

counterpart in the United States Food and Drug Administration.

It is clear that the Government has gone to considerable length to ensure that drugs imported into Canada will have to meet the same high standards of quality and safety required of domestic drugs.

It is legitimate to inquire, however, regarding the capability of the Food and Drug Directorate—on whose shoulders the added burden must necessarily fall—to monitor adequately any increased flow of drugs into this country which may result from passage of the legislation before you today. We have made a careful and soul-searching inquiry into the operational capabilities of the Food and Drug Directorate. In April 1968, 11 man-years were made available to the Food and Drug Directorate for the specific purpose of improving the Directorate's ability to maintain an adequate surveillance over imported drugs. I am pleased to announce that a further 22 man-years will be provided as of April 1, 1969 to improve the present level of surveillance of drug products. These man-years are being, and will be used to provide additional drug inspectors and drug analysts. Furthermore, additional funds and personnel have been made available to provide an increased capability for the review of new drug submissions as well as additional funds for the testing of drugs under research contracts for the next fiscal year. I should emphasize that these resources are over and above the necessary funds and man-years required by the Directorate to maintain its present level of service. This will, in effect, permit the Directorate to substantially improve the level of service in these areas.

As part of continuing studies on more efficient utilization of resources, the Food and Drug Directorate has begun a program of research on the feasibility of employing automated equipment to increase the analytical capabilities of the Directorate's laboratories.

It is anticipated that application of modern technology and instrumentation will markedly increase the analytical output of our chemists and technicians. One knows, for example, that by means of proper automation, it is possible to analyze from 10 to 50 times more of given pharmaceutical preparations in a day than can be analyzed by conventional methods. Procedures have been described in the scientific literature which permit analysis of up to 100 samples of certain drugs per hour. The equipment involved is complicated and considerable development work will be

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required before automated procedures can be used routinely on a broad basis. Nevertheless, we are pressing ahead as rapidly as possible to take advantage of this significant technological advance, which, if successfully applied, will permit the Directorate to substantially increase the routine survey type of analytical work on drugs with a relatively small increase in staff. If we increase the number of drug samples analyzed, our chances of locating inferior quality drugs will of course be increased.

• (12:10 p.m.)

The Directorate's knowledge of drugs on the market has been markedly increased as a result of the drug notification program. The Food and Drug Regulations relating to drug notification require that a manufacturer must provide, within 30 days after the drug is first sold, information on its name, the purpose for which it is recommended, a quantitative list of the medicinal ingredients and the recommended dosage. Notification is also required when a drug formulation is changed or a drug is withdrawn from the market. Data on nearly 30,000 pharmaceutical preparations have now been received and stored in a mechanical information retrieval system. The Directorate thus has rapid access to data on the drugs on the Canadian market.

Hon. members have no doubt read about, and been exposed to, arguments relating to therapeutic equivalency of drugs. This issue—of which much has been made recently by certain drug manufacturers—boils down to this fundamental question: Will two drug products containing the same amount of the same active ingredient give essentially the same clinical effects. The answer to this question has great significance to physicians, manufacturers, Government and the public. If the answer to the question is "yes"—if, in fact two products with the same amount of active ingredients will give comparable clinical responses, a physician's choice between the two products may well be based on relative costs. If a less expensive product is equally effective, there is no advantage to prescribing a more expensive brand of the product. For the direct determination of therapeutic equivalency, the ideal method would be to compare two or more drug products containing the same amount of active ingredients, in the same dosage form, by measuring their capabilities to alleviate the symptoms or control a specific disease in