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Role of pharma industries in the improvement of pharmacovigilance system

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Before a medicine is authorized for use, evidence of its safety and efficacy is limited to the results from clinical trials and pre-clinical studies. This means that at the time of a medicine's authorization, it will only have been tested in a relatively small number of patients of a specific group, for a limited length of time. Once a product has been authorized and marketed a key role in the ongoing activity of pharmacovigilance. Some side effects or 'adverse reactions' may not be seen until a very large number of people have received the medicine and used it over longer time periods in real life use often in more diverse populations and with more concomitant medications than used in clinical trials. The real life use of medicines only happens once healthcare professionals begin prescribing. It is therefore vital that the safety of all medicines is monitored throughout their use in healthcare practice with a robust Pharmacovigilance systeM.Pharmacovigilance system to be functional and efficient, all the stakeholders including, but not limiting to, regulatory bodies, manufacturer and health care professionals need to be alert and attentive throughout the lifetime of the drug in the market. The pharmaceutical industry has prime responsibility for the safety of medicines. Manufacturers are uniquely placed for monitoring the safety of medicines, from the start of drug development and thereafter throughout the lifetime of the drug. Pharmaceutical and biotechnology companies must not only monitor, but also proactively scrutinize and manage drug risk throughout a product's lifecycle, from development to post market. There should be an interest by stakeholders to enhance patient care and patient safety in relation to the use of medicines; and to support public health programs by providing reliable, balanced information for the effective assessment of the risk-benefit profile of medicines.

Biography

Pranjal Bordoloi is a trained MD in Pharmacology, with more than 12 years of experience in working with Pharma, Biotech and CROs of global repute. He has vast experience in various therapeutic areas and has played key roles in Clinical Trial Management, Medical & Regulatory Affairs and Pharmacovigilance. He has successfully lead the designing, strategizing and execution of various phases of drug development from preclinical studies to post marketing safety monitoring. Currently, he is head of Pharmacovigilance operations at Lambda Therapeutic Research Ltd.

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