

testing to ensure standards of quality and safety at stated stages of processing, 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 new controls over clinical trials and marketing of new drugs carry out provisions of the Food and Drugs Act amendment passed in 1962. Detailed information must 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 putting a product into clinical testing, a manufacturer also must file complete data on the experience with the drug including any evidence of adverse side effects, and the qualifications of the persons to be engaged in its experimental use. If from this evidence a new drug is considered not in the interest of public health, the Minister may suspend the proposed clinical testing, in which 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 also 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.

Early in 1965 the Directorate initiated an adverse-drug-reaction reporting program in 16 teaching hospitals across Canada to recognize and investigate unexpected reactions to drugs. The co-operation of the medical, dental, veterinary and pharmaceutical professions was 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.

Regulation of the supply and use of narcotic drugs is carried out under the Narcotic Control Act, as revised in 1961. This legislation prescribes a maximum penalty of seven years with no minimum for illegal possession; a maximum penalty for trafficking of life imprisonment; and minimum and maximum penalties for illegal export and import of seven years and life imprisonment, respectively. Persons convicted of offences under the Act who are found to be drug addicts may be sentenced for treatment, for an indeterminate period, in institutions operating under the penitentiaries system and the National Parole Board service, when Part II of the Act comes into force.

Subsection 5.—Medical Services

The Department of National Health and Welfare provides nine types of direct medical service through the Directorate of Medical Services. These are described in the following paragraphs.

Indians and Eskimos.—Responsibility for the general welfare, education and medical care of Indians is shared with the Indian Affairs Branch of the Department of Citizenship and Immigration, and of Eskimos with the Department of Northern Affairs and National Resources. The Department of National Health and Welfare provides medical and public health services to registered Indians or Eskimos who are not included under provincial arrangements and who are unable to provide for themselves. A large volume of the service in treatment and health education is rendered to patients through departmental out-patient clinics staffed by medical and other public health personnel. In remote areas, the key facility is frequently the departmental nursing station, a combined emergency treatment and public health unit having two to four beds under the direction of one or two nurses: about 44 of these are operated throughout Canada.