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An Overview on the Third Annual Pharmacovigilance Forum

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Introduction

In the middle of September of this year I was invited to be a speaker in the 3rd Annual Pharmacovigilance Forum, held in Wienn, Austria. My topic for this prestigious scientific event was about pharmacovigilance in pediatric respiratory medicine. In addition, I was nominated as chair in session for all two days of conference.

A brief Introduction in Pharmacovigilance

Pharmacovigilance is the fourth steps (the last phase) in clinical development of the drugs –after the drug is marketed. New prescription drugs are only marketed after carefully controlled clinical trials have shown them to be safe and effective. Farmacovigilance is the postmarketing surveillance and study of ADRs, with the ultimate goal of preventing or minimizing their occurrence. It is a continuous process that involve both health authorities and pharmaceutical industry. It is a necessary interface between therapeutics and clinical epidemiology. The costs (billions of dollars annually) includes collection, compilation, quality control, and analysis of the spontaneus reports. Although it is the "poor relative" of pharmacology and the "bogeyman" of the sellers of new drugs, pharmacovigilance is, neverthless, very important component for the rational use of drugs [1-3].

Epidemiology of ADRs

Although some ADRs are minor and resolve without sequelae, others can cause permanent disability or death. ADRs occur commonly, but estimates of incidence vary considerably. This is due to substantial underreporting of ADRs and differences in study methodology, populations studies and ADR definitions. ADRs account for 2.9-15.4 of all hospitals admissions in the US. The incidence may be highest in the elderly and other compromised populations. Nearly 16% of nursing home residents are hospitalized because of an ADR. A significant risk factor for hospitalization is the concomitant use of sever or more medications. ADRs are believed to be fourth to sixth leading cause of death among hospitalized patients. A recent study suggests that an estimated 6.7 of hospitalized patients experience serious ADRs (defined as those that require or prolonged hospitalization, are permanently disabling, or result in death). ADRs increase lenght of hospital stay by 2.2 to 4.6 days. The hospital costs are also increased (more that \$ 2500/ event). [1]

Aim of 3rd Pharmacovigilance Forum

Visionary pharmacovigilance experts across the world are eager to develop a new global network, to share benefit and risk based intelligence of medicinal products. With the fast spread of globalisation, crossborders & trade-blocs, medical practitioners and drug manufacturers are force to adopting holistic strategies to battle the increasing pressure from their stake holders [4].

The main aim of GLC's 3rd Annual Pharmacovigilance Forum, is to provide a platform for these practitioners in the hope of finding the answers to some of the pressing issues they face nowadays. Listen to industry experts discussing ready-made and tested solutions to transparency issues in ADRs. Discover the correct directions, to adhere to upcoming regulatory deadlines, discussed by its creators, if not by its supporters. Witness the highlight of the event, a participative workshop providing practical insights to overcome inefficiencies and redundancies in PV processes [4].

Topics, Fields and Speakers

During the 3rd Pharmacovigilance Forum a lot of topics were covered and highly skilled speakers in PV field were present. The main, but not all of topics and specialist are listed below: Senior Pharmacovigilance Regulators and Inspectors, Pharmacovigilance and Drug Safety Officers, Regulatory Affairs Officers, Clinical Risk-Benefit Groups, Local Medicines Authorities, CRO and Consultants providing QPPV Services, Pharma Industry Heads, Directors and Managers of: Compliance Drug Safety Officers, Global Drug Safety Officers, Heads of Safety and Pharmacovigilance, Inspection and Audit, International PV Auditors, Lead Safety Scientists, Medical Affairs, Patient Safety, Pharmacoepidemiology Pharmacovigilance Consultants, Pharmacovigilance Managers, Pharmacovigilance Team Leaders PSMF, PV Quality System, QPPV Personnel's, Regulatory Affairs Managers, Safety and Risk Management Safety Evaluation, Safety Surveillance Senior Safety Specialists, and Signal Detection [4].

* NH Danube City Hotel, Wienn, 17-18 September 2015

References

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