adverse drug reactions (ADRs**)**. These reports can make both patients and healthcare workers worried about using certain medications.Sometimes, patients may even stop taking their prescribed medicine because of fear, which can lead to health problems that are worse than the original side effect they were worried about.Pharmacovigilance, as defined by the World Health Organization (WHO), is the science and activities involved in detecting, understanding, and preventing side effects or any other issues related to medicines. It helps make sure doctors and patients have enough information to make safe and informed choices when selecting a treatment. The purpose of this review is to explain the main methods used in pharmacovigilance to keep medicines safe.

It also talks about recent advances in the field and what still needs to be done in the future.To give an idea of the kinds of challenges pharmacovigilance deals with, the review includes a few examples of recent safety concerns and how they were handled. Safety ConcernsOne well-known case was the withdrawal of a drug called rofecoxib. This brought renewed focus to drug safety.The decision to remove rofecoxib from the market was made after a study (the APPROVe trial) found that patients taking the drug had a higher risk of heart problems compared to those who were given a placebo (a harmless substance used in studies for comparison). Another issue that has been widely discussed in the past year is the link between rosiglitazone (a diabetes medicine) and heart problems.In June 2007, a large study (called a meta-analysis) was published that showed rosiglitazone might increase the risk of heart attacks and death from heart-related causes.

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This study sparked a lot of debate about how safe the drug really is. Soon after, more studies were done to either confirm or challenge these findings.After reviewing all the available data, both the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) decided that the benefits of rosiglitazone are greater than its risks when used as approved.However, the safety information about the drug must be regularly updated, and ongoing monitoring of this side effect is still very important.

Important drug safety updates from 2011 are summarized below:

- Dronedarone: Linked to serious heart and liver side effects, with questionable effectiveness.
- Proton Pump Inhibitors (PPIs) (used for acid reflux): Long-term use may cause low magnesium levels in the blood.
- Bisphosphonates (used for bone diseases like osteoporosis): May increase the risk of unusual thigh bone fractures.
- Dasatinib (a cancer medicine): Reports of high blood pressure in the lungs (pulmonary arterial hypertension).
- Lenalidomide (a cancer drug): May increase the risk of developing a second type of cancer.

Daptomycin (an antibiotic): Some cases of eosinophilic pneumonia, a rare lung inflammation, have been reported. Tigecycline (an antibiotic): Found to be less effective than other similar drugs.

1) Drotrecogin alfa (used for severe sepsis): Removed from the market because it was not effective.
2) Nimesulide (a painkiller/NSAID): Found to be more harmful to the liver than other similar drugs.
3) Topiramate (used for epilepsy and migraines): Linked to birth defects, especially cleft lip or palate.
4) Valproate (used for epilepsy and bipolar disorder): Can cause learning and developmental problems in children, in addition to known birth defects.
5) Antipsychotics used late in pregnancy: May lead to health problems in newborn babies.

A more recent drug safety concern is the link between aprotinin (a medicine used to reduce bleeding during surgery) and a higher risk of death. In 2006, a study by Mangano and colleagues raised questions about how safe aprotinin really is. Then, on November 21, 2007, aprotinin was removed from the market in the European Union after a clinical trial (called the BART trial) showed that patients who received the drug had a higher death rate. Whenever a safety issue with a drug is found, the first step is to ask: "How did this happen?" For example, in the case of rofecoxib, it led to a careful review of the systems and methods used to ensure that medicines are safe to use. The main goal of pharmacovigilance is to understand the risks of side effects from medicines—knowing that no drug is completely free of risk. This safety monitoring starts when a drug is approved and continues for as long as it is available on the market. Pharmacovigilance is very important for keeping patients safe and ensuring good treatment results. However, for some diseases, it's especially important to report side effects early, accurately, and in detail. One key example is cancer treatment. These medicines often have serious side effects and must be used very carefully, with the right dose. That’s why they are a top priority for safety monitoring. nfortunately, there are not many studies that focus on monitoring the safety of cancer drugs after they are released for use. Different organizations may define pharmacovigilance in various ways, but the main goals are the same: To improve patient care and safety, and to provide clear, reliable information about the risks and benefits of medicines. The World Health Organization (WHO) sets the global standard for pharmacovigilance. WHO defines it as:"The science and activities related to detecting, understanding, and preventing side effects or any other problems caused by medicines." By 2010, 134 countries had joined WHO’s pharmacovigilance program. This program is supported through teamwork between the Programme for International Drug Monitoring and the WHO Collaborating Centre for International Drug Monitoring. In the United States, the term post-marketing surveillance means keeping track of a drug’s safety, effectiveness, and quality after it has been approved and is being sold. In the European Union (EU), a similar term is used—post-marketing activities—but it covers more areas and gives health authorities more control over different aspects of a drug’s use. In both the US and EU, pharmacovigilance efforts have increased in recent years. This includes collecting more data after a drug is approved, coming from many sources—such as government agencies, pharmaceutical companies, and even patients themselves. Countries in the European Union (EU) have worked together to make their drug safety systems more consistent. This helps make things easier for those who fund and support healthcare, and it also makes drug safety efforts more effective.

Now, most EU countries follow a shared approach to pharmacovigilance. This includes working with:

- Regulatory agencies (that oversee drug safety),
- Post-marketing surveillance (monitoring drugs after approval),
- Risk management,
- Research after drug approval, and

- Rules and enforcement.

Even though each country's health agency might define pharmacovigilance a bit differently, they now use similar methods. In the United States, pharmacovigilance rules are even stronger than those in the European Union. This was especially improved by a law called the Modernization Act in 2007 and later guidelines from the FDA (Food and Drug Administration). Because of these rules, the FDA must:

- Regularly check the database of reported side effects very often,
- Share public reports every three months about any new safety concerns or serious risks.

The FDA can also ask drug companies to:

- Create Risk Evaluation and Mitigation Strategies (REMS) if it's unclear whether a medicine's benefits are greater than its risks,
- Do extra studies and tests after the drug is approved to check on known or possible serious side effects,
- Watch for any unexpected risks from available information.

If companies do not follow these rules or fail to complete required studies or REMS, the FDA has the power to penalize them.

This paper is the first in a series of three about drug safety in cancer treatment. It looks at the roles and responsibilities of both national and international drug safety activities. One question is whether pharmacovigilance should pay special attention to drugs with a narrow therapeutic index (where the difference between a safe and harmful dose is small) and drugs that need very precise dosing. For example, there is a common rule that the difference in how the body absorbs two versions of a drug should fall between 80% and 125%. But is this rule good enough for all drugs, or should there be stricter rules for certain medicines? As the European Medicines Agency (EMA) and the FDA create new guidelines for drug safety, we also discuss how to measure quality and share results. Today, pharmacovigilance should not only focus on the finished drug but also look into where the ingredients come from, including inactive ingredients, to check if they might cause unexpected side effects. We also explain that modern drug safety must include recording when treatments don't work as well as expected, which is already done for cancer drugs by agencies like the FDA, Health Canada, and EMA. Finally, we talk about the growing use of real-world data (information collected outside of clinical trials) as a key part of drug safety. We also discuss challenges like figuring out what causes side effects and how different factors interact in drug safety work in the USA, EU, and other places like Asia. Pharmacovigilance is the science and activities involved in finding, studying, understanding, and preventing side effects and other problems caused by medicines. It is very important for good drug regulations, public health programs, and medical practice. Pharmacovigilance helps make sure medicines are used safely and correctly by:

a) Finding new side effects or drug interactions and noticing if known side effects happen more often,
b) Identifying what increases the risk of side effects, and
c) Measuring the balance between benefits and risks, and sharing this information to help doctors prescribe drugs better and improve drug regulations.

Les alertes de sécurité des médicaments en 2011 sont résumées ici :

- Dronédarone : provoque de graves problèmes cardiaques et hépatiques, avec une efficacité limitée.
- IPP (inhibiteurs de la pompe à protons) utilisés longtemps : peuvent causer un faible taux de magnésium dans le sang.
- Bisphosphonates (médicaments pour les os) : risque de fractures rares du fémur (cuisse).
- Dasatinib (médicament contre le cancer) : cas d'hypertension pulmonaire (tension élevée dans les poumons) signalés.
- Lénalidomide (médicament contre le cancer) : risque de développer un second cancer.
- Daptomycine (antibiotique) : cas de pneumonie à éosinophiles (inflammation rare des poumons) rapportés.
- Tigécycline (antibiotique) : moins efficace que d'autres antibiotiques.
- Drotrécogine alfa : retiré du marché car il n'est pas efficace.
- Nimésulide (anti-inflammatoire) : risque plus élevé d'atteinte du foie.
- Topiramate (médicament contre l'épilepsie et migraines) : peut causer des malformations chez le bébé, comme des fentes au palais.
- Valproate (médicament contre l'épilepsie) : peut provoquer des troubles du développement mental en plus des malformations.
- Neuroleptiques (médicaments psychiatriques) pris tard pendant la grossesse : peuvent causer des problèmes d'adaptation chez le nouveau-né.

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A. Pharmacovigilance and Substandard Medicines

Making sure a medicine is high quality is important both before and after it is approved for use. Like keeping medicines safe, checking quality is a scientific and educational process that needs good teamwork between many people involved, including regulators, drug makers, and healthcare workers, throughout the whole time the medicine is being used. This process won't be easy or cheap, and it will need everyone to get more involved and work together in new ways. Also, drug companies must take responsibility for the quality of their products and be able to measure it properly. The FDA has taken the lead in showing how important data is for modern drug safety work. In 2011, many important medicines for treating cancers like leukemia, lymphoma, and testicular cancer were in short supply. This happened mostly because some manufacturers had problems with poor-quality production. Because of this, the FDA became more involved in drug safety activities. In 2014, the FDA created the Office of Pharmaceutical Quality to watch over the safety, effectiveness, and quality of medicines. Since no medicine that is low quality can be considered safe, the FDA now checks where ingredients and inactive parts of medicines come from. They use a risk-based system that looks at data from factory inspections, reports of side effects, and problems with low-quality medicines.This approach helped fix problems with generic versions of drugs like bupropion in 2012, metoprolol in 2014, and methylphenidate in 2015, where the medicines did not work as well as they should. Because of the FDA's efforts to make sure medicines are made well and supplied properly, many shortages of important medicines have been avoided. Problems with bioequivalence (when a generic drug works the same as the original) are rare, but it's important to have a smart plan to find where problems might happen—like with special types of drugs called modified-release formulations.

For example, testing generic extended-release methylphenidate (a drug for ADHD) has been difficult. This shows how hard it is for companies to make generic extended-release drugs, which need special skills to produce. The FDA is paying close attention to these types of drugs and has set aside $20 million to test their safety and quality, starting with drugs for attention deficit.

Because of this work, the FDA has created a new way of inspecting and reporting that will help improve drug quality. The FDA has also shared its goals for regulating drug quality.

Their work shows that it's very important to regularly check the quality of both the drug and the suppliers of its ingredients, especially when changes are made. The FDA now focuses more on quality when reviewing and monitoring all kinds of drugs, including brand-name drugs, generic drugs, biological medicines, and complex drugs.

***Panel 1:* Standardised approach to manufacturer inspections**

- Data gathering to inform quality intelligence of sites and products
- Risk-based and rule-based process, using expert questions
- Semi-quantitative scoring to allow for comparisons within and between sites
- More common inspection report structure
- Positive behaviours recognised and rewarded where facilities exceed basic compliance

***Panel 2:* Aims of regulation of drug quality by the US Food and Drug Administration[11]**

- Put patients first by balancing risk and availability
- Ensure clinically relevant quality standards
- Integrate review and inspection across product lifecycle
- Maximise efficiency by applying risk-based approaches
- Strengthen lifecycle management by using team-based processes
- Apply staff expertise effectively to enhance quality regulation
- Encourage innovation by advancing new technology and manufacturing science
- Enhance cross-disciplinary interaction, shared accountability, and joint problem-solving
- Build collaborative relationships by communicating openly, honestly, and directly

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B. Role of New Media and Patients

In today's world, where social media is very popular, getting lots of real-time information from people doesn't always mean the information is good. Even though there is a lot of extra or unclear data, social media is becoming an important source of useful drug safety information.

In some important cases, social media has helped improve safety for rare diseases (like myelodysplastic syndrome) and has helped report side effects of drugs (like problems linked to fluoroquinolones). These examples show that drug safety agencies may not fully understand new social media tools or have enough staff and skills to find the important drug safety information.

There is a worry that current systems might be overwhelmed by too much low-quality information. Because of this, it's important to ask: How many trained people and what kind of training do we need to handle modern drug safety work properly? In May 2014, the European Commission published a report about what they did during the first year of new drug safety laws, working with drug authorities in EU countries.

From July 2012 to July 2013, reports from patients about possible side effects of medicines increased by more than 9,000. Because of this, changes were made to medicine information based on new safety concerns.

Big reviews about public health were started, including studies on:

- Combined hormonal contraceptives and blood clots
- Medicines with cyproterone acetate or ethinylestradiol and blood clots
- Codeine pain medicines and overdoses in children

Also, thousands of patients were trained about drug safety during this time. In many ways, drug safety work by US and EU agencies shows that modern pharmacovigilance (drug safety) should use something called design thinking. Unlike critical thinking, which focuses on analyzing problems, design thinking is creative and focuses on coming up with action plans.This approach means carefully looking at how we define problems and being willing to change our ideas before starting to solve them. It also requires different experts to look at the problem from many angles and to keep asking questions. Watching and learning from what is happening is very important.Design thinking is about changing current situations into better, preferred ones

C. Biosimilar and Generic Drug Safety

A big challenge in 21st-century drug safety monitoring is keeping a close eye on biosimilar drugs after they hit the market. Biological drugs are different because of where they come from, how they're made, their quality, and their unique safety concerns. This means regulators need better science and tools to carefully check both the data from early testing and how the drugs work in real life after approval.Everyone involved in watching over drug safety will find it hard to spot problems with biosimilars because we don't have tested methods to predict which parts or suppliers might cause issues. So, monitoring biosimilars will need to improve as new drugs are introduced. Since these drugs are new, come in small amounts, and may have unique safety issues—especially when combined with other medicines—it will be tough for drug makers, doctors, and patients to keep track of any risks. We are now in a time where we don't have all the answers about drug safety after they're on the market. The first step is to study and understand the differences between generic drugs and biosimilar drugs better. For example, generic drugs can have different safety issues compared to biological drugs because of differences in how much of the drug is absorbed and the other ingredients used.When it comes to monitoring biosimilars, there are extra worries. These include side effects caused by the treatment itself, differences between batches made by different companies, and the flexible rules about what makes a biosimilar "similar." All of these affect safety.For example, between 1998 and 2004, more people developed a rare blood condition caused by a change in how a drug that helps make red blood cells was made. But since there were three similar drugs on the market, it was hard to figure out which one was causing the problem.This problem is especially important and urgent for patients and health experts when planning how to watch over generic and biosimilar drugs used to treat cancer in the 21st century.

D. Regulatory action after rofecoxib Withdrawal

After the drug rofecoxib was taken off the market, the FDA and the system for watching drug safety after approval faced a lot of criticism. First, the FDA only looks at limited sources of information about drug safety, like clinical trials and reports from doctors or patients. Second, the FDA can't control how well drug companies carry out safety studies after the drug is approved. Most of these promised studies never even start, and the number of completed safety studies after approval dropped from 62% (between 1970 and 1984) to just 24% (between 1998 and 2003). Third, the FDA doesn't have the power to take legal action against companies that fail to complete these safety studies.

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Some people also say that the FDA has gotten too close to the drug companies it's supposed to regulate, and they think it would be better to separate the FDA's regular duties from its job of watching drug safety after approval.Because of this criticism, the FDA's Centre for Drug Evaluation and Research (CDER) asked the Institute of Medicine (IOM) to review the US drug safety system. In September 2006, the IOM shared their report called *The future of drug safety: promoting and protecting the health of the public*.The main idea of the report is that the FDA should monitor the safety of a drug throughout its entire life—from before approval to long after it's on the market. This "life-cycle" approach means the FDA should watch for safety problems, design studies to check these problems, weigh the benefits and risks, use these results to understand the overall safety, and share important information with patients and doctors.

In Europe, when rofecoxib was taken off the market, the drug safety system in different European Union countries was reviewed. This review, published in March 2006, looked at the good points and the problems of the European drug safety system. The wide range of data they use, how actively they register information, how quickly they make decisions, how their rules affect things and how they share information, how well companies follow the rules, and the overall focus on good quality and always trying to improve.

Table 1 Drug safety concerns that have arisen in Europe since 1995 and evidence for these[a]

Drug	Safety concern	Key evidence	Regulatory action
Trovofloxacin	Hepatoxicity	Spontaneous ADRs	Withdrawn
Tolcapone	Hepatoxicity	Spontaneous ADRs	Suspended
Cisapride	QT prolongation; cardiac arrhythmias	Spontaneous ADRs	Patient registration licences subsequently cancelled
Bupropion	Seizures; drug interaction	Spontaneous ADRs	Posology change, Warnings
Cerivastatin	Rhabdomyolysis	Spontaneous ADRs	Withdrawn
Hormone replace therapy	CVS risk; cancer long term	Epidemiological studies	Warnings and restriction of indication
SSRIs	Suicidal behaviour in children	Clinical trials	Warnings accompanied by clinical guidance
COX IIs	CVS risk	Clinical trials	Warnings and clinical guidance
Topical macrolide immunosuppressants	Risk of cancer	Spontaneous reports	Restriction of use, Risk management plan

E. Methods used in Pharmacovigilance

Pharmacovigilance (watching drug safety) is mostly done by three groups: government regulators, drug companies, and universities. The main goal of government regulators is to make sure that the drugs available to the public are more helpful than harmful. This section will talk about the problems in how safety is checked after drugs are approved, explain how new side effects are found, and go over the good and bad sides of each method.

Clinical trial data insufficient to evaluate drug risk

Before a drug is approved, the main way to study it is through clinical trials. These are done in phases, and Phase III trials are usually the most detailed. They are often "double-blind" and "randomised," meaning neither the patients nor the doctors know who is getting the real treatment. This helps test if the drug truly works.But when it comes to checking for side effects, this type of study has some problems. The number of people in the trial is small, so rare side effects might not show up. Also, the trials don't last very long, so they can miss side effects that only appear after a long time.Another issue is who joins the trials. The people tested often don't fully match the real-world patients who will later use the drug. So, it can be hard to apply the results to the general population—especially for older adults, women, or people from minority ethnic groups.That's why it's really important to keep carefully watching the drug after it's been approved and is being used by more people.

F. Spontaneous Reporting

In 1961, an Australian doctor named WG McBride wrote a letter to a medical journal called *The Lancet*. He said he had noticed that babies born to mothers who took a drug called thalidomide during pregnancy were more likely to have birth defects. Over time, it became clear that thousands of babies had been born with deformed limbs because their mothers used thalidomide. To make sure something like this didn't happen again, countries around the world created systems to check and monitor the safety of medicines. Spontaneous reporting systems (SRS) were set up to help track the safety of drugs after they're on the market. These systems are mainly used to catch early signs of new, rare, or serious side effects (called adverse drug reactions, or ADRs).

Doctors—and more recently, pharmacists and even patients—can send in reports if they think a drug has caused a side effect. These reports go to a drug safety center, which collects and studies them. If a new risk is found, the center alerts people like doctors, drug companies, and health officials. Drug companies also use these systems to gather safety data on their own products.One good thing about SRS is that it can track all drugs on the market for their whole lifespan—and it doesn't cost too much.But there are problems. Not everyone reports side effects, and some only report certain ones. A review by Hazell and Shakir found that over 94% of all side effects don't get reported at all. This could make it seem like a drug is safer than it really is. On the other hand, reporting only certain risks could make a drug seem more dangerous than it is.Interestingly, even these problems—underreporting and selective reporting—can sometimes be helpful, depending on how the data is used.

G. Data mining in Spontaneous Reporting

In the past, drug safety signals were mostly found by looking at each report one by one. But in recent years, data mining has become more important.Data mining means looking at large sets of information from different angles to find useful patterns. In pharmacovigilance, it helps find unexpected links or rare side effects in huge drug safety databases.Special computer programs (algorithms) are used to spot patterns or unusual results—these are called signals. Even though the methods may be different, they all try to measure how much the number of reported cases is higher (or lower) than what was expected.

II. METHODS OF QUANTIFYING ADRs

The frequency of ADRs has been measured using a variety of techniques. Prescription-event monitoring, which gathers all drug-related incidents that take place while patients are taking specific monitored drugs, ecological research and analysis of medical claims databases, spontaneous ADR reporting, and meta-analyses are a few of these . The most popular pharmacovigilance technique for producing signals on novel or uncommon ADRs is pontaneous reporting (43). This reporting system can be thought of as the foundation of pharmacovigilance and has made a substantial contribution to the success of post-marketing drug safety surveillance (44). The program has several drawbacks, such as low-quality reports that are filed, trouble calculating rates due to missing numer-ator (adverse occurrences) data and erroneous denominators (number of prescriptions), and a restricted capacity to establish causation. But the primary drawback is underreporting.

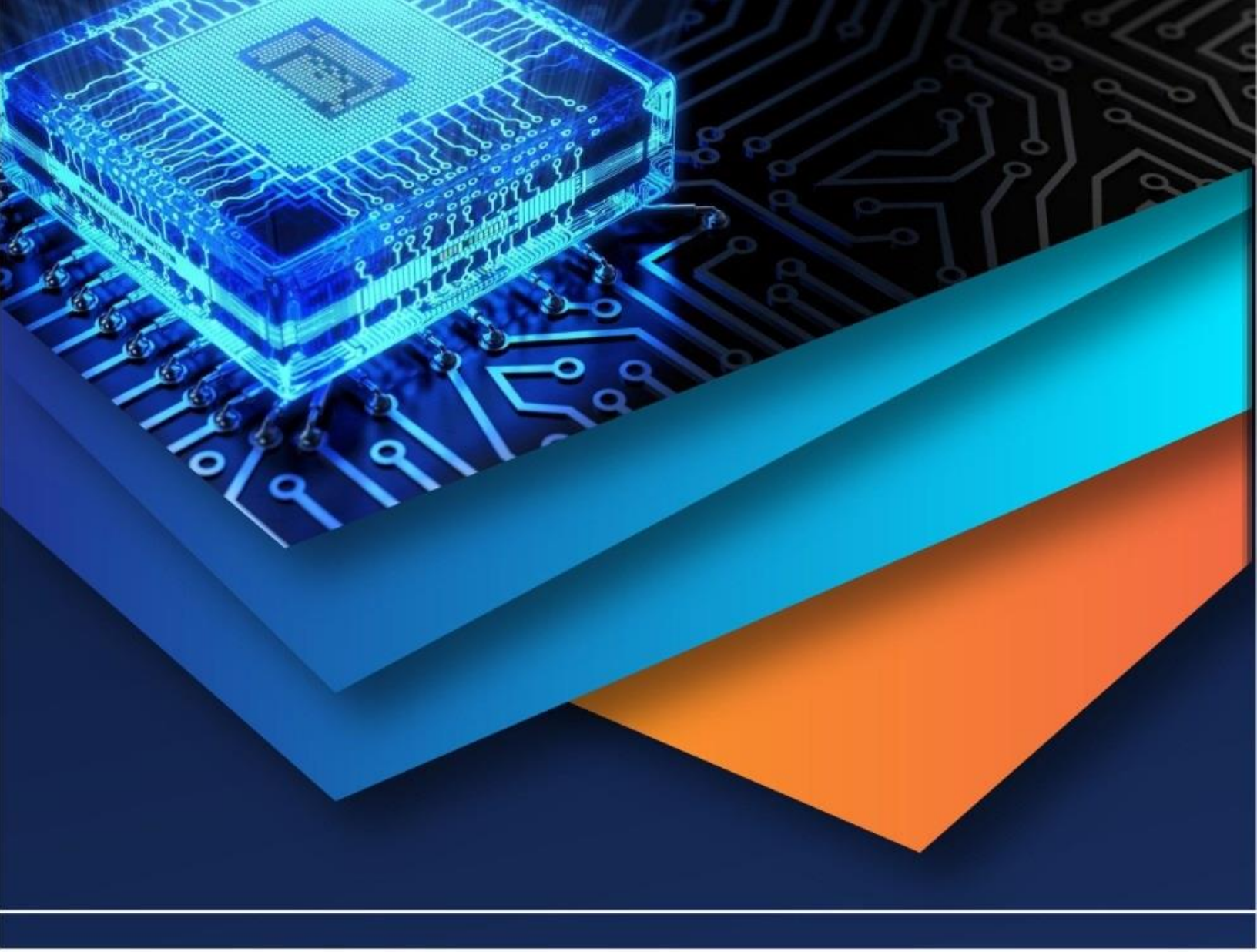
III. CONCLUSION

Adverse drug reactions, especially those that are rare and delayed, are not all known at the time of market approval. They can be identified based on reports from prescribers, as was the case for some of those mentioned here. Doctors and patients can contribute to pharmacovigilance by reporting adverse effects to health authorities, especially those that are serious or unexpected.Approval may sometimes be granted based on limited evidence of effectiveness, as was the case for dronedarone and drotrecogin alfa. In such cases, it is important not to rush and to remain critical, as new does not always mean useful.India's pharmaceutical industry is now the third largest in the world by volume, 14th by value, and is becoming an important center for clinical trials. With the launch of new medicines, India needs a strong drug safety monitoring system to protect people from possible harm and side effects.Pharmacovigilance is key to managing the growing number and power of modern medicines. However, India's current pharmacovigilance system still needs improvement. Even though the Central Drugs Standard Control Organization (CDSCO) recently launched a structured drug safety program in line with WHO's goals, the system has not yet achieved the desired impact.Still, better awareness and training for doctors and the public, clearer rules for reporting side effects, stronger enforcement, and cooperation among the government, drug companies, healthcare workers, regulators, and patients could help build a more effective pharmacovigilance system in India.

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