Executive Summary

This submission is the response of the Canadian Medical Association to Health Canada’s request for feedback on its detailed “Health Protection Legislative Renewal” legislative proposal released in June 2003. Our submission calls for and is embedded in the broader context of a comprehensive approach to public health.

The Canadian Medical Association is committed to working with others to realize the vision of a comprehensive, robust public health strategy as a vital component of Canada’s health care system. This strategy should rest upon three pillars:

- **Emergency Response** Empowering rapid and effective response to health emergencies, e.g. communicable disease outbreaks, water contamination, bio-terrorist attacks.

- **Health Protection:** Ensuring that Canadians are protected from health risks in their daily environment; for example, risks associated with the use of health or consumer products, or with the potential spread of infectious disease.

- **Health Promotion and Disease Prevention** Instituting programs to encourage healthy behaviour and advocating for public policy and fiscal policy that supports health.

Though these three pillars have different foci and different legislative instruments, they must all be part of a strategy to enhance public health and public health service delivery in Canada.

With specific reference to health protection, CMA believes that legislation should rest on the following principles:

- **Commitment to the primacy of health and safety.**
- **Commitment to evidence-based decision making.**
- **A thorough risk-analysis procedure based on the relative risk of products or services.**
- **Support for informed patient decision-making.**
- **Accountability vested in the Government of Canada.**
- **A comprehensive, effective post-marketing surveillance system.**
- **Enforcement through effective, meaningful penalties for noncompliance.**
- **Flexibility to quickly and efficiently accommodate new technologies.**
- **Openness and transparency.**
Encouragement of collaboration and co-operation with other stakeholders, while respecting existing jurisdictions and legislative mechanisms.

**Recommendations**

**A Canadian Public Health Strategy**

1) That the federal government ensure that legislative and administrative measures related to public health complement one another in function and are connected through communications and co-ordination mechanisms.

**The Drug Review Process**

2) That the federal government implement a timely and efficient drug review process to reduce review times to the fastest level consistent with ensuring improved health outcomes and the safety of the drug supply.

3) That the federal government consider co-operative agreements for drug review with comparable agencies in Europe, the United States and Australia, while retaining final authority as to whether a new product should be allowed on the Canadian market.

4) That the drug review and approval process be open and transparent, providing updates on review status and the opportunity for stakeholder input.

5) That Health Canada apply a priority review process to “breakthrough” drugs, i.e. those that demonstrate a substantial improvement over products already on the market.

**Patient Safety and Post-Marketing Surveillance**

6) That Health Canada work in partnership with stakeholders including CMA and other national medical and health professional associations, to develop a rigorous post-marketing surveillance system to monitor the ongoing safety of marketed drugs.

7) That government accelerate activities to establish the Patient Safety Institute using a systems approach to support a culture of safety.

8) That all stakeholders join in supporting and encouraging outcome-based research to ascertain best practices in prescribing.

9) That the federal government invest in measures such as electronic communications networks, to increase physicians' capacity to report medication incidents and to improve the timeliness of adverse event reporting.

**Drug Information and Advertising**

10) That all stakeholders work to ensure that Canadians have ready access to a source of comprehensive, reliable information on health products and their uses, and that governments fund development and dissemination of validated information to physicians and to the public.

11) That the legislation define “promotion” and “advertising” so as to clearly distinguish them from unbiased health information, and from counselling by health professionals.

12) That the current safeguards against deception be strengthened in order to

- Forbid fraudulent or misleading health claims in advertisements, on labels or in any other promotional or descriptive material pertaining to the product;
- Ensure pre-clearance and ongoing review of all health claims by an objective agency;
- Provide meaningful penalties for infraction.

13) That Health Canada maintain the current ban on advertising health products for
treatment, prevention and cure of conditions or disease states to be identified in a regulatory schedule or administrative list; the inclusion of conditions in this list should be determined through a set of criteria that are written into the Act or regulations.

14) That the existing ban on direct to consumer advertising of prescription drugs be maintained and enforced to the full extent of the law, and that the loophole that currently permits advertising the name, price and quantity of a prescription drug be closed.

15) That all stakeholders, including medical associations and industry groups, work together toward effective regulation of drug promotion to health practitioners.

Safeguarding the Privacy of Health Information

16) That the Health Protection Act respect the provisions of the Charter of Rights and Freedoms, the Federal Privacy Act and the Personal Information Protection and Electronic Documents Act (PIPEDA).

17) That the privacy provisions in the Health Protection Act meet the legislative test outlined in Section 3.6 of CMA’s Health Information Privacy Code.

Other Issues

18) That the Health Protection Act give Health Canada a clear mandate to develop guidance documents to address health and safety issues raised by new technologies.

19) That Natural Health Products be regulated on a strict framework that ensures their safety, quality and efficacy as well as the provision of complete and unbiased information to the public.

20) That the Act provide Health Canada with a clear mandate to collaborate with provincial/territorial and local governments across Canada in reviewing legislation governing all aspects of drinking water from source to consumption to ensure that comprehensive programs are in place and being properly implemented.

21) That Health Canada urgently review the Quarantine Act and modernize its provisions.