Advanced Therapeutic Products

An Introduction to Health Canada’s Approach

CASSS Cell and Gene Therapy Products Symposium
June 6-8, 2022
Outline

• Provide an overview of the Advanced Therapeutic Products (ATP) framework

• To highlight status of prime candidates to pilot the advanced therapeutic product pathway

• Next steps
The need for a specialized pathway is apparent

• Products are becoming increasingly complex and personalized (e.g., AI-enabled devices, advanced cell therapy, 3D-printed bio-products)

• Many of these products are challenging the current regulatory system and need agile solutions to enable access

• Canadians are demanding greater access to innovative products and greater engagement on how and when they are made available
A new pathway for Advanced Therapeutic Products

to ensure a flexible approach for innovative drugs and devices that challenge the current regulatory system

Advanced Therapeutic Products (ATPs) are drugs and/or devices so unique, complex and distinct that our existing regulatory frameworks and enforcement tools are not equipped to handle them.

- Changes to the *Food and Drugs Act* have enabled Health Canada to create a legislative pathway to authorize ATPs.
- The use of tailored requirements will address a product’s unique characteristics while maintaining Health Canada’s high standards for patient safety.
- A collaborative and iterative approach with a wide variety of stakeholders, both upfront and throughout, will be used for the implementation of tailored ATP pathways.
What are the differences between existing pathways and ATP pathway?

**THERAPEUTICS**

- Therapeutic product X meets one Food and Drugs Act (FDA) definition (or multiple definitions in the case of a combination)

**ADVANCED THERAPEUTICS**

- Therapeutic product X is so novel, complex, and distinct that it does not fit existing regulatory framework(s)

**Schedule G**

- ATP legislative factors
  - Decision to use ATP pathway
  - Development of requirements through on-going engagement with stakeholders

**Schedule of information over time**

- Collection of information
- 2 market access options

**New/amended regulations**

**APPLICATION**

- Food and Drug Regulations (FDR)/Medical Device Regulations (MDR)
  - Application
  - Review
  - Authorization

**LICENSED SCHEME AND TAILORED REQUIREMENTS**

- Licensing scheme and tailored requirements
  - Application
  - Review
  - Authorization

**ORDER OF PERMISSION WITH GENERAL RULES**

- Order of Permission with general rules
  - Application
  - Review
  - Authorization

**Decisions**

- Decision to use ATP pathway

**Stakeholders**

- On-going engagement with stakeholders
How will the tailored ATP pathways work?

- Tailored regulatory requirements will be developed based on the unique characteristics of each ATP.
- Stakeholders (those who make, use and pay for products) will be consulted in the development of regulatory requirements.
- Early alignment with health technology assessment bodies and provinces and territories.
- International approaches will be leveraged to design tailored ATP pathways.
- Risks will be managed through different regulatory tools that enable flexibility (e.g., terms and conditions and modernized inspector powers).
- Once sufficient regulatory experience is acquired, existing regulations will be amended, or new regulations will be created, to transition ATPs out of the tailored ATP pathway environment.
- Health Canada has committed to providing enhanced client service, known as a “Concierge Service” for tailored ATP pathways that use the licensing scheme.
The Food and Drugs Act - The Factors

(2) Before adding a description of a therapeutic product or a class of therapeutic products to Schedule G, the Minister shall consider the following factors:

(a) the degree of uncertainty respecting the risks and benefits associated with the therapeutic product or products and the measures that are available to adequately manage and control those risks;

(b) the extent to which the therapeutic product or products are different from therapeutic products for which therapeutic product authorizations have been issued under the regulations;

(c) the extent to which existing legal frameworks are adequate to prevent injury to health or to prevent persons from being deceived or misled; and

(d) the prescribed factors, if any.
**Approach to identify candidates for ATP pathway**

**Environmental scan**
- To identify items using various sources that are novel and/or do not fit in our current regulatory framework(s).

**Preliminary analysis**
- To confirm whether these items are potential candidates for the ATP framework by using the legislative factors (risks & benefits, novelty compared to previously approved products, and whether appropriate controls are in place through provincial, territorial and federal legislation).

**In-depth analysis**
- To conduct deeper, more comprehensive analysis to determine the needs of each product/product class and their suitability for Schedule G.

Some of these items may not be good candidates after a more in-depth analysis is conducted.
6 ATP candidates have been identified for further investigation

- Fecal Microbiota Therapy
- Adaptive Machine Learning Enabled Medical Devices
- Islet cells
- Point-of-care manufacturing CAR-T Cell Therapies
- Phage Therapy
- 3D Bio-printing

Timeline for addition to Schedule G:
- 2023: Fecal Microbiota Therapy
- 2024: Point-of-care manufacturing CAR-T Cell Therapies

Market ready ➔ Clinical trials ➔ R&D ➔ Long-term
Key Takeaways for ATP

• The ATP pathway provides a mechanism for Health Canada to **tailor a set of requirements for unique and innovative therapeutic products that cannot be appropriately regulated under current frameworks**

• The **vast majority of therapeutic products** will continue to be regulated under **existing frameworks**

• A **concierge service** will be created to assist stakeholders in navigating the ATP process

• A range of **compliance and enforcement** options, including modernized inspector powers and terms and conditions will enable Health Canada to be responsive and agile to new and emerging risks

• **Canadians will have access to novel and innovative drugs and devices** which were not marketed in Canada previously

• The **first 2 tailored ATP pathways** being created in 2023-2024 will be for Adaptive Machine Learning-Enabled Medical Devices and Fecal Microbiota Therapy
Questions?