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Role of pharma industries in the improvement of pharmacovigilance system

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Over recent years the requirements for companies to conduct rigorous pharmacovigilance on their clinical trial and post-marketed products has increased. The legislation on not only reporting adverse reactions on time but also involving methodology to adequately follow up on such reports so that there can be enough information to assess whether the reported adverse event is serious or non-serious, whether the event is expected (in the currently approved data sheet/product monograph or Investigator Brochure) and most importantly whether the Company thinks the reported event is related to the Company product or not has again increased. So, the Pharma Companies have been expected to demonstrate in Regulatory Inspections the processes they have implemented to ensure such activities exist are robust and are performed by competent well trained individuals who can interpret the reported information in order to review each reported event the Company receives. All of this has been happening in an environment where many Companies over recent years have also out-sourced all or part of their Pharmacovigilance activities. Therefore there is a dilemma the Company faces in terms of losing experienced staff who knew the Company product safety profiles as well as the experience in many Company processes and ways of performing the safety activities versus the requirement for maintaining control on the safety status for the products as well as maintaining Regulatory compliance for safety reporting (whether for individual case submissions or periodic reports). Added to this is an overall demonstration that the Company is performing Quality assessments on all of its safety activities to validate that the Quality of what is being processed and reported to Regulatory Authorities is being carefully monitored to ensure accuracy in all safety deliberations. The implementation of such a Quality ethos has to come from Senior Management within a Company and the key is to demonstrate that this is still being achieved.

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Mechanisms of antibiotic resistance of gram negative strains isolated from nosocomial infections. The active compounds derived from plant extracts by chromatographic methods involved in blocking resistance mechanisms of gram-negative strains

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We could say that life is unthinkable without antibiotics. However, immediately after the appearance of a new antibiotic, at the same time it appeared as new form of antimicrobial resistance. The prevalence of multidrug-resistant strains isolated from nosocomial and community infections increased lately. The traditional treatments of infectious diseases based on the microbicidal active compounds led, due to the overuse, the selection and the emergence of phenomen of resistance and MDR. Pathogenic strains' therapeutic exposure to high concentrations of antibiotic creates sever pressure conditions and induces high-level resistance. Recycling antibiotics is a short-term measure, because resistant strains do not disappear, and when reintroduced into the antibiotic therapy resistance genes will be selected soon. In those situations where antibiotics seem to be compromised, it is necessary to find substitutes whose action are to be lasting and without any secundare. Medicinal plants seem to be an inexhaustible source of active compounds whose antibacterial activity is known ancient times. The number and mode of action of compounds obtained from extracts of medicinal plants are not fully elucidated. This study is intended to assist those immunocompromised persons with multiple infections, which the body does not respond to standard treatment with antibiotics. In vitro studies have been made on isolated nosocomial infections with multiple resistances to antibiotics. To highlight the mechanisms of resistance of strains, we used PCR. The active compounds of plant extracts were determined by GC and HPLC and antibacterial activity demonstrated by diffusion method.

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