

Business Situation

- The client required pricing & market access support for an in-line brand that was approved for hypertriglyceridemia and in development for major adverse cardiovascular event (MACE) reduction

Approach & Methodology

- Provided support to help the client optimize their pricing and market access strategy for their cardiovascular product, including
 - Support on ad-hoc requests
 - Qualitative primary market research and other subject matter expert interviews as necessary
 - Market access training and scenario planning
- For this project, the scope of work included pricing and market access support for international markets, and was not specific to the US payer landscape

Deliverables & Business Outcomes

- Provided recommendations and guidance regarding their upcoming launch of their product in international markets
- Buy-in and support from all internal stakeholders

Canadian Pricing Background
Public Reimbursement Process Overview

Drug list pricing is regulated federally at the “top end” by PMPRB; however, net prices are negotiated by the payers through Product Listing Agreements

Health Canada only assess efficacy, safety, and quality, and the following four organizations determine drug prices

The Patented Medicine Prices Review Board (PMPRB)

- Sets the ceiling for list price based on the level of therapeutic improvement, domestic cost, and prices in the PMPRB7 countries

Health Technology Assessment (HTA) Bodies

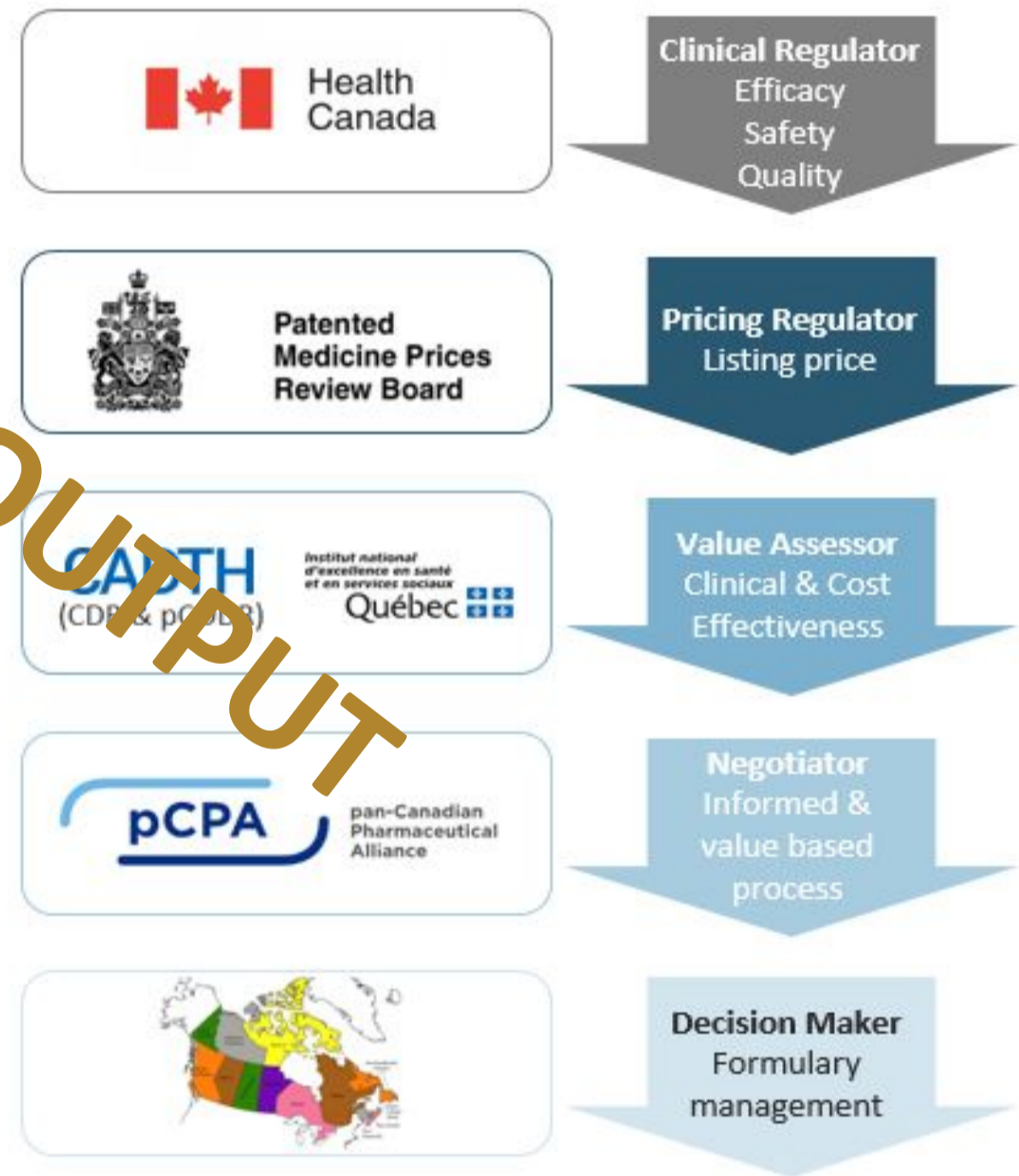
- Evaluates the value of a drug (clinical effectiveness & cost-effectiveness), and makes recommendations to drug plan decision-makers

Pan-Canadian Pharmaceutical Alliance (pCPA)

- Responsible for facilitating the value negotiations between the public drug plants and pharmaceutical companies
- Net prices are determined by Product Listing Agreements (PLAs) with the payers, similar to managed care contracts in the US

Individual Jurisdictions (i.e., Provinces & Territories)

- Manages the formulary and determines how and when the drug will be listed in each formulary



Canadian Pricing Background
Patented Medicine Prices Review Board’s (PMPRB)

A new patented medicine’s listing price ceiling is determined by its therapeutic value and the listing prices of international and domestic comparators

- PMPRB sets a drug’s price ceiling based on its category of therapeutic improvement, the price of domestic comparators and its price elsewhere in the PMPRB7
- Theoretically, the price ceiling decreases based on the following four therapeutic category – the breakthrough category would have the highest price ceiling
 1. Breakthrough – Median International Price Comparison (MIPC) price
 2. Substantial improvement – Higher of the top of the Therapeutic Class Comparison (TCC) price and MIPC price
 3. Moderate improvement – Higher of the mid-point between the top of TCC price and the MIPC price, and the top of the TCC price
 4. Slight/No Improvement – Lower of bottom TCC price and MIPC price
- After the introduction, an existing drug is eligible for annual inflation based on consumer pricing index

