

Integrative Pharmacovigilance: Monitoring Adverse Effects in Herbal, Nutraceutical, and Conventional Therapies

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Abstract

Herbal teas, plant-based powders, and nutraceutical supplements are now common parts of modern treatment plans. You can find these products in most pharmacies, and they are often advertised on wellness websites, which is why so many people use them with regular medications. Even though these products are becoming more popular, many of them are not covered by strict pharmaceutical rules. Because of this, there are big holes in the records and knowledge of their possible negative effects. Patients may be at risk for unexpected health problems because there is not enough government oversight. This is especially true when these supplements are taken without a doctor's advice. To deal with this problem, it is very important to improve post-market surveillance by using integrated pharmacovigilance systems. It is also important to encourage patients and healthcare providers to talk openly about using these kinds of products. These steps can work together to make safety monitoring stronger, lower the number of avoidable bad outcomes, and raise public awareness of the risks that come with using complementary therapies that aren't regulated or used correctly.

Keywords: Integrative Pharmacovigilance, Herbal medicine safety, Nutrivigilance, Adversedrug reactions (ADRs)

Introduction to Integrative Pharmacovigilance.

Pharmacovigilance has become a very important part of the pharmaceutical industry over the past 20 years. At first, it was only about drug safety, but its focus has grown to include drug development, regulatory science, and patient protection. The main job of pharmacovigilance is to find, assess, and stop bad effects or other drug-related problems as soon as a product hits the market. This duty now includes not only traditional drugs but also complementary and alternative therapies. There is an urgent need to expand safety monitoring frameworks to include herbal medicines and nutraceutical products, which are becoming more popular but don't always have strict regulatory oversight. Integrative pharmacovigilance tries to fill this gap by combining regular pharmacovigilance with special monitoring of these therapies that aren't well regulated. This strategy also promotes cooperation with global health organizations and the use of real-world data in safety evaluations to improve patient safety.[1]

It is more important than ever to guarantee the safety of all therapeutic modalities, whether conventional or alternative, in a time when medical technologies are developing quickly and patient preferences are changing.[21]

A greater range of pharmacovigilance activities has extended to the following core Activities:

- Prioritizes patient safety during clinical trials via ensuring adherence to knowledgeable authorization and the Ethical Review Board.
- There is Participation in surveillance activities through a set of signal management processes; the production specialist helps in keeping an eye on the manufactured product through cooperative endeavors.[1]

- Integrative pharmacovigilance is done by integrating the data of new medical technologies and also by collaborating with large organizations in the world, which are international organizations. It also focuses on the safety of patients by offering clinical trials.

INTRODUCTION TO HERBAL DRUGS.

Herbal medicine is the support system of secondary or alternative medicines, which recently have gained interest in this new era of medical healthcare systems. This surge in herbal medicines is because of their claimed innocuousness, high effectiveness in defined diseases, and formulation that is not as complicated as synthetic modern drugs. An indication of the Traditional Herbal medicines is that they are divergent from the allopathic medicines. The diseases comprise many simple health conditions, which include colds, pain, and topical wounds, and also serious conditions such as psychosis, diabetes, malaria, sickle cell disease, tuberculosis, cancer, hypertension, infertility, and many more.[4]

In the world wide, many of countries establish the traditional medicine for general use without any compulsory safety measures or drug testing. There is even a lack effective testing to regulate production methods and guidelines in many countries. These herbal products are continuously being provided to The consumers are consistently supplied with these herbal products with nonprescriptions from medical professionals, which relates to many adverse health conditions. So we need to look forward toward the safety of the herbal drugs for future use.[7]

INTRODUCTION TO NUTRACEUTICALS AND CONVENTIONAL THERAPIES.

Newly developed medications that combine the advantages of pharmaceuticals and nutrients are known as nutraceuticals. These medications, such as specific vitamins, minerals, and herbs that have health benefits and are taken as drug doses, are taken out of food and transformed into a medicine form.

- Omega-3 fatty acids are good for heart and skin health;
- Probiotics help to maintain gut health; and
- Antioxidants guard against cell damage and oxidative stress.

The only problem with nutraceutical medications is that they are tested using different methods than contemporary new medications, which increases the likelihood that some safety and efficacy concerns will go unnoticed.

The most important factor for any drug is its purity.

Testing and a small number of clinically based tests are occasionally disregarded due to their low economic benefits.

Since it treats illnesses, mental disorders, and some chronic diseases, conventional therapy has become increasingly important in the modern era. Professional healthcare uses a variety of therapies, including physical therapy, medication, and physiotherapy, to treat this condition. Drugs are the mainstay of this conventional therapy, but occasionally they can also have negative side effects. For example, some conventional medications can cause allergic reactions, nausea, or even emotional distress. Negative effects can occasionally result from inadequate therapeutic activity. To avoid any patent conditions, this must be tested with certainty.[1]

This article provides insights about integrative pharmacovigilance with monitoring the adverse event in herbal, nutraceutical, and conventional therapies.

CONVENTIONAL MEDICINE: REGULATED SYSTEMS AND STRUCTURED PHARMACOVIGILANCE.

Most health professionals use conventional treatment or therapy in medical professions. Examples of conventional treatment used in

- In many brain disorders, psychiatrists and psychologists use conventional therapies.
- They provide patients with rapid relief from the symptoms of certain disease
- Conveniently used therapies help in blocking or stopping the further spread of diseases in the body.
- These therapies are available widely to everyone, and they are stable economically for every patient.

Adverse Drug Reactions (ADRs) Due to Conventional Therapy

ADRs are the unwanted side effects that are experienced by the patient after taking drugs. Conventional therapies are being used for many health conditions. But with that, it leads to certain side effects like allergic reactions, loss

of blood cells as in radiation therapy and chemotherapy, and emotional instability while dealing with such treatments. We cannot ignore that it is affecting the patient's health condition when getting treated.

Pharmacovigilance helps to test and analyze records of all cases in the market or in the health field. They study patient history and their condition while taking conventional therapy and which drugs they are taking as a secondary treatment source. They also help regulatory compliance of data, helping the high bodies for decision-making to make sure that the used therapy with other complementary medicines in certain diseases or disorders is not giving a negative impact to the patient's body. Conventional therapies that use drugs are continuously evaluated by pharmacovigilance even after approval for public safety and knowing the efficacy of the drug. Used herbal medicine is the support system of secondary or alternative medicines, which recently have gained interest in this new era of medical healthcare systems. This surge in herbal medicines is because of their claimed non-toxic, high effectiveness in defined diseases, and formulation that is not as complicated as synthetic modern drugs. This comprises simple health conditions such as colds, pain, and surface wounds to serious conditions such as psychosis, diabetes, malaria, sickle cell disease, tuberculosis, cancer, hypertension, infertility, and many more.[9]

HERBAL THERAPIES: VARIABILITY, UNDERREPORTING, LACK OF STANDARDIZATION.

Pharmacovigilance in herbal medicine is defined as the study done to ensure safety, to detect, and to understand the problems related to the herbal drugs that are marketed under practical conditions in clinical usage.[20]

Herbal products from different cultures

Table 1:- Wal, P., Wal, A., Gupta, S., Sharma, G., & Rai, A. (2011). Pharmacovigilance of herbal products in India. *Journal of Young Pharmacists*, 3(3), 256–258. <https://doi.org/10.4103/0975-1483.83>

Type of herbal medication	Natural sources	Origins
Ayurvedic	P, A, M	India
Chinese	P, A, M	China
Indusynunic	P, A, M	Pakistan
Islamic	P, A, M	Middle East
Aromatherapy	P	European
Herbalism	P	European
Homeopathy	P	European
Botanicals	P	European

P: Medicinal plants; M: Minerals; A: Animal sources [20]

Herbal medicine and its formulations are pivotal in treating various diseases, including many disorders of the liver and also disorders of memory, and more, worldwide. A prevalent misconception of these medicines is that they can be taken in use without any medical prescription and also that are absolutely safe. Nevertheless, numerous reports in the literature have highlighted the adverse drug reactions associated with these medicines. In conclusion, this chapter addresses the current challenges and future outlook of herbal pharmacovigilance.[2]

3.1.1 Pharmacovigilance of Herbal Formulations:

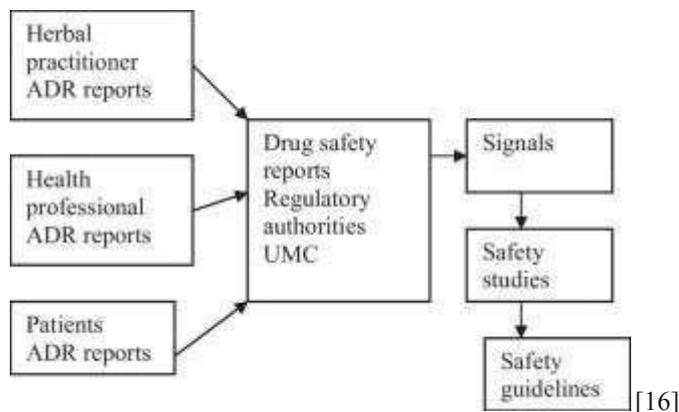
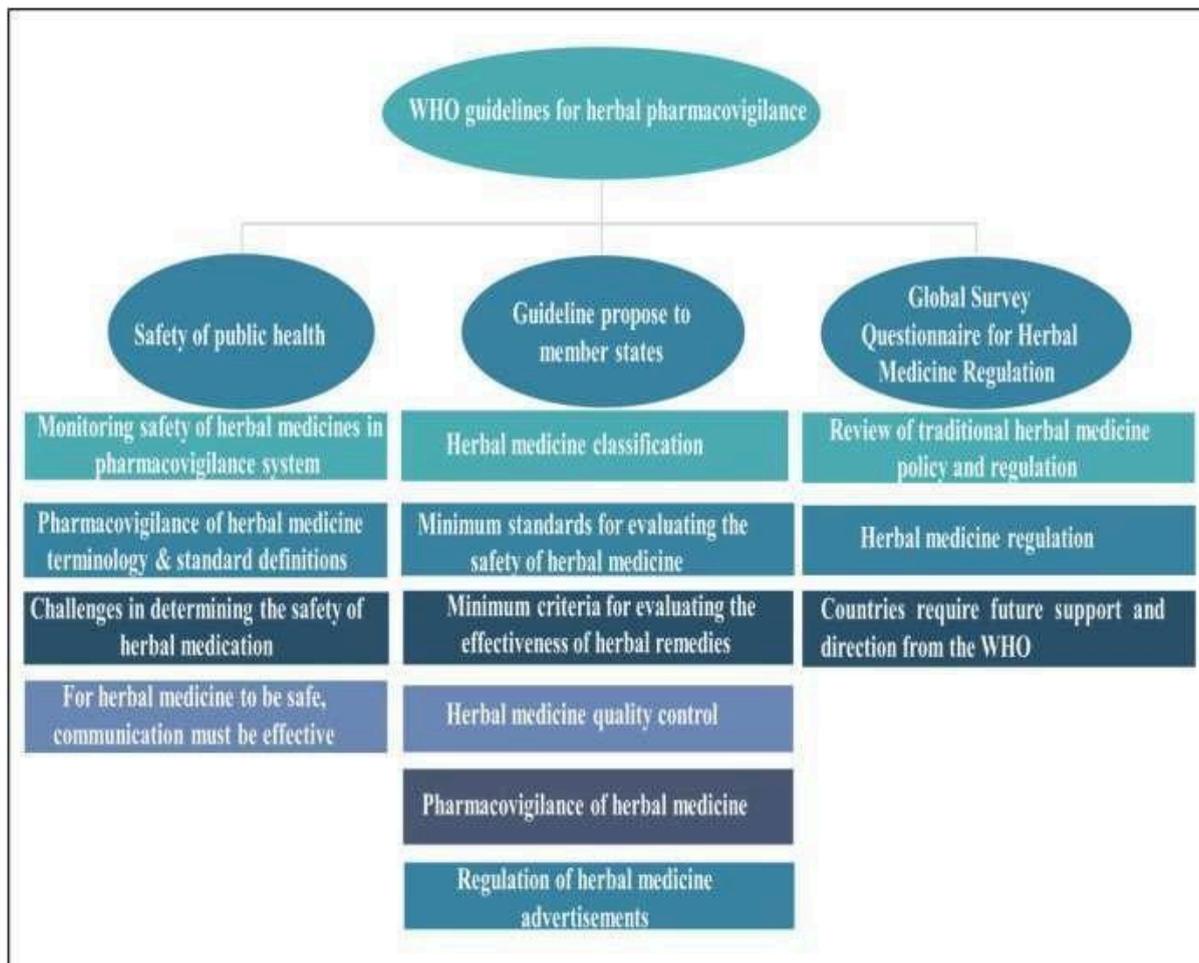


Fig 1:- Shaw, D., Ladds, G., Duez, P., Williamson, E., & Chan, K. (2012). Pharmacovigilance of herbal medicine. *Journal of Ethnopharmacology*, 140(3), 513–518. <https://doi.org/10.1016/j.jep.2012.01.051>

The notion that "nature is a true healer and safer" is illusory because certain plants or herbs known for their therapeutic properties are inherently toxic in their crude form. Hence, they required specific processing to neutralize their toxic compounds before consumption. Like all other medicines, drugs, and supplements of botanical origin could also be associated with particular side effects that may be linked to various issues, mainly substandard product quality or inappropriate use. Other associated factors include scanty regulatory measures, ungoverned distribution channels (i.e., via e-commerce routes), and inadequate quality control systems. Moreover, the negative incidents associated with the substandard quality of products include the adulteration or replacement of phytomedicine with unmarked component and powerful drug substances, such as corticosteroids and NSAIDs.[18]

WHO Guidelines for Herbal Pharmacovigilance:



[9]

Fig 2:- Hassen, G., Belete, G., Carrera, K. G., Iriowen, R. O., Araya, H., Alemu, T., ... Jain, N. (2022). Clinical implications of herbal supplements in conventional medical practice: A US perspective. *Cureus*, 14(7), e26893. <https://doi.org/10.7759/cureus.26893>

1.1.1 How can pharmacovigilance for traditional medicine be improved?

Networking should involve manufacturers, pharmacies (including pharmacists), consumers, and healthcare facilities (such as traditional medicine practitioners). The safety of drugs and herbal medicines all depends upon the pharmacovigilance throughout the whole cycle of product life. For instance, the regulatory framework should create a thorough pharmacovigilance system for gathering safety data both before and after marketing authorization. Furthermore, pharmacovigilance should be part of the good pharmacy practices in community pharmacies. It is vital to promote the use of modern technology and its advancement through information technology resources and mobile application tools. Continuous training programs should be promoted to improve national capacity for assessing the safety of traditional medicine products and to increase awareness. To foster a culture of ADR reporting, it is recommended to commence professional training for healthcare students at an early stage. The use of herbal materials should comply with national quality standards and criteria, including GMP, labeling, and licensing protocols for production, importation, and marketing, which cover selection, sampling, testing of plant materials, and stability studies.[6]

Future Strategies.

The following strategies should be considered:

1. By assessing this data, regulatory agencies will be better able to weigh the advantages and disadvantages of these medications and take the appropriate steps to improve their safe use.
2. Traditional Herbal Registration holders should provide succinct synopses and a critical evaluation of the product's risk-benefit ratio, taking into account newly available or developing information.
3. Research on the pharmacogenetics and pharmacoepidemiology of herbal medicines should be undertaken. Offering financial incentives and research grants will encourage learning about traditional herbal medicine.
4. A national herbal medicine safety monitoring program should be set up, with the capacity and willingness to react to signals resulting from reports of negative effects linked to herbal medicines and to carry out the necessary regulatory actions.
5. To strengthen the role of complementary and alternative medicine providers, the sources for case reporting should be expanded to include all practitioners of traditional medicine.
6. Herbal medicine producers should also be involved, consumer reporting should be encouraged, and information-sharing mechanisms involving drug information centres, poison centres, consumer groups, and manufacturers should be established. Strengthening awareness and communication at all levels—global, regional, national, local, and community—is crucial.
7. To guarantee the successful implementation of the pharmacovigilance system, it is essential to track the results of any actions taken regarding the reporting of Adverse Drug Reactions (ADRs). To keep an eye on safety issues, manufacturers, regulatory agencies, the World Health Organisation (WHO), and the Central Drugs Standard Control Organisation (CDSCO) can work together.[3]

DARK SIDE OF BOTANICALS.

Since our forefathers' era, botanicals have been deployed as the first line of treatment to avert several existing or newly emerging diseases and improve humans' overall health. In recent years, advancements in scientific and technological aspects have paved the way to utilize bioactive compounds and their structural analogs as potential pioneering agents for drug discovery [71]. Beyond that, the most prevalent herb toxicity has been caused by herb-herb/herb-drug interactions. Therefore, it is always advised not to combine pharmaceutical drugs with herbal medicine, as both may exhibit the same pharmacological activity and may eventually cause serious health complications. Nevertheless, as per the current situation, health risks due to herb toxicity require special consideration to protect public health. [17]

Scarce human clinical trials, ambiguous regulatory measures, marketing of unstandardized herbal products, and weak pharmacovigilance systems of herbs/supplements/formulations are perhaps new thrust areas where further research is needed.[17]

NUTRACEUTICALS: GREY ZONE BETWEEN FOOD AND DRUGS, SELF-MEDICATION RISKS.

"Nutraceutical" is a word merge of "nutrition," meaning the process of intaking and utilizing the food for nourishment, and "pharmaceutical," meaning medicinal drugs. It is a marketing term also known as 'functional foods.' They not only have nutritive benefits like energy, proteins, minerals, etc., but also many health benefits.[11]

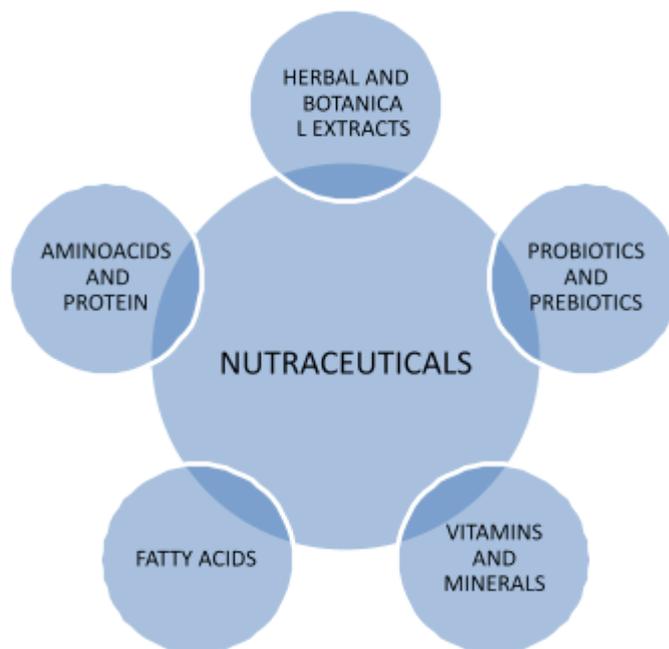


Fig 3:- Luthra, V. R., & Toklu, H. Z. (2023). Nutrivigilance: The road less traveled. *Frontiers in Pharmacology*, 14, 1274810. <https://doi.org/10.3389/fphar.2023.1274810>

CONCEPT AND IMPORTANCE OF NUTRIVIGILANCE.

Nutrivigilance was described as “ the learning for assessment, detection and preventing the detrimental effects associated to use of any kind of healthful food and other medical field” in the 2014 article. In the US, Europe, India, and many other countries there has been surge of interest in nutrivigilance due to rapid expansion in product availability claiming to improve health outcomes and offer wellness advantages. The leading explanation behind nutrivigilance is that the substance should be assessed for efficacy and safety before it reaches the consumer—whether the substance is applied topically or ingested. Compounds from fruits and vegetables are the main source from which nutraceuticals are derived. Catechins from tea, resveratrol from red grapes, polyphenols and flavanols from dark chocolate, and anthocyanins from berries are flavonoid plant pigments that are widely used as nutraceuticals.[11]

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ADVERSE EFFECTS OF SPECIFIC NUTRACEUTICALS.

Metabolites of epigallocatechin gallate present in green tea extract, which is responsible for antioxidant properties in green tea, are responsible for liver injury and suspected to enhance oxidative properties. The most comprehensively studied functional flavonoids are the soy-derived isoflavones genistein and daidzein. Compared to other flavonoids, purified isoflavones have been shown to act like estrogen in lab studies. They have the ability to produce uterine hypertrophy, reduce testes size, endometriosis, and stimulate estrogen-dependent tumors.[14]

NEED FOR RESEARCH AND DEVELOPMENT .

The role of research and development plays a significant part in nutraceuticals. The principal requirement of research in this field relates to the standardization of products and implementing clinical trials to ensure the nutritional and therapeutic claims. There is growing interest by the market forces in nutraceuticals mainly because

MARKET DEMAND AND BUYER NEEDS:

There are many people leaning towards natural ways of healing and improving their health and managing conditions like chronic diseases. This encourages companies to develop new nutraceutical products.

HEALTH LITERACY:

Growing health consciousness is driving demand for nutraceuticals. Consumers seek products that support a healthy lifestyle as they become aware of the impact of diet and exercise on lifelong health.

DEMAND FOR VERIFIED PRODUCTS:

The growing interest in this field is fueled by the need to ensure products' safety, purity, and reliability for the consumers.

NEED TO DEVELOP METHODS FOR VERIFYING THE DOSAGE.

Inaccurate dosing leads to possible health risks and also reduces the efficiency and effectiveness. Therefore, the main purpose of this is to guarantee the safety of the consumer by doing precise administration of dose. This is the reason why companies are keen to invest in advanced technologies to measure the content of ingredients and concentration of active compounds in supplements.

The FDA (Food and Drug Administration) governs and manages them in the same way they regulate all food products. Safety assurance of ingredients is essential and must be assured in advance, and the claims must be true with no misleading facts.

- The regulatory authorities globally keep on changing and updating their laws according to the consumer requirements, but in India certain cumbersome laws still exist, like
- Prevention of Food Adulteration Act, 1954.
- Standards of Weights and Measures Act, 1976.
- Edible Oils Packaging (Regulations) Order, 1998.

Before launching the products in India, licenses for manufacturing, marketing, and other state and national licenses are required.[15]

1.2 POLYPHARMACY AND INTERACTIONS:

Herb-drug interaction[13]

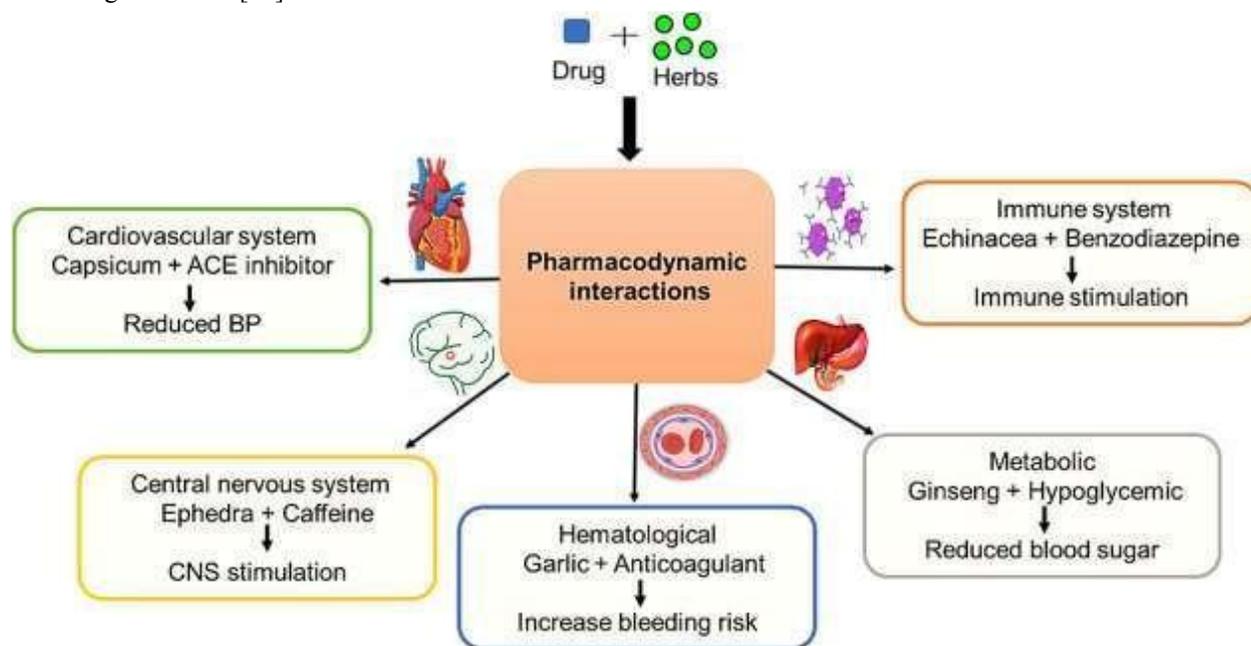


Fig 4:- Polaka, S., Chaudhari, S., Tekade, M., Sharma, M. C., Malviya, N., Malviya, S., & Tekade, R. K. (2022). Chapter 13: Clinical importance of herb–drug interaction. In R. K. Tekade (Ed.), *Pharmacokinetics and toxicokinetic considerations* (Vol. 2, pp. 323–356). Academic Press

Existing Pharmacovigilance Systems And Gaps In Post- Marketing Surveillance In India.

As of now in India, there are no guidelines for post-marketing surveillance events for nutraceuticals. A systematic step-by-step process used to identify risks for nutraceutical supplements is critically needed, one that incorporates their diverse product classes and subclasses. A structured framework would help both the FSSAI and the food industry in determining on threats in the product.

Role of pharmacovigilance in monitoring adverse drug reactions (ADRs) from nutraceuticals: There is an immediate need for enhanced pharmacovigilance in this sector with the increasing occurrence of ADR involved with the unreasonable use of nutraceuticals. In response to this, the programme concluding Pharmacovigilance that is PvPI has encouraged all investors, including manufacturers and consumers, to make use of ADR reporting mechanisms designed by the Indian Pharmacopoeia Commission (IPC). Indian Council of Medical Research-National Institute of Nutrition (ICMR-NIN), Hyderabad, is one of the PvPI coordinating centers for monitoring and overseeing the safety of nutraceuticals.[10]

CASE STUDY: NEUROTOXICITY FOLLOWING CO-ADMINISTRATION OF ST. JOHN’S WORT AND PAROXETINE

Background mechanism of action.

Hypericum is an extract of the flower of St. John’s Wort (*Hypericum perforatum* L.) that has been used for the treatment of depression for times.

St. John’s Wort contains natural chemicals like hypericin, pseudohypericin, and flavonoids such as quercetin and rutin, which are believed to have antidepressant properties.

Hypericin is considered to be a major bioactive substance of the extract that helps in inhibiting serotonin receptor

activity. It also inhibits the production of interleukins (IL-1 β and IL-6), which in turn reduces the release of corticotropin-releasing hormone (CRH), which leads to less ACTH and less cortisol being produced, and thus it dampens the brain's stress response system. It blocks the reabsorption of neurotransmitters like dopamine, serotonin, and norepinephrine, hence enhancing their availability.[12]

Case Study.

This case highlights the importance of managing transitions between herbal and pharmaceutical antidepressants. For the last 8 months, a 50 year old female with chronic depression and asthma was taking paroxetine 40 mg/day. She was presented with sudden-onset lethargy, incoherence, and grogginess. 10 days prior to this incident, she stopped taking paroxetine 40 mg/day on her own and began self-medicating with St. John's Wort 600 mg/day in pulverized form as a natural alternative. The night before the symptoms arose, she took a 20 mg dose of paroxetine as she was experiencing insomnia. The very next day she was found to be extremely nauseous, weak, and nearly bedridden. On being examined, her vitals were normal except for slow motor response and limp muscle tone. Laboratory tests, including CBC, were unremarkable. The MMSE test was normal. The condition resolved, and no further drug therapy was needed once the offending agents were withdrawn and she was sent back home. She recovered within two days after that.[8]

Discussion

This case is a classic example of pharmacodynamic interaction between paroxetine and SJW leading to excessive serotonin in the brain—serotonin syndrome. In this case the patient had a milder sedative neurotoxic response. This was a preventable adverse drug reaction (ADR).

1. It reflects real-world pharmacovigilance failure:
2. Individuals ingest herbal medicines without seeking professional guidance.
3. Lack of communication between physician and patient.
4. Patient being misinformed.
5. Established drug safety protocols often exclude herbal substances from routine monitoring.

Hence, there should be an integration of herb-drug safety warnings into electronic prescribing systems. Physicians should routinely ask patients about their additional herbal intake and educate them on the serious interaction risks.

STRATEGIES FOR IMPROVING INTEGRATIVE PHARMACOVIGILANCE

Many strategies are used to address the problems faced in integrative pharmacovigilance

HARMONIZATION OF REGULATORY DEFINITIONS

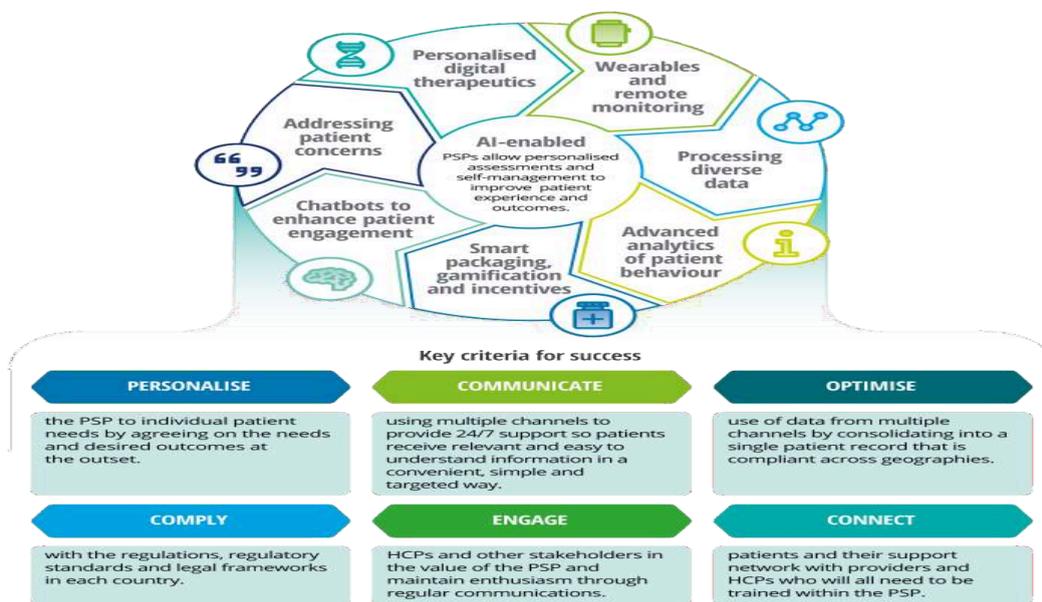
Every nation in the world has its own framework for regulation in the field of vigilance. These types of frameworks basically contain ideas and thoughts, however. The below-mentioned frameworks include cooperation among regulatory bodies, healthcare practitioners, industry participants, and global organizations to guarantee prompt identification, evaluation, and handling

of unfavorable incidents and hazards linked to these commodities. Pharmacovigilance in medicine is defined as a study done to ensure safety, to detect and to understand the problems related to the drugs that are marketed under practical conditions in clinical usage have been assembled by the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH). In most nations, the law is required to make efforts for pharmacovigilance. Businesses in the pharmaceutical sector have the following requirements, like accumulating, examining and communicating to regulatory agencies. Pharmaceutical organizations, clients, and medical personnel may report adverse drug reactions using mechanisms set up by regulatory bodies. There is a high chance of risk being created in strategy management because they have to lower threat associated with their products. These kinds of preparations require some strategies, like observing and administering the responses which are not positive. Pharmacovigilance systems include procedures for recognizing and evaluating what are concluded to be signs of issues related to the safety of pharmaceutical products. Authority remarks, analytical techniques, and documentation may be used in this. There has been evolution, enrollment, standards, protection and efficacy in the various regions of the pharmaceutical sector due to the guidance supplied by the ICH. The main objective of this guidance is to have uniformity in regulatory standards at every corner and also to improve and facilitate by making it easier for pharmaceutical products to be established and documented internationally. Stability testing, pharmacovigilance, quality control, and clinical trials are the things which have been advocated by the ICH [22].

USE OF DIGITAL TOOLS, AI AND REAL WORLD DATA

FIGURE 6

How AI can improve patient-support programmes and the key criteria for success



Source: Anita Osborn, "10 steps to a successful patient support programme," Pharmaphorum, 25 February 2016; Deloitte analysis. Deloitte Insights | deloitte.com/insights

Fig 5:- Taylor, K., May, E., Powell, D., & Ronte, H. (2022). Intelligent post-launch patient support. In *Artificial intelligence in healthcare & pharmacovigilance*. Deloitte Insights.

CONCLUSIONS

Strong pharmacovigilance across all treatment modalities is more important than ever as patient preferences move toward natural and integrative therapies. Because of their natural origin, herbal and nutraceutical products are frequently thought to be safe; however, they can still have negative effects, particularly when taken without a doctor's supervision or in conjunction with prescription medications. These risks are frequently not adequately captured by the regulatory frameworks in place today. This problem is addressed by integrative pharmacovigilance, which combines conventional monitoring techniques with tools that can assess alternative therapies. Creating a more responsive and inclusive safety network that safeguards patients at every stage of the product lifecycle—from development to post-market use—is the aim.

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