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Pharmacovigilance

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Abstract: *Pharmacovigilance, as defined by the World Health Organization, refers to the scientific discipline and set of activities aimed at detecting, assessing, understanding, and preventing adverse effects or any other medicine-related problems. It serves as an essential component of drug safety by ensuring that patients receive therapies with well-characterized risks and benefits. Information on Adverse Drug Reactions (ADRs) is strengthened through various methods, including large health-database studies, intensive monitoring programs, spontaneous reporting systems, and several newly evolving regulatory and scientific approaches designed to enhance pharmacovigilance. Regulatory measures such as risk-management plans and conditional approvals, along with scientific advancements like increased patient engagement and improved transparency, contribute to the ongoing progress of the field. This review intends to highlight the different dimensions of pharmacovigilance, with a focus on emerging methodologies and recent developments.*

Keywords: Pharmacovigilance, Adverse Drug Reactions, WHO, Drug Safety

I. INTRODUCTION

Drug safety and pharmacovigilance have grown into rapidly advancing scientific and clinical specialties. The World Health Organization (WHO) defines pharmacovigilance as the field devoted to identifying, evaluating, understanding, and preventing adverse effects or any other problems related to the use of medicines. It ensures that healthcare professionals and patients have sufficient, reliable information to make informed decisions when selecting appropriate treatments.Although medicines are developed to improve health, adverse drug reactions (ADRs) remain a considerable challenge. Many ADRs are frequent, often avoidable, and continue to be a major cause of illness, disability, and even death. In several regions of the world, ADRs are ranked among the leading causes of mortality. For this reason, robust systems that continuously assess and monitor the safety of medicines used in clinical practice are essential for reducing harm and improving public health.

The word pharmacovigilance is derived from two roots: the Greek term pharmakon, meaning “drug,” and the Latin term vigilare, meaning “to remain watchful.” Together, they capture the essence of monitoring and safeguarding the safe use of medicines.

Pharmacovigilance represents a crucial part of the drug development and post-marketing process. It requires ongoing surveillance, evaluation, and interpretation of potential adverse effects to ensure a favorable balance between benefit and risk throughout a medication’s entire lifecycle. Modern information technologies have strengthened pharmacovigilance systems by enabling faster data collection, improved analysis, and more effective communication, ultimately enhancing patient safety and clinical decision-making.

Looking ahead, pharmacovigilance is expected to evolve significantly over the next decade. Factors such as globalization, online drug sales, widespread access to digital information, expanding safety concerns, and the need to balance public health with economic pressures pose complex challenges. Additional issues include monitoring long-established products, addressing the needs of developing and emerging countries, and understanding how patients perceive risks and benefits. These challenges will continue to shape the direction and advancement of pharmacovigilance as a scientific discipline.

Pharmacovigilance remains an essential and irreplaceable component of clinical research and healthcare practice.

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CLINICAL RESEARCH:

1) Definition and Phases of Clinical Trials :

A clinical trial is a planned and ethically supervised study carried out in human volunteers to scientifically evaluate, confirm, or compare the effects of one or more therapeutic interventions such as drugs. When laboratory and animal studies suggest a new compound is suitable for human testing, regulatory authorities are approached. If the evidence is satisfactory, they grant an Investigational New Drug (IND) approval, allowing human trials to begin.

Phase 0 – Microdosing Studies:

Phase 0, also known as a microdosing study, is a relatively recent strategy developed to shorten drug-development time and reduce early-stage costs. Regulatory agencies such as the FDA and EMA have supported these innovative approaches. In this phase, extremely small doses of the investigational drug are given to a very limited number of volunteers to obtain early human pharmacokinetic data before moving on to Phase I. The dose is far below the therapeutic level, making it primarily exploratory.

Phase I – Human Pharmacology and Initial Safety Assessment:

Phase I marks the first administration of the drug to humans. These trials are performed by experienced clinical pharmacologists or trained physicians in a controlled facility where vital signs can be continuously monitored and emergency support is available. The main objectives are to evaluate basic safety, identify any immediate adverse effects, and determine key pharmacokinetic parameters. Phase I studies are usually open-label and involve a small group of healthy volunteers.

Phase II – Therapeutic Exploration and Dose Optimization:

Phase II trials are conducted by certified clinical investigators and typically involve 100 to 500 patients who meet predefined inclusion and exclusion criteria. The primary goals are to explore the drug's therapeutic potential, establish effective dose ranges, and identify the dose at which maximum benefit occurs without additional improvement. Safety, tolerability, and extended pharmacokinetic information are also assessed. These trials are generally randomized and controlled, and may be either blinded or open-label.

Phase III – Therapeutic Confirmation and Comparative Evaluation:

Phase III studies are large, well-controlled trials usually involving 500 to 3,000 patients across multiple centers. They are often conducted by specialists who manage the condition being targeted. The purpose of this phase is to confirm the drug's efficacy, compare it with existing treatments, and gather comprehensive safety data. These trials are typically randomized, double- blind, and comparative. If the results are favorable, a New Drug Application (NDA) is submitted to the regulatory authority (e.g., the FDA). Upon approval, the drug can be marketed.

Phase IV – Post-Marketing Surveillance and Long-Term Safety Studies:

Phase IV begins after a drug has been approved for marketing and made available for general clinical use. In this phase, the medicine is monitored under real-world conditions to gather additional information about its long-term safety, effectiveness, and patterns of use in diverse patient populations. These studies help detect rare, delayed, or previously unrecognized adverse drug reactions that may not have appeared during earlier phases due to limited sample sizes or shorter study durations.

Functions of the Drug Controller General of India (DCGI) and CDSCO:

Functions of the DCGI:

The Drug Controller General of India (DCGI) is the key authority responsible for drug regulation and safety monitoring in the country. The DCGI's major responsibilities include:

1. New Drug Approval:The DCGI reviews and approves new pharmaceutical products after examining evidence of their quality, safety, and effectiveness. Approval is granted only when clinical trial data submitted by drug manufacturers meet regulatory requirements.

2. Oversight of Clinical Trials:The DCGI supervises and regulates clinical trials conducted in India to ensure they follow ethical standards, protect participant safety, and adhere to approved study protocols.

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3. Post-Marketing Safety Monitoring:Even after a drug is approved, the DCGI continues to track its safety through post-marketing surveillance. Reports of adverse events from healthcare professionals, patients, and pharmaceutical companies are evaluated to detect safety concerns.
4. Quality Assurance:The DCGI ensures that medicines available in the Indian market meet required quality standards. This includes inspecting manufacturing sites, reviewing production methods, and regulating imports of pharmaceutical products.
5. Regulatory Enforcement:The DCGI enforces legal and regulatory requirements related to drug manufacture, labeling, distribution, and marketing in order to safeguard public health.

Functions of CDSCO:

The Central Drugs Standard Control Organization (CDSCO) is India's national regulatory agency responsible for overseeing the safety, quality, and approval of drugs, cosmetics, medical devices, and biological products.
The Central Drugs Standard Control Organization (CDSCO) serves as India's primary regulatory authority for ensuring the quality, safety, and effectiveness of drugs, cosmetics, medical devices, and biological products. It plays a crucial role in maintaining public health by regulating and supervising these products throughout their lifecycle.
1. Regulatory Oversight:CDSCO is responsible for evaluating, approving, and issuing licenses for the manufacturing, import, and distribution of drugs and related products. It carefully reviews scientific data submitted by manufacturers to ensure that every product meets national safety, quality, and efficacy standards before it becomes available to the public. Pharmaceuticals,medical devices, and Cosmetics in India.
2. Drug Approval:CDSCO reviews applications for new drugs and formulations and grants approval only after confirming that they meet the required standards of safety, therapeutic effectiveness, and quality before entering the Indian market.
3. Quality Control:The agency enforces strict quality-assurance measures to ensure that pharmaceutical products being manufactured, imported, or distributed in India comply with regulatory specifications. This includes inspections, product testing, and action against low- quality or adulterated medicines.
4. Clinical Trial Regulation:CDSCO oversees clinical trials conducted across the country to ensure that they follow approved protocols, uphold ethical principles, and prioritize participant safety throughout the study.
5. Post-Marketing Surveillance:Even after approval, CDSCO continues monitoring drugs and medical devices to ensure they remain safe and effective during widespread use. Any safety issues or quality concerns reported after marketing are carefully evaluated.

Types of Regulatory Applications:

1. Investigational New Drug (IND)
2. New Drug Application (NDA)
3. Abbreviated New Drug Application (ANDA)

1) Investigational New Drug (IND):

The Investigational New Drug (IND) application is the initial step in obtaining permission from the U.S. FDA to begin clinical testing of a new compound in humans. It does not allow marketing of the drug; instead, it authorizes researchers to study the drug in human volunteers or patients.
The primary aim of the IND is to demonstrate that the investigational drug can be tested in humans without exposing participants to unreasonable risks. This includes providing detailed information on preclinical safety, study protocols, and informed-consent procedures. Researchers are required to report any serious side effects or unexpected adverse events that occur during the trials. Properly designed study methods must also be submitted to ensure that participants are not exposed to harmful or scientifically unjustified investigational drugs.

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2) New Drug Application (NDA):

The New Drug Application (NDA) is a critical, multi-step process used to obtain regulatory approval to market a new pharmaceutical product in the United States. The process begins with extensive preclinical research, including laboratory testing and animal studies, to evaluate the drug's safety profile and potential therapeutic benefits.

Once preclinical testing shows promising results, the sponsor submits an IND to the FDA to begin human trials. After completing Phase I, II, and III clinical studies, the sponsor prepares the NDA, which includes all collected data on safety, efficacy, pharmacokinetics, manufacturing methods, proposed labeling, and risk-management plans. The FDA reviews this comprehensive dossier to determine whether the drug can be approved for public use.

3) Abbreviated New Drug Application (ANDA):

An Abbreviated New Drug Application (ANDA) is submitted to the FDA when a company wants approval to market a generic version of a previously approved medicine. This pathway is available after the reference drug's patent or exclusivity has ended.

In an ANDA, the manufacturer must prove that the proposed generic product is bioequivalent to the original brand drug. This means the generic must contain the same active ingredient, follow the same dosage strength, have the same dosage form, use the same route of administration, and show comparable therapeutic performance.

GOOD CLINICAL PRACTICE (GCP):

Objectives of ICH Good Clinical Practice:

1. Protection of Participants:

The guidelines aim to ensure that the rights, safety, and welfare of all individuals taking part in a clinical study are safeguarded throughout the trial.

2. Reliable and Accurate Data:

GCP promotes the generation of high-quality, trustworthy clinical data by setting unified international standards for conducting research.

3. Ethical Research Conduct:

It provides clear ethical principles for trial planning, execution, and reporting, including strict requirements for informed consent and respect for participant autonomy.

4. Quality Assurance:

The standards support proper monitoring and quality control processes so that the trial is carried out correctly and the resulting data are dependable.

5. Transparency of Results:

GCP encourages clear and complete reporting of clinical trial outcomes, helping regulators and researchers evaluate the benefits and potential risks of investigational products.

Scope of ICH Good Clinical Practice:

1. Clinical Trial Planning:

The scope covers the development of sound and scientifically justified study protocols designed to produce reliable results while maintaining ethical conduct.

2. Informed Consent Process:

GCP outlines how informed consent must be obtained, ensuring participants fully understand the study before agreeing to take part.

3. Data Handling and Management:

Standards apply to the collection, verification, and storage of trial data to maintain its accuracy, consistency, and completeness.

4. Safety and Adverse Event Reporting:

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The guidelines describe responsibilities for monitoring participant safety and documenting any adverse events during the study.

Objectives of New Drugs and Clinical Trials Rules, 2019:

1. Enhance Participant Protection:

The rules aim to ensure maximum safety for individuals enrolled in clinical trials by mandating ethical conduct, close monitoring, and timely reporting of any adverse events.

2. Speed Up Approval Processes:

One of the main aims is to shorten the review and approval timelines for new drugs and clinical trials so that promising medical innovations can reach patients sooner.

3. Support Research and Innovation:

The framework encourages the development of new drugs by offering a clearer, more supportive regulatory system that motivates pharmaceutical research and innovation.

4. Increase Availability of New Treatments:

By simplifying regulatory steps, the rules aim to make innovative and effective therapies more accessible to patients in need.

Scope of the New Drugs and Clinical Trials Rules, 2019:

1. Oversight of Clinical Trial Procedures:

These rules outline the entire process for conducting clinical trials, including planning, initiation, monitoring, and completion, ensuring scientific quality and participant safety.

2. Approval Mechanism for New Drugs:

The scope involves submission, evaluation, and regulatory decision-making for new drug applications, ensuring the products meet established safety and efficacy standards.

3. Ethics Committee Responsibilities:

The rules define the functions of ethics committees, emphasizing their role in reviewing study protocols and ensuring that trials adhere to ethical practices.

4. Compensation and Medical Care:

Clear provisions are included regarding compensation for trial-related injuries or death, along with guidelines for sponsors to offer appropriate medical care to participants.

Protocol Designing for Clinical Trials:

A clinical trial protocol is a structured document that describes how a clinical study will be carried out. It ensures participant safety and guarantees that the results generated are scientifically valid.

Key Elements of a Clinical Trial Protocol:

Background: Explains the scientific reasoning and need for the study. Objectives: States the goals the trial intends to achieve.

Study Design: Describes the type of study and overall plan for conducting it. Methodology: Covers detailed procedures, measurements, and observational methods. Typical Components of a Clinical Trial Protocol:

1. Title Page
2. Signature Page
3. Table of Contents
4. List of Abbreviations
5. Introduction / Summary
6. Study Objectives

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7. Background Information
8. Participant Eligibility Criteria
9. Study Design
10. Safety Measures

Process for Clinical Trial Application (CTA):

A Clinical Trial Application (CTA) is a regulatory submission prepared for the health authority of a specific country when a sponsor intends to conduct a clinical study using an investigational medicinal product (IMP) or an approved drug being evaluated for a new indication.

To receive approval to begin the trial, the sponsor must file a complete CTA package that meets the documentation requirements and regulatory standards of the respective health authority.

Since each country has its own regulatory framework, the format, documentation, and safety reporting procedures for CTA submissions differ from one jurisdiction to another.

CONCEPT OF PHARMACOVIGILANCE:

Definition, Objective, types & components of pharmacovigilance:

A. Definition:

Pharmacovigilance is the field of science that focuses on the ongoing evaluation of medicine safety. It involves systematically identifying, reviewing, interpreting, and reducing adverse effects or any other issues linked to the use of drugs, starting from their testing in clinical trials and continuing throughout their use in the general population.

B) Objectives:

1) Patient safety
2) ADR detection
3) Risk assessment
4) Public health
5) Communication
6) Regulatory compliance

C. Types of Pharmacovigilance:

There are six important methods in Pharmacovigilance such as,

1. Passive surveillance
a. Spontaneous reports
b. Case series
2. Stimulated reporting
3. Active surveillance
a. Sentinel sites
b. Drug event monitoring
c. Registries
4. Comparative observational studies
a. Cross-sectional study
b. Case-control study
c. Co-hort study
5. Targeted clinical investigations
6. Descriptive studies

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a. Natural history of disease
b. Drug utilization study

Constitution and Objectives of the Pharmacovigilance Programme of India (PvPI):

The Pharmacovigilance Programme of India (PvPI) was set up to create a strong national system for monitoring medicine safety. Its main purpose is to identify and evaluate adverse drug reactions (ADRs) in the Indian population and ensure that medicines used in the country remain safe and effective.

Objectives of PvPI:

To systematically track and document adverse drug reactions across India.
To encourage and educate healthcare workers about the importance of reporting ADRs. To review and maintain the overall benefit–risk balance of medicines used by patients.
To prepare unbiased, evidence-supported recommendations regarding the safety of medicines.
To assist the Central Drugs Standard Control Organisation (CDSCO) in making regulatory decisions related to drug safety.
To share safety findings with healthcare professionals, policymakers, patients, and other stakeholders.
To develop a national centre capable of meeting global standards in drug safety monitoring and research.

National Adverse Drug Reaction Monitoring Centres (AMCs):

1. Department of Pharmacology, Therapeutics & Toxicology, Government Medical College, Bakshi Nagar, Jammu
2. Department of Pharmacology, PGIMER, Chandigarh
3. Department of Pharmacology, R.G. Kar Medical College, Kolkata
4. Department of Pharmacology, Lady Hardinge Medical College, New Delhi
5. Department of Clinical Pharmacology, Seth G.S. Medical College & KEM Hospital, Parel, Mumbai
6. Department of Clinical & Experimental Pharmacology, School of Tropical Medicine, Chittaranjan Avenue, Kolkata
7. Department of Pharmacology, JIPMER, Puducherry
8. Department of Clinical Pharmacy, JSS Medical College Hospital, Karnataka
9. Department of Pharmacology, Medical College, Guwahati, Assam

International Conference on Harmonization ICH E2E Guidelines:

Non-Clinical Safety Information:

In this part of the safety specification, any non-clinical findings that are not fully addressed or supported by clinical trial data should be highlighted. These may include:
Results from toxicity studies such as repeated-dose toxicity, reproductive and developmental toxicity, kidney and liver toxicity, genotoxicity, or carcinogenicity.
General pharmacology effects, including cardiovascular risks (e.g., QT prolongation), effects on the nervous system, or other organ systems.
Information on possible drug–drug interactions identified during laboratory or animal testing. Any additional toxicity-related findings that could influence the safe use of the medicine.
If the medicine is expected to be used in special patient groups (e.g., children, pregnant women, elderly), the need for specific non-clinical data should also be considered.
Clinical Safety Information:

a) Limitations of the Human Safety Database:

Any gaps or weaknesses in the clinical safety data should be clearly described. These may include:
A limited number of participants in clinical trials.
Strict inclusion or exclusion criteria that prevent full understanding of safety in the general population.

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Lack of adequate exposure data for certain patient groups.
The global experience with the medicine should also be summarised briefly, including: The extent of its worldwide use.
Any newly observed safety concerns.
Safety-related regulatory decisions taken by authorities.

b) Populations Not Adequately Studied Before Approval:

The safety specification should outline which groups of patients have little or no clinical trial data—such as pregnant women, elderly patients, children, or those with specific diseases.
It should also explain what these gaps mean for predicting how safe the medicine will be once it is widely used.
Identification and Evaluation of Risks Including Drug–Drug and Drug–Food Interactions:
Interactions occur when a drug's action is altered by another drug, a type of food, a drink, or other substances. These interactions often disturb how a medicine works by blocking or competing for receptor binding sites. This may lead to unexpected or harmful effects.
For example, taking alcohol along with zolpidem (a sedative) can overstimulate GABA-related pathways, causing severe drowsiness or loss of consciousness.
As the number of medications increases, the likelihood of harmful drug interactions also rises. Many older adults take multiple medicines daily, placing them at greater risk.
Types of Drug Interactions:
Drug–Drug Interaction: When two prescription medicines, or a prescription and a non- prescription product, affect each other's action.
Drug–Food Interaction: When foods or nutrients interfere with the effect of a medication. Drug–Alcohol Interaction: When alcoholic beverages modify the action of a drug.
Drug–Disease Interaction: When a medical condition alters the safety or efficacy of a drug. Drug–Laboratory Interaction: When a drug affects laboratory test results.
Design and Conduct of Observational Studies:
Well-planned observational studies (non-experimental research) play an important role in pharmacovigilance. In these studies, the investigator simply observes treatment outcomes in routine clinical practice without influencing the therapy.
Before starting an observational study under a Pharmacovigilance Plan, a detailed study protocol must be prepared. Experts in fields such as pharmacovigilance, pharmacoepidemiology, and statistics should be consulted.
It is advisable to discuss the study protocol with regulatory authorities in advance. Any criteria for early termination of the study should also be agreed upon beforehand.
After completing the study, a final report—and interim reports when needed—should be submitted according to the timelines defined in the Pharmacovigilance Plan.
A protocol should include, at minimum: Study purpose and objectives Methodology
Data collection plan Analysis strategy

SELECTION OF DRUG CLASS:

Class: Antidiabetics Subclass : Sulfonylureas

I. Mechanism of action:

1. Sulfonylureas administered
2. Attach to sulfonylurea receptors located on pancreatic β-cells
3. Block ATP-sensitive potassium (K^+) channels, reducing potassium efflux
4. Depolarization of the β-cell membrane occurs
5. Voltage-gated calcium (Ca^{2+}) channels open
6. Influx of Ca^{2+} into the cell increases
7. Exocytosis of insulin granules is triggered

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8. A greater amount of insulin is released into the bloodstream

II. Pharmacological Effects:

1) Stimulation of Insulin Secretion:

These drugs trigger the pancreas to release more insulin. They work by binding to ATP- dependent potassium channels on β-cells, causing the channels to close and promoting insulin release.

2) Enhancement of Insulin Activity:

Sulfonylureas help the existing insulin in the body work more effectively. This improves glucose uptake and can also reduce glucose production by the liver.

3) Improved Insulin Sensitivity:

They may increase the responsiveness of peripheral tissues—such as skeletal muscles—to insulin, which helps enhance glucose transport and storage.

III. Indications:

Sulfonylureas may be used in conditions associated with impaired glucose regulation, such as:

1. Diabetic neuropathy
2. Diabetic nephropathy
3. Polycystic ovary syndrome (PCOS)
4. Gestational diabetes (under specific clinical guidance)

IV. Adverse Effects:

Common side effects include:

1. Digestive disturbances
2. Allergic skin reactions
3. Headache and dizziness
4. Increased heart rate

V. Drug Interactions:

1) Corticosteroids:

These drugs can elevate blood glucose levels and may reduce the overall effectiveness of sulfonylureas.

2) Beta-blockers:

They may increase the risk of low blood sugar and can also mask hypoglycemia symptoms.

3) Thiazide Diuretics:

These may raise blood glucose levels, requiring more careful monitoring when used with sulfonylureas.

VI. Contraindications:

1) Allergic Reactions

Patients with known hypersensitivity to sulfonylureas or sulfonamide-containing drugs should avoid them.

2) Type 1 Diabetes:

These medications do not work in type 1 diabetes, where insulin therapy is essential.

3) Diabetic Ketoacidosis (DKA):

Sulfonylureas are not effective in treating DKA; insulin is required for management.

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Classification of sulfonylureas:

SELECTION OF DRUG: GLIMEPIRIDE

Background:

Glimepiride is an oral medication used in the management of type 2 diabetes and is classified as a sulfonylurea. The compound was first patented in 1979 and later gained approval from the U.S. FDA in 1995. It is widely sold under the brand name Amaryl, although several generic formulations are also available. The drug helps control blood sugar levels in individuals whose pancreatic function is still partially active.

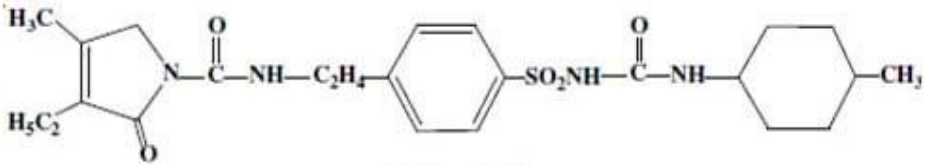
Pharmacodynamics:

Glimepiride works by enhancing the body's ability to regulate glucose. It promotes the release of insulin from pancreatic β-cells and also improves how peripheral tissues respond to circulating insulin. These combined effects contribute to reducing elevated blood glucose concentrations in patients with type 2 diabetes.

Mechanism of Action:

The glucose-lowering effect of glimepiride is primarily due to its action on ATP-sensitive potassium (K^+ATP) channels in pancreatic β-cells. By binding to these channels, glimepiride causes them to close, leading to depolarization of the cell membrane. This triggers the opening of voltage-dependent calcium channels, allowing calcium ions to enter the cell. The rise in intracellular calcium stimulates the release of insulin. Beyond promoting insulin secretion, the drug may also enhance insulin sensitivity in peripheral tissues, further aiding in glucose regulation.

Structure:



Glimepiride

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IDENTIFICATION OF ADVERSE EFFECTS OF GLIMEPIRIDE:

Glimepiride can produce several adverse effects, some of which may be serious. The following reactions have been associated with its use:

1. Severe allergic responses – These may include anaphylaxis, swelling of the deeper layers of the skin (angioedema), and rare but life-threatening skin conditions such as Stevens–Johnson syndrome.
2. Hemolytic anemia – Destruction of red blood cells can occur in individuals regardless of whether they have a G6PD deficiency.
3. Liver-related adverse events – Cases of cholestasis, jaundice, and drug-induced hepatitis have been reported, and if severe, these may progress to acute liver failure.
4. Skin and photosensitivity issues – Reactions such as porphyria cutanea tarda, sensitivity to sunlight, and immune-mediated skin inflammation (allergic vasculitis) may develop.
5. Hematologic abnormalities – Reductions in different blood cell types may occur, including leukopenia, agranulocytosis, aplastic anemia, and pancytopenia.
6. Low platelet counts – Thrombocytopenia, including severe forms with platelet levels dropping below 10,000/mcL, and thrombocytopenic purpura have been noted.
7. Other metabolic and cutaneous reactions – Episodes of hepatic porphyria and reactions resembling those seen with disulfiram have also been reported in some patients.

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ADR MONITORING FORM:

SUSPECTED ADVERSE DRUG REACTION REPORTING FORM

INDIAN PHARMACOPOEIA COMMISSION
(National Coordination Centre-Pharmacovigilance Programme of India)
Ministry of Health & Family Welfare
Government of India
Sector-23, Raj Nagar, Ghaziabad-201002
www.ipc.nic.in

(AMC/ NCC Use only)
AMC Report No.
Worldwide Unique

A. PATIENT INFORMATION

1. Patient Initials _____
2. Age at time of Event or date of birth _____
3. Sex ☐ M ☐ F
4. Weight ___ Kgs

12. Relevant tests / laboratory data with dates

B. SUSPECTED ADVERSE REACTION

5. Date of reaction started (dd/mm/yyyy)
6. Date of recovery (dd/mm/yyyy)
7. Describe reaction or problem

13. Other relevant history including pre-existing medical conditions (e.g. allergies, race, pregnancy, smoking, alcohol use, hepatic/ renal dysfunction etc)

14. Seriousness of the reaction
- ☐ Death (dd/mm/yyyy)
- ☐ Life threatening
- ☐ Hospitalization/prolonged
- ☐ Disability
- ☐ Congenital anomaly
- ☐ Required intervention to prevent permanent impairment / damage
- ☐ Other (specify)

15. Outcomes
- ☐ Fatal
- ☐ Continuing
- ☐ Recovering
- ☐ Recovered
- ☐ Unknown
- ☐ Other (specify)

C. SUSPECTED MEDICATION(S)

S.No	8. Name (brand and /or generic name)	Manufacturer (if known)	Batch No./ Lot No. (if known)	Exp. Date (if known)	Dose used	Route used	Frequency	Therapy dates (if known, give duration) Date started	Date stopped	Reason for use of prescribed for
i.										
ii.										
iii.										
iv.										

S.No As per C	9. Reaction abated after drug stopped or dose reduced					10. Reaction reappeared after reintroduction				
	Yes	No	Unknown	NA	Reduced dose	Yes	No	Unknown	NA	If reintroduced dose
i.										
ii.										
iii.										
iv.										

11. Concomitant medical product including self medication and herbal remedies with therapy dates (exclude those used to treat reaction)

D. REPORTER (see confidentiality section on first page)

16. Name and Professional Address : _____
Pin code: _____ E-mail _____
Tel. No. (with STD code): _____
Occupation _____ Signature _____

17. Causality Assessment

18. Date of this report (dd/mm/yyyy)

HOSPITAL VISIT:

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Interaction With Physicians and Nurses for Identifying Unreported ADRs

To detect adverse drug reactions (ADRs) that may not have been formally documented— particularly for widely used drugs such as NSAIDs (e.g., ibuprofen)—direct engagement with healthcare staff is essential. Discussions with physicians, nurses, and pharmacists can provide practical insights into real-world drug safety concerns.

Step 1: Preparing for the Interaction

Identifying Participants

Physicians: Include general doctors and relevant specialists such as cardiologists, gastroenterologists, and nephrologists who frequently encounter drug-related complications.

Nurses: Focus on nurses working in patient-care areas like ICUs, surgical wards, and medical units where ADRs are commonly noticed.

Pharmacists (Optional): Pharmacists who review medication charts and monitor patient therapy can add valuable safety information.

Step 2: Interviews and Survey Activities

1. Key Questions for Structured Interviews General Awareness of ADRs:

Have you come across any unexpected or unusual effects in patients taking ibuprofen or other NSAIDs?

Are there any reactions that you think remain underreported in routine practice? Patient-Specific Experiences:

Can you recall any cases in which an ADR was observed but not officially recorded?

How was the reaction handled (e.g., dose reduction, stopping the medicine, supportive treatment)?

Organ-Related Reactions:

Have you encountered rare renal, hepatic, cardiovascular, or neurological issues linked to ibuprofen/NSAIDs?

Do patients report symptoms that are not commonly documented in standard drug monographs? Barriers to ADR Reporting:

What obstacles make it difficult to report ADRs? (e.g., insufficient time, lack of clarity about reporting systems, limited motivation)

What improvements would make ADR reporting easier and more effective within the hospital?

Step 3: Approaches for Collecting Data

1. Face-to-Face Conversations: Conduct interviews directly in hospital wards, outpatient departments, intensive care units, or pharmacy areas.

2. Digital Surveys: Use tools such as Google Forms or online questionnaires to collect responses from a broader group of healthcare professionals.

3. Focused Group Sessions: Organize small group meetings where multiple practitioners can discuss trends and share their experiences with ADRs.

4. Anonymous Reporting Options: Provide a confidential drop-box or form that allows staff to report suspected ADRs without concern of blame or consequences.

PATIENTE INTERVIEW:

Patient interviews are a key method for recognizing and documenting adverse drug reactions (ADRs), particularly those that may go unreported in regular clinical settings. The following framework provides a structured approach for conducting these interviews.

1. Ethical Guidelines

Obtain informed consent from the patient before starting the interview. Maintain strict confidentiality of all personal and health-related information.

Clarify that participation is voluntary and will not affect the patient's ongoing treatment.

2. Patient Interview Procedure

A. Personal Information Name (Optional): Age:

Gender: ☐ Male ☐ Female ☐ Other Weight: kg

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Medical History: (e.g., chronic conditions, allergies) Current Medications and Supplements:
B. Details of Medication Use Medication Name and Dosage: Duration of Use:
☐ Less than 1 week
☐ 1–4 weeks
☐ More than 1 month
Other Medications Taken Concurrently: ☐ Yes ☐ No If yes, specify:
C. Adverse Drug Reactions
Have you experienced any new symptoms since starting this medication? ☐ Yes ☐ No If yes, please select the symptoms experienced:
☐ Nausea or vomiting
☐ Stomach pain or ulcers
☐ Headache or dizziness
☐ Skin rash or itching
☐ Swelling (face, hands, or legs) When did the symptoms appear?
☐ Immediately after taking the medication
☐ Within a few hours
☐ After several days
Action Taken: Did you stop taking the medication? ☐ Yes ☐ No If yes, did the symptoms improve? ☐ Yes ☐ No
If no, did the symptoms worsen? ☐ Yes ☐ No
D. Effect on Daily Life
Did the ADR interfere with your daily activities?
☐ Slightly
☐ Moderately
☐ Severely (unable to perform routine tasks)
Did you seek advice from a healthcare professional regarding this reaction? ☐ Yes ☐ No If yes, what guidance were you given?
Have you had similar reactions to other medications in the past? ☐ Yes ☐ No

II. CONCLUSION

Pharmacovigilance is essential for ensuring medication safety by continuously monitoring and evaluating adverse drug reactions. Strong reporting mechanisms and vigilant oversight help identify potential risks, protecting both patients and public health. As the field of medicine advances, evolving pharmacovigilance practices are vital to maintaining the balance between drug effectiveness and safety. By systematically analyzing adverse effects, healthcare professionals and regulatory authorities can enhance patient care and refine therapeutic strategies. Although challenges like underreporting and inconsistent data remain, strengthening global pharmacovigilance systems is crucial. Collaboration between healthcare providers, regulatory agencies, and the pharmaceutical industry is key to creating a proactive and reliable framework for drug safety.

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