

trial, and if the minister, or the director in this case, requires to see these reports, he must make them available to the director for examination. That is all covered under present section C.01.307.

Mr. NICHOLSON: Thank you.

Mr. VALADE: Can I ask a question in this regard? What is the essential element required to classify a drug as a new drug in comparison with similar drugs that could be on the market?

Dr. MORRELL: There are several reasons for calling a drug a new drug. No. 1, and the one that occurs probably to all of us at once, is that it is a new chemical structure that has not been used previously in medicine. It may have been known but not used for medical purposes, or it may have been developed simply for medical purposes. These things are now appearing on the market because the pharmaceutical industry is interested in developing new products. If it is a new compound obviously it is a new drug. Now, a combination of known drugs that have not been previously used in combination, is also a new drug. It may be a combination of two or more perhaps well known drugs. This is, in most instances, called a new drug. If it is a combination of known vitamins, it is not considered to be a drug. A decision must be made as to whether the combination used is really to be considered as a new drug.

If a known drug has been recommended for a brand new use in medicine it is a new drug. Let us take as an example aspirin which has been known for 60 years or more; let us suppose that someone came out today with a recommendation that aspirin was effective in the treatment of cancer. In this case we would consider that aspirin in that context was a new drug and we would require the manufacturer to submit evidence on the effectiveness and safety of the drug under those conditions of use. If a drug has been given by the oral route, that is taken by mouth, and some manufacturer finds that it would be more effective or beneficial if injected, then we would also consider that to be a new drug. These are the main categories of new drugs and they are defined in the existing section C.01.301. A new drug therefore is not just a new compound, but it also has those connotations.

Mr. VALADE: Let us follow this line of questioning, Dr. Morrell. Did you classify thalidomide as a new drug compared to other brands of tranquilizers with other brand names in America, such as Stemetil?

Dr. MORRELL: We classified thalidomide as a new drug because it was a new chemical structure, so obviously it was a new drug. There was no debate on that with the manufacturer or with anyone else. I continue with my statement.

A clerk then prepares a routine form and the new drug submission is taken to the central registry where it is given a file number. The submission is then put into a docket, together with forms for routing and recording of comments, and sent to the associate director. The duplicate copy of the submission is kept by the medical section.

The associate director examines the submission in reference to the type of drug and the claims made for it and sends it to the appropriate laboratory section.

The laboratory, using criteria related to the recommendations for use of the drug, and those are recommendations given by manufacturers, reviews the pharmacological, toxicological and clinical work and also the chemistry, the manufacturing controls including the method of analysis. An actual trial of the method of analysis is seldom made at this stage.

It should be noted that the submission may be passed to more than one laboratory section; it may go to two or three sections if there is data or information in it requiring expert comment by specialists in different disciplines.