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Canadian Healthcare Association
Association canadienne des soins de santé
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Policy Positions Regarding Issues addressed by the National Pharmaceuticals Strategy

EVALUATION OF REAL-WORLD DRUG SAFETY AND EFFECTIVENESS

(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 fourth action of the National Pharmaceuticals Strategy is to strengthen evaluation of real-world drug safety and effectiveness. CHA defines the evaluation of real-world drug safety and effectiveness as *the collection and analysis of reports on outcomes, including adverse events, for drugs that have been approved previously for marketing. Often rare outcomes, including adverse reactions, are identified only after use in a larger patient population.*

Policy Positions

- CHA supports the federal government's efforts to monitor and evaluate drug safety and health outcomes, through Health Canada's Canadian Adverse Drug Reaction Information System.
- The federal government should improve the adverse event reporting system by involving stakeholders such as the Canadian Patient Safety Institute and by encouraging more complete reporting.
- Federal, provincial, and territorial governments and industry should support research, such as population-based studies, on the long term safety of pharmaceuticals.
- Federal, provincial, and territorial governments should utilize an existing independent agency to monitor utilization and health outcomes, including drug safety and cost-effectiveness and report this information to health providers and the public.

Background

- Many adverse reactions to drug therapy are known to increase health system costs.
- Costs increase unnecessarily when health providers prescribe, administer, or dispense drugs inappropriately.
- The Food and Drugs Act requires drug manufacturers to report serious adverse reactions to Health Canada. The act does not mandate reporting by health providers or patients. In 2002-2003, Health Canada received 9,500 domestic adverse reaction reports and 106,650 foreign reports. This may represent a small proportion of the actual number of adverse reactions (Canadian Pharmacists Association, 2005b).
- Pharmaceuticals are rarely tested prior to approval with some population groups (e.g., children, pregnant women). Evaluation of real-world drug safety and effectiveness (sometimes called post-market surveillance) may provide information regarding the effect of drugs on these populations. Real-world evaluation can be done by a variety of methods, including the analysis of adverse event reporting and population-based studies of drug use.
- The Romanow Commission recommended that a National Drug Agency be established to evaluate and approve new prescription drugs, provide ongoing evaluation of existing drugs, negotiate and contain drug prices, and provide comprehensive, objective and accurate information to healthcare providers and to the public (2002).

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.

The Canadian Healthcare Association is a leader in developing, and advocating for, health policy solutions that meet the needs of Canadians.

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