

collection, evaluation, and dissemination of drug interaction information by the APha Drug Interactions Evaluation Program

by Frank J. Ascione, Pharm. D.

The American Pharmaceutical Association's Drug Interactions Evaluation Program (DIEP) is a multidisciplinary group approach to the evaluation and dissemination of drug interaction information. More than 200 health-care professionals from dentistry, medicine, and pharmacy participate in the Program, with most serving as members of Scientific Review Panels or Practitioner Panels. The major results of this group effort have been the publication of *Evaluations of Drug Interactions-1973* (EDI-1973) and its 1974 Supplement. A complete revision of EDI is scheduled to be completed in mid-1976.

The Drug Interactions Evaluation Program, originally called the Drug Interactions Project, was established by APhA in response to the expressed needs of its members for useful and accurate drug interaction information. During the early stages of this project, the staff mainly coordinated communications between panel members and monograph authors. There was little, if any, staff input in the content of the monograph, except for editorial changes.

However, it became apparent in the late stages of the production of EDI-1973 that this approach was not resolving satisfactorily many comments made during the initial review. The process of compiling the panel members' comments and sending them to the monograph author to incorporate into the monograph was very time-consuming. Moreover, because of differences in the various authors' interests, motivation, or writing ability, there was considerable variability in the content and quality of the monographs.

Therefore, during the production of the 1974 Supplement, it was decided to do more in-house review of the monograph content and to exert more staff control over the DIEP review process. To do this task effectively, a data base containing pertinent information about drug interactions had to be developed. Development of such a data base was begun in mid-1974.

THE DATA BASE

The first step was to determine the type of information needed by the DIEP staff. It was decided that copies of the published literature rather than abstracts were necessary. Moreover, comprehensive and current information about a particular drug interaction was also required. Additionally, current information about the pharmacokinetics, pharmacology, and toxicity of the drugs involved in the drug interaction was also needed.

Since the DIEP has limited staff and limited funds, cost and time were important factors to be considered when developing the data base. Therefore, the system designed to store this data base had to be inexpensive, easy to develop and implement, and simple to use. The system had to allow quick access to the necessary information about a particular drug interaction. Furthermore, because the publication of the next edition of EDI is on a tight schedule, the data base needed to be operational as quickly as possible.

The data base is now functioning and contains more than 3000 published articles on drug interactions. This information is stored either in hard copy or in microfiche. Five by eight-inch index cards are used to catalog this information, filed by author and, in some cases, by drug name. It is anticipated that a comprehensive cross-reference index by drug name will be completed sometime next year.

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Toxicological Evaluation of Chemical Interactions ,1994 Drug Discovery and Evaluation: Safety and

Pharmacokinetic Assays Franz J. Hock, Michael K. Pugsley, 2024-10-21 Many aspects of drug safety have become an outstanding and even persistent issue and may occur during the process of both drug discovery and development Until 15 years ago drug discovery and evaluation was primarily a sequential process starting with the selection of the most pharmacologically active compound from a series of newly synthesized small molecule chemical series by means of distinctive pharmacological assays Safety aspects were addressed by evaluation of the selected compound at high doses in a series of specific studies directed at indications other than the intended indication of the new compound These tests are then followed by pharmacokinetic studies which are primarily conducted to confirm whether the selected compound possesses a suitable half life for sufficient exposure and efficacy and whether it has the desired properties specificity to the intended route of administration Safety aspects relied predominantly on the conduct of single and repeat toxicology dose studies which inform changes in organ structure rather than organ function Both toxicological and pharmacokinetic studies are adapted to the progress of studies in clinical pharmacology and clinical trials The new edition of this well and broadly accepted reference work contains several innovative and distinguished chapters This sequential strategy has been abandoned with this new version of the book for several reasons Of the possible multitude of negative effects that novel drugs may impart on organ function e g ventricular tachy arrhythmia many are detected too late in non clinical studies to inform clinicians On the other hand negative findings in chronic toxicity studies in animals may turn out to be irrelevant for human beings New scientific approaches e g high throughput screening human pluripotent stem cells transgenic animals knock out animals in silico models pharmaco genomics and pharmaco proteomics as well as Artificial Intelligence AI methods offered new possibilities There are several examples that show that the druggability of compounds was considerably underestimated when the probability of success of a new project was assessed The success rate in the pharmaceutical industry and the introduction of new chemical entities to the market per year dropped dramatically whereas the development time for a new compound increased sometimes exceeding the patent protection Research and development scientists involving the following changes therefore adopted a change of strategy Parallel instead of sequential involvement of the various disciplines multidimensional compound optimization The term Safety Pharmacology was coined The International Conference on Harmonization ICH founded a Safety Pharmacology Working Group and the Safety Pharmacology Society SPS was launched The discipline provided for evaluation development and validation of a multitude of safety tests outlined in the Core Battery of Studies Characterizing the exposure profile of a drug by conducting pharmacokinetic studies that evaluates the absorption distribution metabolism and excretion should to be investigated at an early stage of development as results contribute to the selection of a compound for further development Advancements in Toxicology were achieved by the introduction of new methods e g in silico methods genetic toxicology computational toxicology and AI The book is a landmark in the continuously

changing world of drug research and developments As such it is essential reading for many groups not only for all students of pharmacology and toxicology but also for industry scientists and physicians especially those involved in clinical trials of drugs and for pharmacists who must know the safety requirements of drugs The book is essential for scientists and managers in the pharmaceutical industry who are involved in drug discovery drug development and decision making in the development process In particular the book will be of use to government institutions and committees working on official guidelines for drug evaluation worldwide Liposome Technology Gregory Gregoriadis,2006-09-12 Liposome Technology Volume III

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