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Commentary

Pharmaceutical Medicine and Translational Clinical Research

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Abstract

The Faculty of Pharmaceutical Medicine was founded in 1989 as one of two faculties of the three Royal Colleges of Physicians in the UK. From its inception, the Faculty has had a strong association with clinical pharmacology. Indeed, many would be surprised if it were otherwise, as clinical pharmacology and therapeutics are fundamental to the pharmaceutical business of the discovery, development and registration of drugs. The founder President of the Faculty was Sir Abe Goldberg, an academic clinical pharmacologist and a previous chairman of the Committee on Safety of Medicines, and other clinical pharmacologists were well represented on the founding committees. Pharmaceutical Medicine and Translational Clinical Research covers clinical testing of medicines and the translation of pharmaceutical drug research into new medicines, also focusing on the need to understand the safety profile of medicine and the benefit-risk balance. Pharmacoeconomics and the social impact of healthcare on patients and public health are also featured. It is written in a clear and straightforward manner to enable rapid review and assimilation of complex information and contains reader-friendly features.

KeyWords : pharmaceutical medicine, Clinical Pharmacology, including biosimilars, biobetters, super generics

Introduction

Advances in clinical and basic science, preventive medicine, pharmaceuticals, imaging, and surgical techniques have helped increase life expectancy every decade since the 1930s (National Center for Health Statistics, 2006). Disorders of the central nervous system (CNS) still evade much of our medical expertise, however. Nevertheless, there is a growing consensus that the nervous system has greater capacity for repair than was previously believed. The traditional view was that the complement of cells present at birth slowly diminishes with aging. We now know, however, that the nervous system is constantly birthing new cells, particularly glial cells, but also new neurons, and that there is greater plasticity and capacity for spontaneous repair.

Clinical Pharmacology

Clinical Pharmacology is the study of drugs and the interactions of chemical substances with living beings, with a view to understanding the properties and their actions, including the interactions between drug molecules drug receptors and how these interactions induce an effect.

Methods in Clinical Pharmacology

Clinical Pharmacology & Biopharmaceutics, Clinical & Experimental Pharmacology, Journal of Pharmaceutical Sciences & Emerging Drugs, Biochemistry and Pharmacology: Open Access, The Journal of Clinical Pharmacology, International Journal of Basic & Clinical Pharmacology,-Journal of Anaesthesiology Clinical Pharmacology,Clinical Pharmacology:Advances and Applications,Pharmacology and Toxicology, International Journal of Basic & Clinical Pharmacology.

Pharmaceutical Medicine

it is a medical discipline concerned with the discovery, evaluation, registration, monitoring and clinical aspects of pharmaceutical development. All medical specialties overlap to some extent, and likewise the boundaries of pharmaceutical medicine are elastic.

The basics of pharmaceutical medicine are founded in clinical pharmacology. In addition to expertise in basic research, drug development, and the structure and function of clinical trials, pharmaceutical physicians must possess thorough understanding of pharmacoeconomics, medical aspects of the marketing pharmaceuticals, and business administration, and public health.

Super Generics

A super generic drug is an improved version of an original drug which has lost product patent protection. The product patent for the original drug will have expired or have

been circumvented by the company developing the super generics.

Need for Super Generics

Drug makers today are burdened by the huge costs incurred in research and development. The average

R&D-to-marketplace cost for a new medicine is nearly USD 4 billion, sometimes exceeding USD 10 billion. Moreover, out of all NCEs developed worldwide, only 12% make it to the clinical trials. This is one of the major reasons for declining ROI in the research and development of therapeutics - new chemical entities and new biologic entities.

Biosimilars and Biobetters Pharmaceuticals

A biobetter is a recombinant protein drug from the same class as an existing biopharmaceutical but is not identical; it is superior to the original. It isn't exclusively a new drug, neither a generic version of a drug. Biosimilars and biobetters are both variants of a biologic; with the former being close copies of the originator, while the latter ones have been improved in terms of efficacy, safety, and tolerability or dosing regimen. While biosimilars enjoy a speedy FDA approval process, biobetters are evaluated and tested as a new drug because they differ significantly from the reference product. Their formulation has been intentionally modified to improve the drug for a variety of reasons such as efficacy, safety and performance.

Conclusion

The whole experience of modern drug use covers a period of not much more than three-quarters of a century. The history of medicine dwarfs this short period and it is perhaps not surprising that the final result is something less than the con-sistent and rational outcome that some would like to believe it to be. Much of the information which best shows its inconsistencies is only slowly and irregularly entering the scientific domain. The period during which this book has been written and printed has seen a marked change in this respect, important data on drug side-effects and adverse experience having been recently published in response to political questioning as well as scientific activity.