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Reviewing drug package inserts available in UAE for FDA recommended pharmacogenomic information

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Pharmacogenomics aims to characterize the contribution of genetic polymorphisms to variability in drug response and toxicity. FDA has issued a list of drugs which exhibit polymorphism and relevant sections for providing pharmacogenomic information and their biomarkers to reduce the risk of drug toxicity. The objective of the study was to review the package insert for the presence and extent of pharmacogenomic information as per FDA recommendations. A total of 67 Package inserts of 41 drugs in different therapeutic areas available in UAE under various brand names were thoroughly reviewed for direct and indirect information signifying polymorphism. The description of serious drug-drug interaction and its management was also reviewed for risk assessment. The type of pharmacogenomic biomarker and related toxicity mentioned under different labeling sections was compared. Only 26 package inserts of 17 drugs (41%) prescribed for treating cancer, cardiovascular, CNS and Gastrointestinal disorders provided direct genetic evidence and information on the type of polymorphism influencing drug efficacy and toxicity. Indirect indicators describing genetic variation in metabolizing enzyme activity was present in 20 inserts (30%). Though rare adverse reactions had been mentioned under warning and contraindications, no special reference to genomic cause was identified. The FDA recommended pharmacogenomic information was lacking in 59% package inserts available in UAE. This information needs to be incorporated to enhance patient safety and awareness.

Biography

Anoop K Agarwal completed his PhD in 1988 from Postgraduate Institute of Medical Education and Research, Chandigarh, India. He has 27 years of experience in Pharmacology teaching and research. He is currently the Associate Dean of College of Graduate Studies at Gulf Medical University, Ajman, UAE. He has published more than 50 papers in reputed journals apart from having presented his work in several national and international conferences. He has also been a resource person in several Pharmacology workshops and seminars.

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