- a revision of current Good Manufacturing Practices (cGMP) for biological products;

- an agreement with the European Free Trade Association (EFTA) Scheme for mutual recognition of evaluation reports on pharmaceutical products (PER Scheme), as part of an international effort to recognize drug evaluations completed by EFTA countries, as well as Australia and Iceland. (The PER Scheme provides members with a standardized system for the drafting and exchange of evaluation reports in order to reduce duplication in the assessment program);

- an agreement with Australia, which provides for sharing of information on the chemistry, manufacturing, and preclinical and clinical trial portions of drug submissions (Canada allows the export of products that have not yet been approved for sale in its own territory);

- Health Canada approval for the sale of 122 original medicines, between 1988 and 1993;

- approval, during the same period, of 24 new chemical entities for cardiovascular diseases and 21 for anti-infective and anti-viral therapy, including five HIV therapies;

- approval of 16 new compounds for the treatment of central nervous system disorders, and of 14 to treat cancer; and

- introduction in 1994 of 80 new products, including 21 new chemical entities.

Emergency Drug Release

The Drugs Directorate provides a service through which Canadian practitioners (physicians, dentists and veterinarians) can obtain the emergency release of a quantity of a drug that has not yet been approved for marketing or sale in Canada. This service is known as the emergency drug release program. Emergency drug releases are made for an individual patient or a specific group of animals, when a medical emergency exists and standard therapy is not effective.

Drug Evaluation Fees Regulations

In 1995, the government started charging fees for the evaluation of submissions related to human pharmaceutical, radiopharmaceutical and biological drug products. In return, the pharmaceutical industry will have a more efficient, streamlined and effective drug review process.

Updated Laws

The *Canadian Patent Act*, which legislates intellectual property rights, was amended in 1987 and again in 1993 to bring patent protection for new pharmaceutical products up to the world standard.

Under the 1987 amendment, a Patented Medicine Prices Review Board (PMPRB) was established. This independent quasi-judicial body ensures that the factory-gate prices of patented medicines charged by patentees in Canada are not excessive. It also reports annually to Parliament on pharmaceutical price trends, and research and development.