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Potential role of pharma-industries in addressing the challenges in pharmacovigilance: practice changes & outcome trends

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India is a vast country and there is a surfeit of drug brands — more than 6,000 licensed drug manufacturers and over 60,000 branded formulations. India is the fourth largest producer of pharma in the world and is also emerging as a clinical trials hub. Pharmacovigilance is the study of the safety of marketed drugs examined under the practical conditions of clinical use in large communities. Pharmacovigilance generate evidence that will inspire public confidence and trust. Pharmacovigilance is still in its infancy in India and there exists very limited knowledge about the discipline. While major advancements of the discipline of pharmacovigilance have taken place in the western countries with several training programmes developed by various stakeholders in both academia and the pharma industry, not much has been achieved in India. The challenge of maximizing drug safety and maintaining public confidence has become increasingly complex. Drugs appear to be safe and well-tolerated, but the safety in the 'real world' is unclear. Safety reporting is an obligation for companies in marketing phase. Due to recent high-profile drug safety problems, the pharmaceutical industry is faced with greater regulatory enforcement and increased accountability demands for the protection and welfare of patients. This changing climate requires biopharmaceutical companies to take a more proactive approach in dealing with drug safety and pharmacovigilance. The development and use of standard-based pharmacovigilance system with integration connection to electronic medical records, electronic health records, and clinical data management system holds promise as a tool for enabling early drug safety detections, data mining, results interpretation, assisting in safety decision making, and clinical collaborations among clinical partners or different functional groups.

Biography

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