Helping the people of Canada maintain and improve their health

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

Real World Safety and Effectiveness - Moving Forward

Knowledge Translation Workshop November 26, 2007



Canada

Outline

- Background and context
- Progress to date
- Next Steps

Context

- Drugs are an increasingly important resource for preventing, treating and managing illness

- But, there are major system challenges …
  - medicalization, appropriate use
  - safety and effectiveness
  - reconciling commercial and public objectives
  - promoting and managing innovation
  - harmonizing regulatory and health system interests
  - access and coverage – the “unfinished business of Canadian medicare”
  - rising costs, value for money questions, concerns about who should pay, overall affordability

National Pharmaceuticals Strategy

- NPS agreed to as part of the September 2004 First Ministers' Meeting and the "10-Year Plan to Strengthen Health Care"
  - Led by federal and provincial/territorial governments (except QC)
- Designed as a collaborative approach to address many individual system challenges
- The NPS builds on previous FPT efforts to manage pharmaceuticals as a means to improve health while contributing to system sustainability by realizing system efficiencies
- Shared agenda … but underlying differences in objectives

Nine 9 Inter-related Elements

Improving Canadians' access to medicines

1. Develop, assess and cost options for Catastrophic Pharmaceutical Coverage
2. Common National Drug Formulary
3. Accelerated Access to Breakthrough Drugs through Regulatory Improvements

Safe, effective and appropriate drug prescribing and use

4. Strengthen the evaluation of Real World Safety and Effectiveness
5. Influencing Prescribing Behaviours
6. E-prescribing implementation (linked to Electronic Health Record)

Sustainability - managing costs

7. Accelerating Access to, and Improving Pricing of Non-Patented Medicines
8. Pricing and Purchasing Strategies for drugs and vaccines
9. Analysis of Cost Drivers and Cost-effectiveness

Progress Report - 2006

FIVE FOCUS AREAS

- Catastrophic Drug Coverage
- Expensive Drugs for Rare Diseases
- Common National Formulary
- Drug Pricing and Purchasing Strategies
- Real World Drug Safety and Effectiveness

http://www.hc-sc.gc.ca/hcs-sss/pharma/nps-spp/index_e.html

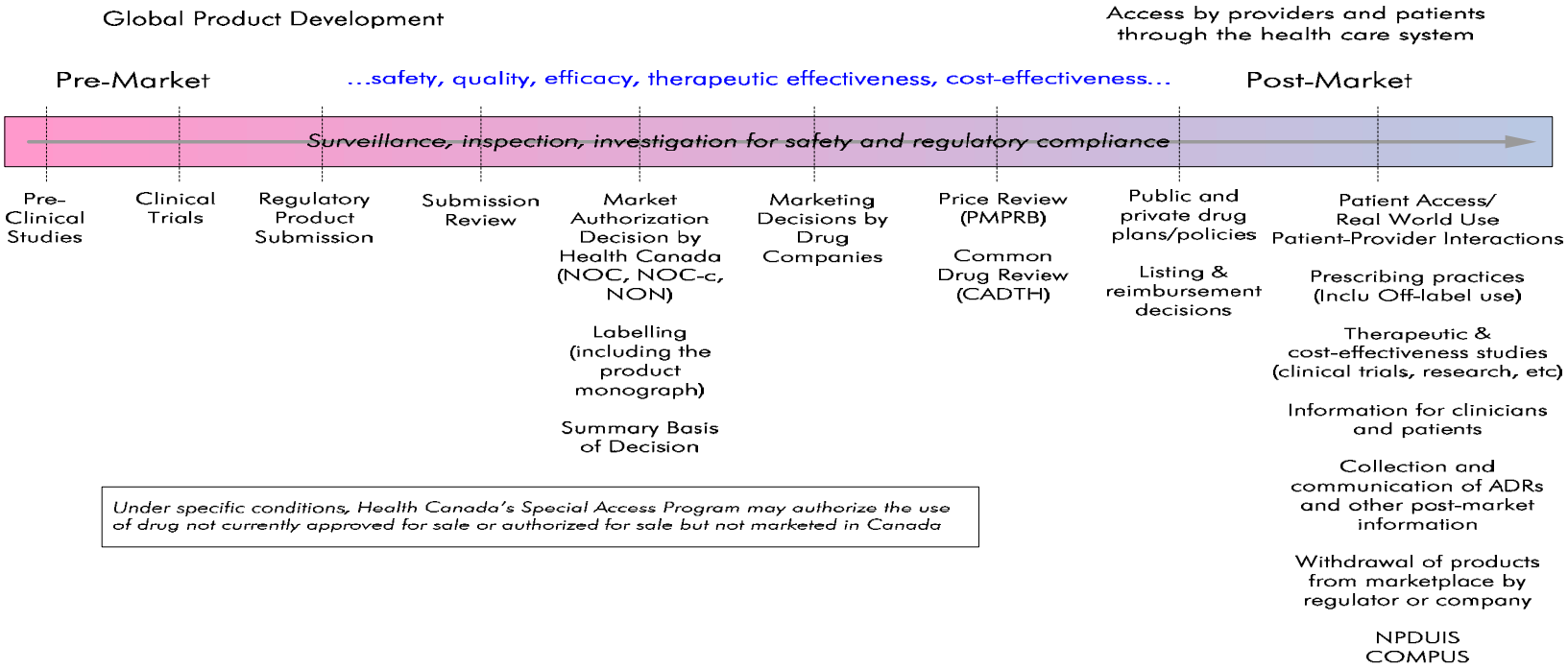
Real World Safety and Effectiveness - Issues

- Inclusion of RWSE in the NPS reflected
  - a recognition of significant gaps in post-market drug safety and effectiveness evidence – a clear barrier to effective, evidence-based decision making
  - the need for greater coordination of efforts to generate and transfer information necessary to fill evidence gaps and support decision makers

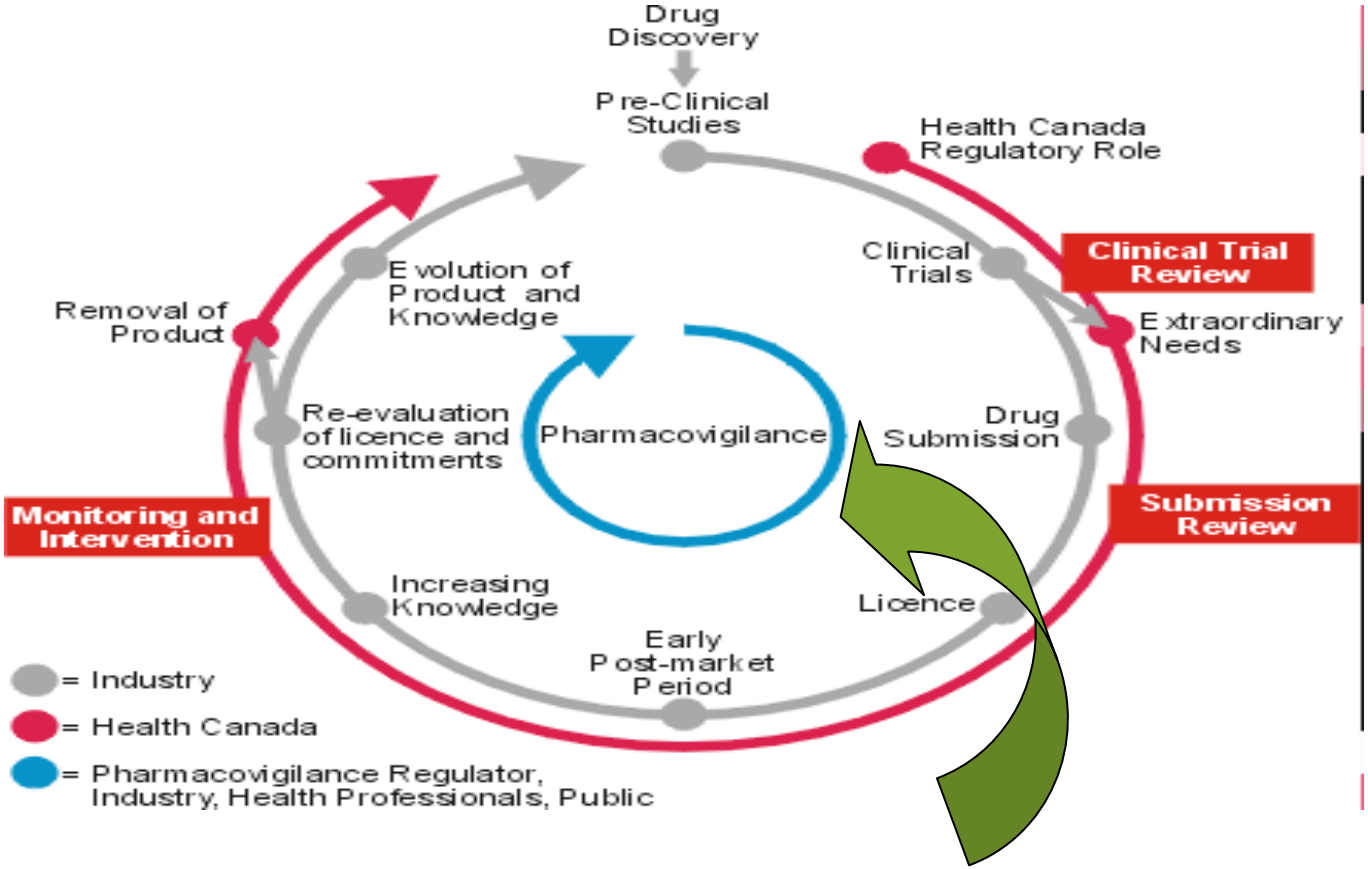
- Evolution of knowledge about medicines demands that governments and other decision-makers seek better evidence about the balance of benefit and risk throughout the product life cycle

Product life-cycle approach

On-going assessment of whether the therapeutic benefits of a drug continue to outweigh its risks – shift in balance of effort across pre-and post-market stages



Health Canada Progressive Licensing Model



RWSE Evidence

Progress to Date

- Collaboration under the NPS advanced the RWSE agenda
  (NPS Progress Report 2006)

- Completion of consultant's report: ***Medicines that Work for Canadians: Business Plan for a Drug Effectiveness and Safety Network***
  - Proposes model for developing an integrated and comprehensive approach to support the evaluation of safety and effectiveness in Canada and estimates potential cost
- Potential benefits of such a network include:
  - Improved coordination and prioritization of the RWSE research agenda in Canada and enhanced research capacity
  - Increased availability of new, unbiased and timely evidence upon which reasoned decisions can be made about safe and effective access, prescribing, and beneficial use of medicines
  - Facilitates national and international partnerships to share research and information

(http://www.hc-sc.gc.ca/hcs-sss/pharma/nps-snpp/securit/index_e.html)

More to be done – Next Steps

- **RWSE Network Development**
  - Evaluate funding options
  - More in-depth analysis of the model proposed in the business plan
  - Develop implementation plan: selecting host; establishing oversight committee; etc.

- **Development of Knowledge Transfer/Translation (KT) Strategy**
  - Missing component of business plan - moving the knowledge generated into action

    "*Knowledge Transfer, particularly as it relates to the effectiveness of the program in informing policy decisions and in changing treatment practice patterns, is a critical element of what this program will set out to achieve. However, it is a large and complex issue and will be addressed in detail outside the scope of this business plan*".

Knowledge Translation Process

- Proposed network model begins to address some elements of KT process:
  - Oversight Committee and stakeholder meetings to identify knowledge gaps and suggest projects
  - Network infrastructure facilitates linkages and exchanges between researchers and decision-makers to:
    - refine research questions
    - adapt the knowledge or research to the specific context

Knowledge Translation/Change Management Processes

- Still needed…a strategy to:
  - Ensure uptake and implementation by key stakeholders of knowledge synthesized in order to improve health outcomes and efficiencies in the health system;
  - Monitor the uptake and use of the knowledge
    - Determine extent of diffusion and ensuing changes in policy, practice and culture
    - If less than expected/desired, identify barriers and adjust strategy
  - Assess the impact of applying the knowledge
    - Do policies and practices change in the direction suggested by the evidence? If not, why not?

Why the quest for a drug strategy keeps turning into bitter medicine

Monday, Nov. 5/07
Globe and Mail

JUDITH MAXWELL

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Canadian business has extracted major cost savings from pro-active procurement practices. Can governments reap the same rewards with respect to drug purchases? If they do, employers can save on employee benefit costs while more patients could get affordable access to drugs.

The cost of drugs consumed in Canada has nearly doubled since 1997 – the total reached $25-billion in 2006. About 40 per cent of that amount was paid by employers' group insurance plans and 20 per cent by patients from their own pockets. The other 40 per cent comes from public drug benefit plans, which focus primarily on seniors and people with low incomes.

With the advance of science, drugs are playing roles in health care that could not have been imagined in earlier decades. Some new therapies enable people with chronic illness to work and live a full life, others serve as a substitute for surgery or medical interventions that require hospital care. On the negative side, many new drugs come on the market with great fanfare, even though they add little or no therapeutic value to existing medications.

As the bills mount, drug policy is on a collision course. Employers with group insurance plans and governments are looking for ways to curb the cost, while more Canadians need a better drug plan because they cannot afford the drugs being prescribed by their physicians. It's estimated that 20 per cent of working age Canadians are underinsured. Coverage depends on where people live (there are wide variations across provinces) and where they work (many jobs do not provide supplementary health benefits).

Quebec made drug insurance mandatory for all citizens in 1997, based on a mixed private-public model. Quebeckers can buy their insurance from a private company or from the public plan, where the premiums are adjusted for ability to pay.

The Ministerial Task Force on the National Pharmaceuticals Strategy set up by the other nine provinces and the federal government confirmed in 2006 that it too was looking at a mix of private and public insurance for drugs. But unlike Quebec, where taxpayers pay a premium through their income tax, the task force is examining a "percentage of income threshold option," which is currently in use in four provinces (B.C., Saskatchewan, Manitoba and Ontario). Ontario seniors, for example, pay from their own pocket for up to 3 per cent of their income, while people of working age who are eligible for drug benefits pay up to 4 per cent. The drug plan pays all the costs above those thresholds.

According to Megan Coombes and her colleagues at the Centre for Health Services Policy and Research, the four provinces using income thresholds provide the best protection for both seniors and working age households. The plans in the Atlantic provinces provide the least protection.

If the task force opts for this approach, the big policy question will be what income threshold is fair and reasonable. The 2002 Senate report on health care suggested a threshold of 3 per cent of income.

But there is a Catch-22 to drug insurance: "No pharmacare without cost control, and no cost control without pharmacare."

No government should expose itself to the financial risks of catastrophic drug insurance without a parallel strategy to control the cost of drugs. And no government will have the political will to achieve cost control without the threat of those financial risks.

This is where procurement policy comes in. Governments need to work together to use their market power to negotiate better prices for drugs.

[Governments] have to overcome their reluctance to extract full value from both the big international pharmaceutical companies and the Canadian-owned generic producers.

They also have to overcome their reluctance to extract full value from both the big international pharmaceutical companies and the Canadian-owned generic producers.

There are at least three levers to moderate the growth in drug costs. One is already in place – to create a Common Drug Review process to fully assess new drugs for their therapeutic and economic value. But to achieve cost effectiveness, governments have to use the assessments. When a recent review recommended that a drug should not be listed at the proposed price, it identified an opportunity to negotiate a lower price. Yet one province immediately listed the drug at the proposed price. So much for drug assessment.

A second is to create a buying syndicate for all governments so they can bargain for volume discounts. Today, they don't negotiate as a team.

A third is to ensure that patients and physicians have the information they need to choose the most cost-effective option and then monitor patterns of prescribing to find ou if the most cost-effective drug are actually being used. Current IT systems in the health sector fall short of meeting these information and monitoring needs.

To break through the Catch-22, governments have t demonstrate progress on man aging drug costs paid by both private and public drug plans. That in turn will open the door to fairer access to the drug therapies Canadians need.

So there is a lot riding on this Ministerial Task Force. Watch for the next progress report due in December.