



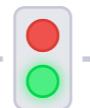
4 Key Steps for Bringing Your Innovations to the Market in Quebec



Clinical trial completed



Federal regulatory review
(Health Canada)



Evaluation of health
technologies (INESSS)



Pan-Canadian negotiations
(pCPA)



Decision to list the drug on the
Quebec drug formularies (MSSS)

Available in Quebec



Reimbursed by public or private general
prescription drug insurance plans for the
indication that was initially assessed.

Step 1

Step 2

Step 3

Step 4

Federal regulatory review (Health Canada)

After the clinical trials, a sponsor who would like to put its innovation on the market must submit an application to **Health Canada**, including data on the safety, efficacy, and quality of the drug. Health Canada then conducts a rigorous scientific assessment to determine whether the product can be approved for release on the Canadian market.

Market authorization - Notice of Compliance (NOC)

Available for prescriptions in Canada (Quebec)

May be reimbursed by certain private prescription drug insurance plans or other special access or exception patient programs.

Evaluation of Health Technologies

Once approved, the drug is assessed by the *Institut national d'excellence en santé et en services sociaux* (INESSS, National Institute of Excellence in Health and Social Services), which reviews its therapeutic value, cost, cost-efficiency ratio, and impact on the health care system. This assessment then results in a recommendation regarding the drug's listing on one of the Quebec drug formularies (*Régie de l'assurance maladie du Québec* (RAMQ, Québec Public Health Insurance Plan)) or institutional drug formularies.

Quebec is known for the rigorous, inclusive and context-based approach used by INESSS with respect to health technology assessment. INESSS takes into account the needs of the Quebec population, the specific features of the health care system, and the perspectives of the patients, users and caregivers. Besides prescription drugs, INESSS also assesses medical devices and clinical practices based on evidence and economic and budgetary analyses. These assessments inform decisions on the adoption and reimbursement of health innovations.

Price Negotiations

At the same time, pricing is negotiated with the **pan-Canadian Pharmaceutical Alliance (pCPA)**, which brings together provinces, territories, and federal programs. This step aims to guarantee equitable access to treatment while ensuring the financial viability of the health care system.

Listing on Provincial Drug Formularies

Based on INESSS's recommendations and the negotiation results, the **Quebec Minister of Health** decides whether the drug will be listed on the *Régie de l'assurance maladie du Québec* (RAMQ, Québec Public Health Insurance Plan) drug formulary or on the list of drugs covered in health care institutions. If listed, the drug then becomes available to patients covered by both public and private general prescription drug insurance plans, since Quebec has a universal system for prescription drug coverage that is unique in North America.