

BOOK REVIEW

DRUG SAFETY: A Shared Responsibility

*By the International Drug Surveillance Department of
Glaxo Group Research Ltd.*

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In consideration of the recent cases of benoxaprofen and nomifensine the issue of drug safety is important from several standpoints. The authors, from an industrial perspective, present a work designed to introduce the various aspects of drug safety, from defining adverse drug reactions (ADRs) to reporting them to the proper authorities. The book is clearly aimed toward the practicing health professional who may be confronted with recognizing and reporting an adverse drug reaction.

The book provides an introduction to the whole arena of drug safety in the first chapter and moves to an overview of clinical phase trials in the second chapter. Chapters three and four contain introductory material on post-marketing surveillance and spontaneous reporting. The most important chapter is chapter five, which discusses the criteria for determining whether an untoward effect is due to an ADR. This chapter provides useful material to the health practitioner who encounters a possible ADR.

In chapter six the authors seek to persuade the health practitioner of the need to report suspected ADRs to both the regulatory agencies and to the pharmaceutical industry. The authors contend that the legal liabilities are minimal and that the pharmaceutical industry will act responsibly with the given information. In chapter seven, the authors overview the role of the pharmaceutical industry in drug safety, stressing the argument that industry is primarily concerned with patient welfare.

Chapters eight and nine highlight the process of ADR reporting and the role of the regulatory authorities within the United Kingdom. A chapter discussing the regulatory process within the USA and other countries would have been an added benefit. Chapter ten discusses careers associated with drug safety; the authors draw heavily on the system that Glaxo employs to illustrate their point. Chapter eleven discusses information sources that may be utilized by the health practitioner when investigating a possible ADR.

Drug Safety: A Shared Responsibility is a useful resource to those interested in the issues of drug safety.

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