
ELSEVIER

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Foreword

The thalidomide disaster in the early sixties has given an enormous impetus to a commitment to make sure that such a thing would never happen again. It led, first, to regulations requiring extensive toxicological work in animals and to more rigorous clinical testing of new drugs. Yet, despite all of these extraordinary efforts, new drugs, now and then, have caused unexpected and unacceptable toxicities which have resulted in their removal from the market. Such toxicities have been at the roots of the demand for more efforts and new approaches that should be helpful in the timely detection of unacceptable side effects of — mainly new, but also of existing — medicines. It is the new discipline of pharmacovigilance that tries to achieve this aim; in order to do so, it must reconcile the enormous burden of scientific effort that is required for such a timely detection with the need to contain the ever escalating cost of drug development — a financial burden that, ultimately, must be paid for by society in one form or another.

In the area of pharmacovigilance, clinicians, academics and the pharmaceutical industry are natural allies, who should also work closely together with the regulators. This must be borne in mind whilst reading this publication that describes today's practice of pharmacovigilance in a transnational pharmaceutical industry. This publication does not discuss the situation as it exists today in every pharmaceutical company, but refers to a large extent to that in the Janssen Research Foundation. This probably has both advantages and disadvantages, but it will hopefully give the newcomer in the field a fair flavour of what is going on in the pharmaceutical industry at large and it might offer a couple of new insights to those who are already working in post-marketing drug safety.

Although the author's personal experience in this field has been the starting point in writing the present work, a lot of information has also been borrowed from the medical literature. In such circumstances, it is often impossible to reconstruct where such information has originally come from. The author, therefore, wishes to express his deep appreciation to all authors who have

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contributed to this field before and whose ideas or findings may, therefore, be reflected in this publication, and makes no claim as regards the originality of the same, apart from those elements that have been developed by himself and that are indicated as such.

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