Benefit-Risk Appraisal of Medicines

A systematic approach to decision-making

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With a Foreword by
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Benefit-Risk Appraisal of Medicines: A systematic approach to decision-making, Filip Mussen, Sam Salek, Stuart Walker, John Wiley & Sons, 2009, 0470748125, 9780470748121, 304 pages. Benefit-risk assessment is at the centre of the approval process for every new medicine. The ability to assess the risks of a new medicine accurately and to balance these against the benefits the medicine could bring is critical for every regulatory authority and pharmaceutical company. Despite this there are very few tried and tested evaluative models currently available.The authors of this book have developed a new, pioneering tool for the assessment of benefits and risks for new medicines in development. This model utilises a multi-criteria decision analysis which involves selecting, scoring and weighting key benefit and risk attributes and leads to an overall appraisal of benefits and risks of medicines.Benefit-Risk Appraisal of Medicines establishes the background and criteria required to assess benefit and risk in general and reviews the current practices by regulatory authorities and the pharmaceutical industry, including those models currently available. It outlines the development and evaluation of the authorsÐ²Ð‚â„¢ new model and analyses the implications of its implementation.Describes an innovative, systematic model which leads to transparent and responsible benefit-risk decision makingContributes important ideas to the debate on benefit-risk appraisalProvides a future framework for benefit-risk appraisal of medicinesBenefit-Risk Appraisal of Medicines covers the entire process from the discovery of new medicines to their marketing and is ideal for all those who work in the pharmaceutical industry and regulatory authorities,, as well as post-graduate students of pharmaceutical medicine and clinical pharmacology..

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adverse events agencies alosetron application approach assessment of medicines benefit and risk benefit criteria benefitâ€“risk analysis benefitâ€“risk assessment benefitâ€“risk balance benefitâ€“risk decisions benefitâ€“risk framework benefitâ€“risk profile Chapter CHMP CIOMS clinical relevance clinical trials CMR International Institute comparator considered criterion decision-making defined described discussed disease drug efficacy and safety enalapril European Medicines Agency evaluation evidence example identified important incidence of adverse indication Institute for Regulatory interactions judgement label MCDA medicinal products methodology methods model for benefitâ€“risk multi-criteria decision analysis off-label options outcomes Overall incidence patients pharmaceutical pharmacovigilance pivotal trial placebo population Potential for non-demonstrated primary endpoints quality-adjusted quantify quantitative regulators regulatory authorities Regulatory Science relative risk and benefit risk criteria rizatriptan safety and efficacy safety data safety issues observed serious adverse effects stakeholders Stuart Walker studies subgroups sumatriptan templates therapeutic therapy trade-off transparency triptans uncertainty versus weights Workshop

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