database on EC 1992 on behalf of External Affairs and International Trade Canada. Canadian companies could also provide views on the proposed standards to the Council for transmission to CEN before the standards are adopted in Europe (i.e. during the 60-day public comment period on proposed CEN standards).

At the same time, pharmaceuticals would be subject to common approval, clinical evaluation and testing requirements under EC directives for registration in all Member States. The EC has adopted directives on procedures for considering applications for market authorization, i.e. licensing, of proprietary medicinal products as well as for analytical, pharmacological, toxicological and clerical protocols for testing such products. These directives are also intended to shorten the current four- to six-month period for technical evaluation of applications for product licensing. Applicants in the EC could supply results of tests and clerical trials. In cases where a product is similar to one already authorized, the EC would allow applicants to limit submissions to a summary dossier of bibliographical information.

Applications are processed under authority of special EC committees. EC directives on pharmaceuticals could facilitate access for Canadian products through common procedures. Implementation would be the responsibility of regulatory authorities and would not involve standards organizations.

d) Transparency

As we saw earlier, EC governments play a major role in determining pharmaceutical prices. In some instances the reimbursement policies of health services determine whether or not a drug can be sold at all. National pricing and reimbursement policies appear to have been used in the past to discriminate in favour of national producers. The EC method for eliminating this non-tariff barrier is through a directive on "transparency" of Member State decisions on the prices of medicines and on social security refunds.

It requires: i) tight deadlines for discussions on marketing authorizations, pricing decisions, and access for pharmaceutical products to the reimbursement list; ii) justifications for decisions in forms that can be objectively verified; iii) the establishment of a data bank containing a summary of the characteristics of each drug product and its retail price.[42]

e) Intellectual Property

Three broad areas of concern affect intellectual property. First, there is the counterfeiting of brand-name goods, which includes everything from pharmaceuticals to running shoes.[43] Through a series of directives dealing with trademarks the EC commission has moved fairly aggressively to reinforce intellectual property rights in this area.[44] Second, there is the modification of intellectual property law to accommodate the specific properties of new technology. Particularly relevant here are protections for biotechnological inventions. These are dealt with in the proposed directive COM(88)496 which, among other things, makes some progress in defining what is patentable (e.g. which surgical animal treatments are regarded as therapeutic and therefore not patentable and which are non-therapeutic and therefore patentable), and also clarifies the procedures for establishing the novelty of a procedure or some biological material. Third, there is the issue of the speed with which patents are granted.

Some concern has been expressed over whether EC intellectual property law will be enforced in a non-discriminatory fashion.[45] Certainly, the text of the