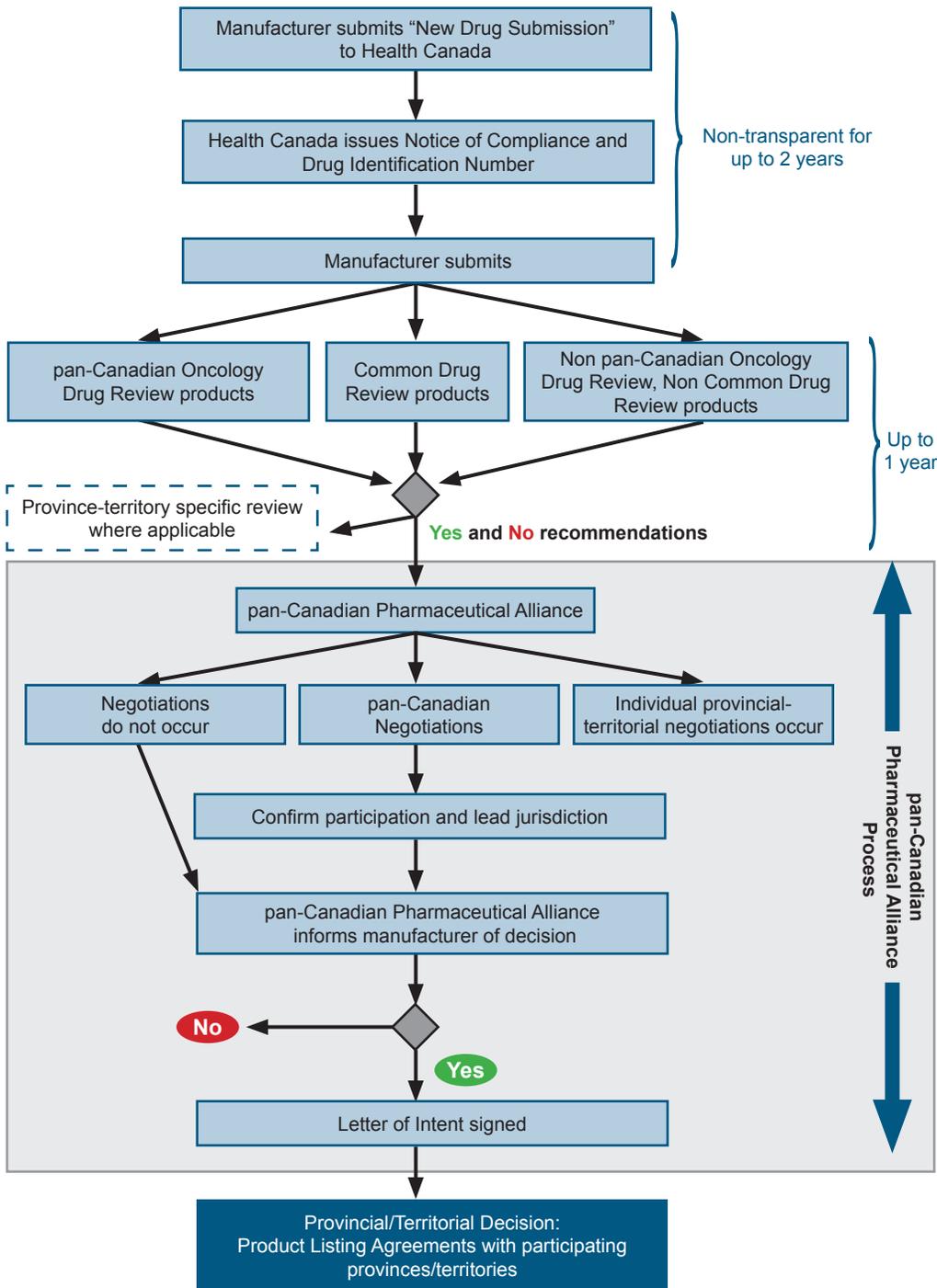


Scope of pan-Canadian Pharmaceutical Alliance



Before a drug product is authorized for sale in Canada, the drug manufacturer must submit an application to Health Canada for review. Health Canada assesses the submitted scientific evidence about the drug's safety, clinical effectiveness and the quality of its manufacturing process. The federal review process can take between one and two years, depending on the nature of the product. Health Canada's approval of a drug for sale in Canada does not necessarily mean that provincial and territorial governments will fund it.

In general, all new drugs approved for use by Health Canada are then submitted by the drug manufacturer for review under the national Common Drug Review (CDR) process for non-oncology drugs and under pan-Canadian Oncology Drug Review (pCODR) for oncology drugs. CDR and pCODR's expert advisory committees assess a new drug's clinical effectiveness and value for money (cost-effectiveness) relative to other treatment options available for treatment of the disease and provide common listing recommendations to participating federal, provincial and territorial drug benefit plans in Canada. Province-territory specific review may occur following the recommendations of CDR or pCODR.

Once CDR or pCODR releases its final recommendation, the pan-Canadian Pharmaceutical Alliance (pCPA) decides whether joint pan-Canadian negotiations will occur for the drug product. If the decision is to move forward with negotiations through the pCPA, one jurisdiction will assume the lead and confirm with the manufacturer which jurisdictions are participating. If a mutually acceptable agreement can be reached between participating jurisdictions and the manufacturer, a Letter of Intent will be signed by both the manufacturer and the lead jurisdiction. This Letter of Intent will then be shared with all participating jurisdictions. This step concludes the pCPA process component.

It is then up to each participating jurisdiction to make their final decision on funding the drug product through their own public drug plan and enter into a jurisdiction-specific product listing agreement with the manufacturer.