Pharmaceut Reg Affairs 2012, 1:4
http://dx.doi.org/10.4172/2167-7689.S1.008

OMICS Group Conferences
Accelerating Scientific Discovery

2nd International Conference and Exhibition on
Pharmaceutical Regulatory Affairs

November 23-24, 2012 Hyderabad International Convention Centre, India

Overview of generic drugs review process

Durgacharan A. Bhagwat and John I. D'Souza
Tatyasaheb Kore College of Pharmacy, India

The Office of Pharmaceutical Science (OPS) is an integral part of the FDA Center for Drug Evaluation and Research (CDER) new and generic drug product application review process. The office provides uniform policies and review processes for the pharmaceutical industry. A generic drug product is one that is comparable to an innovator drug product in dosage form, strength, route of administration, quality, performance characteristics and intended use. The OPS laboratory programs support efforts to determine the correct quality standards, and in certain cases, validate the information companies provide. Drug companies, as part of the new drug approval, provide FDA with a list of relevant patents. FDA publishes the patent information and refers generic companies to review patents as part of the research and development process. FDA awards 180 days of exclusivity to the first generic holder to file a complete application (ANDA) with a patent challenge. This exclusivity does not apply against the brand company already in the marketplace but provides protection from other generic competition. FDA has some special issues in the generic review process: consistency among reviews of multiple applications, fairness and timing of reviews, patent and exclusivity issues and demonstration of bioequivalence. The value of generics is the reduction in cost. FDA knows that if a drug costs less, it increases use and prevents shortages resulting from product rationalization or supply disruption. Ultimately, FDA wants consumers to feel confident. Brand or generic, the consumer is getting a FDA-approved product that is interchangeable.

Biography

Durgacharan Arun Bhagwat M. Pharm.(Industrial Pharmacy): completed UG from Shivaji University, Kolhapur and PG from SGB Amravati University and pursuing Ph.D. from JJT University, Rajasthan, presently working as Asst. Professor Dept. of Pharmaceutics, Tatyasaheb Kore College of Pharmacy, Warananagar. He has 4 yrs of teaching experience. He published 1 Book and 14 research papers in reputed National and International journals and also presented 40 papers at various national and international conferences. He is Life Member of Indian Pharmaceutical Association (IPA) and Associate Life member of Indian Hospital Pharmacist Association (IHPA). He is Hon. Secretary of IPA Kolhapur Local Branch. He is Executive editor of International Peer reviewed journal "Pharmacum Consequat".

durgapharma@gmail.com

Global patterns of adverse drug reactions over a decade: Analyses of spontaneous reports to vigibase

Ebba Holme Hansen
University of Copenhagen, Denmark

To characterise adverse drug reactions (ADRs) reported to the WHO-ADR database, VigiBase, and to relate data to national income. We analysed ADR reports submitted to VigiBase from 2000 to 2009 with respect to reporting rate, age and sex of patient, type, seriousness and medications. Reports were also analysed with respect to national income level, classified in accordance with the World Bank definition: low, lower-middle, upper-middle and high. We analysed 1,359,067 ADR reports including 3,013,074 ADRs. Sixteen percent of reports were serious and sixty percent were reported for females. High-income countries had the highest ADR reporting rates (range 3 to 613 reports/million inhabitants/year) and low-income countries the lowest (range 0 to 21). Distribution of ADRs across income groups with respect to age group, seriousness and sex was non-significant. Overall, the majority of ADRs were reported for nervous system medications, followed by cardiovascular medicines. Low-income countries reported relatively more ADRs for anti-invectives for systemic use than high-income countries, and high-income countries reported more ADRs for antineoplastic and immunomodulating agents than lower-income groups. High-income countries had the highest ADR reporting rates and low-income countries the lowest. Significant differences in ADR reporting rates were only found for ADRs of the type "skin and subcutaneous disorders" and for the therapeutic groups "anti-infectives for systemic use" and "antineoplastic and immunomodulation agents". To strengthen ADR reporting rates, especially in low-income countries, more research is needed about the impact of organisational structures and economic resources of national pharmacovigilance centres and ADR reporting practices.

Biography

Ebba Holme Hansen has been the professor at the Section for Social Pharmacy, University of Copenhagen since 1992, and has worked for the University since she earned her MSc degree in pharmacy in 1968. She has been the driving force behind the development of social pharmacy as an academic disciplineHer research focus is children's medicine use, psychotropic medicines, adverse drug reactions and the experience and rationale of users in their use of medicines (the user perspective), national drug policy, prescription practices and self-medication, conducted nationally and internationally. Professor Hansen has held numerous posts on national and international committees and boards.

ehh@farma.ku.dk