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The safety of nutraceuticals monitoring through pharmacovigilance programme of India

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Abstract

The term "Nutraceutical" was coined by combining the terms "Nutrition" and "Pharmaceutical" in 1989 by Dr. Stephen De Felice, Chairman of the Foundation for Innovation in Medicine. "Nutraceutical" is a marketing term developed for nutritional supplement that is sold with the intent to treat or prevent diseases. Nutraceutical refers to a food having medicinal effect on human health. It consists of food supplements, herbal products, probiotics and prebiotics meant for prevention and treatment of diseases. The Pharmacovigilance Program of India (PvPI) was launched with a broad objective to safeguard the health of 1.27 billion people of India since the adverse drug Reactions (ADRs) are reported from all over the country to NCC-PvPI. The Pharmacovigilance Program of India (PvPI) also works in collaboration with the WHO Programme for International Drug Monitoring (PIDM) and contributes to the Global ADRs database. In 2017, the Pharmacovigilance Programme of India (PvPI) and Indian Pharmacopoeia Commission (IPC), Ghaziabad, India together became as a WHO Collaborating Centre. The Pharmacovigilance Programme of India encourages all healthcare professionals and consumers to report ADRs associated with nutraceuticals. The submitted ADR reports are reviewed and analyzed at NCC and finally submitted to World Health Organization - Uppsala Monitoring Centre (WHO-UMC), Sweden.

Keywords: Nutraceutical, pharmaceutical, pharmacovigilance, pharmacovigilance programme of India

Introduction

The term 'Nutraceutical' refers to a food having medicinal effect on human health. It consists of food supplements, herbal products, probiotics and prebiotics meant for prevention and treatment of diseases. Most of nutraceuticals possess multiple therapeutic effects that help in prevention of diseases (Pulipati *et al.*, 2016) [1].

The term "Nutraceutical" was coined by combining the terms "Nutrition" and "Pharmaceutical" in 1989 by Dr. Stephen DeFelice, Chairman of the Foundation for Innovation in Medicine. "Nutraceutical" is a marketing term developed for nutritional supplement that is sold with the intent to treat or prevent diseases (Dutta *et al.*, 2018) [2]. It is a "non-toxic food component that has scientifically proven for health benefits, including disease treatment or prevention".

The term nutraceutical is encompassing nutrition & pharmaceutical. These products contain carbohydrates, lipids, proteins, vitamins, minerals and other necessary nutrients. The most common type of nutraceutical products are dietary supplements. A dietary supplement is a liquid or capsule version of nutrients found in foods and is taken as an additional supplement to the daily diet (Prabu *et al.*, 2018) [3]. The functional component of food must be standardized in the nutraceutical product and produced under good manufacturing practices.

Classification of nutraceuticals

- Substances with established nutritional functions, such as vitamins, minerals, amino acids, and fatty acids–Nutrients.
- Herbs or botanical products as concentrates or extracts–Herbals.

Reagents derived from other sources (e.g., pyruvate, chondroitin sulfate, steroid hormone precursors) serving specific functions, such as sports nutrition, weight-loss supplements, fortified conventional foods and meal replacements – Dietary supplements (Srividya *et al.*, 2018) [4].

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Table 1: Benefits of different Nutraceuticals

Type of Nutraceuticals	Source	Use
Carotenoids		
Lycopene	Guava, papaya, water melon, tomatoes, pink colored grape fruit.	Reduces cholesterol levels, acts as an antioxidant, protects against cancer
β -Carotene	Vegetables, fruits, oats, carrots.	Acts as an antioxidant, protects cornea against UV light
Lutein	Spinach, corn, avocado, egg yolk	Protect eyes from age related muscular degenerations, cataracts, possess anti-cancer activity (colon)
Tocotrienol	Palm oil, different grains	Improves cardio vascular health, fight against cancer (breast cancer)
Saponins	Beans like soya beans, chickpeas	Very effective against colon cancer, reduces cholesterol levels
Polyphenolic Compounds		
Flavonones	All citrus fruits	Acts as an anti-oxidant and possess anticancer activity
Flavones	Different types of fruits, soya beans, vegetables.	Acts as an anti-oxidant and possess anti-cancer activity
Flavonols	Broccoli, tea, onions, fruits like apple	Gives antioxidant activity
Curcumin	Turmeric root	Strongest anti-inflammatory, effective anti-clotting agent, acts as an antioxidant
Glucosinolates	Cauliflower, cruciferous vegetables	Produces anticancer activity, protect against bladder cancer
Phytoestrogens		
Isoflavones	Legumes (soy bean)	Helps to lower LDL cholesterol levels, protects against prostate, breast, bowel and other cancers, acts as an antioxidant.
Lignans	Vegetables, rye, flaxseed	Protect against development of cancers like colon and breast cancer
Dietary fibre		
Soluble fibre	Beans like legumes, cereals like oats, barley, some fibrous fruits	Helps in maintenance of healthy digestive tract & have anticancer activity
Insoluble fibre	Whole grain cereals, millets, nuts	Helps in maintenance of healthy digestive tract, and have anticancer (colon) activity.
Sulphides/Thiols	Cruciferous vegetables	Helps in maintenance of healthy immune function
Fatty Acids		
Omega 3 fatty acids	Salmon fish, flax seed	Potent controllers of the inflammatory processes, helps in maintenance of brain function & reduces cholesterol disposition.
Mono unsaturated fatty acids	Tree nuts	Reduces the risk of coronary heart disease
Prebiotics/Probiotics	yogurts, other dairy and nondairy applications with Lactobacilli, bifidobacteria	Improve gastrointestinal health and systematic immunity
Minerals like zinc, calcium, selenium, copper, potassium	Foods	They are important constituents of balanced diet
Polyols or sugar alcohols (xylitol, sorbitoletc)	Foods	Reduces risk of dental caries(cavities)

Advantages of nutraceuticals

1. Reduce the side effects.
2. Increases health benefits.
3. Provide dietary supplements naturally.
4. Easily available and inexpensive.
5. Acts as a special food for populations with special needs (Eg: nutrient-dense foods for the elderly) (Kumar and Rajpo 2018) [5].

Disadvantages of nutraceuticals

1. **Bioavailability:** Nutraceuticals are being eliminated from the body and do not provide any medicinal benefit with poor bioavailability.
2. **Impact of placebo effect:** Consumers may not use nutraceuticals accurately for healing illness, when the body is often able to recover on its own.
3. **Product quality issues:** Nutraceuticals from the international market may claim to use organic ingredients, but the lack of regulation may compromise the safety and effectiveness of products.
4. **Safety and interactions with other Drugs:** The problem is that many of the nutraceutical products do not provide

consumers with proper information about the safety and effectiveness, possible side effects, interaction with prescription medicines or the effect that produce on existing medical conditions (Kumar and Rajpo 2018) [5].

Role of nutraceuticals in the present era

- Higher confidence in product quality and effectiveness.
- Improved market for nutraceutical products.
- Increased public awareness.
- Increased healthcare industry awareness.
- Establishment of a self-governing agenda
- Increase the health value of diet.
- Help to live longer.
- Help to avoid particular medical conditions.
- Have a psychological benefit from doing something for oneself.
- Be perceived to be more "natural" than traditional medicine and less likely to produce unpleasant side-effects.
- Special food for populations with special needs (e.g., nutrient-dense foods for the elderly)

Table 2: Examples of Nutraceuticals currently available in market

<p>Fortified Cereals</p>	<p>Contain Vitamins and Minerals</p>	
<p>Vitamin and Mineral Supplements</p>	<p>Vitamin A, Lycoten forte etc.</p>	
<p>Additional Supplements</p>	<p>Supplements other than vitamin and minerals which have beneficial effect on health - Cod liver oil, and Flaxseed oil (omega pure) etc.</p>	
<p>Energy Drinks</p>	<p>Calorie dense juices- Red Bull, Tropicana fruit juice, Minute maid pulp, Frooti, Real Juice etc.</p>	
<p>Protein Powder</p>	<p>Nutral-P, Nutral-D, Protein-X.</p>	

Nutraceuticals in disease prevention

Dietary factors play an important role in premature chronic disease appearance, disease progression, morbidity and mortality. Approximately 40-50% proportion in cardiovascular disorders, 35-50% proportion in cancers, and 20% proportion in osteoporosis is attributable to dietary factors. Use of food as medicine for treatment and prevention of various disorders is not a recent development. Fortification of table salt with iodine and wheat flour with iron/folic acid has been used with specific aims of prevention of iodine deficiency goiter and anemia for long. Similarly, food fortified with vitamin A has been found to be a feasible and cost-effective approach to reduce vitamin A deficiency (Dutta *et al.*, 2018) [2].

Nutraceuticals, pure medicinal form of food play an important

role in preventing the onset of different diseases and minimize the complications of the diseases. It provides protection against non-communicable diseases, delay aging process, increases life expectancy and improves function of the body (Fig 2)

Nutraceutical products are recognized as health products with benefits like alleviating risk of cancer and heart disease and also to prevent or treat hypertension, high cholesterol, excessive weight, osteoporosis, diabetes, arthritis, macular degeneration (leading to irreversible blindness), cataracts, menopausal symptoms, insomnia, diminished memory and concentration, digestive upsets, constipation and headaches; Some nutraceutical products are touted as cures for thinning hair, lack of confidence, poor complexion, varicose veins, alcoholism, depression, and lethargy (Khan *et al.*, 2016) [7].

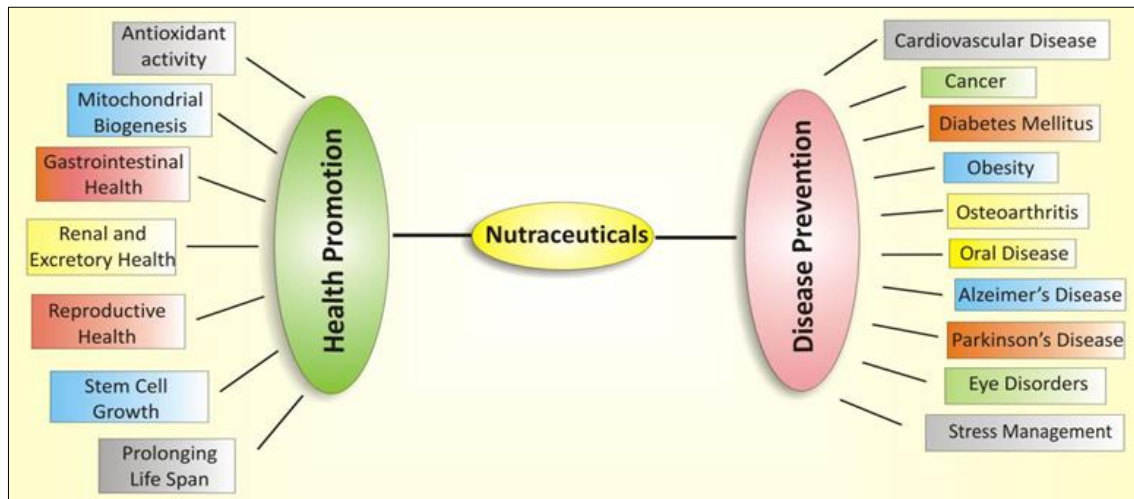


Fig 1: Nutraceuticals in health promotion and disease prevention

Role of nutraceuticals in prevention of non-communicable and communicable diseases

Cardio vascular diseases

Nutraceuticals like flavonoids, flavones, flavanones, quercetin in onion, cruciferous vegetables, black berries, cherries, berries, apples and other antioxidant vitamins and minerals may reduce the risk of death from CVDs. They inhibit cyclooxygenase pathway and angiotensin converting enzyme (ACE) which is responsible for high blood pressure. They also prevent platelet aggregation and stickiness. Flavonoid groups strengthen tiny capillaries which carry oxygen and essential nutrients to all cells. Polyphenols present in grapes alter cellular metabolism and signaling which reduces arterial diseases. A potent antioxidant in ginger is an anti-inflammatory agent is recommended for the prevention of hypertension and palpitation. Allicin lowers blood pressure and cholesterol. Omega 3 series has lipid lowering property and prescribed for the treatment of arrhythmias. CVD could be managed by the supplementation of different lipid lowering nutraceuticals along with maintenance of proper life style. Poly-herbal products could affect synergistically to achieve a potential therapeutic target.

Cancer

Nutraceutical rich bioactive dietary components have the ability to prevent cancer. Herbal nutraceuticals possess anti-mutagenic and anti-carcinogenic properties. Antioxidant activities of carotenoids, lycopene is effective for cancer. They are oxygen quencher and decreases oxidative stress. Nutraceutical controls DNA damaging factors in cells and prevents DNA transcription in tumors. Ginseng is anti-inflammatory molecule that prevents chronic inflammation of cancer. Chemo preventive components in fruits and vegetables have potential anti-carcinogenic and anti-mutagenic activities. Beta carotene from yellow and orange fruits has anti-cancer activity. Cruciferous vegetables lower the chances of colorectal and lung cancer. They block enzymes that promote tumor growth. Sulfur compounds in garlic boosts immune system, reduces atherosclerosis and platelet aggregation. Recent research further reported herbal nutraceuticals has the ability to alter metastatic spread of cancer (Geetanjli and Kaur, 2018) ^[12].

Diabetes

Herbal dietary supplements containing nutraceuticals have proven to offer therapeutic benefit on type 2 diabetes. Soy

isoflavones, omega 3 fatty acid lowers mortality and incidence of diabetes, promote insulin sensitivity, reduce glucose tolerance and bring blood sugar normal. Universal antioxidants like lipoic acid, catechins and the spices like fenugreek, cinnamon are used to treat diabetic neuropathy, nephropathy and retinopathy. Magnesium, chromium, calcium, vitamin D promotes insulin sensitivity, improve glycemic control etc. Caffeic acid reduces elevated plasma glucose in insulin resistant patients. Green tea and epicatechin 3 gallate reduces fasting and postprandial glucose and improve insulin resistance. Bitter melon, pomegranates are good for diabetes which regulates metabolism and transports glucose from the blood into cells.

Obesity

Obesity is a medical condition characterized by accumulation of excess body fat. Nutraceuticals like conjugated linoleic acid, capsaicin, psyllum have an excellent anti-obese property. Herbal nutraceuticals like chitosan, caffeine, fenugreek, vitamin C, green tea, curcumin, black gram, bottle guard reduces body weight. They secrete leptin and other cytokines like IL-1, IL-6 and help to reduce LDL and total cholesterol and regulate food intake.

Alzheimer's disease

Alzheimer's disease is also known as senile dementia. Antioxidants appear to slow down the advancement of the disease. Nutraceuticals like beta carotene, lycopene, curcumin, lutein and lavender exploits their antioxidant effects to combat oxidative stress induced neuronal damage. These compounds are able to delay the development of dementia. Several studies indicate that supplementation of vitamins like folic acid and B₁₂ reduces homocysteine levels which also avert disease progression.

Parkinson's disease

In Parkinson disease the dopamine-releasing cells in the brain damaged due to neurodegeneration. It is the second most common age-related disorder in the world. Plant polyphenols, stilbenes, isoflavones, other phytoestrogens, vitamin C, vitamin D, vitamin E, coenzyme Q and unsaturated fatty acid revealed protective roles against progression of Parkinson's disease. Herbal nutraceutical is a natural brain tonic that helps in mental peace and relaxation, migraine, headache, insomnia, depression, anxiety, brain cell rejuvenation, blood circulation in the brain, improved memory function and hormone

secretion. Researchers also used the dietary supplement inosine, a precursor to irate for slowing the progression of Parkinson's disease (Ahmad *et al.*, 2013)^[8].

Nutraceutical interlinking to pharmaceuticals

In the development process, pharmaceuticals meet a requirement to go through clinical test results from animals and human studies for verification of the therapeutic effects. But in the case of nutrition or nutraceuticals, there was no verification method for foods in preventing diseases in the

past.

Even though, nutraceuticals growing fast and well accepted by the people for natural origin. The demand for less synthetic pharmaceuticals is triggering interest and stimulation for the industry to develop and put the new products which claim beneficial health effect in the market. Nutraceuticals cannot replace pharmaceuticals, but can be a strong high value tool for prevention and aid in therapy of some pathological conditions (Bhowmik *et al.*, 2013)^[9].

Table 3: Nutraceuticals vs. Pharmaceuticals

Nutraceutical is a substance used to prevent disorders and generally referred as health products.	Pharmaceuticals is "a substance used in treatment of diseases"
They can be obtained from plant, animal and mineral sources	The term pharmaceuticals include drugs or medicaments or medications or medicines
Nutraceutical products are mainly promoted and targeted for prevention of disease or avoid future consequences of diseases	They are targeted in market segments as per different diseases, age groups, and lifestyles.
No license is needed from regulatory body for selling the nutraceutical product.	A license is needed to sale the pharmaceutical product.
No prescription is required for purchasing nutraceutical products.	Pharmaceutical products can be purchased only by prescriptions (other than OTC products).

Worldwide and Indian Regulatory aspects of Nutraceuticals

The governmental administration of food and drugs in many countries such as the United States of America, Canada, European Union, China, and India have strict regulations on food and drugs in terms of manufacturing, servicing, marketing, and usage, but not having a complete regulation. Many countries are making corresponding laws, or complementary regulations, or addressing issues with new explanations. The more detailed regulations on nutraceuticals, phytonutriton or phytotherapy, or nutritional therapy are being worked out through consultations with expert panels that can provide descriptions of regulatory hurdles for these products and practices, Good Manufacturing Practice (GMP) compliance, generally recognized as safe (GRAS) status, analytical methods and validation (Yadav *et al.*, 2015)^[15].

Nutraceuticals have no official meaning and do not constitute a distinct category of foods; simply they are natural, consumers have been eating whole foods for thousands of years. As a result, the FDA regulates them in the same way they regulate all foods: The safety of ingredients must be assured in advance, and all claims must be substantiated, truthful and no misleading (Keservani *et al.*, 2014)^[16].

The regulatory framework of nutraceuticals in India needs attention from the relevant authorities. Globally, the regulatory authorities are aware of changing needs of consumers and proactively protect consumers by amending existing laws to accommodate changes but in India old laws such as Prevention of Food adulteration Act, 1954, which regulates packaged foods, still exist for manufacturers. In addition, they need to tolerate by many other cumbersome laws such as:

- Standards of Weights and Measures Act, 1976, and the Standards of Weights and Measures
- (Packaged Commodities) Rules, 1977 (SWMA)
- Infant Milk Substitutes, Feeding bottles and infant foods (regulation of production, Supply and Distribution) Act, 1992 with Rules, 1993 (IMS)
- Edible Oils Packaging (Regulations) Order, 1998
- Fruit Products Order 1955 (FPO)
- Meat product Order 1973
- Milk and Milk Products Order 1992

- Vegetable Oils Products (Regulation) Order 1998 (VOP)
- Consumer Protection Act 1986 and the Consumer Protection (Amendment) Act, 2002 and Rules 1987
- Environment Protection Act, 1986 and Rules 1986
- Agricultural Produce (Grading and Marking) Act, 1937 (as amended up to 1986) and 49
- General Grading and Marking Rules 1986 and 1988 (AGMark)
- Bureau of Indian Standards (BIS) Act 1986

Pharmacovigilance Programme

Pharmacovigilance (PV) was officially introduced in December 1961 with the publication of a letter (case report) in the Lancet by W. McBride, the Australian doctor who first suspected a causal link between serious fetal deformities (phocomelia) and thalidomide, a drug used during pregnancy: Thalidomide was used as an antiemetic and sedative agent in pregnant women. In 1968, the World Health Organization (WHO) promoted the "Programme for International Drug Monitoring", a pilot project aimed to centralize world data on adverse drug reactions (ADRs) (Lihite and Lahkar, 2015)^[17]. In particular, the main aim of the "WHO Programme" was to identify the earliest possible PV signals. The term PV was proposed in the mid-70s by a French group of pharmacologists and toxicologists to define the activities promoting "The assessment of the risks of side effects potentially associated with drug treatment" (Iqbal *et al.*, 2015)^[13].

PV is the science of collecting, monitoring, researching, assessing and evaluating information from healthcare providers and patients on the adverse effects of medications, biological products, blood products, herbals, vaccines, medical device, traditional and complementary medicines with a view to identifying new information about hazards associated with products and preventing harm to patients. The challenge of maximizing drug safety and maintaining public confidence has become increasingly complex. Pharmaceutical and biotechnology companies must not only monitor, but also proactively estimate and manage drug risk throughout a product's lifecycle, from development to post-market (Chauhan *et al.*, 2013)^[10].

Nutraceuticals safety through Pharmacovigilance programme of India

According to World Health Organization (WHO) Adverse Drug reaction (ADR) is defined as “A response which is noxious and unintended, and which occurs at doses normally used in humans for the prophylaxis, diagnosis, or therapy of disease, or for modification of physiological function. This is of major concern now a day to monitor the safety and adverse

drug reaction (ADRs) associated with the use of the nutraceuticals. Pharmacovigilance Programme of India encourages all healthcare professionals and consumers to report ADRs associated with nutraceuticals. The submitted ADR reports are reviewed and analysed at NCC and finally submitted to World Health Organisation - Uppsala Monitoring Centre (WHO-UMC), Sweden (Chakraverty and Banerjee, 2013) [11].

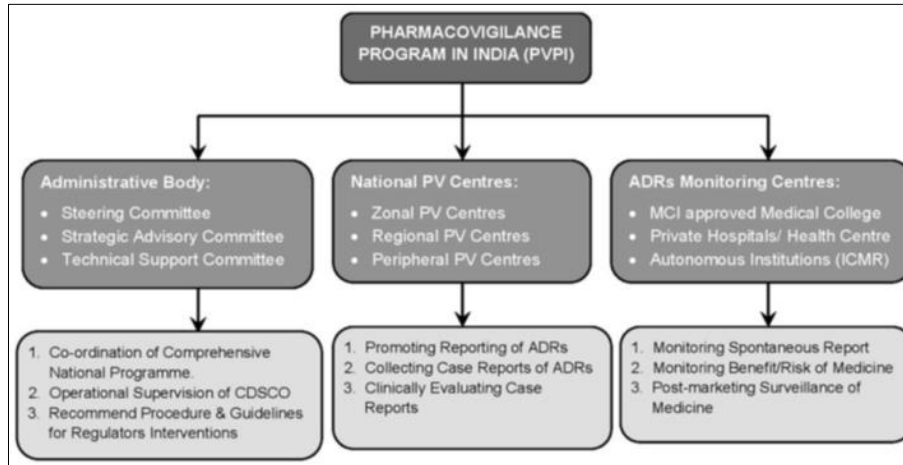


Fig 2: Pharmacovigilance program in India and responsibilities

Table 3: Process of Pharmacovigilance Programme of India

Who can Report?	What to Report?	Whom to Report?
All Healthcare professionals (Clinicians, dentists, pharmacists, nurses) and non-healthcare professionals including patients/consumers can report ADRs. The pharmaceutical companies can also send the ADRs report for their products to NCC.	PvPI encourages reporting of all types of suspected adverse reactions with all pharmaceutical products irrespective of whether they are known or unknown, serious or non-serious and frequent or rare.	The ADRs can be reported by filling the Suspected ADR reporting form. For healthcare professionals and medicine side effect reporting form (for consumers); which are available on the website of IPC as well as Central Drugs Standard Control Organization (CDSCO). To remove language barrier in ADR reporting consumer reporting form are made available in 10 vernacular languages (Hindi, Tamil, Telugu, Kannada, Bengali, Gujarati, Assamese, Marathi, Oriya, and Malayalam). The filled ADR reporting form can be submitted/send directly to the NCC or to the nearest AMCs or can be directly mailed to pvpi@ipcindia.net or pvpi.ipcindia@gmail.com

The image shows a detailed reporting form titled "SUSPECTED ADVERSE DRUG REACTION REPORTING FORM" for consumers. It includes sections for patient information, suspected adverse reaction, suspected drug details, and reporter details. The form is designed for use by consumers to report adverse drug reactions to the Indian Pharmacopoeia Commission.

Fig 3: Reporting tool I ---Suspected ADR reporting form for Consumers

MEDICINES SIDE EFFECT REPORTING FORM (FOR CONSUMERS)
 Indian Pharmacopoeia Commission, National Coordination Centre - Pharmacovigilance Programme of India,
 Ministry of Health & Family Welfare, Government of India.

Version 1.0

1. Patient Details
 Patient Initials: Gender (v): Male Female Other Age (Year or Month):

2. Health Information
 a. Reason(s) for taking medicine(s) (Disease/Symptoms):
 b. Medicines Advised by (v): Doctor Pharmacist Friends/Relatives Self (Past disease experienced/No past disease experienced)

3. Details of Person Reporting the Side Effect
 Name (Optional):
 Address:
 Telephone No: Email:

4. Details of Medicine Taking/Taken

Name of Medicines	Quantity of Medicines taken (e.g. 250 mg, Two times a day)	Expiry Date of Medicines	Date of Start of Medicines	Date of Stop of Medicines
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

Dosage form (v): Tablet Capsule Injection Oral Liquids If Others (Please specify):

5. About the Side Effect
 When did the side effect start? Side Effect is still Continuing (Yes/No)
 When did the side effect stop?

6. How bad was the Side Effect? (Please v the boxes that Apply)

<input type="checkbox"/> Did not affect daily activities	<input type="checkbox"/> Affect daily activities
<input type="checkbox"/> Admitted to hospital	<input type="checkbox"/> Death
<input type="checkbox"/> Others	

7. Describe the Side Effect (What did you do to manage the side effect?)

This reporting is voluntary, has no legal implication and aims to improve patient safety. Your active participation is valuable. The information provided to this form will be forwarded to ADR Monitoring Centres for follow-up. You are requested to cooperate with the programme officials when they contact you for more details. Please do report even if you do not have all the information.

Fig 4: Reporting tool II-Suspected ADR reporting form for healthcare

PvPI Mobile App
 Now you can report an ADR at any time any where in India.

- Facilitate hassle free ADR reporting for healthcare professionals
- Customized consumer reporting
- Facility to report at preferred centres
- Supports attachment of images, Audios, Events and relevant documents
- Acknowledgement to the reporter
- User-Friendly User Interface (UI)

1800 180 3024

TOLL FREE

Fig 5: Reporting tool III-Reporting Tools for the Stakeholders

www.ipc.gov.in

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NCC-PvPI IPC

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pvpipi.ipc@gov.in

ADR Mobile-app

Fig 6: Reporting tool IV- Connect & Contact us

Pharmacovigilance Programme of India: Recent developments and future perspectives

The reluctance in reporting is now changing as the PvPI has launched a complete roadmap for a proactive Pharmacovigilance system which increases the awareness about the benefits of ADRs reporting. Over 5 years, the NCC has played a significant role in creating awareness among healthcare professionals about reporting ADRs that saw more than 1, 49,000 ADRs reported till December 2015 (Figure 7). Currently, the contribution of India to the WHO global Individual Case Safety Reports (ICSRs) database is 3%. The healthcare professionals are encouraged to report through feedback and Newsletters (Thota *et al.*, 2018) [6].

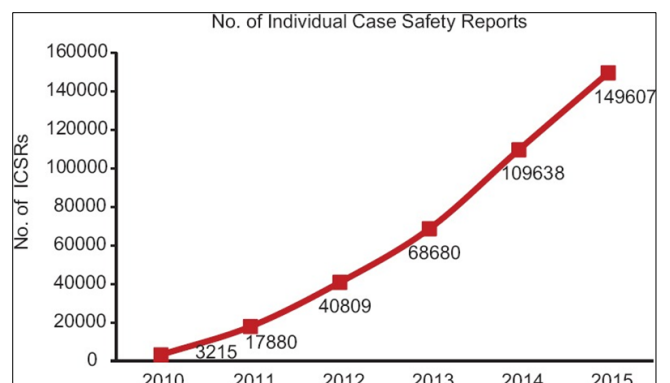


Fig 7: Growth of database of Individual Case Safety Reports since the inception of the Pharmacovigilance Programme of India

Uppsala Monitoring Centre communicates the result of the documentation grading for the Individual Case Safety Reports (ICSRs) to the national centers. The report completeness score is a score from 0 to 1 on an ICSR, calculated from the

information provided in a structured format. The score depends on the required information of the field in the ADR report such as type of report, primary source, gender, and time to onset, age at onset, outcome, indication, and free text. Average completeness score for Indian ICSRs for the period of 2011–2015 is illustrated in Figure 8.

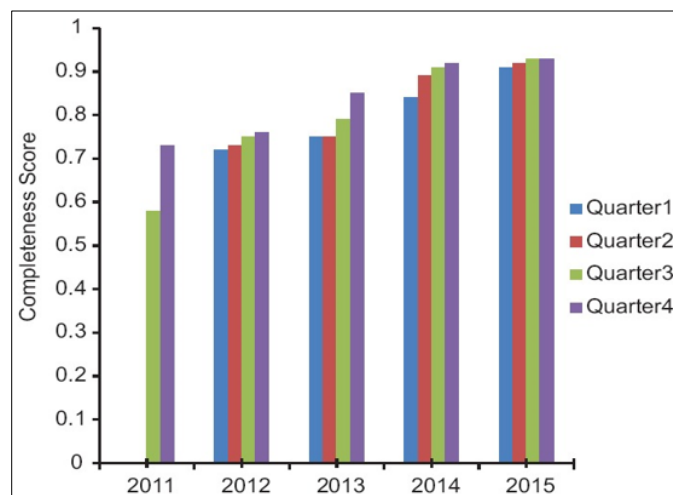


Fig 8: WHO-Uppsala Monitoring Centre completeness score for Indian Individual Case Safety Reports from the year 2011-2015

Integration of Pharmacovigilance programme of India

In India, PvPI is closely working with CDSCO, drug regulatory authority of India. CDSCO understands that Pharmacovigilance plays a specialized and pivotal role in ensuring ongoing safety of medicinal products in India and it seeks inputs from NCC before taking any kind of regulatory decisions. NCC-PvPI is working in close coordination with CDSCO zonal offices also for technical, administrative, and logistics matters related to PvPI.

Conclusion

Nutraceuticals has been expanded to include vitamins, minerals, amino acids, herbs and other botanicals and any dietary substances after the formation of Dietary Supplement Health and Education Act in the year 1994. Due to the multiple therapeutic benefits of nutraceuticals its use has increased worldwide beside the adverse effects associated with its use specially when consumed in large quantities. Lack of proper regulation of nutraceuticals in the pharmaceutical industry and easy availability of nutraceuticals and its regulation has emerged the need to monitor the adverse effect associated with use in public health. Pharmacovigilance Programme of India encourages all healthcare professionals and consumers to report ADRs associated with Nutraceuticals. It is important to become aware of these adverse events and interactions in order to better educate their patients and possibly prevent potential and unexpected adverse reactions.

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