**PHARMACOVIGILIANCE OF HERBAL & TRADITIONAL SYSTEM**

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**The important purpose of Pharmacovigilance programme are:**

**Detecting Adverse Drug Reactions (ADRs)**: Pharmacovigilance aims to identify and monitor adverse drug reactions or side effects associated with medications. This helps in understanding the safety profile of drugs in real-world patient populations.

**Assessing Drug Safety**: By collecting and analyzing data on ADRs, pharmacovigilance programs help assess the safety of drugs on the market. This information is crucial for healthcare professionals and regulatory agencies to make informed decisions about drug use.

**Risk Assessment and Management**: Pharmacovigilance contributes to risk assessment by evaluating the severity and frequency of ADRs. It also helps in devising risk minimization strategies and safety measures for certain drugs.

**Signal Detection**: Pharmacovigilance programs use statistical methods and data mining techniques to detect potential safety signals that may indicate previously unknown risks associated with a drug. This early detection can lead to further investigation.

**Regulatory Compliance**: Regulatory agencies such as the FDA and EMA require pharmaceutical companies to have pharmacovigilance systems in place to ensure compliance with safety reporting requirements. This helps maintain public trust in the regulatory process.

**Public Health Protection**: Ultimately, pharmacovigilance programs aim to protect public health by ensuring that the benefits of a medication outweigh its risks. If a serious safety concern arises, regulatory actions such as label updates, restrictions, or withdrawals may be implemented to safeguard patients.

**Data Collection for Decision-Making**: Pharmacovigilance data is valuable for making decisions related to drug approvals, labeling updates, and post-marketing surveillance. It provides evidence-based information for healthcare providers and policymakers.

**Quality Improvement**: Analyzing ADR reports can reveal patterns and trends that may suggest areas for improvement in drug manufacturing, labeling, or prescription guidelines.

**The major and well known limitation of spontaneous reporting are :**

**Lack of Awareness**: Healthcare providers and patients may not be fully aware of the importance of reporting ADRs or how to do so.

**Perceived Causality**: Sometimes, individuals may not report ADRs if they believe there is not enough evidence to establish a causal relationship between the drug and the adverse event.

**Fear of Consequences**: Healthcare professionals may fear legal or professional repercussions if they report ADRs, especially if they were involved in prescribing or administering the drug.

**Complexity of Reporting**: Reporting ADRs can be a cumbersome process, involving paperwork and sometimes detailed information. This complexity can deter reporting.

**Time Constraints**: Healthcare providers are often busy, and reporting ADRs can be time-consuming. They may prioritize other clinical tasks over reporting.

**Voluntary Nature**: Spontaneous ADR reporting is voluntary in many countries, which means there is no legal requirement to report. This lack of mandatory reporting can lead to underreporting.

**Lack of Feedback**: In some cases, reporters may not receive feedback on the outcome of their reports, which can reduce their motivation to continue reporting.

**Limited Resources**: Pharmacovigilance systems may have limited resources to actively collect and analyze ADR reports, which can result in a backlog of unprocessed reports.

Addressing the issue of underreporting is critical for improving pharmacovigilance and patient safety. Efforts to enhance reporting systems, raise awareness, simplify reporting procedures, and provide feedback to reporters can help mitigate this limitation. Additionally, incorporating technology and artificial intelligence into ADR detection and reporting processes can assist in identifying potential ADRs more efficiently.

**The system of managing a healthy lifestyle & the treatment**

The traditional system of medicine (TSM) includes Ayurveda, Siddha, Homeopathy,Unani, Yoga, and Naturopathy. Ayurveda has been practiced worldwide.

**Traditional system follow**

**Traditional system of**

**medicines**

**Ayurveda**

**Siddha**

**Naturopathy**

**Yoga**

**Homeopathy**

**Unani**

Herbs are used commonly in Ayurveda and it is an ancient system of a healthy lifestyle in India by following natural ways.

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**Natural remedies for the treatment of infectious and non-infectious disorders**

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**Preparation and formulation of herbal medicine**

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**Scope of Pharmacovigilance**

Interaction of medicines

Adverse drug reaction reaction

Lack of efficacy

Medication error

Substandard medicines

Pharmacovigilance

Abuse misuse of medicines

Pharmacovigilance covers not only the conventional medicines but beyond these. These include herbal medicine other complementary product, biological product, vaccines,& possible medical devices.

**Product covered by Pharmacovigilance**

MEDICINES

Traditional & complementary

Herbals

Biological

Blood product

Medical devices

Vaccines

**What is to be monitored?**

Adverse reactions.

Medication error.

Case reports of acute and chronic poisoning (toxicity).

Abuse and misuse of medicines.

Adverse interactions of medicines with chemicals, other medicines and food.

**Pharmacovigilance system**

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**What information should be in the report?**

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**Patient information:**

Identification of the patient/consumer with appropriate confidentiality needs to be provided in order to avoid duplications and to facilitate follow-up.

Age, sex and a brief medical history.

Risk factors,e.g. age, impaired renal function, previous exposure to the herbal medicine(s) concerned, previous allergies, drug misuse or abuse.

**Product information:**

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**Adverse drug reaction/adverse events information**:

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**Reporter information:** Name and address (to be considered confidential and to be used only for data verification, completion and case follow-up)

**What does PV centre do after receiving the report?**

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**Communication network of Pharmacovigilance (PV)**

MASS MEDIA

CONSUMERS/PATIENTS

NATIONAL REGULATORY AUTHORITY

OTHER

**NATIONAL PHARMACOVIGILANCES CENTRE**

MANUFACTUR

**Why is it challenging to do pharmacovigilance for traditional medicine products?**

**Complexity of herbal product**:

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**Difference in product regulation** on categorizations of herbal/traditional medicine.For instance, a herbal product in one country can be classified as a dietary/food supplement in another without any health claim.

**Insufficient information and lack of access to reliable information** support such as product name, part use, etc., for analyzing the products concerned.

**Botanical nomenclature:** The nomenclature of crude plants is not consistent. In many texts the names are in Latin, consisting of two parts, one related to the scientific name and the other indicating the plant part, e.g. digitalis folium. Misleading and inconsistent names are commonly used.

**Safety monitoring:** Many health-care providers are not trained on safety monitoring of medicines including traditional medicine(Pharmacovigilance methods),which results in underreporting or zero report.

**How can Pharmacovigilance for herbal and traditional medicine be improved?**

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List of the unapproved Ayurvedic medicinal products found on the Canadian market thus far, which have been analyzed by Health Canada and found to contain high levels of lead, mercury, and arsenic, are as follows:

* Karela tablets, produced by Shriji Herbal Products, India
* Karela capsules, produced by Himalaya Drug, India
* Karela capsules, produced by Charantia, UK (specifically batch #12011)
* Maha Sudarshan Churna powder, produced by Zandu Pharmaceuticals, Mumbai, India
* Maha Sudarshan Churna powder, D and K Pharmacy, Bhavnagar, India
* Maha Sudarshan Churna powder, produced by Chhatrisha, Lalpur, India
* Maha Sudarshan Churna powder, produced by Dabur India, New Delhi, India
* Safi liquid, produced by Hamdard-WAKF-Pakistan
* Safi liquid, produced by Hamdard-WAKF-India
* Yograj Guggul tablets, produced by Zandu Pharmaceuticals, Mumbai, India
* Sudarshan tablets, produced by Zandu Pharmaceuticals, Mumbai, India
* Shilajit capsules, produced by Dabur India, New Delhi, India