**PHARMACOVIGILIANCE OF HERBAL & TRADITIONAL SYSTEM**

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

* To patient care
* To provide medicines & all medical and paramedical services staff.
* To improve public health services.
* To support understanding, educating & clinical training in Pharmacovigilance
* To asses benefit, risk & effectiveness of medicines.
* To support effective communication to health care professionals & the public.

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

Under reporting

Lack of information

Biased reporting

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**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.

**Food is medicine interventions**

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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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Theireportishouldicontainiinformationionitheifollowingielements:i

**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?**

Conductiindividualicaseisafetyireporti(ICSRs)iassessmentiwhileiclassifyingiitsiseverityiandisuggestingiregulatoryiactionsiandifeedbackitoitheireporter.i

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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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(4)iQualityiassuranceiandicontrol:iUnlikeiconventionalipharmaceuticaliproducts,iherbalianditraditionalimedicinesiareipreparedifromimaterialsiofiherbalioriginiwhichiareiofteniobtainedifromivariousigeographicaliandicommercialisources,iresultingiiniuncertainicondition.iFurthermore,iproceduresianditechniquesiusediiniitsimanufacturingiandiqualityicontrolimeasureiareiofteniveryidifferentifromithoseiusediforiconventionalimedicines.

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(6)iPossibleiinteractionibetweenidifferentitraditionalimedicineiproductsiandiwithiallopathicimedicinesiandifoodstuffs.i

 **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?**

* Networkingishouldicoverihealthifacilitiesi(traditionalimedicineipractitioners),imanufacturer,idrugistorei(pharmacists)iandiconsumer.i
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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