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Role of pharma industries in the improvement of pharmacovigilance system

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India has more than half a million qualified doctors and 15,000 hospitals having bed strength of 6,24,000. It is the fourth largest producer of pharmaceuticals in the world. It is emerging as important clinical trial hub in the world. Every year new drugs are being introduced necessitating health care professional to be well versed with concepts & practice of pharmacovigilance. It is imperative that every health care professional (HCP) sees it as a part of his/her professional duty, keeping in mind about the Hippocrates admonition of "at least doing no harm". From time to time, episodes like thalidomide tragedy (1962) and cardiovascular risks posed by COX 2 inhibitors (2005), only add emphasis to this ever evolving medico-regulatory discipline. Traditionally speaking, the science of pharmacovigilance has been a discipline more focused on the post marketing or post authorization period. As a part of 'Risk Management Tool' it has not only an important role to play in patients' safety, but it has also assumed astronomical significance, to safeguard pharma industry against possible loss of revenue through damaging litigations & declining share value. However, as biological sciences have evolved, pharmacovigilance has also become an integral part of new drug development process. During last few years, pharmacovigilance has been more visible & talked about albeit for undesirable reasons. On the positive side, Union health ministry of India has relaunched National Pharmacovigilance programme (PvIP) in July 2010, reflecting a greater focus on the monitoring of safety of medicines in India. There are essentially only two main approaches to safety monitoring of the marketed drugs namely, Passive Surveillance (Spontaneous reporting) & Active Surveillance, while hybrid combination methodologies such as, Pharmacoepidemiological studies & registries are also being used. Active surveillance encompasses most of the methodologies where pharma is actively involved in data generation like phase IV clinical trials, PMS studies, observational studies, registries and Prescription Event Monitoring. Pharma companies (Sponsors & MAHs) have elaborate and robust pharmacovigilance & drug safety set up employing hundreds of very qualified personnel to process, analyze and take necessary actions to comply with international regulations. The entire chain of processes which can also be called as 'Drug Safety & Risk Management' comprises of collection of safety information and / or case reports, compilation and assessment of safety information using safety database (ARGUS, ARISg), signal management, risk Management including Label changes & communication and periodic reporting. Initiative on educating PG students, interns and staff responsible for PV cell in institutes (Govt. as well as private) through pharma experts are always welcome to establish the strong foundation of Good Pharmacovigilance Practice. Not only that Pharma Industry should come forward and compliment towards Govt. initiatives to hasten the process of education on pharmacovigilance. Regarding biosimilar, data from pre-authorization clinical studies normally are insufficient to identify all potential differences with respect to reference and thus different safety profile in terms of nature, seriousness or incidence of adverse reactions may differ in spite of having similar efficacy. Therefore, it is imperative to have risk management plan (RMP) & pharmacovigilance programme and monitor clinical safety of similar biological medicinal products on an ongoing basis during the post-approval phase. The most critical safety concern relating to biopharmaceuticals (including biosimilars) is immunogenicity thus; risk management plan for biosimilars should focus on heightening the pharmacovigilance measures, identify immunogenicity risk and implement special post-marketing surveillance.

Biography

Kamlesh Patel has more than 13 years experience in Indian pharmaceutical industry and worked from small to large sized Indian and MNC prior to his current role as General Manager - Medical Affairs and Head Pharmacovigilance in Abbott HealthCare, India. He played instrumental role in new product ideation, establishing PV department from scratch, developing regulatory strategies to ensure faster approvals, late phase clinical development program as a part of KOL engagement, launching innovative products, formulation of advocacy across multiple therapy areas and training more than 200 medical colleges of India on PV. He was a key person in planning, developing and implementation of the core medico marketing projects/initiatives across therapy areas along with developing and implementing process of ethics and compliance.

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