Pharmacovigilance & Ayurveda

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Pharmacovigilance is the science which encompasses the activities concerning to the detection, assessment, understanding and prevention of Adverse Drug Reaction (ADRs) or any other possible drug related problems, particularly long term and short term side effects of medicines.

- It is the science dedicated to reduce the risk of the drug related harms to the consumers.
Aims of Pharmacovigilance

- Improve patient care and safety.
- Improve public health and safety.
- To contribute to the assessment of benefit, harm, effectiveness and risk of medicines.
- To promote understanding, education and clinical training.
Adverse Drug Reactions (ADRs) - A response to a drug which is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function.

Adverse Event/Experience (AE) - Any untoward medical occurrence that may present during treatment with a pharmaceutical product but which does not necessarily have a causal relationship with the treatment.
• **Side Effect (SE)** - Any unintended effect of a pharmaceutical product occurring at doses normally used in human which is related to the pharmacological properties of the drug.

• **Serious Adverse Event (SAE)** – Any adverse event which is fatal, life-threatening, permanently disabling or which results in hospitalization.

• **Expected adverse reaction** - As opposed to “unexpected”, an event that is noted in the brochure or labeling.

• **Unexpected adverse reaction** - The nature or severity of which is not consistent with the domestic labeling or market authorization, or expected from characteristics of the drug.
1986
• ADR monitoring system for India proposed (12 regional centres)

1997
• India joined WHO-ADR monitoring programme (3 centres: AIIMS, KEM, JLN)

2010
• Pharmacovigilance programme of India (PvPI)

2004 – 2008
• National PV Prog. (2 Zonal, 5 Regional, 24 Peripheral) overseen by CDSCO
PV was established since 2003 under the control of Central Drug Standard Control Association (CDSCO) under the aegis of Ministry of H & FW, DGHS (Directorate General of Health Service) New Delhi.

WHO emphasized that it should include Traditional medicines in PV system and has published guidelines on safety monitoring of herbal medicines in pharmacovigilance systems in 2004.
IPGT & RA, Jamnagar conducted a two days workshop on 3rd & 4th December 2007, on “Pharmacovigilance for Ayurvedic Drugs: Scope, Limitations & Methods of Implementation”.

Based on the recommendations from the workshop, Pharmacovigilance Cell (PV Cell), has been established.

Reporting Form for Suspected ADRs of Ayurvedic.

Formulations has been developed.
ASU drugs are considered as safe drugs.

This perception is likely to change in the light of some recent incidences of ADR during their use.

The first National Consultative meet of National Pharmacovigilance Programme for ASU Drugs was organized at Dept. of AYUSH, Ministry of Health & FW, New Delhi on August 2008, sponsored by WHO.
Based on the feedback received from the meet, National Pharmacovigilance Programme for ASU drugs was launched on 29th Sept 2008.

The purpose of the programme is to collect and collate data, analyse it and use the inferences to recommend informed regulatory interventions, beside communicating risks to healthcare professionals and the public.
Objectives

- **Short-term objectives** - To develop the culture of notification.

- **Medium-term objectives** - To involve healthcare professionals and professional associations in the drug monitoring and information dissemination processes.

- **Long-term objectives** - To achieve operational efficiencies that would make NPP for ASU drugs a benchmark for global drug monitoring endeavors.
**PV Centres in India**

- National PV centre
- 8 Regional PV centers
- 30 Peripheral PV centers

- IPGT & RA
- BHU
- TVM
- Guwahati
- CCRAS
- Chennai
- B’lore
- Bhopal
- NIA
- W
- E
- C

**Centres in India**

- IPGT & RA
- BHU
- TVM
- Guwahati
- CCRAS
- Chennai
- B’lore
- Bhopal
- NIA
- W
What To Report?

- All suspected adverse reactions.
- Lack of effects.
- Resistance.
- Drug interactions.
- Reactions suspected of causing:
  a. Death
  b. Life threatening (real risk of dying)
  c. Hospitalization (initial or prolonged)
  d. Disability (significant, persistent or permanent)
  e. Congenital anomaly
**NATIONAL PHARMACOVIGILANCE PROGRAMME FORAYURVEDA, SIDDHA & UNANI (ASU) DRUGS**

**Reporting Form for Suspected Adverse Reactions to ASU Drugs**

Please note:
(I) Information about the patients, prescribers and reporters will remain confidential.
(II) It is requested to report ALL suspected reactions as soon as possible, even if complete information is not available. Please note however that column numbers 1, 2, 3, 4, 6 & 10 are compulsory.

1. **Patient / consumer identification (please complete or tick boxes below as appropriate):**

<table>
<thead>
<tr>
<th>Ethnicity/Identifier Initials</th>
<th>Patient’s Record Number (PRN):</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</table>

<table>
<thead>
<tr>
<th>Address:</th>
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<tbody>
<tr>
<td>Village/Town</td>
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<tr>
<td>Post/Via</td>
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<tr>
<td>District/State</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Age:</th>
<th>Sex: Male/Female</th>
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<table>
<thead>
<tr>
<th>Weight:</th>
<th>Prakriti/Mizaj/</th>
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<tbody>
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<table>
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<tr>
<th>Occupation:</th>
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<tbody>
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<td></td>
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</tbody>
</table>

2. **Description of the suspected Adverse Reactions (please complete boxes below):**

<table>
<thead>
<tr>
<th>Date and time of initial observations:</th>
</tr>
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<tbody>
<tr>
<td></td>
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</table>

<table>
<thead>
<tr>
<th>Description of reactions</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</table>

3. **List of all ASU drugs including drugs of other systems used by the patient during the reporting period:**

<table>
<thead>
<tr>
<th>Name of the medicine</th>
<th>Manufacturer’s name/ Batch no./ Manufacture/ Expiry date</th>
<th>Daily dose</th>
<th>Dosage form and route of administration</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
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<td></td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Starting</th>
<th>Stopping</th>
<th>Reason for use</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tbody>
</table>

4. **Brief details of the suspected ASU Medicine:**

a. Composition of the formulation / Part and form of the raw material used
b. Expiry date if any:
c. Remaining part of drug / Product label
d. Please tick: Ayurveda, Siddha, Unani, any other
e. Adjuvant (Anupana):
f. Dietary history (Intake/Restrictions) if any:
g. Whether the drug is consumed under medical supervision or used as self medication.
h. Any other relevant information.

5. **Treatment provided (if any) for suspected adverse reaction:**


6. Outcome of the suspected adverse reaction (please complete the boxes below):

<table>
<thead>
<tr>
<th>Recovered / Recovering</th>
<th>Not recovered</th>
<th>Unknown</th>
<th>Fatal</th>
<th>If Fatal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Severe: Yes/ No</td>
<td>Reactions abated after drug stopped or dose reduced:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Was the patient admitted to hospital? If yes, give name and address of hospital</td>
<td>Reaction reappeared after re introduction:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is any follow up required:</td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tbody>
</table>

7. Laboratory investigations done, which provides suspicion of drug involvement:

8. Please tick, if the patient is suffering with any chronic disorders:

- Hepatic
- Renal
- Cardiac
- Diabetes
- Malnutrition
- Any Others

9. Whether history of allergy / Drug reactions exists:

10. Identity of the reporter:

- Type (please tick): Nurse / Doctor / Pharmacist / Health worker / Patient / Manufacturer / Distributor / Supplier / Any others (please specify)
- Name:
- Address:
- Telephone / E – mail if any:

Sign of the reporter: Date:

Please send the completed form to:

The centre from where the form is received or To the Coordinator
National Pharmacovigilance Resource Centre For ASU Drugs
(0288) 2553936, Fax: 0288 – 267856 / 2553936
Website: www.ayurveduniversity.com, Email: npcasu@gmail.com

Who Can Report?

- Any Health care professionals including, ASU Doctors / Dentists / Nurse / Pharmacists etc.

What to Report?

- All suspected adverse reactions, Lack of effects, Resistance, Drug interactions, Dependence and Abuse

Where to Report?

- Peripheral Pharmacovigilance Centre or Regional Pharmacovigilance Centre or National Pharmacovigilance Centre

Confidentiality:

- The patient’s identity will be held in strict confidence and protected to the fullest extent. Programme staff will not disclose the reporter’s identity in response to a request from the public.
- Submission of report doesn’t constitute an admission that, medical personnel or manufacturers or the product caused or contributed to the reaction.
Who Can Report?

- Any health care professional can report.
- Shall not accept reports from lay members of the public.
- Others can report through the physicians under whom he/she had undergone treatment.
- Consumer can directly report to the concerned PPC / RPC / nearest health centre or physician regarding the suspected ADR.
Where To Report?

- Patient
- Health Professional
- Hospital
- Regional Centre
- National Centre
- Manufacturer
What Happens To The Information Submitted?

- Confidential.
- PPC forward the form to the respective RPC (causality analysis). This information shall be forwarded to the NPRC.
- The data will be statistically analysed and forwarded to the Dept. of AYUSH.

PPC → RPC → NPRC → AYUSH
Responsibilities Of Centers

- To collect ADR reports.
- To fill in the ADR form properly.
- To forward duly filled in ADR forms to next higher centre.
- To maintain a log of all ADR notification forms.
- To provide general technical support, coordinate and monitor the functioning of Centres.
- To carry out causality analysis of all ADR forms.
• To forward all duly-filled ADR forms as per pre-determined time line.
• To report all SADR's within 24 Hrs.
• To forward periodic reports to next higher centre.
• To organize and attend training programs/interactive meetings for all lower level centres.
• Organize the public campaigns.
Ayurvedic concept of PV

- Term PV does not feature in Ayurvedic texts.
- Rational drug use are recurrent themes of Ayurvedic pharmacology (DRB) and therapeutics (chikitsa).
- Along with descriptions related to actions & benefits of medicines, Ayurvedic pharmacology describes detailed adverse reactions & also how to deal with ways to minimize adverse effect in detail.
- On the other hand the classical texts of ayurveda promptly describe all the adverse reactions to irrationally procured, prepared and administered drugs or formulations.
Acharya charka has consider the drug related factors such as; prakriti, guna, karma, prabhava, desha, rutu, grahitam, nihitam and upaskrtam. & patient related factors such as prakriti, vikriti, vaya, bala, satmya, aharshakti, sara, satva, and sanhanana.

1. Precaution in manufacture techniques.
2. Time of drug administration.
3. Compliment diet and life style and so on.
In ancient times, physicians prepared medicines for their patients themselves. Today production and sale of Ayurveda drugs is formalized into a thriving industry. Ayurvedic medicines –

1. Classical Ayurvedic formulations

This industrialization has brought many challenges about safe use of Ayurvedic medicines.
Challenges in introducing PV in Ayurveda

- NPP encouraged reporting of all suspected ADRs, but the number of reports related to Ayurvedic/herbal drugs are abnormally low.
- Concept & terminologies related to ADR monitoring are not covered in the Ayurvedic curriculum.
- Methods to study drug safety problems have not evolved adequately in Ayurveda.
- Information related to medicines are in the form of slokas in the texts, it is not easily available for general public.
• Signal detection is difficult because of inherent belief that Ayurvedic medicines are safe.
• Patients often use medicines from different systems of medicine concomitantly - difficulty in assigning causality.
• Lack of quality assurance and control in manufacture of Ayurvedic medicine.
• Most Ayurvedic formulations are multi-ingredient.
Recommendations

- Introduce pharmacovigilance concepts into the curriculum of ayurveda at the under-graduate and post-graduate level.
- Encourage studies on drug safety.
- Make reporting of adverse reactions to regulators mandatory for ayurvedic formulations.
- Make unbiased and easily accessible drug information available. The Traditional Knowledge Digital Library launched by the Government of India is an example of how ancient knowledge available in the ancient scriptures can be made digitally accessible.
• Create awareness about the science of pharmacovigilance among ayurvedic physicians, patients and paramedical staff.
• Development and validation of scales to assess the causality of the reported reactions to ayurvedic medicines.

• Human resource development is a key feature for the success of this enterprise. It will be necessary to train ayurvedic experts in the science of Pharmacovigilance and include them not only in reporting but also assessment of the adverse reactions. More direct involvement of ayurvedic Academic Institutions in the NPVP after appropriate training would be an appropriate first step in this direction. A strong cooperative effort from experts in Pharmacovigilance and ayurveda together can ensure that this system is up and functioning.
The success of any pharmacovigilance system lies in its ability to prevent further adverse reactions on the basis of information received. This will be possible only when physicians are vitally alert to the onset or offset of any ADRs. They need to prioritize their contributions to make the pharmacovigilance program for Ayurvedic medicines a success.
Conclusion

- By incorporating PV, we will be able to prepare medicines with good **efficacy, quality, safety** and **minimum harmful effect**.

In all, Pharmacovigilance will promote:

- **Systematic and rational use of medicines**
- **Boost confidence for safety**.
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Thank You