ROADMAP TO OPTIMAL ACCESS

Amendments to Patented Medicines Regulations & OHIP+ Kids' Pharmacare

JUNE 14, 2017
8:30 am – 4:00 pm
DELTA HOTEL TORONTO
75 Lower Simcoe St, Toronto, Ontario

HEALTH CANADA AMENDMENTS TO PATENTED MEDICINES REGULATIONS

FOCUS OF FORUM

Patient Focus: We are all patients first. Any system we design must serve:

- The father with advanced pancreatic cancer whose only wish is walk his daughter down the aisle next month
- The first-year university student with thalassemia who just switched from an overnight infusion drug to a once-daily pill and discovered that living in residence was "no big deal"
- The mother of four who for almost 20 yeas has been injecting herself with a biologic to treat her rheumatoid arthritis but is now considering new oral drug options
- The parent of a six-month-old infant diagnosed at birth with a disabling and potentially life-threatening metabolic disease for which there is a newly approved but very expensive therapy, not yet funded by the drug plan

Medicines Focus: Given that it may be another 30 years before the next iteration of the Patented Medicines Regulations, we need to get them right not just for the medicines of today but more importantly the therapies of tomorrow, where the "right patient, drug, time" scenario will be defined by:

- Individual patient profile based on genetics, co-conditions, values, and lifestyle
- Medicines targeted to patient profile to optimize safety, effectiveness, quality of life, treatment goals
- Next generation protein, device-drug combinations, and cellular therapies
- Availability accelerated by progressive clinical trial designs, early access programmes, risk-sharing and managed access plans, and flexible value-based pricing

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System Focus: The solutions must encompass the entire system: individual level, health system level, and social system level. System must be patient centred and patient directed. The medicines of today and tomorrow have the potential for truly delivering on the ultimate goal of "right patient, right drug, right time" and also "right price." In general, we support the factors identified:

- There is a need for greater collaboration and coordination between and among players within that system;
- Systems which recognize and reward therapeutic value encourage the "right kind" of innovation;
- Affordability and sustainability considerations fall within the PMPRB's regulatory purview;
- The price review process should be more responsive to changes in science and market conditions; and
- To the extent possible, the PMPRB should apply "bright line" rules that are consistent with international best practices and provide predictability to stakeholders.

"What if" considerations:

- What if "excessive pricing" is not the real issue? For years, we have been told that PRMPB is effective, that Canada is not paying excessive prices and that price increases are within guidelines.
- If drug prices reflect the "value" of drugs, to what degree does benchmarking price against other those of countries also means other countries will determine the "value" of therapies to Canadians?
- To ensure the cost of drugs in Canada is consistent with other healthcare costs, should we also benchmark the "price" paid for other healthcare services to the median in other OECD countries (regardless of comparability, quality, and accessibility of services)?
- What if the PMPRB introduced other mechanisms that not only promoted affordability and sustainability but also increased the value (cost-effectiveness) of medicines, including managed access, appropriate use and adherence, post-market surveillance, and adjustments based on real-world data.

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OHIP+ (Kids' Pharmacare Consultation)

Helping OHIP+ Deliver Best Possible Drug Access to Ontario's Kids

Outcome: OHIP+ will ensure optimal access to prescription medicines for all Ontarians less than 25 years of age; access will be as good or better than current best access

To that end, we will:

- Identify needs of young patients not adequately served today to ensure they are addressed in OHIP+
- Review what plans are providing the "best coverage" today to compare with models for OHIP+
- Identify the most efficient processes for youth and families for access to OHIP+ (eliminate unnecessary red tape)
- Identify services and added value that are essential to promoting adherence and patient experience receiving medicines
- Consider issues of transition for families coming in or leaving Ontario and youths reaching 25 years of age

We will consider:

All Stakeholder Perspectives: what is the current status of access to prescription medicines and what would ideal OHIP+ look like?

- Ontario Public Drug Programs
- Patients and patient advocates
- Healthcare providers (doctors, nurses, pharmacists)
- Private drug plans and employers
- Pharmaceutical manufacturers
- Pharmacy and other support services

Navigation Issues toward Implementation

- Timeliness of access with total public funding
- Coordination of benefits when drug coverage differs
- Highly specialized needs and specialty drugs
- Impact on drug prices
- Transition: when a youth turns 25
- OTHER ISSUES

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AGENDA

8:00 a.m. – 8:45 a.m.	**Breakfast and Registration**	
8:45 a.m. – 9:00 a.m.	**Welcome and Morning Objectives**	Wayne Critchley, CORD
9:00 a.m. – 9:45 a.m.	**Plenary: How Did We Get Here and Where Do We Need to Go?** • Patented Medicine Regulations and PMPRB: Past, Present and Future (Wayne Critchley, CORD) • Approaches to Pricing and Access: International Comparisons (Neil Palmer, PDCI) • Innovative Therapies: Orphan drugs, Precision Medicines, and Cellular Therapeutics (Neil Palmer, PDCI)	
9:45 a.m. – 10:30 a.m.	**Perspectives Panel: Sharing How We See It** Moderator: William Dempster, 3Sixty Public Affairs **Roundtable of Discussants** • Patients (TBC) • Brokers: Imran Ali (pCPA), Winnie Chan (MOHLTC), Karen Voin (CLIHA), Caroline Jensen (Sunlife) • Suppliers; Pharma (TBC), George Wyatt (Innomar) **Q1: How well are we doing at "putting patients first"?** • What have been challenges and solutions to patient access **Q2: Brokers (Regulator, Public and private payers): are these Navigators or Gatekeepers?** • Challenges and response to optimizing access to innovative drugs **Q3: What are roles of industry, pharmacy, and administrators?** • Collaborative approaches to optimize access to innovative therapies: Role of managed access and risk sharing, patient registries, and real-world data analysis	
10:30 a.m. – 10:45 a.m.	**Refreshment Break**	

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10:45 a.m. – 11:15 a.m.	**Small-Group Deliberative Dialogue: Determining Value** Moderator: Durhane Wong-Rieger, CORD • What is value of medicine at three levels: to patient, to health system, to society? • How do we appraise the economic value of the "values" at each level? Can we translate to economic "benefits" and "costs?	
11:15 a.m. – 12:00 p.m.	**Plenary: Sharing Perspective** Moderator: Wayne Critchley, CORD **Commentary: TBC** • Insights and Recommendations • Feeding into the HC PMPRB Consultation Process • Conclusions	
12:00 p.m. – 1:00 p.m.	**Lunch**	
1:00 p.m. – 1:05 p.m.	**Welcome and Afternoon Objectives**	Durhane Wong-Rieger, CORD
1:05 p.m. – 2:00 p.m.	**Plenary: Where are Best Routes and Roadblocks?** Moderator: William Dempster, 3Sixty Public Affairs • How do kids in Ontario and "best of rest" of Canada get drugs today: public, private, and not at all (Chris Bonnett, H3 Consulting) • What is current access for drugs for small, specialize patent populations? (Nigel Rawson, Eastlake Consulting) • Patient Survey Feedback: What we like, what we need, what we hope for? (Durhane Wong-Rieger)	
2:00 p.m. – 2:45 p.m.	**Panelists: Open Roads, Detours, and Alternative Routes** Moderator: William Dempster, 3Sixty Public Affairs Discussants: Patients (TBC); Vivian Leong (MOHLTC), Karen Voin, Ned Pojskic (Green Shield), John-Paul Dowson, (Roubaix Strategies)	

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	• What is working well today and should be kept? • What is not working today and needs to be fixed? • What must be done to assure OHIP+ delivers optimal access to Ontario children and youth • What are the risks to be navigated in implementation? • What are unintended consequences? What could go wrong? What could be issues if everything goes rights? • What else?
2:45 p.m. – 3:00 p.m.	**Refreshment Break**
3:00 p.m. – 3:30 p.m.	**Small-Group Creative Sessions: Making OHIP+ Best Possible!** Moderator: Durhane Wong-Rieger, CORD • Realistic but Idealistic Future: If OHIP+ works optimally, what would it look like for patient access in 3 - 5 years? • What would make it an unqualified success? How will we know it is serving patient needs? • What would each stakeholder sector (patients/families, healthcare providers, brokers (payers and insurers), and suppliers (pharma companies, pharmacies, administrators) want to serve their constituent needs?
3:30 p.m. – 4:00 p.m.	**Plenary: Sharing Perspective** Moderator: Wayne Critchley, CORD • How Realistic is Ideal Future? • Alternative Routes and Mechanisms of Navigation • Summing UP

Canadian Organization for Rare Disorders