

and that might include the United States, very often a great deal of the investigative work is done in the foreign country. This is the country in which the manufacturer has his research staff and has his hospital and university connections, and it becomes a matter of habit and custom for him to carry out the basic work at least in that country. In many cases when a new drug submission comes in we find that little if any clinical or pharmaceutical testing has been done in Canada. We have been asking for ten years or more that such a drug be tested in Canada, certainly clinically. That is, we have asked that some testing be done here. I think that as a result of the pressure that we have exerted over the years, more and more clinical trials are being carried out in Canada.

There is nothing in the act or regulations that demands that clinical trials must be carried out in Canada.

In respect of ordinary drugs or drugs that are not classed as new drugs, and there are those that are manufactured, as I said before, under licence, and I refer now to those that are listed in schedules C and D of the act, including such drugs as have been listed in schedule C, liver extract injectable, liver extract injectable with other medication, liver extract injectable crude, liver extract injectable crude with other medication, insulin, insulin made from zinc-insulin crystals, globin insulin with zinc, insulin zinc suspension, N.P.H. insulin, isophane insulin, protamine zinc insulin, anterior pituitary extracts and radioactive isotopes and under schedule D, living vaccines for oral or parenteral use, drugs prepared from micro-organisms or viruses for parenteral use, sera and drugs analogous thereto for parenteral use, and antibiotics for parenteral use; these can only be sold in Canada by a manufacturer licenced by the department under the Food and Drugs Act to do so. This implies that before they receive a licence their premises, personnel and facilities are inspected by departmental inspectors making visits.

Mr. HADASZ: Do the inspectors visit Europe?

Dr. MORRELL: The inspector makes a visit to Europe if the manufacturer is in Europe and to the United States if it is manufactured in the United States. The inspector then makes a report which, if satisfactory, leads to the renewal of a licence. If it is a new drug that is to be licenced it must be a new drug submission. That means they must be inspected before they can get their licence. After this process is completed, then they may be licenced if the report of the facilities and all the rest of it is satisfactory and up to our standards. So that in that case I would say that the control of the foreign manufacturer is nearly equivalent to that of the domestic manufacturer. I say "nearly" because perhaps he is not quite as close and does not get as frequent inspections. The foreign manufacturer is usually inspected once a year, and certainly not less than once every two years. The local manufacturer in Canada or in the United States who has a licence is certainly inspected every year. The foreign manufacturer is inspected not less than once every two years, certainly every two years or more frequently.

In respect of the other drugs, the general pharmaceutical specialties, we do not have the authority to require, in our regulations, an inspection of the premises, and our studies must be made on the product as it reaches Canada.

Have I made myself clear?

Mr. HADASZ: Yes. I should like to ask a supplementary question. In your view, Doctor Morrell, do you not think that in the interest of Canadians and in fairness to the Canadian pharmaceutical manufacturers, all imported drugs should undergo the same review as domestic drugs?

Dr. MORRELL: Yes, essentially I think that is correct, and the Food and Drugs Act really applies equally to any product sold in Canada whatever its origin. I think that is essentially correct.