Advanced Therapeutic Products

An Introduction to Health Canada's Approach

CASSS Cell and Gene Therapy Products Symposium

June 6-8, 2022

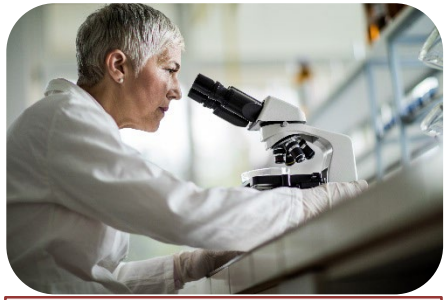
Outline

- 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

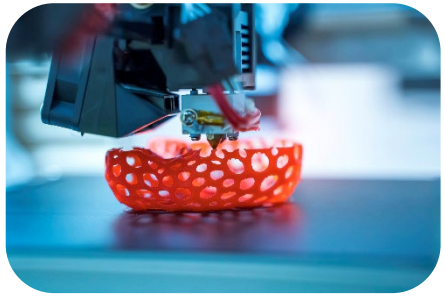
The need for a specialized pathway is apparent

- 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

Artificial Intelligence



Advanced Cell Therapies



3D Bio-Printing

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.

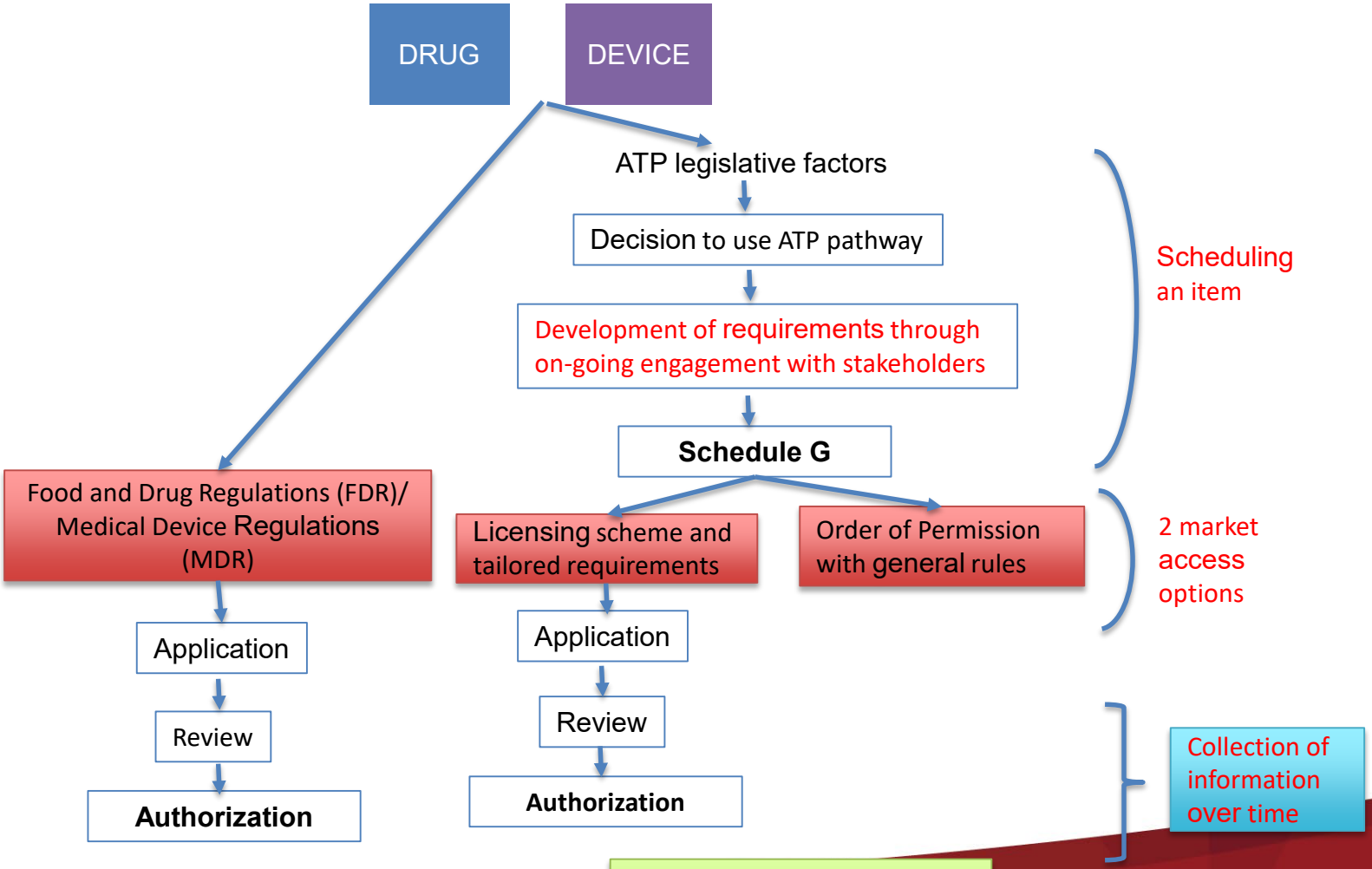
What are the differences between existing pathways and ATP pathway?

THERAPEUTICS

product) 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)



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:

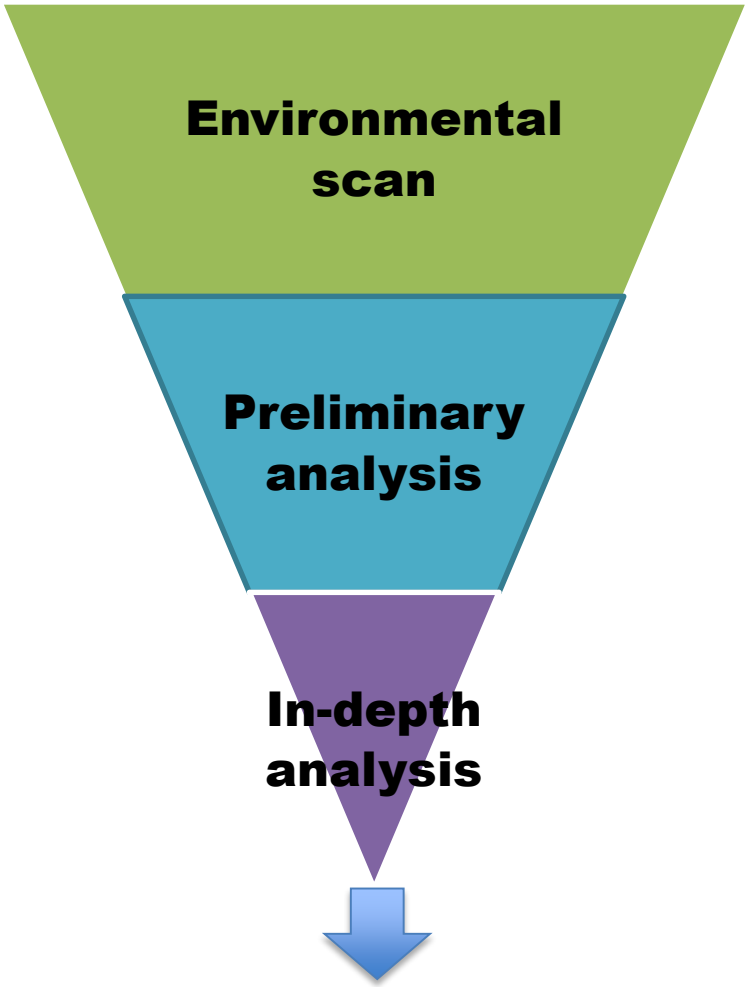
(a) the degree of uncertainty respecting the **risks and benefits** associated with the therapeutic product or products and the measures that are available to adequately manage and control those risks;

(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



Product or class of products to be added to Schedule G

Summer 2019

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

Fall 2019

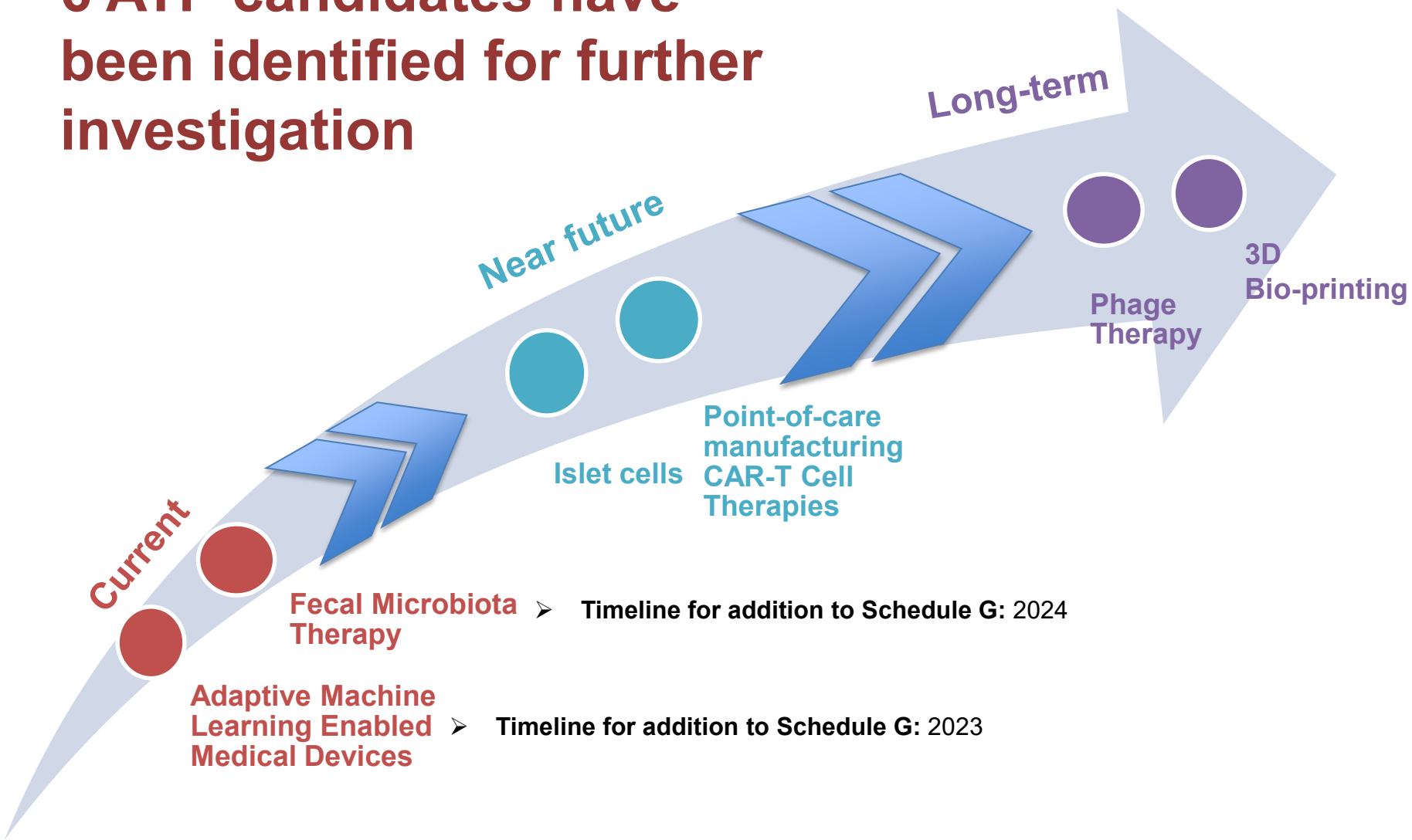
- To confirm whether these items are potential candidates for the ATP framework by using the legislative factors (risks & benefits, novelty compared to previously approved products, and whether appropriate controls are in place through provincial, territorial and federal legislation).

Fall 2019 - Ongoing

- 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** ➢ **Timeline for addition to Schedule G:** 2024
- **Adaptive Machine Learning Enabled Medical Devices** ➢ **Timeline for addition to Schedule G:** 2023

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?

рахмат
danke
謝謝
ngiyabonga
شكراً جزيلاً
teşekkür ederim
Баярлалаа
спасибо
mersi
barka
welalin
tack
spas
faafetai lava
vinaka
dank je
misaotra
matondo
paldies
grazzi
mahalo
tapadh leat
kiitos
dankie
спасибі
blagodaram
thank you
gracias
хвала
asante
manana
dhanyavad
nanni
nandri
obrigada
tenki
bedankt
bayarlalaa
gràcie
hvala
mauruuru
köszönöm
dankon
akun
aciú
djiere dieuf
tau
mochchakkeram
murakoze
enkosi
dziękuję
дякую
mamnun
chokrane
chnorakaloutioun
gratias ago
gràcies
sulpäy
go raibh maith agat
sobodi
dëkuji
sagolun
sukriya
kop khun krap
taiku
obrigado
mèsi
didi madloba
ありがとう
tanemirt
grazie
arigatô
takk
dakujem
trugarez
najis tuke
kam sah hamnida
rahmat
terima kasih
rahmet
ευχαριστώ
diolch
dhanyavadagalu
shukriya
merce
мерси
감사합니다
xièxie
merci