



Health
Canada

Santé
Canada

Your health and safety...our priority

Votre santé et votre sécurité... notre priorité

Helping the people
of Canada maintain and
improve their health

Aider les Canadiens et
les Canadiennes à maintenir
et à améliorer leur santé

The Canadian Pharmaceutical Landscape

June 29, 2007



Outline

Overview of the Canadian context

- Roles and responsibilities for Health
 - Canada Health Act
 - Canada Health Transfer
- Roles and responsibilities for Pharmaceuticals
 - Federal – Health Canada, Patented Medicine Prices Review Board
 - Provincial
 - Federal/Provincial collaborations – Common Drug Review
- Drug expenditures and reimbursement
- Access to drugs - Challenges and Opportunities
- Questions?



Overview of Canada's Health Care System

The roles and responsibilities for Canada's health care system are shared between the federal and provincial-territorial governments.

- The *Canada Health Act* is Canada's federal legislation for publicly funded health care insurance. It aims to ensure that all eligible residents of Canada have reasonable access to insured health services on a prepaid basis, without direct charges at the point of service for such services.

To protect, promote and restore the physical and mental well-being of residents of Canada and to facilitate reasonable access to health services without financial or other barriers.

- The Act establishes criteria and conditions related to insured health services and extended health care services that the provinces and territories must fulfill to receive the full federal cash contribution under the Canada Health Transfer (CHT).

To date, most disputes and issues related to the administration and interpretation of the Act have been addressed and resolved without resorting to deductions.

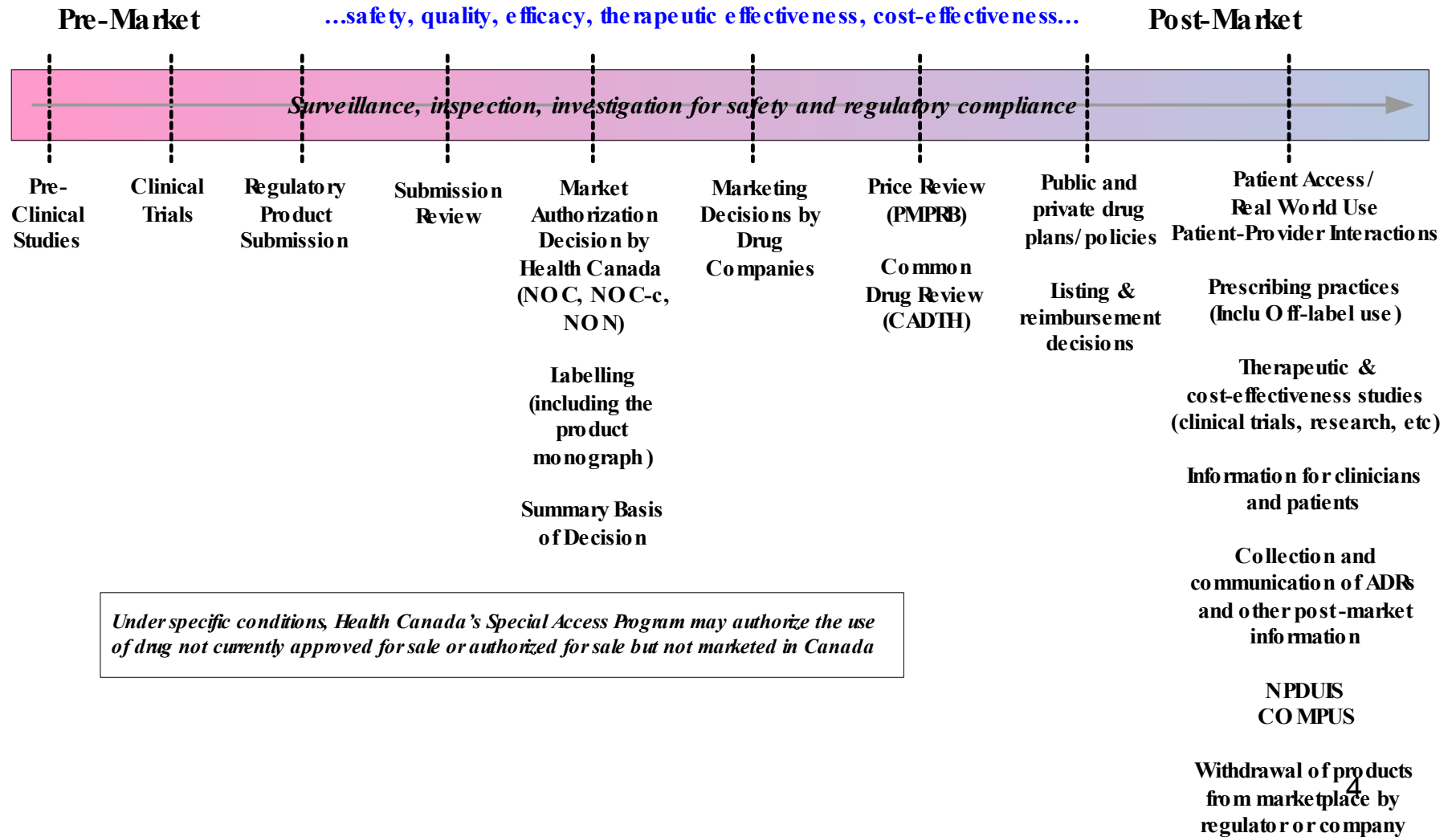
Only Pharmaceuticals provided in hospital are included in the scope of the Act



Access to Drugs in Canada

Global Product Development

Access by providers and patients through the health care system



Federal/Provincial/Territorial Governments share responsibility for drugs

Health Canada's roles and responsibilities include:

- market authorization decisions (product reviews/'approvals')
- surveillance of safety and effectiveness after products reach the market
- interpretation and implementation of the *Patented Medicines (Notice of Compliance) Regulations*
- provision of drug plan benefits to special populations (e.g., First Nations)
- providing leadership for health care renewal in Canada, including collaboration with PTs on initiatives to improve prescribing and utilization, control costs and expand drug plan coverage

Patented Medicine Prices Review Board

- Independent quasi-judicial administrative agency, responsible for regulating the prices that patentees charge (i.e., the "factory-gate" price for prescription and non-prescription patented drugs sold in Canada) to ensure that they are not excessive



Roles and Responsibilities (cont'd)

Provincial roles include:

- provision of drug plan benefits to provincial populations
- drug plan management

Common Drug Review (Federal/Provincial/Territorial partnership)

- Centralized process that conducts evidence-based clinical and pharmacoeconomic reviews of new drugs and new indications for old drugs for potential coverage by participating federal, provincial and territorial drug benefit plans.
- Federal, provincial and territorial drug plans retain final authority to make listing decisions.
- Officials are exploring the feasibility of expanding the CDR to therapeutic class reviews, hospital drugs, and all other drugs



Drug Expenditures / Reimbursement

Under the *Canada Health Act*, federal, provincial and territorial health insurance plans are required to provide coverage to their residents for all medically necessary hospital and physician services on a prepaid basis. Provinces and territories may also offer "additional benefits" under their respective health insurance plans, which may include prescription drug benefits. The scope of coverage varies between public plans.

Over 60% of the cost of pharmaceuticals is privately paid for, either by patients directly or through non-government insurance.

Prescribed drugs account for approximately:

- 83.2% of total drug expenditure in 2005 (approximately \$19.7B)
- 83.8% of total drug expenditure in 2006 (approximately \$21.1B)

Projected public sector expenditure

- \$9.2B in 2005
- \$9.6B in 2006

Projected private sector expenditure

- \$10.6B in 2005
- \$11.5B in 2006



Challenges and Opportunities in Ensuring Equitable Access

Canadians pay at least part of the cost of the pharmaceuticals they use outside of hospitals, although the out-of-pocket shares differ depending on whether or not they have insurance, and if they have insurance, whether they are covered by a public provincial plan or by a private plan. This leads to variation in financial access for Canadians.

- Approximately 20% of Canadians have inadequate access to a robust drug plan
- An estimated 650,000 Canadians have no drug coverage whatsoever, even for catastrophic drug expenses
- This is particularly problematic in areas where there is no broad public plan and the type of employment does not provide drug insurance benefits

Federal and provincial governments are working together to address access issues:

- To better understand gaps in coverage and which subpopulations are most at risk
- To accelerate access to breakthrough drugs for unmet health needs
- To improve public formulary alignment – common policies and best practices



Some Observations

In many ways, the Canadian and the EU systems are very similar

- Both value public health care and must find ways to address rising drug expenditures
- Both have an overarching body which sets standards which are adhered to by members
 - Canada – Federal / Provincial Interface
 - EU – Commission / member states
- Both have made efforts to harmonize regulatory requirements (i.e., Mutual Recognition Agreements and International Conference on Harmonization Technical Requirements)

By working together, we will be able to leverage resources and knowledge, while addressing issues of common concern.





Questions?

