

## **Expected responsibility of Patients in reporting of adverse drug reactions**

Pharmacovigilance is the science and activities relating to detection, assessment, understanding and prevention of adverse effects of drugs. National Pharmacovigilance program (NPP) for Ayurvedic drugs is concerned with promoting rational drug use and drug safety to safeguard the public health. However, its successful implementation is a collective responsibility of the stakeholders viz. physicians, pharmacists, patients and pharmaceutical industry, that needs to be sensitized towards reporting adverse drug reactions (ADRs).

### **Need to report Adverse drug reactions of Ayurveda medicines**

Generally classical/proprietary/over the counter (OTC) Ayurvedic medicines are used by consumers (patients). In such cases, sometimes patient may encounter side-effects or unintended and noxious reaction of a medicinal product [also termed as Adverse drug reaction (ADR)]. Usually, patients do not share any side-effect or may suppress the facts of any untoward effect of medications. The patients can also play a part in decreasing the risks associated with drug therapy. Patients should be vigilant regarding rational medicine use and shall inform to the nearest qualified Ayurveda physician or pharmacist if any ADR is found. After ADR assessment, the physician may report the same to the concerned authorities under NPP. Such reporting from patients could prevent others from facing the side-effects of the same medication.

### **What to report**

Description of adverse reaction, time of onset of this reaction, the drug involved, the concomitant medication, duration of the use of drug, including dates of initiation and discontinuation, and any other relevant information.

### **How to report**

The Government of India, Ministry of AYUSH has launched a 'Central Sector scheme of Pharmacovigilance of Ayurveda, Siddha, Unani & Homeopathy drugs (ASU&H)'. For Ayurveda, several institutes across India are serving as Peripheral (19) and Intermediary (02) Pharmacovigilance centres. The Peripheral centres report to Intermediary centres and the latter report to National Pharmacovigilance Centre i.e. All India Institute of Ayurveda (AIIA), New Delhi. In CCRAS, 5 centres are serving as peripheral pharmacovigilance centres (PPvC); among them, Central Ayurveda Research Institute for Drug Development, Kolkata is serving as PPvC since August 2018. In Pharmacovigilance Programme of ASU&H drugs, there is a prescribed format for reporting Suspected Adverse Reactions, which is available in AIIA website (<https://aiia.gov.in>). In this programme, patient can fill an ADR form and submit it directly to the email ID [pharmacovigilanceayush@gmail.com](mailto:pharmacovigilanceayush@gmail.com) or they can report to the nearest ASU&H clinic/hospital or PPvC. Anyone can visit the website of AIIA for further information.

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