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Emerging importance of pharmacovigilance in Indian drug regulatory system

Dilip Kumar Reddy N and Ramakrishna R
Vaageswari Institute of Pharmaceutical Sciences and Research, India

For the early detection of untoward effects of the drugs and to take appropriate regulatory actions, if necessary, a robust drug safety monitoring system is a must. Thus, an effective pharmacovigilance is very much critical in deciding the fate of any drug product in the market. Notwithstanding to the above, until past decade, the Indian drug regulators are solely dependent on the safety reports generated in innovator countries to decide the rationale of continuing the product in Indian market. This dependency is because of the fact that Pharmacovigilance was not considered too critical, given enough lag time in the launch of product in Indian market post its launch in innovator country, and hardly any new drug was introduced for first time into India. During this lag time, sufficient safety data would be generated which could help take a decision. However, in recent years, there has been an immense need and it has become an incumbent on the nation to have its own pharmacovigilance because of the gradual emergence of India as a hub of global clinical trials & a destination for drug discovery & development, continued presence of drugs in Indian market despite being banned elsewhere in the world, sudden spurt of many fixed dose combinations which are not approved elsewhere in the world. Further, the safety data generated in other countries will not be sufficient considering the vast ethnic variability, different disease prevalence patterns, practice of different systems of medicines, different socioeconomic status in India. As a consequence, the Indian health authorities have initiated the 'Pharmacovigilance programme of India' on a serious note with the objective of having a standardized and robust pharmacovigilance and drug safety monitoring programme for the nation. Since then, the pharmacovigilance in India has made rapid strides and soon the nation will have a database of safety reports of all new drugs being marketed India.

Biography

Dilip Kumar Reddy N. has completed his master's degree from Delhi University by securing an All India Rank of 144 in a prestigious nationwide examination (GATE) conducted by IIT-Kharaghpur. He is a gold medalist in both undergraduate and graduation courses for his outstanding academic credentials. Currently, he is pursuing Ph.D. in the field of pharmaceutical regulatory affairs under the esteemed guidance of Dr. Ramakrishna, Principal, Vaageswari Institute of Pharmacuetical Sciences & Research.

dilip.pharmacy@gmail.com