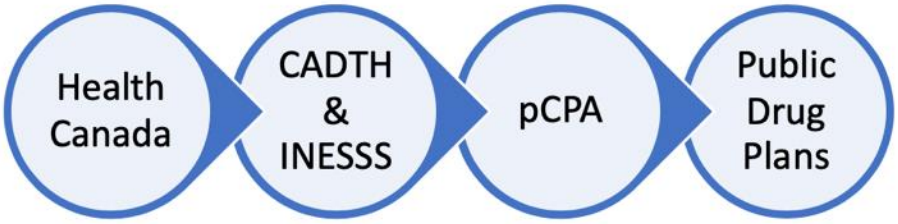
Canadian Drug Review, Approval and Reimbursement Process



As new therapies approach market, they must request Health Canada authorization to be made available to the public. **Health Canada** reviews medicines for safety, efficacy and quality of the manufacturing process before authorizing them for sale in Canada.

If Health Canada authorizes it, the various public drug programs decide whether it will be eligible for public reimbursement on the basis of recommendations stemming from the Canadian Agency for Drugs and Technologies in Health's common drug or pan-Canadian oncology drug review.

In general, all new medicines approved for use by Health Canada are then submitted by the medicine manufacturers to health technology assessment organizations which review the clinical and cost-effectiveness of a drug product: the **Canadian Agency for Drugs and Technologies in Health** (CADTH) or the pan-Canadian oncology drug review and, in Quebec**, l'Institut national d'excellence en santé et en services sociaux** (INESSS). CADTH and INESSS provide a recommendation to Canada's federal, provincial, and territorial public drug plans on whether or not a medicine should be reimbursed for public funding. Reviews are undertaken for new medicines, as well as existing medicines approved for new indications. Among the considerations, the common drug review looks at the

drug's clinical effectiveness and value for money in comparison to other treatments.

Established in 2010, the **pan-Canadian Pharmaceutical Alliance** (pCPA) includes all 13 provinces and territories and, since January 2016, the federal government. The pCPA negotiation process begins for the majority of new medicines, once a recommendation is published by CADTH and/or INESSS. pCPA uses the recommendations from CADTH and INESSS and other factors to determine whether or not it will enter into a negotiation for a drug. If it decides to do so, one jurisdiction assumes the lead on the negotiations with the manufacturer. If they reach an agreement, the manufacturer and lead jurisdiction will sign a letter of intent, which sets the terms of the agreement between pCPA and the medicine manufacturer. **Public Drug Plans** make a final decision to fund a drug once a negotiation has been successfully completed and enters into its own separate agreement with the drug manufacturer.