

## Book Reviews

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### Guidelines for the clinical investigation of drugs for the treatment of involuntary movement disorders

The WHO Regional Office for Europe has issued a draft guide for clinical investigators seeking to set out sound investigational standards for drug trials designated to assess the control of disorders of involuntary movement. The guide addresses the difficulties encountered in classifying and assessing movement disorders, and particularly in selecting the criteria for establishing drug efficacy.

No system of classification and assessment of movement disorders is ideal and none is universally accepted. This poses problems for the understanding of physiological mechanisms, the characterization of certain disorders, measurements of the severity of the disorder and pooling of literature of multicentre data.

The revised draft will be submitted for consultation by experts, Member States and representatives of the pharmaceutical industry before it is finalized by an expanded working group.

**Reference:** *Guidelines for the clinical investigation of drugs for involuntary movement disorders* - Draft 1986. WHO Regional Office for Europe, Copenhagen, Denmark.

### Drug utilization bibliography

The WHO Collaborating Centre for Drug Statistics Methodology in Oslo, Norway, has issued a bibliography derived from a search of the MEDLINE system. It is expected that updated versions will be issued every year.

**Reference:** *Drug Utilization Bibliography*. Publications and reprints May 1981 to January 1986. - WHO Regional Office for Europe, Scherfsgsvej 8, 2100 Copenhagen 0, Denmark.

### Health research strategy

This report of a subcommittee of the WHO Advisory Committee on Health Research considers health development in a historical and evolutionary perspective. Diseases are considered, having regard to environmental determinants and not only to their mechanisms. Of particular interest is the chapter on research needs in which diseases are classified as:

- *Prenatal diseases* determined at fertilization.
- *Prenatal diseases* determined after fertilization.
- *Diseases of poverty* (predominant in developing countries, but present also in subgroups living in or near poverty in developed countries).
- *Diseases of the tropics*.
- *Diseases of affluence*: most of them are due to environmental and behavioural changes associated with industrialization; such "Western diseases" are also observed in developing countries where Westernization has occurred, particularly in the upper class.

Practical research goals are set for achieving in the Third World in one and a half decades what took one and a half centuries in the industrialized world. The report reflects both the urgency and the complexity of the task.

**Reference:** *Health Research Strategy*, Document RPD/ACHR(HRS)/86, World Health Organization, 1211 Geneva 27, Switzerland.

### National Drugs Advisory Board of Ireland Annual report 1985

**Ireland** - This comprehensive report contains information on the following activities :

• *Licensing activities*: at 31 December 1985, 2726 applications were in hand, of which 1649 were under consideration and 338 were held awaiting additional information. During 1985, the Board issued 464 recommendations to the Department of Health.

• *Post-marketing surveillance*: the reports includes comments on side effects of individual drugs.

• *Clinical trials*: although there are no statutory regulations governing clinical studies, the Board has evaluated 223 applications voluntarily submitted. The report contains guidelines relating to ethical committees, guidelines on informed consent of participants and a summary of good clinical and laboratory practice requirements.

**Reference:** *Annual Report 1985 of the National Drugs Advisory Board*, Charles Lucas House, 63-64 Adelaide Road, Dublin 2, Ireland.

## Postmarketing surveillance A book for general practitioners

**Italy** - Under the title *Clinical Evaluation of Drug Tolerance* a book has been published explaining the concepts of "Drug Monitoring" and "Postmarketing Surveillance" which have become important areas of research in recent years. A well-documented historical introduction reminds us that the concepts of efficacy and safety of therapy are not new—the former was mentioned in an Egyptian papyrus as early as 3000 B.C. and the latter in writings by Fabricius Hildanus (1560-1634 A.C.). The phases I to IV of drug research are described and the concept of "risk/benefit evaluation" is clearly expressed. As Professor R. Paoletti points out in the preface, the statement "this drug is highly efficacious and entirely safe" is scientifically unacceptable. This book should be useful to practitioners in understanding the complex problems involved in the clinical evaluation of drugs in general use and in stimulating their participation in this evaluation.

**Reference:** C. Borghi & D. Canti, *Tollerabilità di un Farmaco, Evaluazione Clinica*, Organizzazione Editoriale Medico Farmaceutica, Via Edolo 42, Milano, Italy, 1986.

## Clinical research on new drugs National and international guidelines

**Italy** - An understanding of the clinical stages of research and development of new drugs has become most important in recent years. Legislation and regulations have evolved accordingly and guidelines have been issued by several national and international organizations. In his book *Clinical Testing of Drugs*, G. Battaglino reviews the subject in the light of the most recent developments and on the basis of his personal experience. The book includes the most recent Italian regulations and EEC directives as well as guidelines for testing drugs in different therapeutic categories.

**Reference:** Giuseppe Battaglino, *Sperimentazione Clinica dei Farmaci*, Organizzazione Editoriale Medico Farmaceutica, Via Edolo 42, Milano, Italy, 1986.

## The official control of drugs in Denmark

**Denmark** - The National Board of Health has issued a booklet in English providing a survey of the official drug control activities, including details on the certification of exported products in accordance with the WHO Certification Scheme.

**Reference:** *The Official Control of Medicines in Denmark*, National Board of Health, 1, Store Kongensgade, 1264, Copenhagen, Denmark.

## Pharmacological treatment of bronchial asthma

**Sweden** - The Drug Information Committee of the National Board of Health and Welfare has issued a booklet containing review articles and recommendations on pharmacotherapy of bronchial asthma. A most important aspect of treatment is to provide the patient with authoritative information about the underlying causes of the condition and on how life-style as well as environmental factors may affect the disease.

The information should also include instructions on how to increase drug dosage during periods of deterioration as well as advice on how, and when, dosage should be reduced during periods of improvement to avoid unnecessary long-term routine therapy.

All aspects of the subject are covered, including details on the use of corticosteroid inhalation therapy in maintenance treatment and on treatment of children.

Attention is drawn to the risk of allergic reactions during hyposensitization with modern potent allergen extracts which, it is advised, should only be performed by specialists.

**Reference:** *Workshop on Pharmacological Treatment of Bronchial Asthma*, 1986, National Board of Health and Welfare, Drug Information Committee, Uppsala, Sweden.

## International cooperation in the field of medicinal products

**Spain** - The General Directorate of Pharmacy and Health Products has published the proceedings of a Seminar on International Co-operation in the field of Medicinal Products held in Madrid in 1984, under the auspices of several international organizations including WHO.

The book contains information on the activities of these organizations both at global and regional level in the field of medicinal products as well as on existing and projected activities in Spain aimed at expanding international cooperation.

**Reference:** *La Cooperacion Internacional en materia de Medicamentos*, Dirección General de la Farmacia y Productos Sanitarios, Ministerio de Sanidad y Consumo, 1986, Madrid, Spain.

## Pharmaceutical control in Turkey

The Ministry of Health and Social Assistance has published a book that details all new regulations as

well as related efforts by the General Directorate of Pharmaceuticals to assure the quality of products on the market and ultimately, the safety, well-being and protection of the consumer.

Regulations and requirements relating to GMP's, production of herbal drugs, price control, importation and prescription of narcotic and psychotropic drugs are included as well as information on Turkish pharmaceutical companies.

**Reference:** *Ministerial Provisions concerning Turkish Pharmaceuticals*, Ministry of Health and Social Assistance, Ankara, 1986.

## International nonproprietary names A French study

**France** - In October 1986, B. Ripoll submitted a thesis for the Diplôme d'Etat de Docteur en Pharmacie at the University of Toulouse on the above subject outlining the principles for the selection of INNs, the relationship with trade names and the marketing of generic products.

**Reference:** Université Paul Sabatier, Faculté des Sciences pharmaceutiques, Thèse No. 159, Contribution à l'Etude des Dénominations communes internationales par Bernard Ripoll, 1986.

## British National Formulary

**United Kingdom** - The 12th edition of the *British National Formulary*, published in September 1986, identifies:

- oral liquid preparations which are free from cariogenic sugars (fructose, lactose, sucrose).
- all preparations (such as those containing meprobamate and pentazocine) which are subject to the prescription requirements of the Misuse of Drugs Act.

Other changes include: amendments to the classification of diuretics and analgesics, the incorporation of the WHO guidelines on antileprotic

drugs, and a section on autoimmune thrombocytopenic purpura.

**Reference:** *The Pharmaceutical Journal*, September 1986, p. 326

## Nasal drug delivery A Dutch study

**The Netherlands** - A recent study draws attention to the potential importance of the nasal mucosa as a portal of entry for systemically administered drugs. Although the concept is not new, recent investigations suggest nasal administration could be more frequently utilized.

The nasal mucosa has a large surface area and a high blood flow and this makes it a potential site for drug delivery. The first pass-effect and the gastrointestinal decomposition of drugs are circumvented and even the administration of peptides, hormones and vaccines is possible.

The study includes data on ciliotoxic effects of a corticosteroid aerosol (budesonide) and on the comparative bioavailability of propranolol, some hormones, and gentamicin when administered by this route.

**Reference:** *Studies on Nasal Drug Delivery*, G. S. N. J. E. Duchateau, Thesis 22 October 1986, Department of Biopharmaceutics, University of Amsterdam, The Netherlands.

## Quality assurance A guide published in India

**India** - The Organization of Pharmaceutical Producers of India (OPPI) has published a guide in the form of recommended operating procedures in pharmaceutical factories which, when followed, should provide adequate assurance of quality of drugs. In the foreword, the Chairman of the Research and Development Committee of OPPI, emphasizes that in the pharmaceutical industry consumer protection assumes special significance because the purchaser of a drug product has no way of knowing whether the article he has bought and intends to use will be safe and effective. The recommendations are in accordance with the *WHO Good Practices in the Manufacture and Quality Control of Drugs*, which are general recommendations to be adapted to meet individual needs. The translation of these general principles into more specific advice relevant to specific manufacturing operations and control procedures is an important step towards full implementation of GMP in India.

The following topics are covered in the Guide:

- Sanitation and hygiene.
- Manufacturing areas.
- Manufacturing equipment: cleaning and maintenance.
- Warehousing of raw and packaging materials.
- Manufacturing operations: general.
- Production and process control: capsules, injectables, oral liquids, ointments and creams, tablets.
- Packaging and labelling control.
- Laboratory controls.
- Laboratory records.
- Warehousing of finished products.

**Reference:** *Quality Assurance Guide*, Organisation of Pharmaceutical Producers of India, 1985.