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Canada

Regulatory Update for Cell and Gene Therapies - Health Canada

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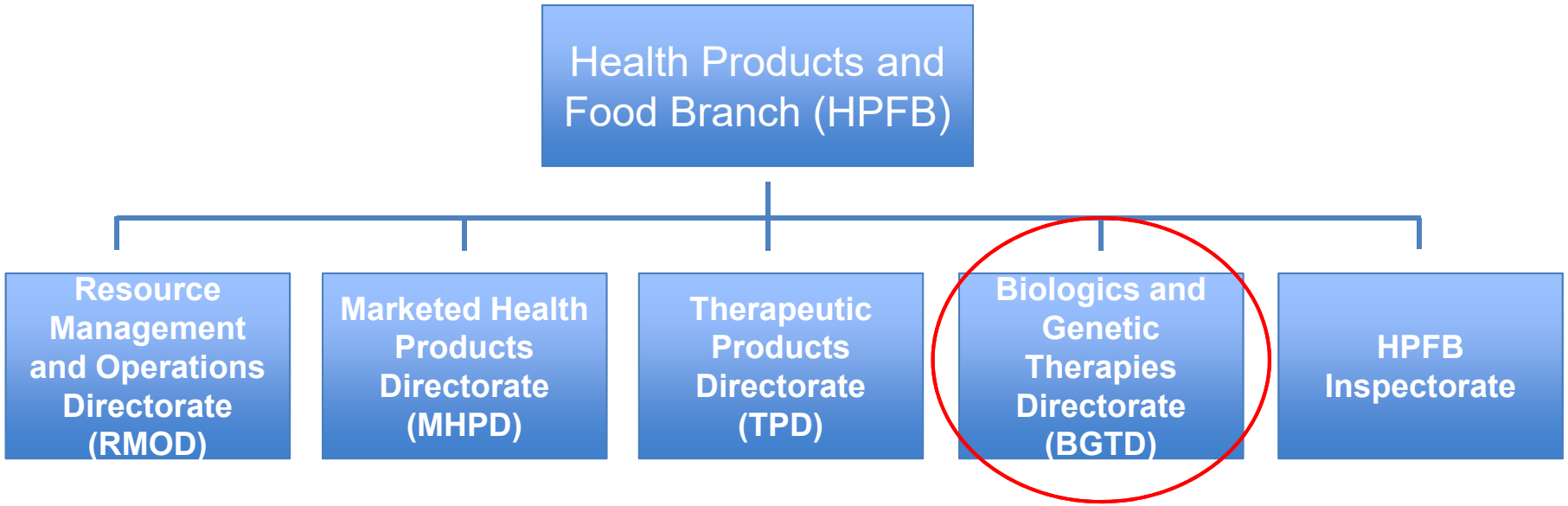
CASSS Cell and Gene Therapy Products 2019

YOUR HEALTH AND SAFETY... OUR PRIORITY.

Outline

- Introduction
- Submissions update
- Recent Trends
- Regulatory Pathway
- Other regulatory considerations
- Health Canada contact information

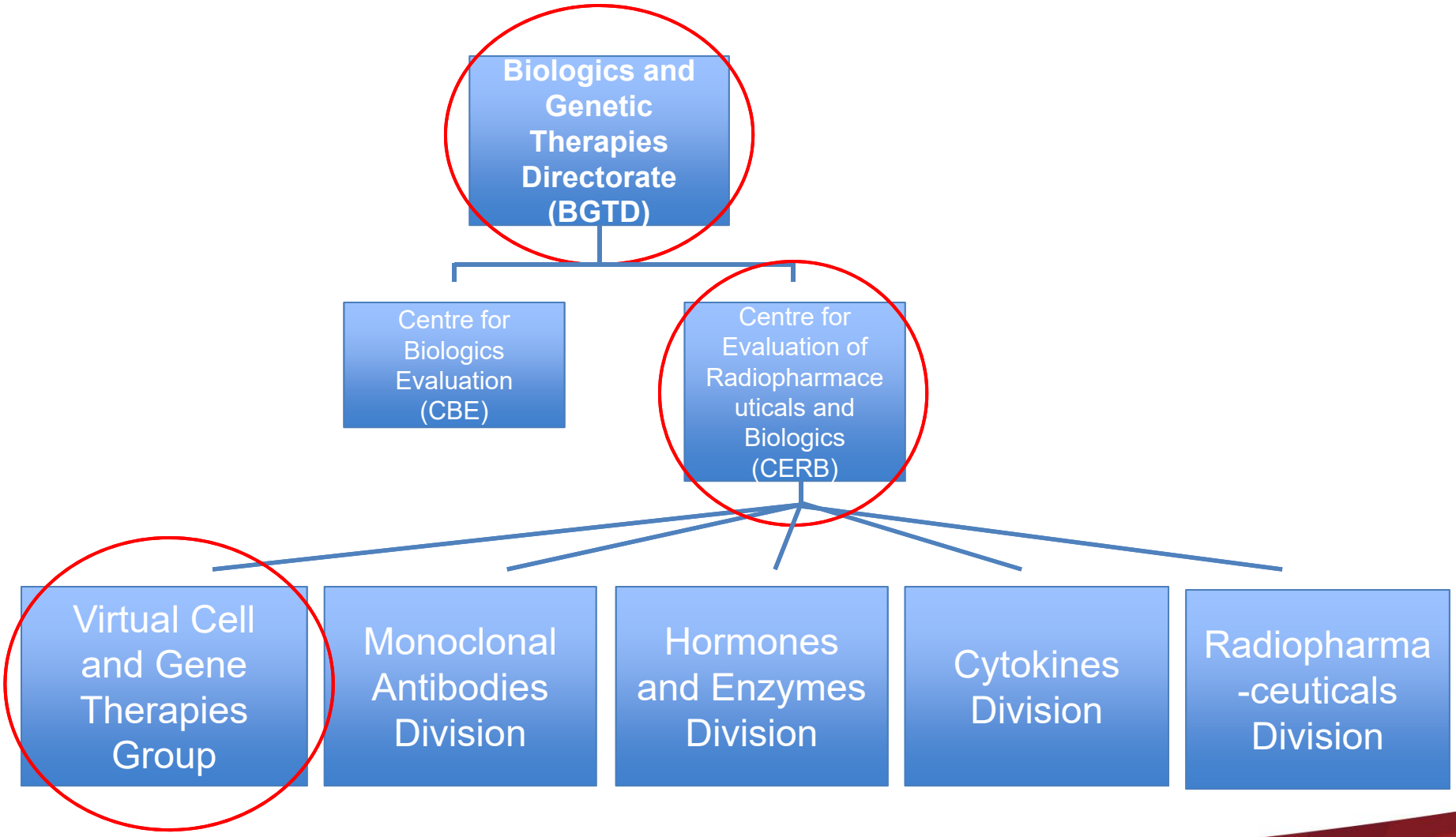
Where does BGTD fit in?



Mission:

BGTD works to maximize the quality, safety and efficacy of biological and radiopharmaceutical products in Canada.

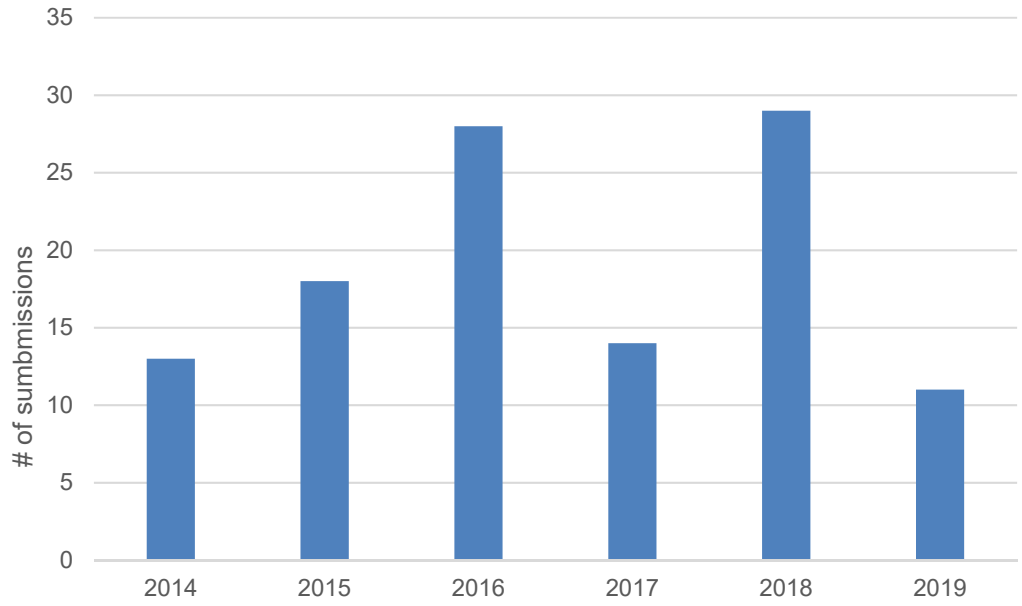
Where do Cell and Gene Therapies go within BGTD (for Quality Review)?



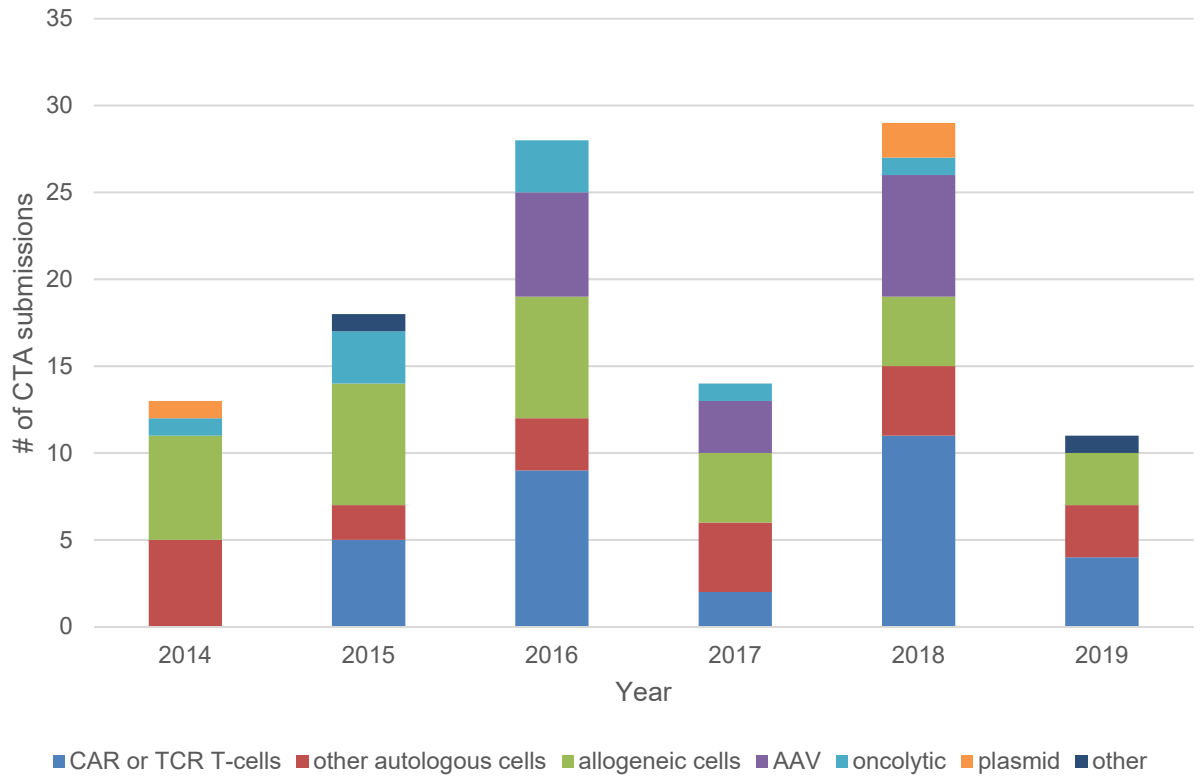
Submissions Update

- Currently two CAR T-cell products approved in Canada
- Expecting Gene Therapy submissions

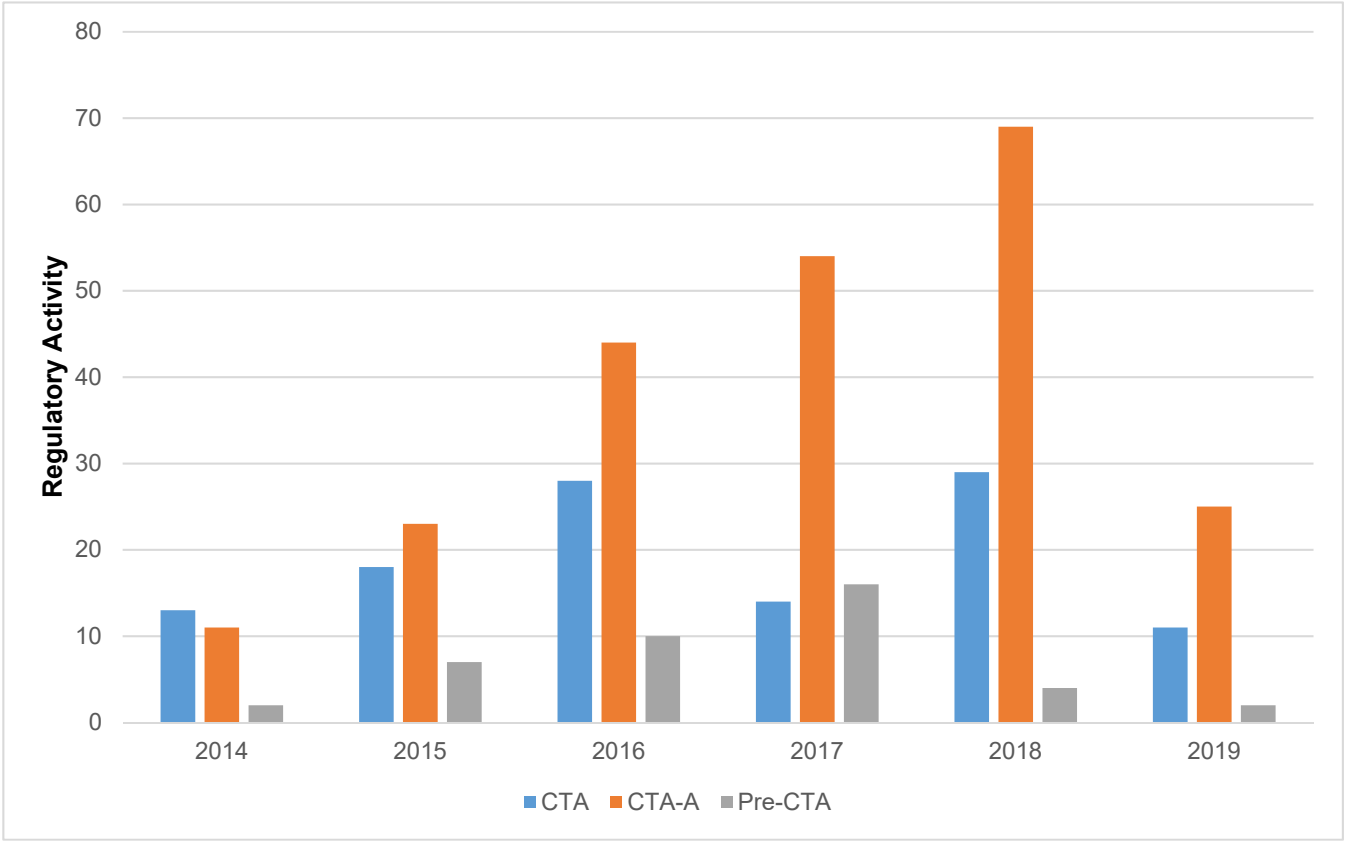
Recent Approved Cell and Gene Therapy Clinical Trial Application Submissions to Health Canada



Recent Approved Cell and Gene Therapy Submissions to Health Canada – CTAs by Product Type



Number of Cell and Gene Therapy CTA applications, CTA amendments, and pre-CTA meetings



Current Trends and comparability

- Larger firms entering Cell and Gene Therapy space
- New facilities
- Comparability studies
  - Linking clinical studies with CMC
  - ICH Q5E
  - Release tests and extended characterization
  - Split apheresis
  - Demonstration of consistent manufacture of product
- Method Transfers

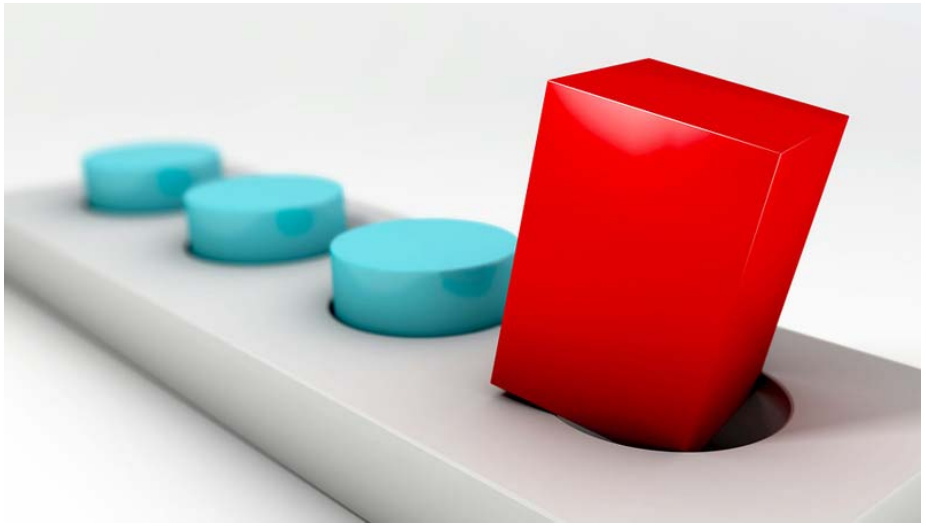
Current Trends, Comparability and Regulatory Considerations

- Point of care manufacture
  - Several centres utilizing point of care closed system devices
  - Single Quality system covering all sites
- Drug master files
  - clear scope of third party and sponsor information
- Out of Specification CAR T-cell therapy lots
- CTAs: CAR T-cell therapeutics targeting solid tumors
  - Smaller targeted trials or several targets in one trial?
  - Potential Changes to Clinical Trial Regulations

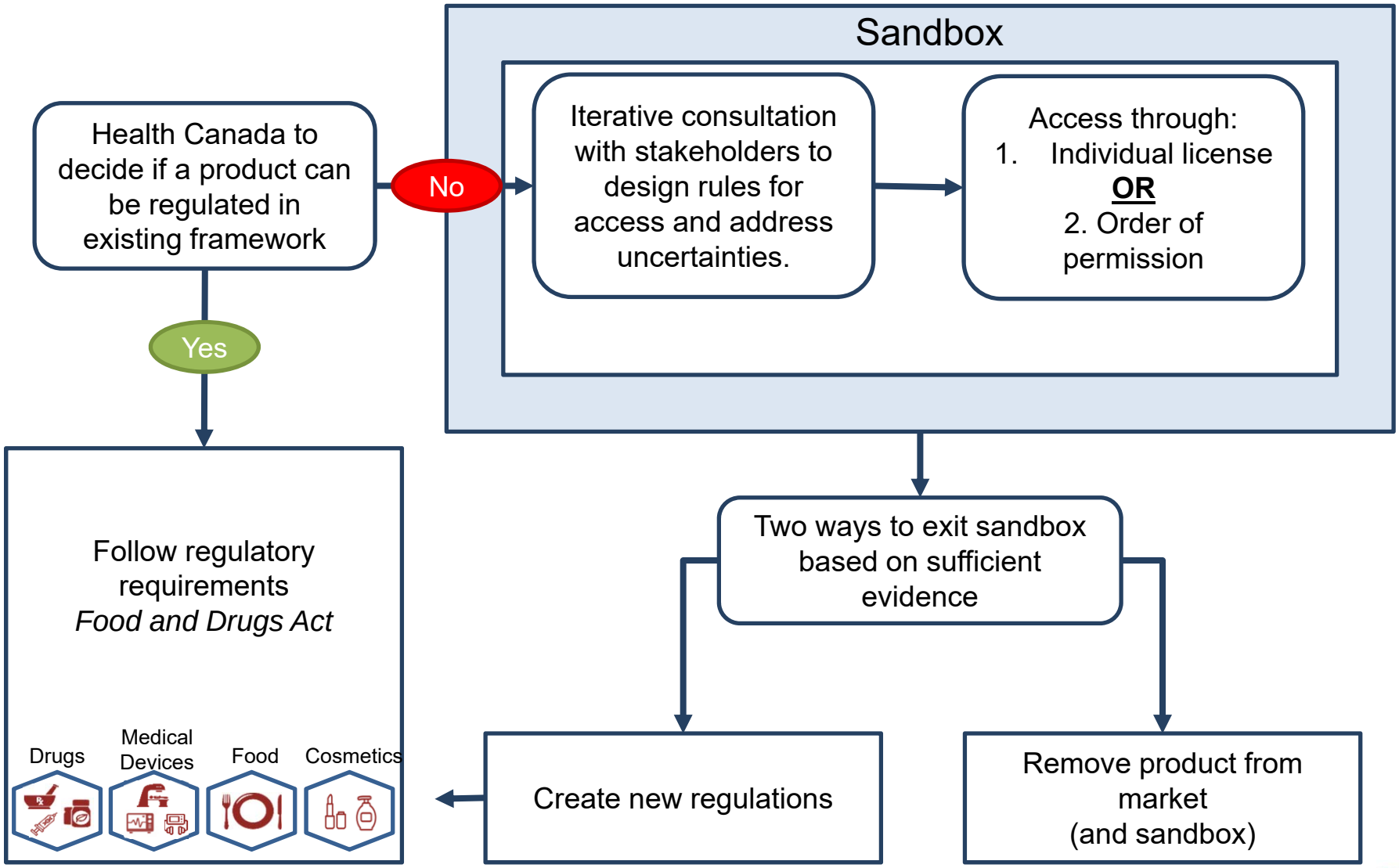
Classifying Novel Advanced Therapeutics

- Some novel products not well captured by existing regulatory paradigm

  - Point of care genetically altered autologous cell manufacturing and associated devices
  - Artificial intelligence



The Advanced Therapeutic Products Pathway – Our Proposed Regulatory Sandbox



Harmonization

- Health Canada embraces harmonization of regulatory approaches with respect to Cell and Gene Therapeutic Products
  - IPRP
    - GTWG
    - CTWG
  - ATMP Cluster
- Contributor to international harmonization efforts through ICH
- Welcome discussion if our position differs significantly from other regulatory authorities

We welcome your questions

- We welcome regulatory questions via pre-CTA meetings or pre-NDS meetings in-person or via teleconference
- Contact Office of Regulatory Affairs

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THANK YOU!