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Problems encountered by third world countries especially Pakistan in pharmaceutical regulatory affairs and their remedies

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Abstract

This research has been conducted keeping in view the vast scope of Pharmaceutical Regulatory Affairs and role & contribution of third world countries especially Pakistan in overall development of drugs. Detailed root-cause analysis of all the encountered problems has been carried out and outcome was also communicated to concerned quarters for further implementation and harmonization with the international prevailing laws. The aim of this research besides developing harmonization was also to safe-guard the health of common people by pursuing the international guidelines only.

The research encompasses all the aspects of pharmaceutical regulatory affairs starting from drug developments, clinical trials studies, marketing authorization system, post-marketing pharmacovigilance activities, provision of bio-availability and bio-equivalence centers and their monitoring and regulatory compliance, monitoring of Adverse Drug Reactions, provisions of training and lacking of experienced human resources on health, financial constraints of regulatory authorities, public health issues, health insurance policies and this research also contains the matter on irrational use of drugs among masses and its possible repercussions, role of MNCs and some national based companies in unethical promotion of their products.

It was also studied that how the counterfeit and fake drugs reach into pharmacies besides implementations of all possible efforts to curb this menace. Lucrative and over-flooded market of fake drugs creates a big problem for all regulatory authorities throughout the world. Different means and methods are being adopted to eradicate it; hence all possible roots and ways were studied to know the exact causes of this problem.

Different research institutes have been contacted to compile the facts and figures during the work also some local law enforcing agencies helped a lot to gather some facts. The researcher is also thankful to Custom authorities, different CROs, BE & PV centers for providing some vital facts in compiling this research.

The research is concluded to help all those who face or encounter same type of problems like us, this would also help all regulatory authorities how to make rules to safeguard the health of their people.

Biography

The researcher is doctor of Pharmacy by qualification and presently doing Master of Science in Public Health from Dow University of Health Sciences Karachi Pakistan. Presently researcher is working in Drug Regulatory Authority of Pakistan (DRAP) as Assistant Drugs Controller with the job responsibilities to ensure the legal import and export of medicines, also to inspect the drug manufacturers to see their GMP compliance level. The researcher has got different trainings during working with DRAP and has also delivered some lectures on topic “how to encounter the counterfeits” to different authorities like customs and other law enforcing agencies. Now a day the researcher is engaged to make rules in newly developed DRA of Pakistan.