What Every Patient Needs to Know About Changes in Drug Pricing Regulations

1. **New Limits on Public Prices:** Maximum List Price (MLP) will not exceed median of list prices of 11 countries (dropping USA and Switzerland).
   - ***Current:*** MLP is based on 7 countries, some with higher list prices than Canada.
   - ***New Price Impact:*** This will lower public prices by about 20%.
   - ***Patient Access Impact:*** This change alone – if implemented well – should not significantly change whether and when new drugs are brought to Canada.

2. **New Regulated Rebated Price:** A Maximum Rebated Price (MRP) will be set unilaterally by the PMPRB prior to price negotiations and will be based almost solely on economic factors (cost of treatment vs. additional years of life).
   - ***Current:*** Negotiated rebated price is based on Health Technology Assessment (HTA) that takes into consideration (albeit imperfectly) not only cost factors but also health systems impact, societal and patient values, such as availability of other treatments, severity of condition, impact on functionality, improved tolerability, ease of administration and caregiver impact. These factors are not captured by a simple cost-effectiveness assessment.
   - ***New Price Impact:*** MRP is estimated to be set at 20% to 90% lower than MLP to arrive at a level approaching Slovenia's prices.
   - ***Patient Access Impact:*** Manufacturers have signaled inability to bring drugs to Canada at proposed MRP that is far below international standards, or will bring them later, only after prices are set in most other countries.

3. **New Thresholds:** MRP will be capped at $60K/Quality Adjusted Life Year (or $90K/QALY for rare disease drugs) prior to negotiations with public payers.
   - ***Current:*** Canada and most other developed countries have no set QALY threshold that applies to all therapies and diseases. No other country uses a QALY threshold to regulate all prices for all sales.
   - ***New Price Impact:*** This arbitrary calculated price is out of line with all other developed countries. As a result, manufacturers have indicated they cannot: (1) bring in some new drugs; (2) set up Special Access, Early Access, and/or Compassionate Access Programs; (3) extend currently reimbursed drugs to new indications; and (4) expand already reimbursed drugs to include broader patient community (e.g., children).
   - ***Patient Access Impact:*** No access or delayed access for patients, resulting in more symptoms, greater disease burden, non-compliance, less optimal treatment outcomes and premature or unnecessary deaths.