Health Canada (HC) is the federal government body that is responsible for ensuring that treatments and medical devices are safe, effective and of good quality. It approves clinical trials, reviews drugs, biologics, natural health products, medical devices, and undertakes post market surveillance. It is governed by the *Food and Drugs Act and Regulations.*

Health Canada (HC) - Biologics and Genetic Therapies Directorate (BGTD) is the Canadian federal authority that regulates biological drugs (products derived from living sources) and radiopharmaceuticals for human use in Canada, whether manufactured in Canada or elsewhere. Prior to being given market authorization, a manufacturer or sponsor must provide sound evidence of the product's quality, safety and efficacy as required by the *Food and Drugs Act and Regulations* such that, upon conclusion of the review, the BGTD can determine that the benefits of the product outweigh its risks and the risks can be mitigated.

Health Canada (HC) - Therapeutics Products Directorate (TPD) is the Canadian federal authority that regulates pharmaceutical drugs and medical devices for human use. Prior to being given market authorization, a manufacturer must present substantive scientific evidence of a product's safety, efficacy and quality as required by the *Food and Drugs Act and Regulations*.

Health Canada (HC) - Marketed Health Products Directorate (MHPD) The mandate of Health Canada's MHPD is to lead an evidence-based vigilance program for health products in Canada. Activities of the MHPD include: monitoring and collecting adverse reaction and medication incident data; reviewing and analysing marketed health product safety data; conducting risk/benefit assessments of marketed health products; communicating product related risks to health care professionals and the public; overseeing the advertising regulatory requirements of health products; and providing policies to effectively regulate marketed health products.

Patented Medicines Pricing Review Board (PMPRB) is a federal agency that has a dual role: regulatory – to ensure that prices charged by patentees for patented medicines sold in Canada are not excessive; and reporting – to report on pharmaceutical trends of all medicines and on research and development spending by pharmaceutical patentees. It is governed by the *Patent Act and Regulations.* It also has a comprehensive set of Guidelines describing its processes.

Canadian Agency for Drugs and Technology in Health (CADTH) - Common Drug Review (CDR)
CADTH is an independent, not-for-profit organization responsible for providing Canada's health care decision-makers with objective evidence to help make informed decisions about the optimal use of drugs and medical devices in our health care system. CDR is a program of CADTH that reviews drugs and makes reimbursement recommendations to Canada's provincial, and territorial public drug plans, with the exception of Québec, to guide their drug funding decisions.

Canadian Agency for Drugs and Technology in Health (CADTH) - Pan-Canadian Oncology Drug Review (pCODR) is a program of CADTH that reviews cancer drugs and makes reimbursement recommendations to Canada's provincial and territorial public drug plans, with the exception of Québec, and to provincial cancer agencies to guide their cancer drug funding decisions.

Institut national d'excellence en santé et services sociaux (INESSS) is the Québec health technology assessment agency equivalent to CADTH. It makes recommendations to the Québec Minister of Health.

pan-Canadian Pharmaceutical Alliance (pCPA) was established in August 2010 by the Council of the Federation's Health Care Innovation Working Group (HCIWG) as a network of federal/provincial/territorial drug plans that conducts joint provincial/territorial negotiations for brand name drugs in Canada to achieve greater value for publicly funded drug programs and patients. As part of ongoing efforts to reduce the cost of drugs, on January 18, 2013, the HCIWG announced the first step in achieving better value for generic drugs through the Value Price Initiative. This joint approach leverages combined purchasing power to obtain the lowest generic prices achieved to date in Canada, and to be consistent with the price for these drugs on the international market.

Canadian Association of Provincial Cancer Agencies (CAPCA) is an inter-provincial organization of provincial/territorial cancer agencies/programs engaged in cancer control. CAPCA describes its mandate as supporting the reduction of the burden of cancer on Canadians by facilitating and supporting effective leadership, collaboration, communication and advocacy for cancer care and control.

Federal Drug Plan(s): The Canadian federal government funds and/or delivers primary and supplementary health care services to certain groups of people. These groups include: First Nations people living on reserves and Inuit (First Nations and Inuit Non-Insured Health Benefits Plan); serving members of the Canadian Forces and eligible veterans (Veteran Affairs' Programs of Choice); inmates in federal penitentiaries (through Correctional Services Canada); and some groups of refugee claimants (Interim Federal Health Program). They also provide services to employees of the federal government through the Public Service Health Care Plan.

Provincial/Territorial Drug Plans: Every province and territory in Canada has a series of public drug plans that cover treatments for different subsets of the population (e.g. seniors, people living with certain conditions). Some provinces and territories also have a catastrophic drug plan for all qualifying residents, such as Ontario's Trillium Drug Program.

Provincial/Territorial Health Technology Assessment Bodies: Most provinces and territories in Canada also have health technology assessment bodies or processes that recommend provincial or territorial public funding for health interventions. British Columbia's and Ontario's Health Technology Assessment Committees are examples. As mentioned above, Québec does not participate in CADTH's CDR or pCODR and uses its own INESSS to make listing recommendations.