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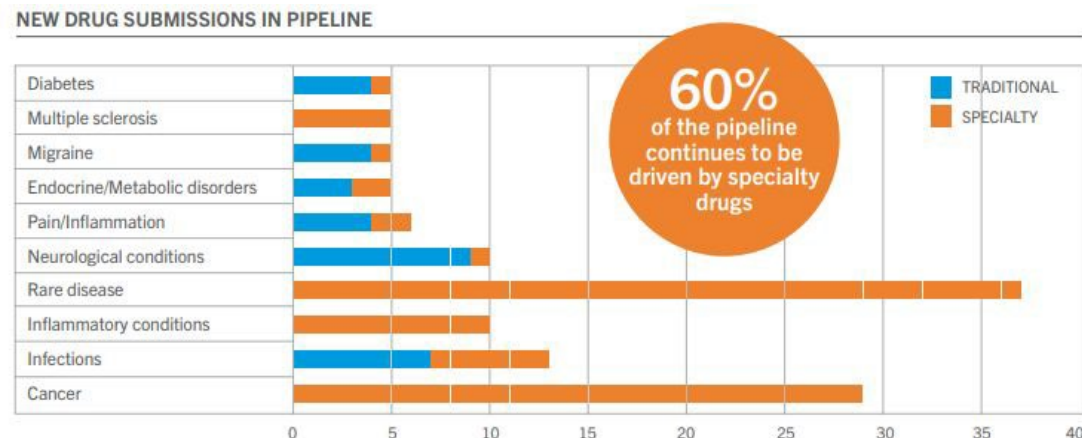
Stephen Lucas, Deputy Minister, Health Canada

Outline of Presentation

- Context
- Objectives
 - ❑ Taking steps to help Canadians have access to affordable medications that they need
 - ❑ Improving pharmaceutical management
 - ❑ Supporting a vibrant biomanufacturing and life sciences sector
- Summary

The prescription drug landscape is evolving rapidly

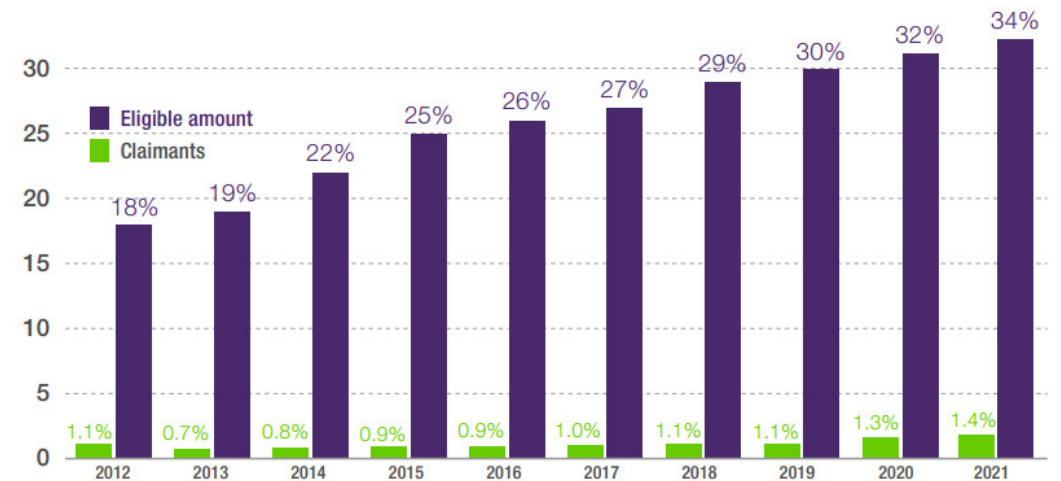
- The vast majority of drugs available on the market are **traditional drugs**:
 - Typically, chemically-based, lower-cost products used to treat common conditions, e.g., heart disease, asthma, diabetes
 - Many have numerous competitors (generics, multi-source brand drugs)
 - Represent approx. **95% of drugs for sale** in Canada and are taken by 98% of beneficiaries (private plans)
- However, the era of ‘blockbuster’ drugs, formulated to treat millions of people with common conditions, has ended.
- In recent years, **specialty drugs** have come to dominate the R&D pipeline



Pharmaceutical companies are developing specialized drugs

- **Specialized products**, including biologics, used to treat complex and/or serious conditions, e.g., cancer, rheumatoid arthritis
 - Often have few direct competitors and command high prices
 - Represent approx. 5% of drugs for sale and are taken by 2% of beneficiaries (private plans)
- This includes a sub-set of specialty drugs for patients suffering from **rare diseases**, e.g., spinal muscular atrophy, cystic fibrosis
 - Limited number of patients and evidence make it very challenging to assess clinical benefit
 - Treatments are in high demand and typically have high prices (\$100K to upwards of \$2M per patient/year, often for life)
 - Despite targeting small patient populations, drugs for rare diseases now account for nearly 15% of Canadian drug sales (\$4.5B in 2020)
 - Pharma R&D trends mean these drugs are the fastest growing segment of Canada's pharmaceutical market

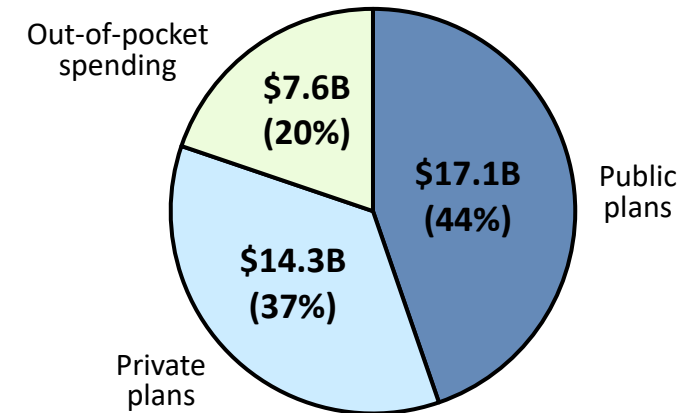
Rising costs of specialty drugs (private plans)



Canada has a patchwork system of drug coverage

- New drugs to treat a growing range of conditions and rising rates of chronic disease have made prescription drugs a central part of health care
 - In 2022, Canadian spending on prescribed drugs was forecast to reach \$38.9B, an increase of 37% over the \$28.3B in drug spending in 2012 (average annual increase of 3.7%)
 - 2nd largest health care cost category (tied with physician services) after hospital spending
- Canada's patchwork system has over 100 public drug plans and 100,000 private drug plans:
 - **Employers** provide thousands of relatively generous drug coverage plans delivered by private insurers
 - Usually cover 80+% of the cost of most drugs approved by Health Canada; some have annual or lifetime limits
 - **PTs** provide varying levels of coverage, with the most comprehensive coverage generally focused on more vulnerable populations, e.g., social assistance recipients, seniors
 - All provinces (but none of the territories) also have programs to protect residents from high ("catastrophic") drug costs relative to income
 - Patients usually pay deductibles ranging from 3-20% of household income under these programs
 - **Government of Canada** provides drug coverage at no cost to registered First Nations and recognized Inuit populations, federal inmates, Canadian forces, veterans, and refugees

2022 Canadian Prescription Drug Spending = \$38.9B



Note: 2022 forecast (numbers may not add due to rounding)
Source: CIHI, *National Health Expenditure Trends, 2022*

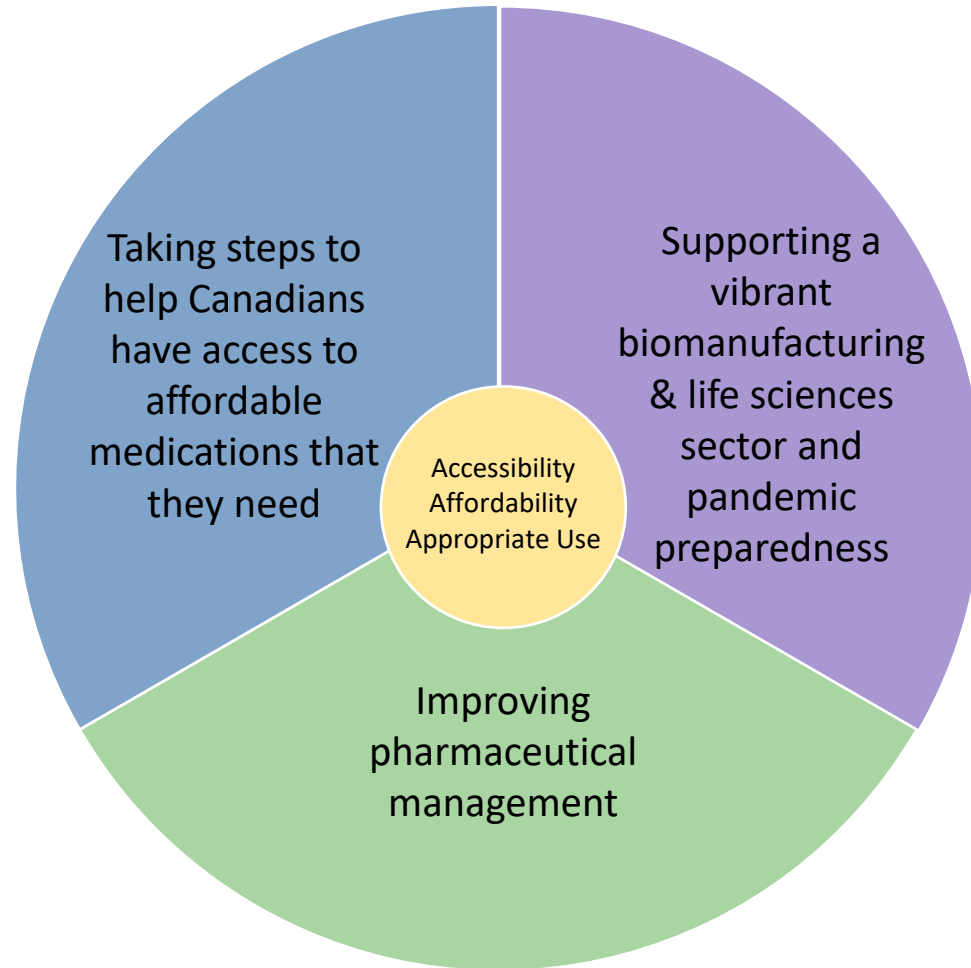
Canadians struggling to afford core part of health care

- An estimated 2.8% of Canadians (1.1M) are **uninsured**
- Larger issue is individuals that are **underinsured**
 - Challenge is affordability – patient charges under existing drug plans mean many insured Canadians struggle to pay for needed medications
- Rising cost of living is making it harder for lower-income Canadians to cover day-to-day expenses, including drug costs
- When Canadians forego prescriptions due to cost, their health often worsens
 - Can lead to additional visits to doctors and emergency rooms
- Reducing cost barriers to prescription drugs could improve health outcomes, reduce health care visits, and lower downstream costs on the health system

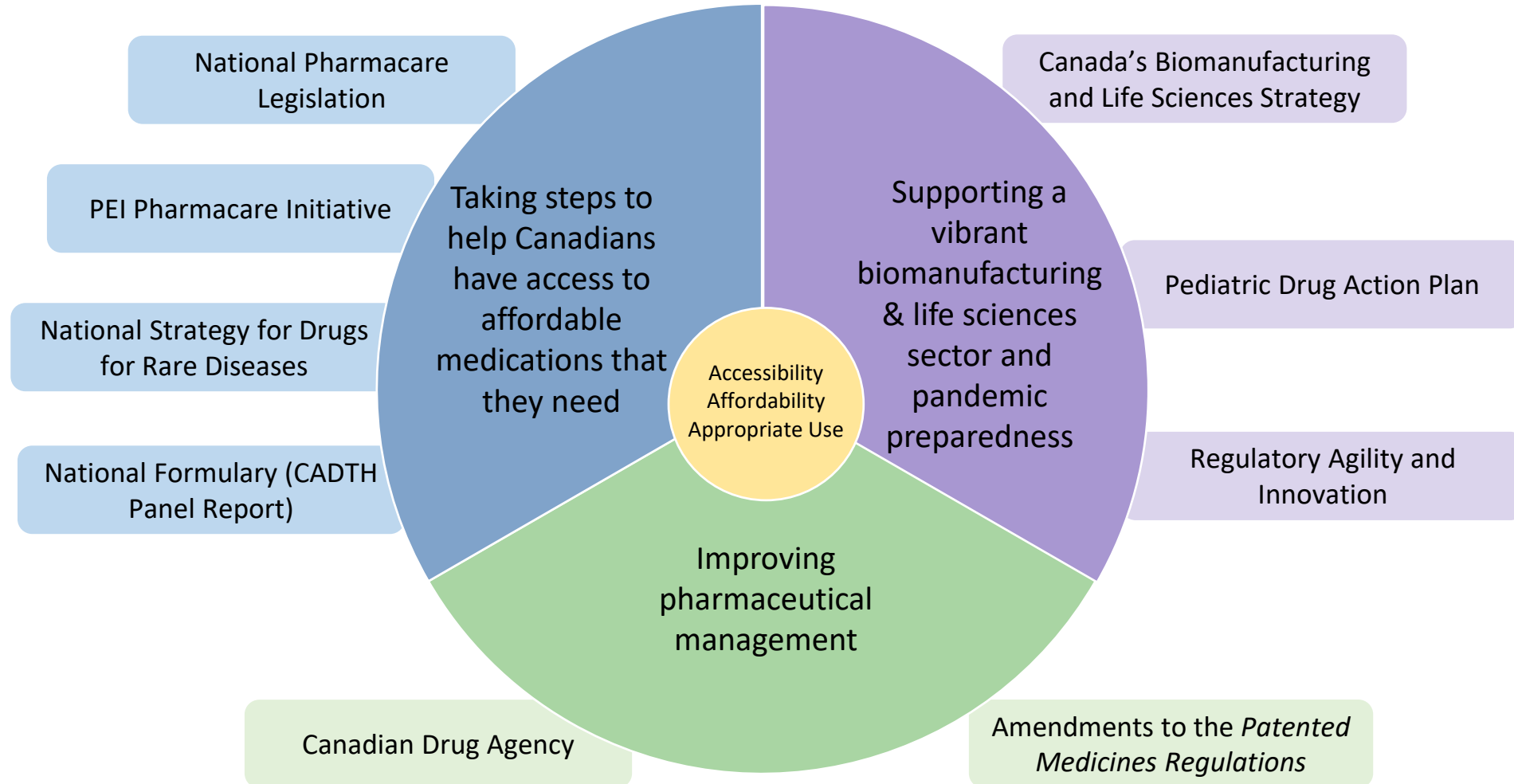
Studies on National Pharmacare

- The Royal Commission on Health Services (1964)
 - Supreme Court Justice Emmett Hall was appointed to lead the commission in 1961 and his final report laid the groundwork for universal, public health insurance introduced through the Medical Care Act in 1966.
- National Forum on Health (1997)
 - The forum recommended that all provinces and territories establish public drug plans to cover drugs that evidence showed offered the best clinical and economic value.
- Commission on the Future of Health Care in Canada (2002)
 - Former Saskatchewan Premier Roy Romanow's commission was asked to investigate Canadians' ideas on the future of health care. It recommended governments work together to cover prescription drugs under the Canada Health Act, with the first step being a system of universal "catastrophic" drug coverage. The commission also called for the creation of a national agency to negotiate prices, decide what drugs should be covered, monitor prescribing and drug safety and provide objective information about medicine to patients and health care providers.
- Standing Senate Committee on Social Affairs, Science and Technology Report on the State of the Health Care System in Canada (2002)
 - Chaired by Senator Michael Kirby, the committee looked at the federal role in health care. On issues related to prescription drug coverage, the committee recommended introducing catastrophic coverage and a national formulary.
- Advisory Council on the Implementation of National Pharmacare (2019)
 - Chaired by Dr. Eric Hoskins, recommended the federal government work with PTs to create a universal, publicly administered system of national pharmacare.

Federal Pharmaceutical Objectives



Federal Pharmaceutical Policy Agenda



Progress to Date

Taking steps to help Canadians have access to affordable medications that they need

- On February 29, 2024, the Government of Canada introduced Bill C-64: *An Act respecting pharmacare*
- Since 2021, the federal government has been working with the Government of Prince Edward Island to improve affordable access to medications for Island residents with an investment of \$35M
- In March 2023, the National Strategy for Drugs for Rare Diseases (DRD) was launched with an investment of up to \$1.5B over 3 years to increase access to, and affordability of DRDs
- In June 2022, a multidisciplinary national panel convened by the CADTH, at the request of Health Canada, recommended principles and a framework for developing a national formulary

Improving Pharmaceutical Management

- On December 18, 2023, the Government of Canada announced the creation of the Canadian Drug Agency (CDA) with an investment of \$89.5 million over 5 years, starting in 2024-25
- On July 1, 2022, the amendments to the *Patented Medicines Regulations* (PMR) came-into-force

Supporting a Vibrant Biomanufacturing and Life Sciences Sector

- From December 17, 2022, to April 26, 2023, Health Canada pre-published proposed amendments to *the Food and Drug Regulations* and the *Medical Devices Regulations* to enhance regulatory agility
- Budget 2021 committed \$2.2B over seven years to the Biomanufacturing and Life Sciences Strategy
- Health Canada's Pediatric Drug Action Plan was developed in 2020

National Pharmacare Legislation

- On February 29, 2024, the Government introduced Bill C-64: *An Act respecting pharmacare*
- Bill C-64 represents the next phase of the federal government's commitment to establish national universal pharmacare
 - Sets the federal government's framework to guide its efforts with partners to:
 - a) improve the **accessibility** of pharmaceutical products, including through their coverage, in a manner that is more consistent across Canada
 - b) improve the **affordability** of pharmaceutical products, including by reducing financial barriers for Canadians
 - c) support the **appropriate use** of pharmaceutical products — namely, in a manner that prioritizes patient safety, optimizes health outcomes and reinforces health system sustainability — in order to improve the physical and mental health and well-being of Canadians
 - d) provide provide **universal coverage** of pharmaceutical products across Canada
 - Formalizes a requirement to work collaboratively with provinces and territories and Indigenous peoples to build **national universal pharmacare** through a step-by-step approach, and provides key next steps
 - Legislates a path to bilateral agreements with willing provinces and territories by providing a federal commitment to **long-term pharmacare funding** beginning with existing funding for drugs for rare diseases
 - Outlines the **advisory roles of the Canadian Drug Agency** including: clinical and cost-effectiveness analysis, advice to inform formulary listing; pharmaceutical data and analytics, appropriate prescribing and use, and pharmaceutical system coordination

National Pharmacare Legislation – Next Steps

- As outlined in the Bill, there are a number of key next steps to build toward national universal pharmacare:
 - The Government will work with willing provinces and territories to increase existing pharmacare coverage, to provide **universal, single-payer, first dollar coverage**, for specific prescription drugs and related products intended for **contraception** and for the treatment of **diabetes**.
 - The Minister will request that the Canadian Drug Agency develop two pieces of technical advice within a year of the bill passing:
 1. **A list of essential prescription drugs and related products** to inform the development of a national formulary that will establish the scope of prescription drugs and related products to which Canadians should have access under national universal pharmacare
 2. **A national bulk purchasing strategy**
 - Building on ongoing work of the Canadian Drug Agency, the Minister will also ensure that a **pan-Canadian strategy for appropriate use** is published within a year of the bill passing
 - In addition, the Minister will establish a **committee of experts** to make recommendations on options for the operation and financing of national, universal, single-payer pharmacare

PEI Pharmacare Initiative

In August 2021, the Government of Canada announced an agreement to provide PEI with \$35 million to:

- Add new drugs to its provincial formulary, and
- Lower out of pocket costs for drugs covered under existing public plans for Island residents

Progress to Date

- PEI has begun to improve drug affordability for Island residents by:
 - **Expanding access to over 100 medications** to treat a variety of conditions
 - Reducing the copays to \$5 for commonly prescribed, eligible medications. This has led to PEI residents a **savings of over 2 million in out-of-pocket costs on more than 230,000 prescriptions** in the first six months alone.
 - Providing no-cost access to opioid and alcohol dependency medications
 - Adding medications to its Community Mental Health program
 - Removing special authorization requirements for 23 medications to improve access and reduce administrative burden
 - Expanding access to its Catastrophic and High-Cost Drug Programs

Next Steps

- The Government of Canada will use early lessons from PEI's efforts to inform its ongoing work to advance national pharmacare.

National Strategy for Drugs for Rare Diseases

- The National Strategy for Drugs for Rare Diseases was launched on March 22, 2023 with an investment of up to \$1.5B over three years.
- The goal of the first three-year phase is to increase access to, and affordability of, effective drugs for rare diseases, which will contribute to improving the health of patients across Canada.
- Health Canada officials are now engaging with provinces and territories towards the development of bilateral agreements, beginning with jointly determining a small set of new and emerging drugs, which will be cost-shared and covered in a consistent way across Canada.
- The Implementation Advisory Group, comprised of individuals from a range of roles including clinicians, patients, and industry, was launched in October 2023 to support the implementation of the National Strategy from a patient-centered perspective.
- \$20M in funding for the Pediatric Rare Disease Clinical Trial and Treatment Network was announced in February 2024, and other research and evidence collection and use activities are advancing.

Pillar	Investment
Support Patient Outcomes and Sustainability	Up to \$1.4B/3 years for new PT bilateral agreements to: <ul style="list-style-type: none"> • improve access to new and emerging drugs • support enhanced access to existing drugs • enhance screening and diagnostics activities
Seek National Consistency	\$16M/3 years to support national governance and establish a multi-stakeholder Implementation Advisory Group for expert advice
Collect and Use Evidence	\$20M/3 years to CADTH and CIHI to improve the collection and use of evidence to support decision-making
Invest in Innovation	\$32M/5 years to CIHR to advance rare disease research with a focus on developing better diagnostic tools and establishing a robust Canadian rare disease clinical trials network

National Formulary

In Budget 2019, the Government committed to develop a national formulary as a foundational step toward national pharmacare and, in Budget 2022, to task the CDA to develop a national formulary of essential medicines and bulk purchasing plan.

Progress to Date

- Preliminary work toward a national formulary has been completed:
 - At the request of Health Canada, CADTH established a time-limited multidisciplinary advisory panel and following stakeholder consultations, in June 2022, the panel:
 - Recommended a framework and process for developing a future national formulary
 - Proposed a sample list of commonly prescribed drugs and related products for three common conditions (heart disease, diabetes, mental health) as a test case for the proposed process

Next Steps

- As outlined in Bill C-64, the Minister of Health will request that the Canadian Drug Agency prepare a preliminary list of prescription drugs and related products to inform the development of a national formulary, which would outline the scope of prescription drugs and related products that Canadians should have access to
- The Bill also requires the Minister to initiate discussions with provinces, territories, Indigenous peoples and other partners and stakeholders about the role of the list in the ongoing work toward national universal pharmacare

Canadian Drug Agency (CDA)

On December 18, 2023, the Government of Canada announced the creation of the Canadian Drug Agency (CDA) with an investment of over \$89.5 million over 5 years, starting in 2024-25. The Agency will provide the dedicated leadership and coordination needed to make Canada's drug system more sustainable and prepared for the future and help Canadians achieve better health outcomes.

The CDA will be built from the existing Canadian Agency for Drugs and Technologies in Health (CADTH) and in partnership with provinces and territories (PTs). The CDA will incorporate and expand on CADTH's expertise in the pharmaceutical sector, including its strong leadership and technical proficiency, to include new work streams:

- **Appropriate prescribing and use:** Collaborating with leaders in the appropriate use field to improve health outcomes and ensure patients are prescribed the safest and most effective treatments for their conditions.
- **Data and analytics:** Working with partners to determine how the CDA can support drug plans, as well as helping to standardize and improve access to drug and treatment data and analytics.
- **Coordination:** Partnering to build a CDA that improves system efficiency, reduces duplication and streamlines processes, ensuring that the Agency is well-positioned to adapt and evolve to address the ever-changing pharmaceuticals landscape.

Patented Medicines Regulations

Canada has among the highest patented medicine prices in the world, and these high prices can impact the ability of patients to access new medicines

On July 1, 2022, the amendments to the *Patented Medicines Regulations (PMR)* came-into-force. The amendments included:

- an updated basket of comparator countries, excluding high priced countries like the US and Switzerland and including countries that are more like Canada from an economic and consumer price protection standpoint
- reduced reporting requirements for lowest risk medicines

The modernized regulations will generate significant savings over the coming years, which will improve access for Canadians to quality medicines

Next Steps

- To operationalize the amendments, the Patented Medicine Prices Review Board (PMPRB) will update its guidelines to provide transparency and predictability to patentees
- The first phase of consultations on new guidelines took place in December 2023
- The PMPRB intends to finalize the new guidelines in 2024 following further consultations.

Regulatory Modernization Plan

- Our modernization plans aim to ensure that our regulatory system is more modern, agile, and internationally aligned.
- These changes will help us to regulate the risks, benefits, and uncertainties of more diverse and complex products, and enable us to be more responsive to the innovative environment, including changes in the biomanufacturing and life sciences sector.



Modernizing
clinical trial
regulations



Enabling
Advanced
Therapeutic
Products



Agile
licensing for
drugs



Agile
licensing for
medical
devices

Web Link: [Regulatory Innovation for Health Products](#)

Regulatory Modernization Plan (cont.)



Modernizing clinical trial regulations

- Enable authorization/oversight of more complex clinical trial types and products within trials
- Tailor requirements and oversight to risk of the trial or product
- Require disclosure of trial information and results in a publicly accessible registry
- Proposed amendments to clinical trial regulations across product lines will be completed in multiple phases, where the first phase would focus on amendments that relate to drugs



Enabling Advanced Therapeutic Products (ATPs)

- ATPs are drugs and medical devices that are so complex and unique that they challenge our current regulatory frameworks
- ATP framework allows us to put ATPs into a regulatory sandbox and determine how best to regulate them, by creating tailored requirements based on the unique characteristics of each product
- Leverage a collaborative approach working with stakeholders to define the evidence standards for regulatory approval



Agile licensing for drugs and medical devices

- From December 17, 2022, to April 26, 2023, Health Canada pre-published proposed amendments to the *Food and Drug Regulations* and the *Medical Devices Regulations* for consultation
- These Agile Licensing amendments aim to modernize the health product regulatory system from a “point-in-time” model to a lifecycle approach and provide health system-wide benefits through
 - The continuous monitoring, assessment, and communication of risks, benefits, and uncertainties throughout the drug and medical device lifecycle;
 - Increased availability of information to support the optimal use of drugs and medical devices to maximize benefits and minimize risks; and,
 - Timely access to new drugs and medical devices.

Pediatric Drug Action Plan

Health Canada's Pediatric Drug Action Plan was developed in 2020 to help ensure that children and youth in Canada have access not only to the medicines they need, but also to age-appropriate formulations

As part of the action plan, the Centre for Policy, Pediatrics and International Collaboration is working with other government departments, as well as external partners and stakeholders, to accomplish 3 goals:

- improve access to pediatric medicines and formulations
- increase the development of pediatric medicines and formulations
- provide more information to people in Canada on pediatric activities and data

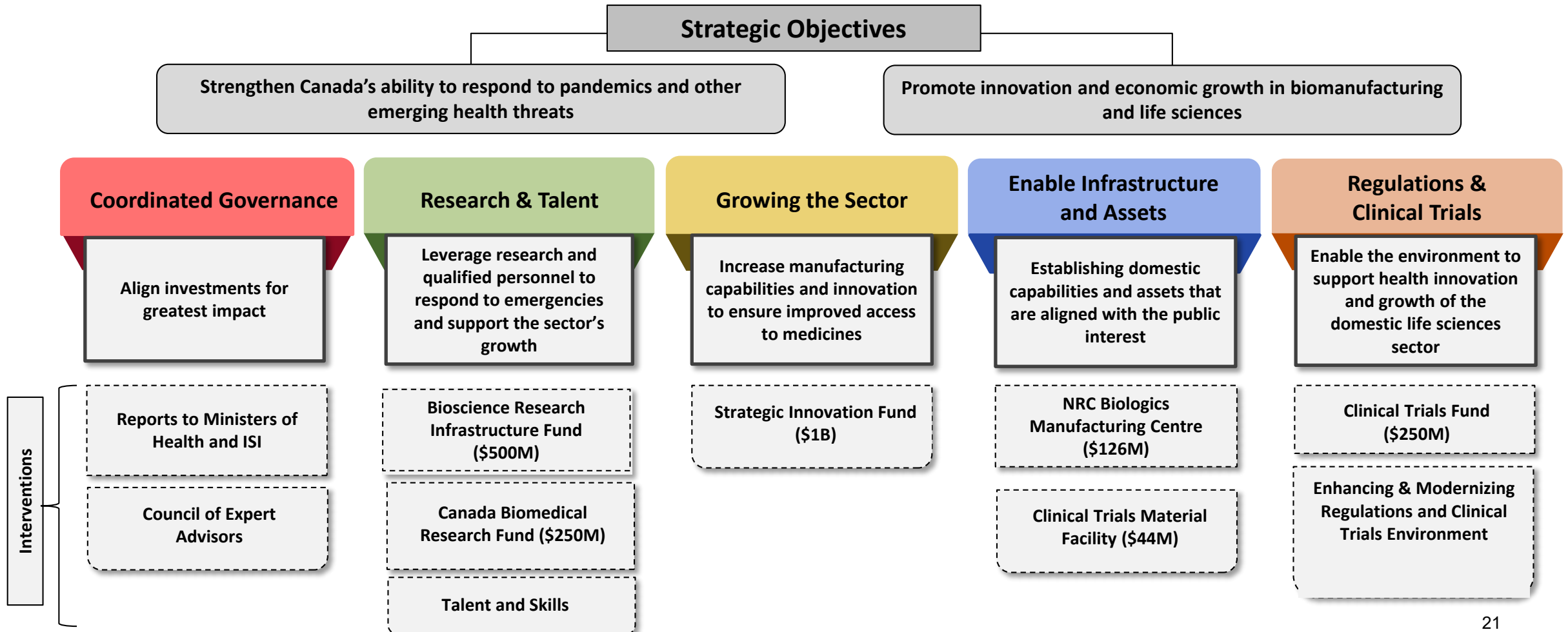
Initial efforts are focused on implementing several key measures to support the action plan

- modernize regulations to require drug manufacturers to provide Health Canada with meaningful information about the safety and effectiveness of drugs in children and youth
- develop a National Priority List of Pediatric Drugs (priority list) that are available elsewhere and needed in Canada
- identify the regulatory pathways and flexibilities that can be implemented to encourage industry to bring these products to Canada

Biomanufacturing and Life Sciences Strategy

Announced in June 2021, the Biomanufacturing and Life Sciences Strategy (BLSS) is co-led by the Minister of Health and the Minister of Innovation, Science and Industry.

Budget 2021 committed \$2.2B over seven years to the establishment of the BLSS through five pillars:



Biomanufacturing and Life Sciences Strategy (cont.)

The BLSS aims to grow a strong, competitive and resilient domestic life sciences ecosystem with cutting-edge biomanufacturing capabilities to ensure Canada is prepared for future pandemics and health emergencies.

Key progress to date:

- Upgrades to **eight biocontainment labs** through **\$127M** funded from the **Biosciences Research Infrastructure Fund**. (Pillar 2)
- Selection of **five research hubs** receiving **\$10M** total through the integrated **Canada Biomedical Research Fund/Biosciences Research Infrastructure Fund** Stage 1 selection process. (Pillar 2)
- **Eight projects** have been funded under the **\$1B** investment to the **Strategic Innovation Fund**. (Pillar 3)
- **\$126M** for the construction of the **Biologics Manufacturing Centre** and **\$44M** for the **Clinical Trials Manufacturing Facility**. (Pillar 4)
- Through the **Clinical Trials Fund**, **\$39M** invested to support the Accelerating Clinical Trials Consortium, **\$32M** for seven clinical trials training platforms, and **\$60M** for 22 clinical trials projects. (Pillar 5)
- **Regulatory Modernization** efforts are underway, including in the areas of advanced therapeutic products, agile regulations for licensing drugs and medical devices, and modernizing clinical trials regulations. (Pillar 5)

Summary

- The Government of Canada continues to take key actions on the federal pharmaceutical policy agenda to improve access, affordability and appropriate use for all Canadians
- A holistic approach to the pharmaceutical sector can help ensure that Canadians have access to the drugs they need when they need them
- Bill C-64 is the most recent demonstration of the Government's commitment
- Together with the additional elements of the Agenda, the bill is a key next step towards national universal pharmacare in Canada