GETTING TO ACCESS

Innovative approaches to innovative medicines

March 29, 2017

10:00 AM - 4:00 PM

SHERATON VANCOUVER WALL CENTRE

1088 Burrard Street, Vancouver

I. INNOVATIVE MEDICINES OFFER OPPORTUNITIES AND CHALLENGES

Why this forum matters: Innovative drug therapies are medicines that can:

- Offer a substantial improvement over existing therapies; for example, biologics can modify the underlying cause of a condition rather than just treat the symptoms;
- Address an unmet need; many drugs for rare disease are the first to be developed for that condition
- Target the (unique) characteristics of a subgroup of patients based on genetic makeup and/or other individual characteristics
- Cure the disease; for example, by eliminating the cause (hepatitis C virus), replacing abnormal cells (stem cell replacement), or modifying the faulty gene

But innovative therapies come at a price that is often considered "unaffordable" under current assessment processes

- Individually, therapies tend to be much higher than the "old" therapies they are replacing
- The number of innovative therapies is increasing, as is the impact on drug budgets
- Our assessment processes do not address innovation; they were developed to determine how much incremental cost should be paid for incremental benefits to existing therapies and how to allocate drug budgets to achieve most overall health of a population, regardless of the conditions and need
- Individual high-cost therapies can have an identifiable impact on overall drug plan budgets, whether private or public

Presented by: ADVOCARE CONSUMER ADVOCARE NETWORK CORD Canadian Organization for Rare Disorders

Tensions among stakeholders have increased, as have the rhetoric and distrust

- Regulators have been challenged for approving drugs that lack evidence of clinical effectiveness
- Drug plans have been "villain-ized" as heartless and more concerned about budgets than patients
- Drug companies have been tasked as to pricing polices and accused of "gouging" and charging "what the market will bear"
- Patient advocates have been criticized for unrealistic expectations and being influenced by the drug developers

GOOD NEWS: No one is happy with the status quo…

- We are talking to one another, identifying common goals, and looking for viable solutions
- There are platforms for dialogue and decision-making

II. FORMAT: COLLABORATIVE FACILITATED DIALOGUE

- Multi-stakeholder representation: international and Canadian "experts", patient representatives, clinicians, policy makers, technocrats, payers, and industry suppliers
- 50 persons, by invitation, facilitated presentations, exercises, dialogue and consensus-building; Chatham House Rules
- Summary, report, and next steps

III. WHAT WE WILL ACHIEVE AT THIS FORUM?

1. **Identify options for access that works for all**
    - Support managed access (criteria-based, monitored)
    - Addresses key concerns of all stakeholder (timeliness, place in therapy, value, budget impact)
    - Forward looking to best integrate future medicines (rare, personalized/targeted, stem cell and gene modification, repurposed, biosimilars)
2. **Identify ways for all stakeholders to work collaboratively toward consensus approach**
    - Identify what is working in current (Canadian) approaches and should be enhanced
    - Identify what is getting in the way and strategies for addressing
    - Identify areas of agreement (keep), disagreement (resolve), and ambiguity (clarify)
    - Identify pathways to open communication, transparency, and engagement (of all stakeholders)

IV. WHAT WILL WE ADDRESS TOGETHER?

3. Understand Managed Access Plans (Managed Entry Agreements) and how they are being used – in Canada and elsewhere
    - What is experience with MAPs in Canada
    - What are international experiences with Canada
    - What does/will it take to make them work?
4. Understand lifecycle/adaptive pathways approach to planning research, collecting data, reviewing drugs, and evaluating in real world (Regulatory-HTA combined)
    - ADAPT SMART
    - NEW DIGS
    - Health Canada – CADTH collaborations
5. Review current challenges in access through CADTH and pCPA
6. Deliberate principles for value, pricing, and value-based pricing
    - How should "value" of innovative medicine be determined, under various scenarios?
    - What about impact on other "economic" impact measures, e.g. hospitalization, disability, return to work, homecare?
    - What about intrinsic value to patients, e.g., disability, quality of life, bridge to next therapy?
7. What are factors that should be considered in setting "right price?"
    - Should there be a "ceiling" price for therapy and, if so, how should it be determined?
    - Should public and private drug plans pay same prices?
8. How should Canadian price(s) be determined?
    - How should Canada be referenced to international references and what is PMPRB role?
    - Should budget impact influence pricing?
    - What about price transparency?

V. HOW WE WILL IMPROVE WORKING TOGETHER?

- Presentations: What are best practices from across Canada and abroad; what can we learn
- Roundtable on sharing perspectives: What each stakeholder values and what influences decision-making?
- Exercise on shared challenges: How can case examples of current and emerging therapies help us to create new solutions?
- Consensus building: Let's assess alternative pathways to compare good, bad, and feasibility

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All sponsors will have first opportunity for added seats.

If you have any questions, or wish to discuss a customized sponsorship package, please contact Angela at angela@raredisorders.ca or call (416) 969-7431 x 200

REGISTRATION

Individual Registration:

- $995 early bird rate (before February 24)
- $1250 regular rate (after February 24)

Patient Registration:

- $495 early bird rate (before February 24)
- $650 regular rate (after February 24)

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