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Fast Facts: Biosimilars in Hematology and Oncology

Karger Medical and Scientific Publishers **Biologics have revolutionized – and are revolutionizing – the treatment of many serious disorders. The evidence acquired from more than 10 years of clinical experience, with more than 50 biosimilar drugs and more than 700 million patient-days' exposure in Europe, shows that approved biosimilars can be used as safely and effectively as originator biologics. Yet concerns persist about biosimilars – particularly in curative cancer treatment, where they are relatively recent therapeutic options. 'Fast Facts: Biosimilars in Hematology and Oncology' provides a concise overview of emerging global practice in this fast-moving area together with practical information on adding biosimilars to a formulary and switching patients. Contents: • Biologics and the need for biosimilars • Why do we need biosimilars? • How is the quality of biosimilar medicines assured? • Legal issues • Switching, interchangeability and extrapolation • Safety and pharmacovigilant • Global issues • Formulary considerations: pharmacy issues • Formulary considerations: supportive care biosimilars • Formulary considerations: therapeutic anti-cancer biosimilars • Communication and awareness**

Oxford Textbook of Rheumatology

Oxford University Press **A strong clinical emphasis is present throughout this volume from the first section of commonly presenting problems through to the section addressing problems shared with a range of other clinical sub-specialties.**

Private Patents and Public Health

Changing Intellectual Property Rules for Access to Medicines

Millions of people around the world do not have access to the medicines they need to treat disease or alleviate suffering. Strict patent regimes introduced following the establishment of the World Trade Organization in 1995 interfere with widespread access to medicines by creating monopolies that keep medicines prices well out of reach for many. 0The AIDS crisis in the late nineties brought access to medicines challenges to the public?s attention, when millions of people in developing countries died from an illness for which medicines existed, but were not available or affordable. Faced with an unprecedented health crisis ? 8,000 people dying daily ? the public health community launched an unprecedented global effort that eventually resulted in the large-scale availability of low-priced generic HIV medicines. 0But now, high prices of new medicines - for example, for cancer, tuberculosis and hepatitis C - are limiting access to treatment in low-, middle and high-income countries alike. Patent-based monopolies affect almost all medicines developed since 1995 in most countries, and global health policy is now at a critical juncture if the world is to avoid new access to medicines crises. 0This book discusses lessons learned from the HIV/AIDS crisis, and asks whether actions taken to extend access and save lives are exclusive to HIV or can be applied more broadly to new global access challenges.

Fast Facts: Biosimilares

Biológicos y biosimilares – ¿son lo suficientemente similares?

Karger Medical and Scientific Publishers **Los biosimilares han estado en uso clínico durante más de 10 años, y la evidencia de exposición de más de 700 millones de días-paciente muestra que los biosimilares aprobados pueden usarse de manera tan segura y efectiva como sus productos biológicos originales. Y sin embargo, persisten las preocupaciones sobre estos medicamentos, especialmente en las áreas terapéuticas donde han sido recientemente incluidos a los formularios. Es de vital importancia abordar estas inquietudes para que los médicos puedan prescribir los biosimilares con confianza, dándose cuenta de los ahorros en costos y mejorando el acceso de los pacientes a tratamientos eficaces. 'Fast Facts: Biosimilares' proporciona una explicación completa pero concisa de los biosimilares: qué son, cómo se regulan y la forma en que se utilizan en la práctica clínica. Es ideal para los profesionales de la salud y tomadores de decisiones que desean comprender a los biosimilares y las principales preocupaciones y controversias en torno a estos valiosos productos.**

Hidden Treasures

Mapping Europe's Sources of Competitive Advantage in Doing Business

Europe is often presented as a declining global power, in which red tape, incumbency interests and governance flaws hamper economic performance, innovation and productivity. Part of this can be traced back to the inherent challenge and ambition of the European integration project; but also to external factors, including the rise of the United States as a global superpower during the past century, and the worldwide diffusion of ideas, especially in politics and economics, which were seldom originated in Europe, or tailored to its peculiar legal, economic and social traditions. Until recently, Europe has sought to carve out its model and role in global governance by mimicking many US policy approaches: shareholder capitalism, deregulation and unconstrained movement of capital. As the global community increasingly sees the rise of protectionist stances, and a growing inability to face emerging challenges such as sustainable development and the breath-taking rise of disruptive digital technologies, Europe should look at its best qualities to revamp and reclaim its position in the global order, to the benefit of all. The prospect of Brexit, while certainly not favourable for the Union, paradoxically opens up new opportunities to face emerging challenges with a greater degree of cohesion. This new book, a joint effort between Donald Kalff and a group of CEPS researchers led by Andrea Renda, aims at identifying and exploring Europe's 'hidden treasures', often neglected competitive advantages that could, if adequately nurtured, return the Old Continent to the forefront of the global order. 'Hidden treasures' are a feature of the EU economy, legal system or legal tradition that are being given insufficient attention in EU public policy, and which bear the potential to increase Europe's competitiveness and overall positioning in the global context. The authors find them in ten policy domains, from contract law to corporate governance, taxation, control of corruption, competition policy, trade, innovation and the EU's unique approach to governing the digital economy. Uncovering and promoting hidden treasures becomes, as of today, a timely and highly needed exercise, as the EU approaches its post-elections transition, and the global governance context seems to be rapidly changing, shaping a new playing field in which Europe has no obvious allies, and is increasingly challenged by superpowers with different, if not diverging, priorities.

Tackling Wasteful Spending on Health

OECD Publishing **Countries could potentially spend significantly less on health care with no impact on health system performance, or on health outcomes. This report reviews strategies put in place by countries to limit ineffective spending and waste.**

Forward Plan for Health

Real World Drug Discovery

A Chemist's Guide to Biotech and Pharmaceutical Research

Elsevier **Drug discovery increasingly requires a common understanding by researchers of the many and diverse factors that go into the making of new medicines. The scientist entering the field will immediately face important issues for which his education may not have prepared him: project teams, patent law, consultants, target product profiles, industry trends, Gantt charts, target validation, pharmacokinetics, proteomics, phenotype assays, biomarkers, and many other unfamiliar topics for which a basic understanding must somehow be obtained. Even the more experienced scientist can find it frustratingly difficult to get an overview of the many factors involved in modern drug discovery and often only after years of exploring does a whole and integrated picture emerge in the mind of the researcher. Real World Drug Discovery: A Chemist’s Guide to Biotech and Pharmaceutical Research presents this kind of map of the landscape of drug discovery. In a single, readable volume it outlines processes and explains essential concepts and terms for the recent science graduate wondering what to expect in pharma or biotech, the medicinal chemist seeking a broader and more timely understanding of the industry, or the contractor or collaborator whose understanding of the commercial drug discovery process could increase the value of his contribution to it. Interviews with well-known experts in**

many of the fields involved, giving insightful comments from authorities on many of the sub-disciplines important to cutting edge drug discovery. Helpful suggestions gleaned from years of experience in biotech and pharma, which represents a repository drug discovery "lore" not previously available in any book. "Periodic Table of Drugs" listing current top-selling drugs arranged by target and laid out so that structural similarities and differences are plain and clear. Extensive use of diagrams to illustrate concepts like biotech startup models, preteomic profiling for target identification, Gantt charts for project planning, etc.

Global Innovation Index 2019: Creating Healthy Lives — The Future of Medical Innovation

WIPO **The Global Innovation Index 2019 provides detailed metrics about the innovation performance of 129 countries and economies around the world. Its 80 indicators explore a broad vision of innovation, including political environment, education, infrastructure and business sophistication. The GII 2019 analyzes the medical innovation landscape of the next decade, looking at how technological and non-technological medical innovation will transform the delivery of healthcare worldwide. It also explores the role and dynamics of medical innovation as it shapes the future of healthcare, and the potential influence this may have on economic growth. Chapters of the report provide more details on this year's theme from academic, business, and particular country perspectives from leading experts and decision makers.**

National Science Foundation

America's Investment in the Future

Jugaad Innovation

Think Frugal, Be Flexible, Generate Breakthrough Growth

John Wiley & Sons **"Jugaad Innovation is the most comprehensive book yet to appear on the subject [of frugal innovation]." —The Economist A frugal and flexible approach to innovation for the 21st century Innovation is a key directive at companies worldwide. But in these tough times, we can't rely on the old formula that has sustained innovation efforts for decades—expensive R&D projects and highly-structured innovation processes. Jugaad Innovation argues the West must look to places like India, Brazil, and China for a new approach to frugal and flexible innovation. The authors show how in these emerging markets, jugaad (a Hindi word meaning an improvised solution born from ingenuity and cleverness) is leading to dramatic growth and how Western companies can adopt jugaad innovation to succeed in our hypercompetitive world. Outlines the six principles of jugaad innovation: Seek opportunity in adversity, do more with less, think and act flexibly, keep it simple, include the margin, and follow your heart Features twenty case studies on large corporations from around the world—Google, Facebook, 3M, Apple, Best Buy, GE, IBM, Nokia, Procter & Gamble, PepsiCo, Tata Group, and more—that are actively practicing jugaad innovation The authors blog regularly at Harvard Business Review; their work has been profiled in BusinessWeek, MIT Sloan Management Review, The Financial Times, The Economist, and more Filled with previously untold and engaging stories of resourceful jugaad innovators and entrepreneurs in emerging markets and the United States This groundbreaking book shows leaders everywhere why the time is right for jugaad to emerge as a powerful business tool in the West—and how to bring jugaad practices to their organizations.**

Securities Exchange Act of 1934 as Amended

Clinical Oncology Fourth Edition

Basic Principles and Practice

CRC Press **A clear and comprehensive introduction to the principles and practice of clinical oncology, for medical undergraduates and clinicians who want to increase their understanding of the challenges of managing patients with cancer. Including questions for self assessment by the same authors, the reader can learn and test themselves on all aspects of cancer medicine, from epidemiology, aetiology, pathogenesis and presentation, through to diagnosis, staging, management and prognosis.**

2018-19 Annual Report

National Library of Medicine Programs and Services

Progress in Medical Research

Springer **This book is a compendium of articles providing insights into a range of contemporary ideas concerning the core yet unsettled clinical issues. Important aspects of pulmonary disorders are tackled such as occupational respiratory health hazards, asthma, or the role of vitamin D in obstructive airway diseases. Genotyping offers a clear promise in the diagnostics of chronic pulmonary lesions of autoimmune background. Cardiac and respiratory-driven pulsation of cerebrospinal fluid content offers novel arguments in the pathophysiologic savvy of a range of brain dysfunctional conditions, including respiratory-related hypoxic pathologies. Some other articles tackle the heady topics of rehabilitation medicine, offering an insight into research-underpinned diagnostics and practical management solutions in a range of musculoskeletal disorders and injuries that affect the human body's movement, particularly those controlled by the autonomic nervous system. The book is addressed to clinicians, researchers, physiotherapists, and medical professionals engaged in patient care.**

Cancer and Society

A Multidisciplinary Assessment and Strategies for Action

Springer **While a number of books have looked at the intersection between human health in general and other topics, such as climate change or diet, this book focuses specifically on cancer as it impacts and is impacted by social justice issues. The massive explosion of research knowledge of cancer immunology and genomics is holding out great promise of therapeutic advances, yet other human actions—climate change, pollution, business decisions, advertising – are fostering health inequalities as well as increasing risks. Those involved in cancer care and research are in a unique position to let their experiences and knowledge inform the public, yet very often have not taken strong public roles when it comes to discussing issues surrounding tobacco, climate change and health risks, financial toxicity of treatments, and diet choices. Written by a multidisciplinary team of authors and for medical oncologists, cancer researchers, occupational health workers, and related medical students, residents, and fellows, this book encourages oncologists to address public health care and the societal issues associated with cancer risk. This volume discusses the overarching theme of environmental justice and oncology, focuses on business and cancer (such as clinical trials, drug development and profits, and global disparities), as well as animals and cancer.**

Dose Finding by the Continual Reassessment Method

CRC Press **As clinicians begin to realize the important role of dose-finding in the drug development process, there is an increasing openness to "novel" methods proposed in the past two decades. In particular, the Continual Reassessment Method (CRM) and its variations have drawn much attention in the medical community, though it has yet to become a commonplace tool. To overcome the status quo in phase I clinical trials, statisticians must be able to design trials using the CRM in a timely and reproducible manner. A self-contained theoretical framework of the CRM for researchers and graduate students who set out to learn and do research in the CRM and dose-finding methods in general, Dose Finding by the Continual Reassessment Method features: Real clinical trial examples that illustrate the methods and techniques throughout the book Detailed calibration techniques that enable biostatisticians to design a CRM in timely manner Limitations of the CRM are outlined to aid in correct use of method This book supplies practical, efficient dose-finding methods based on cutting edge statistical research. More than just a cookbook, it provides full, unified coverage of the CRM in addition to step-by-step guidelines to automation and parameterization of the methods used on a regular basis. A detailed exposition of the calibration of the CRM for applied statisticians working with dose-finding in phase I trials, the book focuses on the R package 'dfcrm' for the CRM and its major variants. The author recognizes clinicians' skepticism of model-based designs, and addresses their concerns that the time, professional, and computational resources necessary for accurate model-based designs can be major bottlenecks to the widespread use of appropriate dose-finding methods in phase I practice. The theoretically- and empirically-based methods in Dose Finding by the Continual Reassessment Method will lessen the statistician's burden and encourage the continuing development and implementation of model-based dose-finding methods.**

Predictive Biomarkers in Oncology

Applications in Precision Medicine

Springer **“Precision/personalized or stratified medicine” refers to the tailoring of medical treatment or drug administration to the individual characteristics of each patient treatment. It does not literally mean that a pharmaceutical company makes a drug for an individual patient for consumption and treatment but rather means the ability to stratify (or classify) individuals into sub-populations that differ in their responsiveness to a specific drug. A marker that provides information on the likely response to therapy, i.e., either in terms of tumor shrinkage or survival of the patient is termed “predictive biomarker”. Despite their promise in precision medicine and the explosion of knowledge in this area, there is not a single source on this subject that puts all this evidence together in a concise or richly illustrated and easy to understand manner. This book provides a collection of ingeniously organized, well-illustrated and up-to-date authoritative chapters divided into five sections that are clear and easy to understand. Section one provides an overview of biomarkers, introduces the basic terminologies, definitions, technologies, tools and concepts associated with this subject in the form of illustrations/graphics, photographs and concise texts. Several recent biomarker endeavors that have been initiated and funded by the National Cancer Institute, National Institutes of Health, FDA and other International organizations are presented. Section two involves the signaling pathways controlling cell growth and differentiation altered in cancer. This section analyzes how predictive biomarkers are altered (expressed or amplified) across cancer types. Section three explores how predictive biomarkers play a role in patient stratification and tailored treatment in relationship to specific cancers. In addition, it includes discussion on the various precision medicine initiatives that are going on across the globe (e.g. TARGET, NCI-MATCH, BATTLE, SHIVA, etc.). Section four discusses: (a) how pharmaceutical companies validate predictive biomarker assays and accompanying companion diagnostics either internally or externally with partner companies such as central laboratories or clinical research organizations, and (b) how predictive biomarker tests fall under the oversight of US FDA, Centers for Medicare & Medicaid Services (CMS) and state laws. Section five wraps up novel agents and targets that are being used as targets for cancer therapeutics. The biomarkers associated with these protocols will also be presented. Throughout the book, sidebars, special interest boxes and illustrations are used to explain terms that are either newly introduced, uncommon, or specialized. Predictive Biomarkers in Oncology will serve as a definitive guide for practicing pathologists, oncologists, basic researchers, and personnel in the pharmaceutical or diagnostic industry interested in learning how “predictive biomarkers” are used in precision cancer therapy.**

Spring Budget 2017

This Budget: i) increases the main rate of class 4 National Insurance Contributions from 9% to 10% in April 2018 and to 11% in April 2019; and ii) reduces the dividend allowance from £5,000 to £2,000 from April 2018. Personal allowance will also rise to £11,500 in April 2017. The Budget further announces polices to create sector specific routes to employment; fund maintenance loans for students pursuing technical education at higher levels; and expand the free schools programme. There will be over £23 billion of additional high value investment committed through the National Productivity Investment Fund (NPID). Tax free childcare for working families with children under 12 will be rolled out and from September 2017 the free childcare offer will double to 30 hours per week for working families with 3 and 4 year olds in England. The government will provide £2 billion additional funding for social care to councils in England. It will also invest a further £425 million to improve local NHS services.

Development of Biopharmaceutical Drug-Device Products

Springer Nature **The biotechnology/biopharmaceutical sector has tremendously grown which led to the invention of engineered antibodies such as Antibody Drug Conjugates (ADCs), Bispecific T-cell engager (BITES), Dual Variable Domain (DVD) antibodies, and fusion proteins that are currently being used as therapeutic agents for immunology, oncology and other disease conditions. Regulatory agencies have raised the bar for the development and manufacture of antibody-based products, expecting to see the use of Quality by Design (QbD) elements demonstrating an in-depth understanding of product and process based on sound science. Drug delivery systems have become an increasingly important part of the therapy and most biopharmaceuticals for self-administration are being marketed as combination products. A survey of the market indicates that there is a strong need for a new book that will provide “one stop shopping” for the latest information and knowledge of the scientific and engineering advances made over the last few years in the area of biopharmaceutical product development. The new book entitled Development of Biopharmaceutical Drug Device Products is a reference text for scientists and engineers in the biopharmaceutical industry, academia or regulatory agencies. With insightful chapters from experts in the field, this new book reviews first principles, covers recent technological advancements and provides case studies and regulatory strategies relating to the development and manufacture of antibody-based products. It covers topics such as the importance of early preformulation studies during drug discovery to influence molecular selection for development, formulation strategies for new modalities, and the analytical techniques used to characterize them. It also addresses important considerations for later stage development such as the development of robust formulations and processes, including process engineering and modeling of manufacturing unit operations, the design of analytical comparability studies, and characterization of primary containers (pre-filled syringes and vials).Finally, the latter half of the book reviews key considerations to ensure the development and approval of a patient-centered delivery system design. This involves the evolving regulatory framework with perspectives from both the US and EU industry experts, the role of international standards, design control/risk management, human factors and its importance in the product development and regulatory approval process, as well as review of the risk-based approach to bridging between devices used in clinical trials and the to-be-marketed device. Finally, case studies are provided throughout.The typical readership would have biology and/or engineering degrees and would include researchers, scientific leaders, industry specialists and technology developers working in the biopharmaceutical field.**

Jugaad Innovation

A Frugal and Flexible Approach to Innovation for the 21st Century

The Right Care, in the Right Place, at the Right Time

Better Health, Better Care

Action Plan

This action plan sets out a programme of comprehensive and targeted action to accelerate progress in health improvement, tackling health inequality and improving the quality of health care in Scotland.

The Innovation Imperative

Contributing to Productivity, Growth and Well-Being

OCDE **Well-timed and targeted innovation boosts productivity, increases economic growth and helps solve societal problems. But how can governments encourage more people to innovate more of the time? And how can government itself be more innovative? The OECD Innovation Strategy provides a set of principles to spur innovation in people, firms and government. It takes an in-depth look at the scope of innovation and how it is changing, as well as where and how it is occurring, based on updated research and data.**

INDIAN PHARMACOPOEIA 2018 (ADDENDUM 2021).

Office for Budget Responsibility

Fiscal Sustainability Report January 2017

Continuing Care Health Service Standards

The British Journal of Surgery