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## Policy Positions Regarding Issues addressed by the National Pharmaceuticals Strategy

### DRUG APPROVAL PROCESS

(Approved by Board of Directors, February 2006)

In September 2004, Canada's First Ministers agreed to establish a ministerial task force to develop and implement a National Pharmaceuticals Strategy (NPS) and to report on their progress by June 30, 2006. The third action of the National Pharmaceuticals Strategy is to accelerate access to breakthrough drugs for unmet health needs through improvements to the drug approval process. CHA defines the drug approval process as *the process used by Health Canada to review applications requesting authorization to market a drug in Canada. Health Canada bases approvals on evaluations of the drug's safety, efficacy, and quality.*

#### Policy Positions

- The federal government should review and, where necessary, strengthen their regulations and processes for reviewing and approving pharmaceuticals. Priority should be given to reviews of drugs with a high potential to improve health outcomes or to reduce health system costs.
- Improvement in the efficiency and cost-effectiveness of the process, while ensuring adequate review of drug safety, should be the focus of changes to the drug approval process. Changes to the drug approval process should be considered in tandem with efforts to evaluate real-world drug safety and effectiveness.
- The federal government should review and revise departmental budgets, including the contributions of industry, in order to fund the drug approval process adequately.
- The federal government should explore opportunities for international cooperation on the assessment of drug submissions in order to reduce duplication of efforts and to facilitate the drug approval process.

## Background

- The drug approval process is a significantly longer process in Canada than in other countries. In 1995, the median time for drug approvals in Canada was 650 days, compared to 562 days in Australia, 464 days in the United States, and 439 days in the United Kingdom (Romanow, 2002). The Romanow Commission identified a lack of sufficient resources for reviews at Health Canada as a reason for longer approval times.
- Health Canada receives about 80 submissions annually for the approval of new drugs, of which very few are breakthrough drugs. This does not count applications for new uses or new formulations of an approved drug, etc. (Canadian Pharmacists Association, 2005b).
- The Priority Review Process allows for expedited review of drugs that treat life threatening or severely debilitating conditions, when no effective drug exists in Canada (Canadian Pharmacists Association, 2005b).
- Time spent in the drug approval process adds to pharmaceutical companies' costs by reducing the time available for marketing under patent protection. A lengthy drug approval process may lead to an increase in drug prices and may discourage pharmaceutical companies from releasing new drugs in Canada or investing in research and development in Canada. Delays may also adversely affect the provision of timely and appropriate healthcare.
- In an effort to reduce drug approval times, Health Canada has implemented the Therapeutics Access Strategy. The success of this strategy is not yet determined.

## References

- *Drugs: From research lab to pharmacy shelf*. Canadian Pharmacists Association, January 2005b.
- Romanow, R.J. *Health Care Renewal: Building on values*. Commission on the Future of Health Care in Canada, Final Report, November 2002.

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