

do not meet prescribed standards, are harmful, adulterated, dirty, improperly stored, or manufactured under unsanitary conditions. The Act also prohibits the advertising of any food, drug, cosmetic or medical device as a preventive or cure for a number of serious diseases and also lists drugs that may be sold only by prescription.

Standards of safety and purity are maintained through constant and widespread inspection and laboratory research. The inspection of food-manufacturing establishments plays a major role in the production of clean, wholesome foods containing ingredients that meet recognized standards. Changing food technology requires the development of methods of laboratory analysis to ensure the safety of new types of ingredients and packaging materials. The Food and Drug Regulations list chemical additives that may be used in foods, the amounts that may be added to each food and the underlying reason. Considerable emphasis is placed upon studies to ensure that the levels of pesticide residues in foods do not constitute a health hazard. The effect of new packaging and processing techniques on the bacteria associated with food spoilage is also of special concern. Since the Act is intended for the protection of consumers, a section of the Directorate obtains consumer opinions, deals with individual consumer complaints and provides information on which consumers can base opinions.

Detailed information on all new drugs must be reviewed by the Directorate to determine compliance with requirements before release for sale is permitted. Drug regulations set standards for drug manufacturing, facilities and controls, and prescribe additional safeguards in the distribution of investigational and new drugs. Drug manufacturing requirements relate to sanitation of facilities, employment of qualified personnel, testing to ensure standards of quality and safety at stated stages of processing, and maintenance of records of testing performance, together with a system of control to enable a complete and rapid recall of any lot or batch of drugs from the market. The controls over clinical trials and marketing of new drugs require detailed information to be submitted to the Directorate concerning the method of manufacture, the tests applied to establish standards of safety and quality, and substantial evidence of the clinical effectiveness of the new drug for the purposes stated. Samples of the final product must also be submitted. Before carrying out clinical trials, a manufacturer also must file complete data on his experience with the drug including any evidence of adverse side effects, and the qualifications of the persons to be engaged in its investigational use. The Minister may suspend clinical testing based on this evidence if he feels that it is in the public interest to do so; in such case the manufacturer has the right to appeal the decision. Drugs expressly prohibited from sale are thalidomide and lysergic acid diethylamide, except under certain conditions as specified in the regulations, whereby sale by a manufacturer to an institution for clinical use or laboratory research by qualified investigators may be approved by the Minister. Any drug that can be classed as a sedative, hypnotic or tranquillizer is listed to be sold only on prescription. The licensing of persons dealing in certain drugs classed as barbiturates and amphetamines is required as well as the keeping of special records and the limitation of their use to medical purposes.

The Food and Drug Directorate administers the Proprietary or Patent Medicine Act, which is concerned with the registration before marketing and the annual licensing of secret-formula medicines sold under proprietary or trade names.

The Directorate conducts an adverse-drug-reaction reporting program in teaching hospitals across Canada to recognize and investigate reactions to drugs. The co-operation of the medical, dental, veterinary and pharmaceutical professions is solicited in advising the Directorate of such reactions in private practice. Close liaison is maintained with the World Health Organization and other authorities in foreign countries for the prompt reporting of such reactions.

Since October 1966, every manufacturer and distributor of drugs in Canada (products registered under the Proprietary or Patent Medicine Act exempt) is required to submit to the Food and Drug Directorate certain information on all products he is marketing in