of the medical journals have proven a valuable source of information of the side effects and toxicity of drugs used in practice. This has been peculiarly useful in the U.K., as compared with North America.

The procedures followed by the Directorate respecting imported drugs are outlined below.

Drugs in Schedule "C" (Insulin, Liver extract injectible preparations, Anterior pituitary extracts, Radio-active isotopes) and in Schedule "D" (Vaccines, Sera, Antibiotics for parenteral use) may *not* be imported into Canada unless the manufacturer has been licensed. A condition of the licence is that the manufacturing plant must be inspected by an officer of the Department. At the present time 46 foreign firms hold such licences (30 in the United States and 16 in Europe and Asia).

All such products are on a release basis (that is, each lot must be tested by the Department and found satisfactory before distribution), until sufficient evidence has accumulated that the drug meets the standard. In addition, an annual survey is made of all such products imported into Canada, with tests being carried out on representative samples. Up to the present time all of these products have been found to be satisfactory.

Drug plants manufacturing sensitivity disks (for use in determining the sensitivity or resistance of germs to an antibiotic) must be inspected and all lots are on a release basis. In addition, all antibiotics requiring certification in the United States must be accompanied by a certificate issued by the United States Food and Drug Administration.

Imported drugs not on Schedules "C" or "D" are controlled by 'spot checking'. Periodically, imported raw materials and finished drug products are sampled at Customs, and analysed. About 10% of drug importations are thus analysed. During drug plant inspections the Food and Drug Directorate examines the protocols on imported raw materials.

Short of testing every shipment of drugs that enters Canada the only manner in which the Food and Drug Directorate can have reasonable assurance that imported drugs are of good quality is to inspect every foreign manufacturing plant in the same way that it inspects Canadian drug manufacturing plants.

At the present time both foreign and domestic manufacturers of drugs listed in Schedules "C" and "D" of the Act must submit to inspection of their premises used for the production of these products before a licence is granted. The inspection is repeated annually, or even more frequently in the case of domestic and U.S. plants; yearly, or at least every second year, in the case of European manufacturers.

At present the detailed requirements for establishing the toxicity of a drug in animals for inclusion in a new drug submission are not covered in the Regulations. This does not mean there are not stringent requirements. The regulations (C.01.302.d; C.01.304.b) require detailed information of the 'test' establishing safety for the purpose and under the conditions recommended. The nature of the tests considered necessary, depends on the drug and its intended use, and the procedure presently followed by the Directorate is minuted (Appendix No. 1,, Pugsley, April 25th, 1962, attachment). The permutations of drug and intended use are limitless and in the opinion of the Committee make it inadvisable to alter the regulations by including specific standards of testing, or altering the actual procedures of the Directorate. The procedures of the Directorate will be altered from time to time with increasing knowledge of toxicological testing, by knowledge of the susceptibility of certain species of animals for certain types of testing, and by the development of tissue culture or other methods of testing toxicity. These procedures