Canadian Organization for Rare Disorders

PRESENTS

NATIONAL PHARMACARE WEBINAR DEBATES

PURPOSE

Engage patients and other stakeholders in informed deliberations on key issues that must be confronted in developing a National Pharmacare Programme, including global factors, defining principles, and optimal outcomes.

TOPICS:

1. DOES NATIONAL PHARMACARE MEAN SAME COVERAGE AND SAME PUBLIC PAYER FOR EVERYONE? (AUGUST 8)

Point: A National Pharmacare Program based on a single formulary and a single public payer will provide the most equitable and sustainable access to prescription drugs for all Canadians at the lowest overall cost.

Counterpoint: There are many strengths in both the public and private systems. "…the best system is one that will: ensure that patients have access to the medicines they need at affordable prices; ensure Canadians do not lose their existing group health benefit plans; and control costs to taxpayers."

Patient Perspective: National Pharmacare must consider more than simple changes to formulary and/or payers; otherwise it will not address many barriers experienced by patients in access, including complex medicines, advanced therapies, new medicines, specialty medicines, and drugs for small patient populations.

2. ORIGINAL AND SIMILAR BIOLOGIC DRUGS: LOW COST, INDIVIDUAL CHOICE, OR BOTH? (AUGUST 15)

Point: Because biosimilar medicines are "highly similar" to the original biologic in safety and effectiveness and introduced at lower prices, Canadian drug plans could save money by listing only the "lowest cost" biosimilar and switching patients to the lowest cost alternative.

Counterpoint: Biosimilars are not "generic" medicines and are not approved as interchangeable with the original. Moreover, biosimilars to the same original are not approved as similar to each other. Therefore, a biosimilar may not work exactly the same as the original or another biosiimlar. Canadian drug plans should allow physicians and patients to access the original or similar biologic that is best for the patient, so long as the cost to the drug plan is similar.

Patient Perspective: National Pharmacare should assure that clinicians and patients are allowed to exercise informed choice about the medicine that is best suited to their individual needs. Moreover, a policy

of mandatory switch based on price alone puts patients at risk of needing to switch biologics on a regular basis.

3. HOW PMPRB REGULATES NEW DRUG PRICES: WILL CHANGES HELP OR HURT ACCESS? (AUGUST 29)

Point: Proposed amendments to Patented Medicines Regulations to allow for key changes to determining the Maximum List Price of prescription medicines will result in lower Canadian prices with no loss in Canadian access new medicines.

Counterpoint: Canadians' ability to access to new medicines will be severely impacted by the proposed PMPRB Price Review, which applies, among other factors, a single "cost-effectiveness" threshold on the Maximum List Price of all new medicines, an approach not used by any other country.

Patient Perspective: National Pharmacare and PMPRB must assure that Canada improves, not worsen, its ability to attract clinical trials and innovative medicines; we should consider processes like "managed entry" as used Sweden, Germany, and the UK where initial (entry) prices are modified afterwards based on "real world" evidence of effectiveness.

4. DRUGS FOR RARE DISEASES: NATIONAL PHARMACARE OR SEPARATE PROGRAM? (SEPTEMBER 12)

Point: Drugs for Rare Diseases or other "targeted" small patient populations should be assessed using the same processes and "cost-effectiveness" thresholds as drugs for more common conditions. Moreover, small and short clinical trials mean many of these drugs are approved with limited evidence of safety and effectiveness; access should be restricted until better data are available (from extended clinical trials or real-world evidence).

Counterpoint: Canada should expand upon the learning from its own experiences as well as programs of other countries to develop specific expedited pathways for approval and access to drugs for small patient populations with severe, progressive, and/or life-threatening diseases for which there are very few or no other viable treatments.

Patient Perspective: Some rare disease patients in Canada have had their lives extended or vastly improved thanks to various "managed access" programs for conditions, such as Fabry's Disease, Cystic Fibrosis, and Pulmonary Arterial Hypertension. A National Pharmacare program should use the learning from these specialized programs to develop a "managed access" scheme with registries and post-market monitoring, which would immediately be applied to most rare disease drugs as soon as they are approved by Health Canada. Patients with rare disease are willing to take an active role in assuring appropriate access, adherence to usage as prescribed, and participation in registries and monitoring.

5. BEYOND THE FORMULARY: SMART PHARMACARE FOR 21ST CENTURY THERAPIES (SEPTEMBER 26)

Point: Some innovative "breakthrough" therapies, including "personalised" medicines and gene therapies have the potential to dramatically improving patient outcomes or cure disease but they are being introduced at prices that are unaffordable for any publicly funded healthcare system. Moreover, at time of approval, there is little evidence of potential long-term benefits and long-term savings in healthcare costs. Canadian drug plans and the healthcare systems are not set up to make these therapies available to the general patient population; they should be introduced only on a "trial" basis.

Counterpoint: The 21st Century life-saving and life-altering therapies are already here, and Canadian patients must not be left behind. A Smart Pharmacare program will go beyond the narrow deliberations on universal formulary and "public vs. private" funding and engage in dialogue with a broad range of experts and stakeholders to create innovative "financing" models and schemes to assuring these 21st century therapies are available to Canadians as soon as elsewhere in the world.

Patient Perspective: Canadian patients run the risk of denial to these breakthrough therapies, caught between the silos of "drug funding" and "healthcare funding" unless new models of integrated access are developed. To assure optimal cooperation, patients must be engaged in this dialogue as informed and equal stakeholders.

6. HOW CAN "RIGHT PRICING" SUPPORT INNOVATION AND COST-EFFECTIVE ACCESS? (OCTOBER 10)

Point: Drugs are the fastest-growing expense in healthcare, accounting for about 16% of total healthcare costs. This is due to a number of factors, such as (1) entry of more expensive drugs, such as biologics; (2) much more effective drugs for large populations such as hepatitis C and those with poorly controlled high cholesterol; and (3) long-term use of drugs for "previously fatal" diseases that are now managed as "chronic" conditions, such as cancer and HIV. National Pharmacare as a single purchaser would allow Canada to negotiate more effectively for lower drug prices.

Counterpoint: Canada already receives some of the lowest drug prices among countries with comparable GDPs. Imposing ceilings on generic drug prices and joint negotiations through the pCPA have already reduced some drug costs. If Canada wants to be a "top-tier" country for investment in R&D, clinical trials, and access to new medicines, it must pay a "fair" price that will balance access for patients, support for innovation, and budget impact. Canada should position itself to be more attractive to researchers and developers, not less, and to that end should look at other jurisdictions that have been able to achieve economic as well as health benefits from innovation in medicines.

Patient Perspective: Patients want clinical trials and new medicines available in Canada as soon as they are in the USA and Europe. Many of our patients are forced to travel to other countries to take part in trials, even sometimes when the drugs are discovered in Canada. For patients with life-threatening conditions, clinical trials and early access make the difference between life and death.

FORMAT: Panel Debate with Discussion

1. Topic presented as question for debate
   - Different (balanced) perspectives plus a patient perspective
   - Patient: example or opinion to set agenda
   - Perspective 1
   - Perspective 2
   - Survey responses
   - Moderated discussion
   - Q&A with audience (written)
   - Conclusions
2. Polling
   - Pre: 1 – 3 questions at time of registration
   - Present responses from CORD patient survey
   - Post: follow-up questions (parallel pre-survey)

Information on how to register for the webinars and other details will be announced shortly.