

Regulatory Matters

Should all ingredients of medicines be disclosed?

United Kingdom — According to the *Pharmaceutical Journal* the Department of Health has drawn up proposals requiring manufacturers to disclose all the ingredients of medicinal products either on the packaging or in data sheets. Once ministerial approval has been obtained the proposals will be submitted to consultation before regulations are formulated, during which time the pharmaceutical industry and consumer groups will be invited to offer comments.

Reference: Ingredients disclosure on the way? *The Pharmaceutical Journal*, 239: 91 (1987).

Advice on drug studies carried out on healthy volunteers

United Kingdom — The Medicines Commission, having completed an inquiry into volunteer studies, has advised the health ministers that the situation does not merit the institution of statutory controls. However, it does call for greater self-control by pharmaceutical companies and universities.

The commission has proposed that a register be compiled of organizations undertaking such studies which specifies the facilities they possess for medical support and resuscitation. The report adds that the procedures for obtaining informed consent from potential subjects should be improved and that a guarantee should be provided that adequate compensation will be payable without the need to prove negligence whenever a volunteer sustains injury.

Reference: More self-regulation, says Commission. *The Pharmaceutical Journal*, 239: 313 (1987).

Applications for product licences in the United Kingdom: revised guidance notes

United Kingdom — The Licensing Authority has recently revised its "Guidance Notes on Applications for Product Licences" which, in addition to a number of amendments and updates to the original text, now includes guidelines issued by the European Economic Community (EEC) on clinical efficacy, fixed-combination products, pharmacokinetics studies in man and investigation of bioavailability.

Reference: Medicines Act 1968 - Supplement to Guidance Notes on Applications for Product Licences (MAL 2), 1987. Her Majesty's Stationery Office, London, United Kingdom.

Health messages on food labels: proposed regulation

United States of America — Consumers are becoming increasingly conscious of the relationship between diet and health and the food industry has responded by issuing health-related messages as a promotional gambit. The Food and Drug Administration now proposes to introduce regulations which will control the use of such information in food labelling and it has proposed criteria that will apply in evaluating the propriety of such labelling. Because of broad public interest the notice in the Federal Register has been widely disseminated with a view to eliciting comments not only from within the United States but also from the competent national authorities in other countries, and particularly those exporting substantial quantities of packaged foods to the United States.

Reference: *Federal Register*, 52: 28843-28849 (1987).