The current paradigm of drug funding: a public funder's perspective

May 5, 2013

Diane McArthur
Assistant Deputy Minister, Executive Officer
Ontario Public Drug Program

Ontario

Landscape

- In Fiscal Year 2012/13, the Ontario Public Drug Program's spending was $4.5 billion, or almost 9% of total healthcare spending in Ontario
- Drug costs are on the rise, and are now nationally the second largest health-care expense (public and private) after hospitals *(National Health Expenditure Trends 1975-2012, CIHI)*
- The cost of innovative therapies continue to increase year over year, leading to high costs to public and private insurers
- Move towards personalized medicine, along with increasing numbers of biologics and targeted therapies being introduced to the market at higher costs and more frequently with other component costs (e.g. genetic testing)
- Innovative treatments for rare diseases and chronic diseases often last for many years (depending on the patient and their response to therapy), therefore the costs can be long-term with limited knowledge of outcomes achieved.

Ontario

Challenges for drug funding

- Many new drugs coming to market offer limited benefits over currently available treatments
- Trials are generally designed to meet regulatory requirements and often do not address what payors and practitioners want to know – what are the real world comparative benefits and harms compared to current therapies?
- Many new products, particularly those for small patient populations, do not meet traditional benchmarks of cost-effectiveness.
- Multiple competing issues – the need to balance uncertainty of clinical and cost effectiveness with values of patients and taxpayers
- Sustainability of public drug funding in the context of overall health care spending is a concern for all public payers
- As one way to address these challenges, there has been a shift in the paradigm of funding of branded drugs with the introduction of product listing agreements (PLAs)

Product Listing Agreements (PLAs)

What are they?

- A product listing agreement refers to an agreement between a pharmaceutical manufacturer and the Ministry/funder

Objective of PLAs:

- Improve patient outcomes by providing patients with improved access to drugs, under certain conditions which are informed by the recommendations of the Ministry's expert advisory committee as well as the recommendations from the national review bodies (Common Drug Review and pan-Canadian Oncology Drug Review)
- Improve accountability and risk sharing by supporting funding decisions through a negotiated process between the Ministry and pharmaceutical manufacturers
- Leverage significant purchasing power to obtain better value for money

Ontario

What have we learned – successes

- Agreements have made a significant impact on improving access to therapies
- Estimating financial exposure of funding decisions has been more accurate and overall spending growth is being more tightly managed
- Improvement in the value of money spent for drugs reimbursed
- Learnings from the implementation of several performance-based agreements
- Innovative agreements have measurable outcomes

Ontario

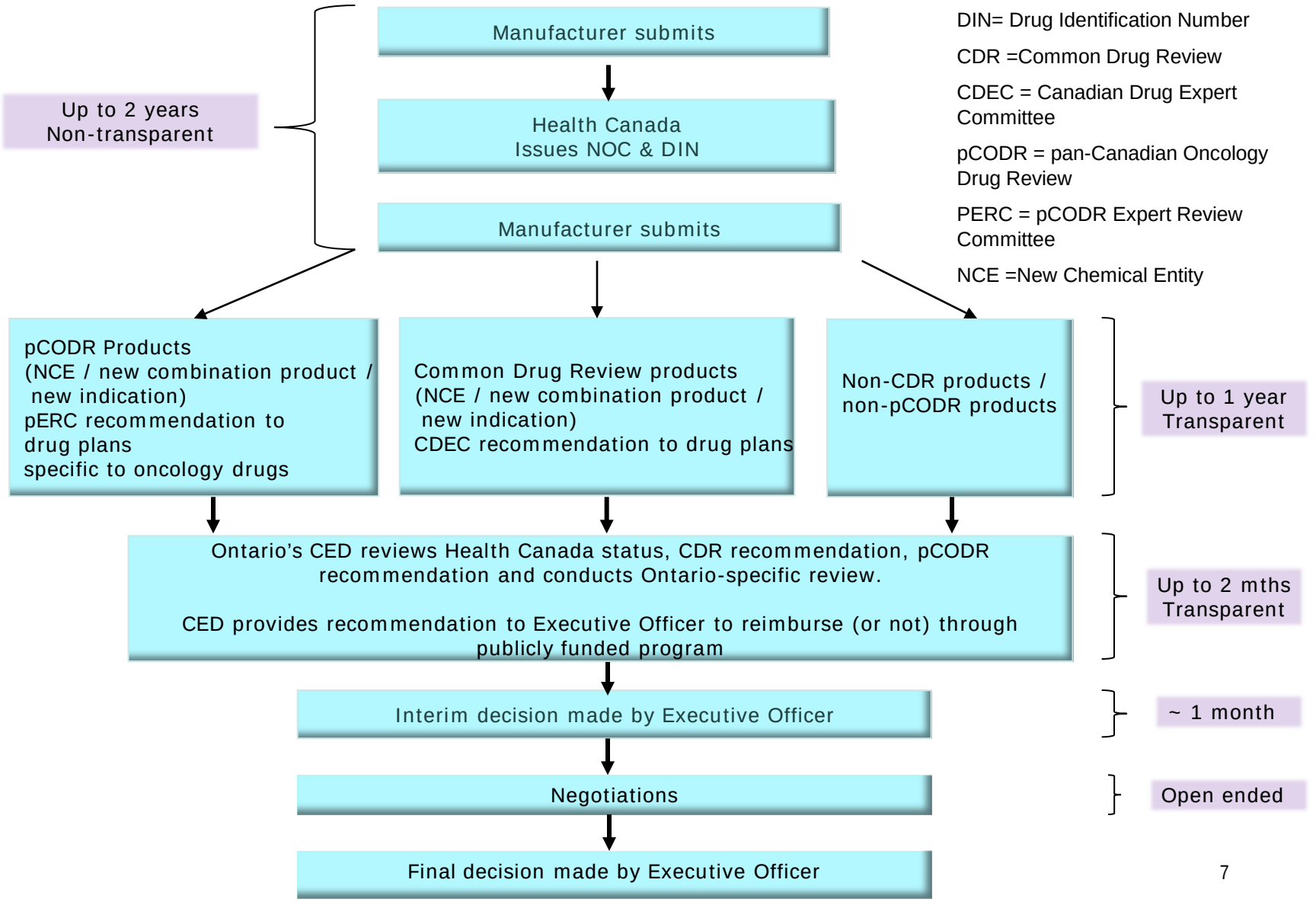
What have we learned – challenges

- Negotiating and monitoring agreements is resource intensive
- Opportunities for innovative approaches need to be further explored
  - Designing and implementing performance-based agreements with measurable outcomes is challenging
  - Portfolio approach from the broader perspective of a therapeutic category versus drugs from individual manufacturers
- Need for Global approval limits some manufacturers ability to enter into PLAs and affects timelines of negotiations
- Increasing non-transparent pricing makes future negotiations and public discussions more difficult
- Similar challenges exist across the country and globally

How do we collaborate to balance innovation with responsible spending of taxpayers dollars on drugs in a publicly funded system?

Ontario

Drug Funding Process



NOC= Notice of Compliance – indicating drug is safe and effective

DIN= Drug Identification Number

CDR =Common Drug Review

CDEC = Canadian Drug Expert Committee

pCODR = pan-Canadian Oncology Drug Review

PERC = pCODR Expert Review Committee

NCE =New Chemical Entity

Collaboration: Pan-Canadian Brand Drug Pricing Alliance

- Announced by Premiers in August 2010 at a meeting of the Council of Federation (COF).
- Purpose: to examine opportunities to conduct joint provincial / territorial (P/T) negotiations for brand name drug products.
- Goals:
  - To increase access to drug treatment options
  - To improve the consistency of drug listing decisions across the country
  - To capitalize on combined buying power of jurisdictions
  - To achieve consistent pricing and lower drug costs
  - Reduce duplication of negotiations and improve utilization of resources

Ontario

Pan-Canadian Drug Pricing Alliance: Progress

- P/Ts agreed to conduct joint negotiations for select drug products to determine if the approach was feasible on a broader scale.
- To date, P/Ts have completed joint negotiations for 10 brand name drug products.
- An additional 17 drug products are under active negotiations
- Building on the success of the Alliance to date, participating jurisdictions agree that moving forward any drug product approved through the national drug review processes (e.g. Common Drug Review, pan-Canadian Oncology Drug Review) should be considered by the Pan-Canadian Drug Pricing Alliance for a harmonized decision on whether negotiations should occur.
- As the direction for a more consistent approach to pan-Canadian negotiations has evolved, the jurisdictions agreed that the development of a permanent and formal operating structure should be considered.

Ontario

Pan-Canadian Pricing Alliance: Challenges encountered

- Differences in public drug plan structures:
  - Program recipients
  - Legislation, regulations
  - Public drug program policies, processes for payment rules (e.g. mark-up, distribution fees, etc.)
  - Formularies – drugs listed and overall structure
- These differences can lead to different priorities/goals for negotiation
- Lack of a formal process or governance structure
- Participation on individual negotiations by Provinces/Territories is not mandatory
- Resources for conducting multi-jurisdictional negotiations

Ontario

Are PLAs here to stay?

- Successful for now
- Increasing numbers of biologic therapies and targeted drug therapies (move towards personalized medicine) leading to increasing costs of drug development
- Expensive therapies used to cost $10,000 per patient per year – now they can cost more than $500,000 per patient per year
- Under current paradigm, publicly funding these therapies will become unsustainable

Ontario

Future vision

- First step - the need to develop a more strategic, comprehensive and coordinated approach to pharmaceutical management in Canada, including both generic and brand name products.
- Approach must address current pan-Canadian challenges
- Recognition that we are participants in a global pharmaceutical market
  - international alignment/collaboration both from a regulatory as well as public reimbursement perspective
  - increased autonomy for Canadian pharma
- The need to balance true innovation with cost
  - For example, do we invest in small incremental improvements in a large therapeutic area vs. large improvements in smaller therapeutic areas?
  - How much of a premium will the public pay for true innovation?

Ontario