

Recent Publications and Documents

Extended release oral dosage forms: guidance for applicants

The United States Food and Drug Administration has announced the availability of a guidance document entitled *Extended Release Oral Dosage Forms: development, evaluation and application of in vitro/in vivo correlations (IVIVC)*, which is intended to provide recommendations for the development of documentation in support of a new drug application, abbreviated new drug application or antibiotic drug application.

This document provides a comprehensive perspective on methods of developing an IVIVC and evaluating its predictability, using an IVIVC to set dissolution specifications, and applying an IVIVC as a surrogate for in vivo bioequivalence when it is necessary to document this during the initial approval process or because of certain pre-approval or post-approval changes in formulation, equipment, process, or a manufacturing site. However, the guidance is not binding and an alternative approach may be used if this satisfies the requirements of the applicable statute, regulations, or both.

Extended Release Oral Dosage Forms: development, evaluation and application of in vitro/in vivo correlations. Available from: Drug Information Branch, HFD 210, Center for Drug Evaluation and Research, Food and Drug Administration, Rockville, MD 20857, USA. Or: <http://www.fda.gov/cder/guidance/index.htm>.

United Nations Consolidated List

The Consolidated List of Products whose Consumption and/or Sale have been Banned, Withdrawn, Severely Restricted or Not Approved by Governments is a unique list of restrictive regulatory actions on pharmaceuticals taken by ninety-four governments which has been compiled in response to a 1982 United Nations General Assembly resolution aimed to protect the public against products harmful to health.

Published in two parts, the first part provides information to inform governments of regulatory decisions taken in other countries and assists them in

considering their own regulatory action. For regulatory agencies reviewing applications for product registration, it provides information on the status of products globally.

To ensure that the List focuses on products harmful to health, criteria for the inclusion of products have been developed. None the less, it is drawn to the reader's attention that decisions taken by a limited number of governments on a specific product may not be representative of the position of other governments, particularly in view of differing risk/benefit considerations. It is also important to note that all pharmaceutical products are potentially harmful if not correctly used. Inversely, the fact that a given product is not listed as regulated by a country does not necessarily mean that it is permitted in that country.

Part two of the list presents commercial information, including data on trade names. It thus provides an easy method of cross-referencing commercial names with recognized common scientific names.

Consolidated List of Products whose Consumption and/or Sale have been Banned, Withdrawn, Severely Restricted or Not Approved by Governments. United Nations, New York, 1997. Price US\$ 120.- ISBN 92 1 130183 1

Manual on quality assurance

Assurance of the quality, safety and efficacy of pharmaceutical products is a continuing concern of WHO's Division of Drug Management & Policies. Despite efforts made in many parts of the world to ensure the supply of high-quality and effective drugs, inadequate pharmaceutical regulation and the presence of substandard, spurious or counterfeit products still compromise health care delivery in many countries.

In response to the need for adequate quality assurance of pharmaceuticals, the WHO Expert Committee on Specifications for Pharmaceutical Preparations has, over the years, made numerous recommendations to promote quality assurance and the application of internationally agreed standards. Many of the recommendations, even though en-

dorsed several years ago, are still valid and are essential to all concerned with the quality assurance of medicines. They provide complementary parts of a comprehensive system to uphold quality assurance and will be reproduced by WHO in two accompanying volumes, supplemented by other relevant supporting material. The two manuals are designed to address not only the pharmaceutical aspects of the quality of medicines but also the intrinsic safety and efficacy of pharmacologically-active substances.

Volume 1 is now available and sets out to cover basic aspects of national drug regulation, assessment of drug products and herbals, stability, basic tests, laboratory services, international trade in pharmaceuticals, counterfeit products and training. Volume 2 is planned to be issued this year and will address issues of good manufacturing practice and inspection.

Quality Assurance of Pharmaceuticals. Volume 1. World Health Organization, Geneva. Price Sw.fr. 50.- (Sw.fr. 35.- developing countries). ISBN 92 4 154504 6

Medicinal claims and food products

Food products are often advertised, marketed and sold to the public with health claims that are similar or mimic therapeutic indications which have been scientifically established for pharmaceutical products. The National Agency for Medicines in Finland has now published a guide indicating which medicinal claims are allowed for food products and which are prohibited.

Under the Foodstuffs Act of Finland, control and marketing of foodstuffs should be carried out by the National Food Administration. This covers advertising and labelling, as well as any other information supplied in a sales context. When required, the National Agency for Medicines assists in deciding whether a marketing claim made for a food product can be considered medicinal or therapeutic. The Act forbids any health related claims, or the supply of medicinal information as a part of the marketing strategy. This also means any suggestive statements indicating that use of the said food product could prevent, treat or cure an illness or its symptoms.

The guide lists some 70 claims that are considered a reference to an illness or a medical condition. The following are listed as examples: prevents insom-

nia, depression; prevents blood clotting and thus vascular obstruction; reduces the risk of cardiovascular disease; boosts circulation; prevents osteoporosis, muscle or joint pain, rheumatism, arthritis; prevents otitis; travel sickness, eczema, herpes or psoriasis; asthma, allergy; strengthens the nervous system; stimulates the memory; activates the endocrine glands; balances hormonal activity; deactivates free radicals known to cause heart disease and cancer; stimulates melatonin production; reduces the need for insulin; reinforces blood cells; heightens potency; increases the body's tolerance.

The guide also sets out statements which are acceptable. These should be based on substantiated medical evidence and should not mislead the consumer. Education on nutritional matters is considered to be in the interests of the consumer and such information may be supplemented with examples when certain foods are clearly beneficial to the vital functions of the body. It is therefore permitted to provide information on nutrition and to educate consumers on what constitutes a healthy diet. This would include information on fat or iron content, quality of the product, stimulation of body functions, contribution to lowering cholesterol levels, etc.

The usefulness of the guide will be evaluated in two years' time when a comparison is made with past and present promotional claims.

Guidebook on Monitoring the Medicinal Marketing of Foods in Finland. Department of Pharmacology, National Agency for Medicines, P.O. Box 55, 00301 Helsinki, Finland.

Paediatric prescribing information

Many physicians and health care providers are faced with the challenge of providing relevant information to patients on the correct use of medications which they have prescribed. Although there has been an increase in both research and studies on drug use in paediatric patients, until now very little specific prescribing information has been produced with children in mind and physicians are often forced to sift through information which has been provided for adult patients.

The American College of Clinical Pharmacy has recently published medication information sheets, in English and Spanish, designed to provide a con-

cise, understandable source of written information for paediatric patients. Two hundred medications are described, focusing on those products most frequently prescribed at hospital discharge or during physician home visits.

The medication sheets also include information on formulations and liquids which can be prepared by pharmacists from solid oral dosage forms. The use of these formulations allows the manipulation of available dosage forms into products more appropriate for small children.

All information relies on United States Food and Drug Administration recommendations and data provided for products available within the United States of America. However, before prescribing, physicians are reminded to consult package leaflets which will give the latest information on dosages, contraindications and use of the medication in question.

Pediatric Medication Education Text is available from: The American College of Clinical Pharmacy, 3101 Broadway, Suite 380, Kansas City, MO 64111, USA. ISBN 1 880401 89 4. e-mail: accp@accp.com.