How New Medicines are Reviewed and Funded in Canada

3 SIXTY PUBLIC AFFAIRS

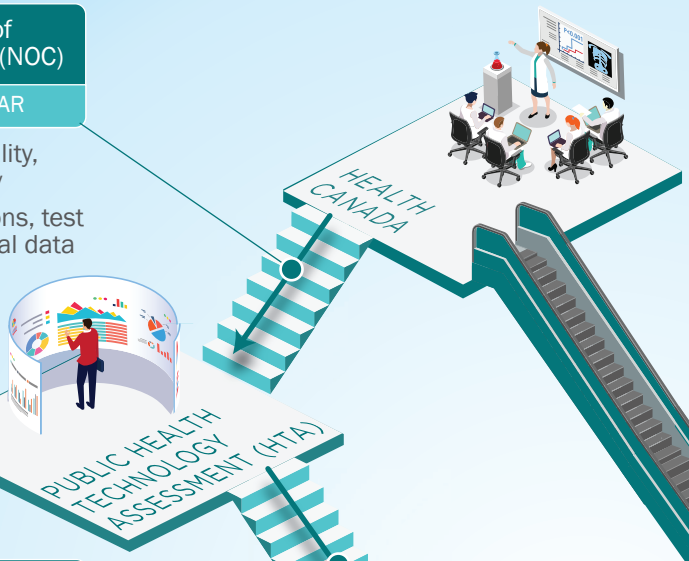
Before patients in Canada can get access to a new innovative medicine or new use for a medicine, it must first pass through a complex review process. The review process starts upon submission of the medicine to Health Canada.

Notice of Compliance (NOC)

AVG: 1 YEAR

Based on: Quality, safety, efficacy

How: Inspections, test batches, clinical data



Formulary recommendation: Reimburse, do not reimburse, reimburse with conditions

6-8 MONTHS

Based on: Comparison of therapeutic alternatives

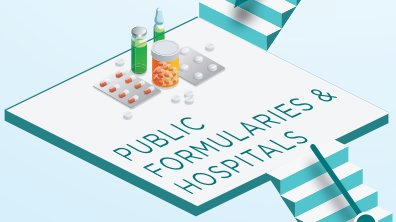
How: Expert review committee considers clinical and economic analyses

Letter of Intent (LOI)

10 MONTHS

Based on: Negotiation between manufacturer & pan-Canadian Pharmaceutical Alliance (pCPA)

How: A jurisdiction leads, reports back to pCPA, parties sign LOI with reimbursement terms

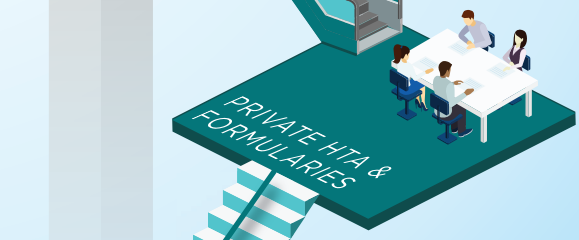


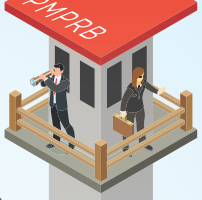
Product listing agreement (PLA)

VARIABLE

Based on: Reimbursement terms in LOI

How: Individual agreements with public plans





The Patented Medicine Prices Review Board (PMPRB) oversees the price of all patented medicines

It assesses the ex-factory price to determine if it is "excessive" using tests that include therapeutic class comparison or comparing the price of the same product in seven comparator countries

PMPRB is the subject of major reforms that will change how it reviews and regulates maximum prices

Indicates what is required at each stage in order to move to next stage

Indicates time typically required at each stage to meet requirements

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