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BEST PRACTICES FOR IMPROVING THE QUALITY OF INDIVIDUAL CASE SAFETY REPORTS IN PHARMACOVIGILANCE

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ABSTRACT
Pharmacovigilance is an important and integral part of clinical research. Pharmacovigilance is "defined as the pharmacological science relating to the detection, assessment, understanding and prevention of adverse effects, particularly long term and short-term adverse effects of medicines. This addresses what exactly is pharmacovigilance. What do we know of its benefits and risks, challenges and the future hold for pharmacovigilance in Indian medicine. Here the main focus on the aims and role of pharmacovigilance in medicines regulation and their Partners.

KEYWORDS: *Pharmacovigilance, Components of Pharmacovigilance, Objectives of Pharmacovigilance, Types of Pharmacovigilance*

INTRODUCTIONS

Pharmacovigilance is an important and integral part of clinical research. Both clinical trials safety and post marketing pharmacovigilance are critical throughoutthe product lifecycle. Pharmacovigilance is "defined as the pharmacological science relating to the detection, assessment, understanding and prevention of adverse effects, particularly long term and short-term adverse effects of medicines." Pharmacovigilance is still in its infancy in India and there exists verylimited knowledge about the discipline.

DEFINITION OF CLINICAL TRIAL

A clinical trial is a research study conducted to evaluate the safety and efficacy ofa new medical intervention, such as a drug, device, or treatment, in human participants. It is a systematic and controlled investigation designed to answer specific questions about the intervention's effects on human health outcomes.

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PHASES OF CLINICAL TRIALS

Clinical trials are typically conducted in four phases, each with a specific purposeand goal:

Phase 1

- First-in-human trials
- Small group of healthy volunteers (20-100)
- Assess safety, tolerability, and pharmacokinetics (how the body processes thedrug)
- Typically lasts several months

Phase 2

- Small-scale trials (100-300 participants)
- Evaluate efficacy and further assess safety
- Identify optimal dosage and administration
- Typically lasts 1-2 years

Phase 3

- Large-scale trials (300-3,000 participants)
- Confirm efficacy and monitor adverse reactions
- Compare new intervention to existing treatments or placebo
- Typically lasts 1-3 years

Phase 4

- Post-marketing surveillance
- Monitor long-term effects and rare side effects
- Gather data on real-world use and outcomes
- Ongoing after the interventionis approved for use.

THE FUNCTION OF DRUGS CONTROLLER

The Drugs Controller General of India (DCGI) is the head of the Central DrugsStandard Control Organization (CDSCO), which is the regulatory body responsible for ensuring the safety, efficacy, and quality of drugs, cosmetics, and medical devices in India.

The key functions of the DCGI include

1. Licensing: Issuing licenses for manufacturing, import, and sale of drugs,cosmetics, and medical devices.
2. Approval: Approving new drugs, clinical trials, and fixed-dose combinations.
3. Regulation: Regulating the standards of drugs, cosmetics, and medical devices.
4. Inspection: Conducting inspections of manufacturing facilities, laboratories,and clinical trial sites.
5. Vigilance: Monitoring adverse drug reactions and taking action to ensurepatient safety.
6. Policy-making: Developing and implementing policies for drug regulation.
7. Coordination: Collaborating with state drug authorities, internationalregulatory agencies, and other stakeholders.
8. Certification: Issuing certificates of compliance with regulatory requirements.
9. Information dissemination: Providing information to healthcare professionals,patients, and the public about drug safety and efficacy

OBJECTIVE OF ICH GOOD CLINICAL PRACTICE (GCP)

The primary objective of ICH GCP is to ensure the safety, rights, and well-beingof participants in clinical trials, while also ensuring the credibility and accuracy of the data collected.

SCOPE OF ICH GCP

The scope of ICH GCP includes

1. Design and conduct of clinical trials
2. Protection of human subjects (participants)
3. Collection and analysis of data
4. Quality assurance and quality control
5. Roles and responsibilities of sponsors, investigators, and monitors
6. Informed consent processes
7. Safety reporting and adverse event management

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8. Data management and record-keeping
9. Monitoring and auditing of clinical trials
10. Compliance with regulatory requirem

ICH GCP guidelines apply to all aspects of clinical trials, from planning to completion, and are intended to be followed by:

- Sponsors
- Investigators
- Monitors
- Institutional Review Boards (IRBs)
- Ethics Committees (ECs)
- Regulatory authorities

SCOPE OF PHARMACOVIGILANCE

The scope of pharmacovigilance is broad and encompasses various activities to ensure the safe use of medicines. Some of the key areas within the scope of pharmacovigilance include:

1. Adverse Drug Reaction (ADR) monitoring: Identifying, collecting, and analyzing reports of adverse reactions to medicines.
2. Signal detection: Identifying potential safety issues or "signals" from ADR data.
3. Risk assessment: Evaluating the potential risks and benefits of medicines.
4. Risk management: Implementing strategies to minimize risks associated with medicines.
5. Post-marketing surveillance: Monitoring the safety of medicines after they areapproved for use.
6. Pharmacovigilance planning: Developing plans to monitor and manage safetyissues for specific medicines
7. Regulatory compliance: Ensuring compliance with regulatory requirements forpharmacovigilance.
8. Education and training: Educating healthcare professionals, patients, and othersabout pharmacovigilance and safe use of medicines.
9. Research and development: Conducting studies to improve understanding ofsafety issues and develop new methods for pharmacovigilance.
10. International collaboration: Collaborating with global partners to shareknowledge and best practices in pharmacovigilance.

DEFINITION OF PHARMACOVIGILANCE

Pharmacovigilance is the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other possible drug-related problems.

OBJECTIVES OF PHARMACOVIGILANCE

The main objectives of pharmacovigilance are to

1. Enhance patient safety: Identify and minimize risks associated with medicationuse Improve public health: Contribute to the protection of public health by
2. ensuring the safe use of medicines.
3. Support regulatory decision-making:Provide data and insights for informed regulatory decisions
4. Promote rational use of medicines: Encourage the appropriate use ofmedicines, reducing misuse and overuse.
5. Detect and prevent adverse reactions: Identify and mitigate risks associatedwith medication use.
6. Monitor and manage risk: Continuously monitor and manage risksthroughout a product's lifecycle.
7. Educate and inform: Share knowledge and insights with healthcareprofessionals, patients, and the general public

TYPES OF PHARMACOVIGILANCE

1.Spontaneous Reporting: Voluntary reporting of adverse drug reactions(ADRs) by healthcare professionals and patients.
2.Active Surveillance: Systematic collection of data on ADRs throughtargeted studies and surveys.
3.Passive Surveillance: Collection of ADR data through literature reviews,database searches, and other indirect sources

COMPONENTS OF PHARMACOVIGILANCE

1. Adverse Event (AE) Detection: Identifying potential safety issues.
2. Signal Detection: Analysing data to identify patterns or "signals" indicatingpotential safety concerns.
3. Risk Assessment: Evaluating the potential risks and benefits of a medication.
4. Risk Management: Implementing strategies to minimize risks associated witha medication.
5. Pharmacovigilance Planning: Developing plans to monitor and manage safetyissues for specific medications.
6. Data Management: Collecting, storing, and analyzing pharmacovigilancedata.
7. Regulatory Compliance: Ensuring compliance with regulatory requirementsfor pharmacovigilance.
8. Communication: Sharing safety information with healthcare professionals,patients, and regulatory authorities.

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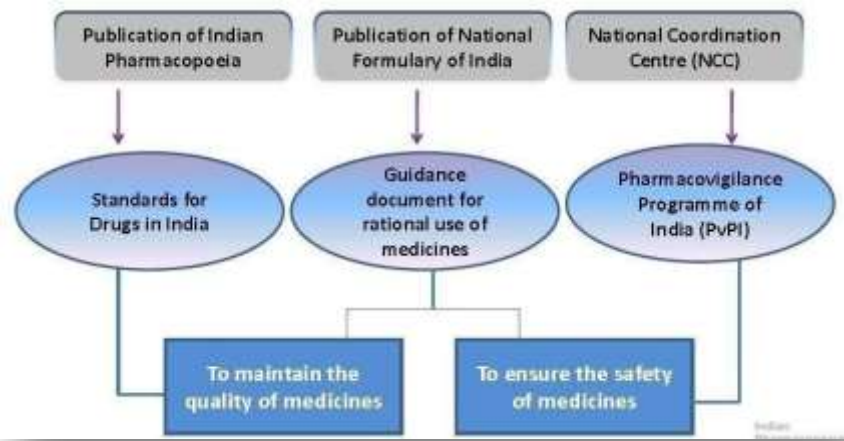
9. Education and Training: Educating healthcare professionals and patients aboutpharmacovigilance and safe medication use.



CONSTITUTION OF PHARMACOVIGILANCEPROGRAMME OF INDIA (PVPI)

The PvPI was launched in 2010 by the Indian government to monitor and ensurethe safety of medicines in India. The program is:

1. Managed by the National Coordination Centre (NCC) at the IndianPharmacopoeia Commission (IPC).
2. Supported by a network of Peripheral Centres (PCs) at various medicalinstitutions across India.
3. Guided by an Expert Advisory Committee (EAC).

NATIONAL ADVERSE DRUG MONITORING CENTRES ININDIA, ALONG WITH THEIR FUNCTIONS:

1. Indian Pharmacopoeia Commission (IPC), Ghaziabad
   - National Coordination Centre (NCC) for PvPI
   - Oversees and coordinates adverse drug reaction (ADR) monitoring
   - Develops and implements PvPI policies

2. National Centre for Pharmacovigilance, New Delhi
   - Monitors and analyzes ADR data
   - Identifies safety signals and trends
   - Provides safety recommendations to regulatory authorities

3. Adverse Drug Reaction Monitoring Centre (ADRMC), Mumbai
   - Collects and processes ADR reports from Western India
   - Analyzes and disseminates safety information

CLINICAL SAFETY SPECIFICATIONS

1. Adverse Event (AE) Reporting: Collection and analysis of AE data fromclinical trials.
2. Serious Adverse Event (SAE) Reporting: Collection and analysis of SAE datafrom clinical trials.
3. Adverse Drug Reaction (ADR) Monitoring: Ongoing monitoring of ADRsduring clinical trials.
4. Dose-Response Relationship: Study of the relationship between drug dose andefficacy/safety.
5. Clinical Pharmacokinetics: Study of drug absorption, distribution, metabolism,and excretion in humans.
6. Clinical Pharmacodynamics: Study of drug effects on human physiology andbiochemistry.
7. Special Populations: Study of drug safety in specific populations (e.g.,paediatrics, geriatrics, renal/hepatic impairment).
8. Drug-Drug Interactions: Study of potential interactions between the drug andother medications.
9. Clinical Trials: Conducting clinical trials to assess drug safety and efficacy.

DESIGN OF OBSERVATIONAL STUDIES

1. Cohort Study: Follows a group of individuals over time to examine outcomes.
2. Case-Control Study: Compares individuals with a specific outcome to thosewithout.
3. Cross-Sectional Study: Examines a population at a single point in time.
4. Ecological Study: Examines the relationship between exposure and outcome ata population level.

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AIMS OF PHARMACOVIGILANCE

1. Identify previously unrecognized adverse effects or changes in the patterns ofadverse effects
2. Assess the risks and benefits of medicines in order to determine what action, ifany, is necessary to improve their safe use
3. Provide information to healthcare professionals and patients to optimize safeand effective use of medicines
4. To improve patient care and safety in relation to the use of medicines and allmedical and paramedical interventions.
5. To improve public health and safety in relation to the use of medicines.
6. To detect problems related to the use of medicines and communicate thefindings in a timely manner.
7. To encourage the safe, rational and more effective (including cost effective) useof medicines.

Promotion of Rational Use of Medicines

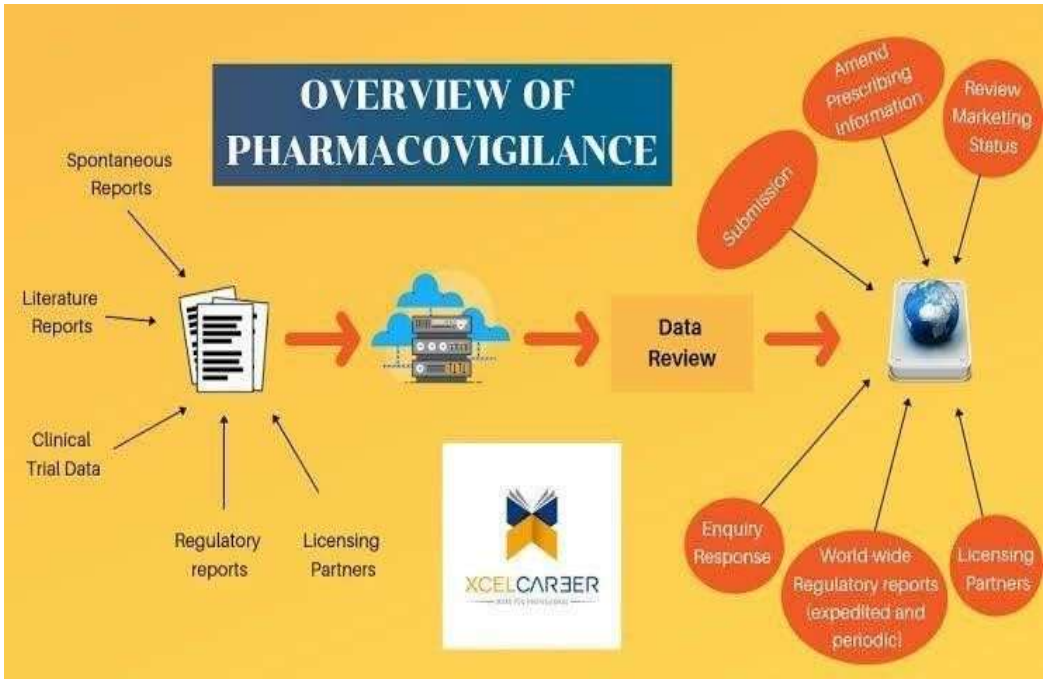
1. Education of healthcare professionals on drug safety
2. Promotion of evidence-based prescribing practices
3. Support for patient education and empowerment

ECONOMIC BENEFITS

1. Reduction of healthcare costs associated with ADRs
2. Minimization of litigation costs related to drug safety
3. Optimization of resource allocation for healthcareDuring the pre-marketing phase,

PRE-MARKETING SURVEILLANCE

Pharmacovigilance (PV) focuses on anticipating or evaluating possible AdverseDrug Reactions (ADRs) at an early stage of drug development. One important method is to conduct preclinical in vitro Safety Pharmacology Profiling (SPP), which involves evaluating the safety features of compounds by testing them in biochemical and cellular assays. The idea is that if a substance attaches to a specific target, it might lead to adverse drug reactions (ADRs) in humans. However, identifying ADRs through experiments is difficult and costly. Researchers are actively working on computer-based methods to forecast potential ADRs by analysing preclinical properties of compounds or screening data. Researchers predominantly explore two main approaches in their studies: one focuses on identifying specific protein targets, while the other revolves around analysing chemical structures. Additionally, some investigations delve into a holistic approach that combines both strategies for a more comprehensive understanding.



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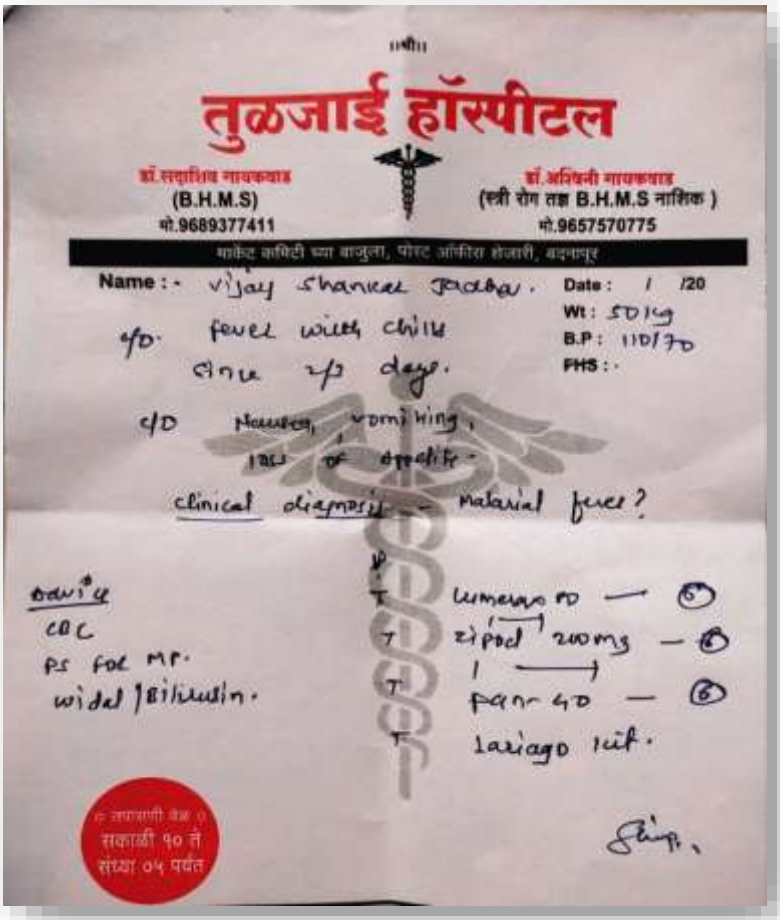
POST MARKETING SURVEILLANCE

Even with thorough screening before FDA approval, some adverse drug reactions (ADRs) might be overlooked due to limitations in premarketing trials, which are often small, brief, and may exclude patients with other health conditions. These trials may not accurately reflect real world clinical situations, especially for diverse populations. Post-market surveillance, facilitated by Pharmacovigilance (PV), becomes crucial forongoing analysis and monitoring of newly approved drugs in diverse settings, helping identify and addressing unforeseen adverse effects that might arise during actual clinical use.The competitive landscape among pharmaceutical companies, coupled with stringent regulatory evaluations, underscores the intricate research and development journey preceding the introduction of a new drug. Various distinctive data sources play a crucial role in post-marketing pharmacovigilance. PV research focuses on examining "signals," which the WorldHealth Organization defines as unrevealed statements suggesting direct connections between theimpact of a drug on the human body and the likelihood of causing adverse events .

HOSPITAL VISIT

- Hospital Name – Tulajai Hospital
- Doctor Name – Dr.Sadashiv Gaikwad (B.H.M.S)
- Adress- Near By Market Committee,Side Of Post Office,Badnapur
- Patient Name –Vijay Jadhav
- Disease-Malaria Fevar



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INTERVIEW

1. Doctor: Good morning. What brings you in today?
   Patient: Good morning, doctor. I've been having a high fever for the past few days, along with chills and sweating. I think it might be malaria.
2. Doctor: I see. When did the fever start?
   Patient: It started about four days ago. It usually comes in the evening and is followed by severe chills and then heavy sweating.
3. Doctor: Have you noticed any other symptoms?
   Patient: Yes, I've had headaches, muscle pain, nausea, and I feel very weak and tired all the time.
4. Doctor: Have you traveled recently or stayed in an area where malaria is common?
   Patient: Yes, I visited a village last week, and there were a lot of mosquitoes there.
5. Doctor: Did you take any preventive medication for malaria before traveling?
   Patient: No, I didn't.
6. Doctor: Have you experienced malaria before?
   Patient: No, this is the first time I'm having these kinds of symptoms.
7. Doctor: Alright. Based on your symptoms and travel history, malaria is a possibility. I'll order a blood test called a peripheral smear or a rapid diagnostic test to confirm it. Once we have the results, we can start treatment.
   Patient: Okay, doctor. Thank you.

Malaria Fever - Patient Disease History

Presenting Complaints

High-grade fever with chills and rigors
Sweating, particularly after fever subsides
Headache
Body aches and fatigue
Nausea and/or vomiting
Dizziness
Possible jaundice or dark urine (in severe cases)

History of Present Illness

Onset: Fever started [X] days ago
Pattern: Intermittent/Continuous fever with paroxysms (typical of Plasmodium vivax or P. falciparum)
Progression: Symptoms intensified over [X] days
Associated symptoms: [e.g., cough, abdominal pain, diarrhea]
Prior treatment: Self-medication / OTC antipyretics taken (if any)

Past Medical History

Previous episodes of malaria (Yes/No; if yes, specify year and treatment)
Any chronic diseases: Diabetes, Hypertension, Tuberculosis, etc.
Any history of blood transfusion or travel to endemic areas Any known drug allergies.

Investigations

Peripheral blood smear: Presence of malarial parasites (P. falciparum / P. vivax)
Rapid Diagnostic Test (RDT): Positive/Negative
Complete Blood Count (CBC): Anemia, thrombocytopenia common
Liver and renal function tests: (if complications suspected)

Treatment Given

Antimalarials:
Artemisinin-based combination therapy (ACT)
Chloroquine (if applicable)
Primaquine (for liver stage of P. vivax)
Supportive treatment:
Antipyretics (paracetamol)
IV fluids
Antiemetics, antacids

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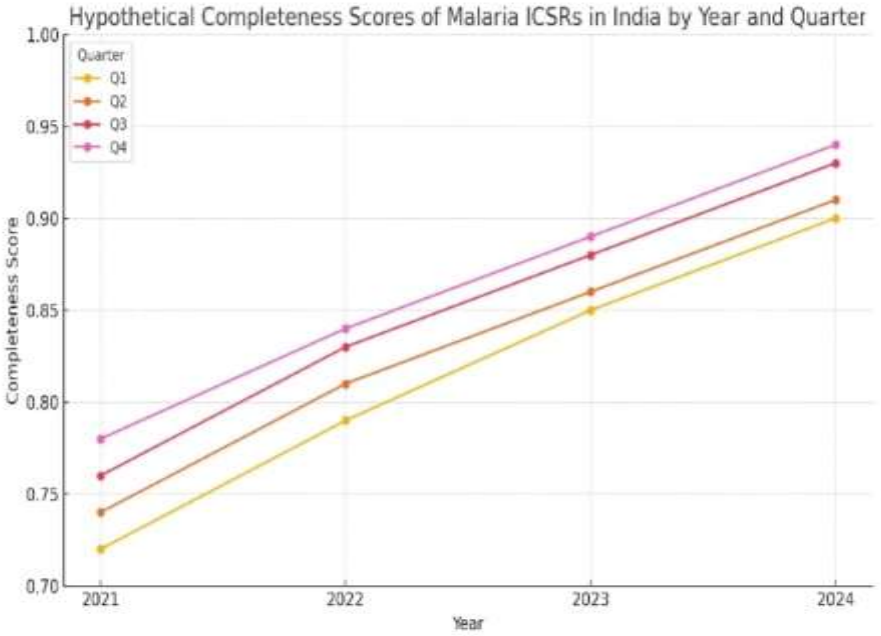
Blood transfusion (if severe anemia)
Outcome / Progress
IV fluids
Antiemetics, antacids
Blood transfusion (if severe anemia)
Symptom improvement within [X] days
Fever subsided after [X] hours of treatment
Discharged / Referred / Admitted for observation
Follow-up advised after [X] days



- Completeness scores of Indian individual case safety reports by year and quarter.

CONCLUSION

Medication surveillance plays a vital function in securing drug protection bysystematically monitoring, assessing, and preventing adverse effects. Its primary objectives include detecting, assessing, and understanding risks associated with pharmaceutical products. Various types of monitoring drug system, such asspontaneous documenting and signal detection, contribute to a comprehensive safety profile. The components of Pharmacovigilance encompass data collection,analysis, risk communication, and regulatory 、 oversight. Overall, an effective Pharmacovigilance system is essential for safeguarding public health andpromoting the responsible use of medications. Pharmacovigilance involves thesystematic monitoring and analysis of information related to the identification,evaluation, comprehension, and avoidance of adverse effects and other issuesassociated with medications. Its objectives include ensuring patient safety,improving medication use, and minimizing risks associated with pharmaceuticalproducts. Pharmacovigilance encompasses various types, such as spontaneousreporting, intensive monitoring, and targeted surveillance. Its components involve data collection, signal detection, risk assessment, risk communication, and risk management, all crucialfor maintaining the integrity of the pharmaceutical market and safeguarding public health.

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