The Detection of New Adverse Drug Reactions

The Detection of New Adverse Drug Reactions

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with a guest chapter contributed by
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and
contributions on drug regulations
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Second edition

M
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P R E S S

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Foreword

We stand on the threshold of what has been called 'the second pharmacological revolution'. During the past three decades major therapeutic advances have been made, but they may well be overshadowed by those of the rest of the century, as new molecular biochemical discoveries, and techniques for genetic engineering, permit control of viral, psychiatric, malignant and autoimmune disease. Tragically, however, this optimistic prediction is threatened by ill-advised yet widespread public fear of, and indeed hostility to, new drugs, fostered by a variety of consumer and media lobbies who have not yet understood that a chemical's therapeutic efficacy is inevitably associated with unwanted effects, particularly if used unwisely.

Many books have been written about the design of clinical trials and determination of therapeutic efficacy of drugs, but little has been published on the systematic detection, quantification and evaluation of adverse drug reactions. This process should begin, of course, with the earliest administration of a drug to man, and continue throughout its controlled clinical trials, but is likely only to identify relatively common or bizarre adverse effects. Less common, but nevertheless important, unwanted effects will be recognised only when it is prescribed for larger numbers of patients, usually after it has been marketed, and when its use, therefore, is less closely supervised.

Dr Stephens has been closely involved in the practical problems of adverse drug reaction monitoring for many years, and this book represents an important contribution to the subject which I believe will be of value to all involved in the scientific assessment of drug treatment.

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London

Preface to the First Edition

This book sets out to describe the problems involved in the detection of new adverse drug events both before and after a drug reaches the market and the various methods available to overcome these problems. The methods cover the collection, storage and assessment of the information. It is hoped that it will be found useful to those involved in clinical trials, whether clinical or pharmaceutical scientist. For the latter it is also hoped that he or she will find sufficient information and referenced papers to be able to set up a drug surveillance unit within a pharmaceutical company.

The withdrawal from the market of numerous drugs over the last few years has prompted changes in the regulations in many countries and, therefore, in turn has caused, and will cause, great changes within the pharmaceutical industry.

The most important change will be the realisation that equal effort and money will need to be put into both sides of the cost/benefit ratio in the clinical research of a new drug.

I have resisted the temptation to stray into the more fascinating and controversial areas, such as the law on liability and compensation for drug injury or the history of various established adverse drug reactions, but I hope that the bibliography will have covered these gaps.

All opinions mentioned in this book are my own, unless specifically stated as being otherwise. It should not be presumed that any views or practices described here are those of the Glaxo Group or any of its subsidiary companies, unless stated.

Bishop's Stortford, 1984

M.D.B.S.

Preface to Second Edition

Since the original edition was published in 1985 there have been a number of changes in the field of adverse drug reactions. Important changes in pharmaceutical law in several countries have brought about changes within the industry so that most large pharmaceutical companies now have a department to deal with drug surveillance.

There have been recently several Drug Information Association meetings and workshops dedicated to relevant topics, such as clinical data management, pre-marketing adverse drug experiences, data management procedures, the future of ADR diagnosis: computers, clinical judgement and the logic of uncertainty.

As a result I have rewritten the chapters on assessment of adverse medical events and post-marketing surveillance, and there is a new chapter on laboratory investigations. The chapters on methodology of the collection of adverse event data; the pre-marketing establishment of the side effect profile of a new drug; ethical problems; collection, storage, retrieval and management of ADR data and regulations have all had extensive changes in order to bring them up to date. The general expansion has resulted in almost double the number of references. In this edition any new information which has arrived after completion of the list of references has been inserted in the relevant chapter with the reference incorporated in the text. Information arriving just prior to going to press has been added after the Appendix.

Bishop's Stortford, 1988

M.D.B.S.

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