● (1220)

[*Translation*]

The new regulations concerning proprietary medicines will contain provisions enabling my Department to respond rapidly to the changing scientific and technological developments in the pharmaceutical field. There will be sections enabling a continuous scientific review of data pertaining to the manufacture, quality control, safety, and effectiveness of proprietary medicines.

For example, where additional information on the safety or effectiveness of a proprietary medicine is considered necessary, the manufacturer will have to supply that information upon request. It will be mandatory for the manufacturer to notify my Department whenever changes are made in the composition of the product since these may affect its safety or effectiveness. Once the manufacturer meets the requirements of the regulations, a certificate of registration will be issued for his product, permitting him to sell the product. However, if in the light of subsequent experience the information submitted is found to be insufficient, the certificate of registration could be revoked. If this occurred, it would no longer be permissible to sell the product as a proprietary medicine.

As I said before, proprietary medicines are intended for self-medication with minimal, or no, medical supervision. Therefore, as with the present Proprietary or Patent Medicine Act, certain drugs considered dangerous will not be permitted at all in proprietary medicines. Other, less hazardous drugs will be permitted only within specified limits. To that end, the new regulations will contain a schedule listing both types of drugs. This schedule will, of course, include all those drugs not now permitted in medicines registered under the Proprietary or Patent Medicine Act such as prescription, controlled and narcotic drugs as well as others.

Permit me to summarize: the new Regulations under the Food and Drugs Act will provide for,

(1) review on initial registration of the medicine,

(2) review as the need arises during the currency of the registration of the proprietary medicine,

(3) review of information submitted by the manufacturer regarding changes in his product which might affect its safety and effectiveness,

(4) scheduling drugs prohibited or permitted in only limited amounts in proprietary medicines, and

(5) more readily applying the Food and Drug Regulations to proprietary medicines.

[*English*]

Now I would like to outline briefly the conditions under which various drug products can be sold, and to indicate the concern of my department that we do not disrupt this established pattern unnecessarily. As hon. members know, prescription drugs can be sold on the authorization of a prescription issued by a practitioner. Non-prescription drugs can be sold without such authorization. By virtue of provincial legislation, prescription drugs and those non-prescription drugs not presently registered under the Proprietary or Patent Medicine Act can be sold only in drug stores or pharmacies. In general, also by virtue of provincial laws, only proprietary medicines presently registered under the Proprietary or Patent Medicine Act are available outside pharmacies. Thus, in a pharmacy one can obtain all types of drugs, while in a non-pharmacy outlet one may obtain only proprietary medicines.

Finally, I would like to consider some of the timing involved in this legislation. The bill before us proposes that the effective date of repeal of the Proprietary or Patent Medicine Act be July 1, 1976. The majority of provincial pharmacy acts contain references to the Proprietary or Patent Medicine Act. As I have indicated, such references exempt drugs registered under the Proprietary or Patent Medicine Act from the general prohibition of sale of drugs outside pharmacies. The repeal of the Proprietary or Patent Medicine Act and the transfer of proprietary medicines to a separate division of the Food and Drugs Act regulations will therefore require changes in the provincial acts. I understand that the necessary changes in the various pieces of provincial legislation are considered to be minimal, consisting essentially of the deletion of references to the Proprietary or Patent Medicine Act and insertion of appropriate references to the new regulations concerning proprietary medicines under the Food and Drugs Act.

As I indicated in reply to a question put by the hon. member for Vaudreuil (Mr. Herbert)—who has shown great interest in this issue, for which I congratulate him—I have had contacts with my provincial colleagues in connection with this bill. At the federal-provincial conference of health ministers in February, 1974, my colleagues agreed that the federal government could repeal the Proprietary or Patent Medicine Act and substitute other regulations providing for greater disclosure. Further, the provincial registrars of pharmacy met with officials of my department on October 3 and 4, 1974, and due consideration was given to the changes that would be required in provincial pharmacy legislation. Moreover, there have been extensive consultations with representatives of the industry on this subject. Prompt passage of this bill will enable the provinces to have sufficient time to pass the necessary legislation to ensure a smooth transitional period; I wish to thank the House for its co-operation to date in ensuring prompt consideration of the bill.

In concluding, Mr. Chairman, I am confident that if the House passes this bill, we will have removed the secrecy aspect inherent in the Proprietary or Patent Medicine Act and will, thereby, make available to the general public essential information by requiring that medicinal ingredients be listed on the labels of proprietary medicines, without interfering with the availability of such products for self-medication. Indeed, as I indicated in reply to another question of the hon. member for Vaudreuil, this bill is intended to protect consumers and to improve access by consumers to information on drugs sold over the counter.

Mr. Holmes: Mr. Chairman, I assume that while we are in committee of the whole we have an opportunity to make comments and perhaps to intersperse them with questions. If that is the case, that may well be my format. Let me say at the outset that I welcome the opportunity to participate in this debate. Although the bill before us is rather short, I think it is an important piece of legislation, as has been indicated by the minister. I want to tell him at the outset that we agree in principle with the repeal of the