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An Outlook to Pharmacovigilance in India

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Pharmaceutical companies that have been marketing generic drugs in India have to deal with a number of regulatory reinforcement and increased accountability demands to ensure a favorable and significant benefit-risk balance of their products. There is need to implement an active approach of pharmacovigilance (PV) that includes monitoring and reporting of spontaneous adverse reactions of Periodic Safety Update Reports (PSUR) while conducting the risk-benefit analysis of new drugs. Any pharmaceutical company with a marketing license must ensure that they have an adequate PV system to undertake the responsibility and liabilities of their marketed products, as specified in Schedule Y. An individual department should be setup to report PV in the Ministry of Health comprising of doctors, pharmacists, chemists and nurses. All adverse reaction reports and relevant information concerning benefit-risk analysis of a product needs to be shared with the Drug Controller. An effective PV system is required to track, receive the feedback and record the data of the world conditions on the effects, side effects, contraindications, drug interactions, new indications or symptoms and implications in the huge populations.

The legislative requirements of PV in India are monitored by the specifications of Schedule Y of the Drugs and Cosmetics Act 1945. Schedule Y specifies the regulations relating to pre-clinical and clinical studies for the development of a new drug and clinical trial requirements for import, manufacture and marketing in India. Schedule Y has been thoroughly reviewed and its amendments till dated January 20, 2005, indicate the continued commitment to ensure adequate compliance of PV obligations of the pharma companies. In the amended Schedule Y, attempts have been made to emphasize the responsibilities of pharma companies for their marketed products. All cases involving serious or unexpected adverse reactions must be under the notice of licensing authority within stipulated time period of 15 days from initial receipt of the information by the applicant. Individual adverse reaction reports should be included in the next periodic safety report. The guidance like ICH, ICH E2D is referred to develop detailed protocol to validate the adverse reaction reports.

The government should encourage such practices by providing subsidy, tax relaxation to promote them. Drug inspectors should ask for these reports during his inspection to medical shops. A pharmacist should follow up the possible effects of medicines after dispensing and should call the patient to brief them about the further implications of medicines. Irrational combinations may be prescribed by doctors, like a combination of two or more drugs given parenterally. To deal such situation, we have to involve people in PV activity. It can be achieved by creating general awareness through campaigns and advertisements in all newspapers, magazines, scientific discussions through media for effective reporting of ADR. A medical team should verify complaints received before reporting them. A dedicated phamacovigilance centre should be created for its effective implementation. The Indian PV system is currently under developmental stages and more adverse drug monitoring centers are being established with the aim of building the Indian PV system on par with International standards. Because of this new establishment, there has been a boom in the career opportunities for aspirants who would like to build their career in PV domain in India. CDSCO, NIPER (Mohali) have been widely promoting it. Indian Pharmacopoeia Commission, Ghaziabad has already made numerous significant and fruitful efforts while many new intellectual planning are taking the shape.

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