distribution of what we now call drugs for investigational use only. The manufacturer informs the minister of an identifying name or mark by which the drug can be recognized. That is the first thing, and that has a practical value from an enforcement standpoint. If this drug comes into the country from outside, and I can tell you that a great majority of them do, at least we can notify our inspectors at the customs that such and such a drug with the mark of such and such a kind is to be admitted if it is addressed to the proper people.

It should be labelled also, of course, "to be used by qualified investigators only."

The manufacturer prior to making the shipment must assure that any person to whom the drug is sent is a qualified investigator and has the facilities for the investigation to be conducted by him. This individual must assure the manufacturer that the drug will be solely used by him or under his direction for investigation. That information must be obtained by the manufacturer and that assurance given to him in writing so that we can see that he has received it. The manufacturer as well must keep accurate records of such distribution and the results of such investigation and make these records available for inspection by the directorate.

Those are the total regulations in force now at this moment covering drugs for investigational use prior to the submission of a new drug submitted to the minister.

Mr. HARLEY: I was wondering in respect of the qualifications of researchers whether this is something to be considered by the manufacturer and in respect of which the department has nothing to do at this stage?

Dr. MORRELL: We can argue about that, sir, but as far as the final decision is concerned, it would have to be made in court. If a manufacturer refused to accept our arguments and wished to carry on, it would be up to the magistrate or the judge to decide whether the persons to whom the manufacturer had sent the drug were really qualified investigators.

The CHAIRMAN: Dr. Morrell, have you the power under the act to initiate such action?

Dr. MORRELL: We can always initiate action for a violation of the regulations. This would in our opinion be a violation of the regulations, that is, if we disagreed with the qualifications of the investigator.

Mr. BALDWIN: Dr. Morrell, I wonder whether you would speak a little louder when you are carrying on a discussion with someone closer to you?

Dr. MORRELL: Yes. I am sorry.

Mr. VALADE: Dr. Morrell, I should like to ask you a question. When you have cause to think that a drug should be investigated further, do you advise the pharmaceutical or medical organizations in each province, or what is the procedure taken in this regard?

Dr. MORRELL: Are you referring now to a drug that is in the category of a drug for investigational use prior to marketing?

Mr. VALADE: Yes, I am referring to drugs in this category prior to marketing.

Dr. MORRELL: No. We have had very little experience and very little action in respect of drugs for purely investigational use. They are not yet the subject of new drug submissions and are simply put out for trial to a qualified investigator.

We have had some action and have taken some action in this respect, including one action not too long ago, which you may remember. In that case we notified the manufacturer that he must cease distribution for that purpose or