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Role of Pharmacovigilance in off-label drug use

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The new definition of Adverse Drug Reaction (ADR) laid by 2012 Pharmacovigilance (PV) legislation has included a wide range of drug related effects importantly off-label use, misuse and abuse of medications. According to Good Pharmacovigilance Practice (GVP), Off-label use is defined as "situations where a medicinal product is intentionally used for a medical purpose not in accordance with the authorised product information". The FDA regulations allow doctors to prescribe drugs for off-label use, but pharmaceutical industries holds no right to promote such uses. If physicians want to use a medicinal product for an indication beyond the authorised product information, they hold the responsibility to be well informed about the product, to base its use on firm scientific basis and on evidence based medicine, and product's use and effects should be documented. Also the off-label use of medicinal product doesn't require submission for an Investigational New Drug Application (IND), Investigational Device Exemption (IDE) or review by an Institutional Review Board (IRB). But Off label medicines are more likely to be associated in an ADR than authorised medicines. Indian PV system for off-label use is still not well developed, even after implementation of Pharmacovigilance programme of India (PvPI) based on the recommendations of WHO laid by CDSCO; still the rate of ADR reporting for off-label use is below par and there have not been any conclusive studies which gives the present status of rate and extent of ADR reporting for off-label use in India. The objective here is to give an Overview of Off-label drug use in India and the role of Pharmacovigilance for ADR reporting related to Off-label use.

Biography

Imran Maniyar has completed his MBBS from Yenepoya Medical College, Mangalore and is now pursuing his PG In Pharmacology in JJM Medical Davangere. At present he is involved in two research paper.

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