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Pharmacovigilance in Italy: An Italian experience

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Background: Adverse drug reactions (ADRs) underreporting is a serious drawback of the pharmacovigilance system. Spontaneous reporting of ADRs is a valid instrument to enhance pharmacovigilance.

Objectives: To avoid prescribing again to patients the drug that caused them the ADRs; to evaluate spontaneous reporting of ADRs by patients to their General Practitioner (GP); to investigate the most involved anatomical therapeutic chemical (ATC) classes in ADR signaling; to focus on sex-related differences in reporting ADRs and to propose suggestions to increase awareness about the issue.

Methods: All ADRs reports collected by an Italian GP, during a period of five years, have been recorded by himself into his own array of records and then evaluated. The database of case histories in which data were filed allows data mining through queries formulated in SQL (Structured Query Language). We analyzed the numbers of prescriptions for each class of every ATC group in order to demonstrate the most involved ATC classes in ADR signaling.

Results: We observed a total of 1278 ADRs for 11596 medical acts (11.02 ADRs per 100 consultations). Four ATC groups (N, J, C, M) were responsible for the majority of ADR reports. Women had a higher reporting aptitude than men and 58% of women versus 38.9% of men has done at least one ADR report.

Conclusion: The autonomous attention of the GP has led to more knowledge about the issue. The importance of reporting ADRs has been stressed in his local community, and, therefore, he has definitely changed the quality of life of his patients. Our study demonstrates that a close collaboration between GPs, patients and pharmacovigilance authorities may lead to a better pharmacovigilance practice and may provide useful data about reporting trend and about unknown drug adverse reactions. We suggest to offer GPs some training courses to raise awareness to the problem of underreporting.

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Smart regulation therapies challenges and opportunities: In future pharma industries

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Research and development of therapeutic drugs are varying on both regulatory and scientific grounds. The regulatory framework desires to retain pace by fine-tuning its rules and paying attention to strengthen harmonization and competitiveness. These new insights have provided to develop communication amongst all research centers, pharmaceutical industry, stakeholders, and healthcare professionals. Present-day, the expensive, prolonged and challenging measure of the drug regulatory system is supporting the immutable dominance of the pharma industries. Unique products and technologies that may interrupt conventional strategy of big pharma industries, such as smart drug delivery system and stem cells, is a challenging task for the smaller enterprises. Furthermore, the following regulatory guidelines may pave the way for the life sciences like: 1) Innovation strategies are critical while constructing and reconstructing the smart regulatory system for novel drugs; it has transformative impact on specific industry sector. 2) Regulatory modification differs from unexpected consequences in each area and make attentive of potential beneficial product and developmental processes within the broader innovation networks. 3) It will support the innovation strategies and provide sufficient discrimination among the novel products and will definitely disturb the speed of the regulation impact. 4) The suitability of its process or product discrimination will regulate its efficiency in guiding development of product in appropriate directions. 5) Finally smart regulatory products are most suitable for novel and new innovative technology. Furthermore, it must fulfill the efficacy of delivering, estimated standards of safety, more manageable product development strategy and potential marketing tricks for smaller developing industry sectors.

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