Basics of pharmacovigilance pdf books online free

Version 1 Download 2825 File Size 0.00 KB File Count 1 Create Date September 13, 2020 Last Updated March 4, 2022 Pharmacovigilance Book Free PDF Download Scope: This paper will provide an opportunity for the student to learn about development of pharmacovigilance as a science, basic terminologies used in pharmacovigilance, global scenario of Pharmacovigilance, train students on establishing pharmacovigilance programme in an organization, various methods that can be used to generate safety data and signal detection. This paper also develops the skills of classifying drugs, diseases and adverse drug reactions. The layout of the book is simple, attractive and reader-friendly - it is a unique blend of basic and fundamental aspects of pharmacovigilance. Contains a dedicated chapter of 100 Case Studies with answers for hand-on training and experience in Pharmacovigilance practices. Key points are given in the initial page of every chapter for chapter overview. Sample Model Papers comprising of MCQs, Case Study, Long and Short Answer questions have been given at the end of the book to prepare students for exams. Enriched with lots of flowcharts, tables and line diagrams for making learning easy and interesting. Includes a glossary of terminologies used in the text in the beginning of the book with useful abbreviations. References for further reading are provided at the end of each chapter. Exhaustive appendices on different reporting forms of various countries. Good guide for medical, clinical research and pharmacovigilance students and other healthcare professionals. Customer Reviews, including Product Star Ratings help customers to learn more about the product and decide whether it is the right product for them. To calculate the overall star rating and percentage breakdown by star, we donâ€™t use a simple average. Instead, our system considers things like how recent a review is and if the reviewer bought the item on Amazon. It also analyzed reviews to verify trustworthiness. Learn more how customers reviews work on Amazon 1. WELCOMES YOU PHARMACOVIGILANCE 2. Pharmacovigilance Pharmacovigilance (PV) Drug Safety It is the pharmacological science relating to the collection, detection, assessment, monitoring, and prevention of adverse reaction with Pharmaceutical products. "Pharmacovigilance" (Pharmakon -drug +Vigilare to keep watch) PHARMACOVIGILANCE 3. Aims & Scope • To improve patient care & safety in relation to medicines & all medical & para-medical interventions • To improve public health & safety in relation to the use of medicines Patient Care Public Health • To contribute to the assessment of benefit, harm, effectiveness and risk of medicines Risk Benefit Assessment • To promote understanding, clinical training & effective communication to health professionals & the public Communication PHARMACOVIGILANCE 4. Dying from a disease is sometimes unavoidable; but dying from a medicine is unacceptable. 5. Pharmacovigilance in India: A Brief History • • National Pharmacovigilance Programme • Pharmacovigilance Programme of India • India joined WHO-ADR monitoring programme (3 centers: AIIMS, KEM, • JLN) •ADR monitoring system for India proposed (12 regional centers) 1982 & 1989 1997 2004 – 2008 2010 6. Why do we need pharmacovigilance? Humanitarian concern ADR May cause sudden death Promoting rational use of medicines and adherence Ethics To know of something that is harmful to another person who does not know, and not telling, is unethical PHARMACOVIGILANCE 7. Why do we need pharmacovigilance? It has been suggested that ADRs may cause 5700 deaths per year in UK. Humanitarian concern – Insufficient evidence of safety from CLINICAL TRIALS ANIMAL EXPERIMENTS Pirmohamed et al, 2004 ADRs were 4th-6th commonest cause of death in the US in 1994 Lazarou et al, 1998 ADRs are expensive !! 6.5% of admissions are due to ADRs Seven 800-bed hospitals are occupied by ADR patients Cost £446 million per annum PHARMACOVIGILANCE 8. The Minimum Requirements for a functional Pharmacovigilance System 1. A National Pharmacovigilance Centre with designated staff (at least one full time), stable basic funding, clear mandates, well defined structures and roles and collaborating with the WHO Programme for International Drug Monitoring. 2. The existence of a National spontaneous reporting system with a national individual case safety report (ICSR) form i.e. ADR reporting form PHARMACOVIGILANCE 9. 3. A national database or system for collating and managing ADR reports 4. A national ADR or pharmacovigilance advisory committee able to provide technical assistance on causality assessment, risk assessment, risk management case investigation and where necessary crisis management including crisis communication 5.Clear communication strategy for routine communication and crises communication PHARMACOVIGILANCE 10. What information should be reported ? PHARMACOVIGILANCE 11. ANY INFORMATION on an ADR or lack of efficacy connected with the use of a Bayer product. on ADRs occurring in the course of the use of a drug from drug overdose whether accidental or intentional from drug abuse / misuse / non-approved use from drug withdrawal in the infant of a nursing mother possibly as a result of exposure of the mother or the fetus during pregnancy. even if no ADR has been observed, From drug overdose whether accidental or intentional From drug abuse / misuse / non-approved use From drug administration during pregnancy. PHARMACOVIGILANCE 12. PHARMACOVIGILANCE 13. PV Work Flow Data collection (ICSR) Data entry in Data base Case processing (AMC) Review Panel (NCC) Causality Assessment Signal Detection Aggregate reporting (PSUR) Regulatory Authorities (CDSCO) Action UMC , Sweden 14. PHARMACOVIGILANCE 15. PHARMACOVIGILANCE 16. ADR Reporting through vigiflow. VigiFlow is a web-based Individual Case Safety Report (ICSR) management system that is specially designed for use by national centres in the WHO Programme for International Drug Monitoring. VigiFlow 5.1(Released on 14 June 2013) Subscription for Vigiflow is free in India. Other tools: ARISg (mainly used by Drug manufacturer in Europe) Argus (mainly used by Drug manufacturer in USA) Vigibase PHARMACOVIGILANCE 17. Vigiflow Reporting System. PHARMACOVIGILANCE 18. PHARMACOVIGILANCE 19. Overview Of PSUR As per Schedule Y, PSUR includes all safety reports - Spontaneous AE reports, PMS studies, Safety info from other sources - published articles etc. Subsequent to approval of the product, new drugs should be closely monitored for their clinical safety once they are marketed. The applicants shall furnish Periodic Safety Update Reports (PSURs) in order to - Report all the relevant new information from appropriate sources; Relate these data to patient exposure; Summarize the market authorization status in different countries and any significant variations related to safety; and Indicate whether changes should be made to product information in order to optimize the use of the product. PHARMACOVIGILANCE 20. Aggregate Reporting (PSUR) • Key role in safety assessment of Drugs. • It involves compilation of safety data of drug over a prolonged period of time. Advantages: Provides broader view of safety profile of a drug. • PSUR Worldwide, the most important aggregate report is the Periodic Safety Update Report (PSUR). PHARMACOVIGILANCE 21. Periodic safety update reports (PSURs) • (PSURs) now called as PBRER (Periodic benefit risk evaluation report, 21Jul2012) are Pharmacovigilance documents intended to provide an evaluation of the risk-benefit balance of a medicinal product for submission at defined time points during the post-authorisation phase. • The PSUR should focus on summary information, scientific safety assessment and integrated benefit-risk evaluation. PHARMACOVIGILANCE 22. PHARMACOVIGILANCE 23. Submission frequency for PSURs • First 2 yrs: every 6 month • Next 2 yrs: every year • After that every 3 years. On the basis of PSURs: Regulatory Authorities take the appropriate decision for marketing of particular medicinal product. PHARMACOVIGILANCE 24. PHARMACOVIGILANCE 25. What We Do….. Pharmacovigilance / Safety / Medical Writing Services ACPL provide services entails the generation of well-structured individual reports supporting extensive medical writing programs, including: Aggregate report writing/ Medical and technical writing for PSURs Product Feasibility Reports for Medical Devices/Drugs Medical and technical writing for clinical study reports and annual reports Clinical Summaries. SAE Narratives for Clinical Study Reports RMP, SOP writing PHARMACOVIGILANCE 26. Recently banned drugs in India • Serodiagnostic test kits for diagnosis of tuberculosis (with effect from 7Jun2013). • Dextropropoxyphene (with effect from 23May2013) . • Fixed dose combination of Flupentixol+Melitracen (with effect from 18Jun2013). • Analgin (with effect from 18Jun2013) • Pioglitazone (with effect from 18Jun2013) PHARMACOVIGILANCE 27. THANK YOU ACCREDITED CONSULTANTS PVT. LTD. (Email: bhatbio@gmail.com, info@acplgroupindia.co.in, Website: acplgroupindia.co.in) (Contact: +91 22758204, 9350040434, 9310040434, Fax: 22758994) D-29, 1ST FLOOR, ACHARYA NIKETAN, MAYUR VIHAR PHASE-I, NEW DELHI-110091 PHARMACOVIGILANCE

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