



CIAJ Legislative Drafting Conference: Post-modern Regulation: Keeping Up with a Changing World

Claude Lesage, General Counsel and Director, Health Canada Regulations Section

Patricia Pledge, General Counsel, Bijuralism and Advisory Services Section

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Canada's Regulatory Modernization Agenda





Canada's Regulatory Modernization Agenda

- Continued and enhanced focus on regulatory cooperation (internationally and domestically), including amendments to the *Red Tape Reduction Act* and *Red Tape Reduction Regulations*
- New *Cabinet Directive on Regulation* and revised policy suite
- Budget 2018: Regulatory Reviews with focus on innovation and competitiveness with Regulatory Roadmaps published June 2019



2018 Targeted Regulatory Reviews: High-growth Sectors

- Stakeholders have identified regulatory reviews as a key part of modernizing Canada's regulatory system (e.g. Advisory Council on Economic Growth)
- In 2018, the Government made regulatory reviews a priority by funding, over three years, targeted reviews of regulatory requirements and practices that are bottlenecks to innovation
- The first wave of targeted reviews focused on 3 high-growth sectors:





Targeted Regulatory Reviews: Second Round

- Second Round of Regulatory Reviews focusing on
 - Clean technology
 - Digitalization and technology neutrality
 - International standards

- Many proposals include “novel regulatory approaches” – what does this mean for regulation-making?

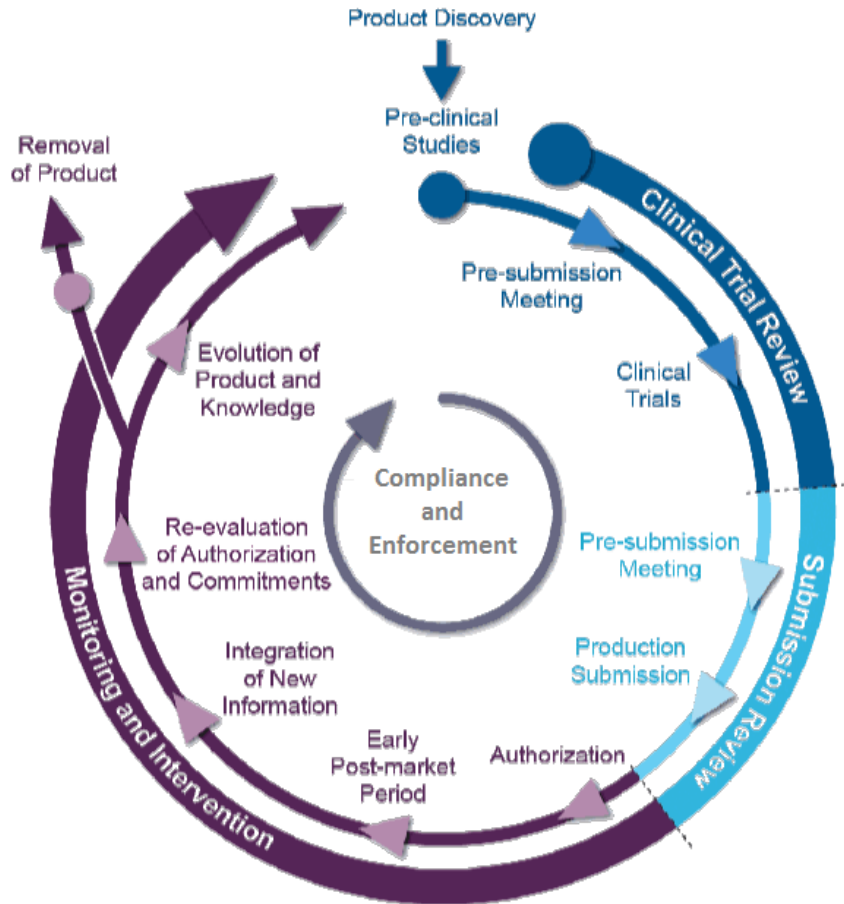


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Targeted Regulatory Reviews: Health and Biosciences Sector



Health Canada's Role in Product Life Cycle



- Move too slowly – regulators risk leaving the public vulnerable or falling out of step with market realities. Move too quickly – regulators risk stifling innovation.
- How can Health Canada become a more effective regulator?



 Health Canada Activities
 Industry Activities
 Health Canada Compliance and Enforcement Activities (e.g., licensing, inspection, compliance verification)



Targeted Regulatory Reviews: Health and Biosciences Sector

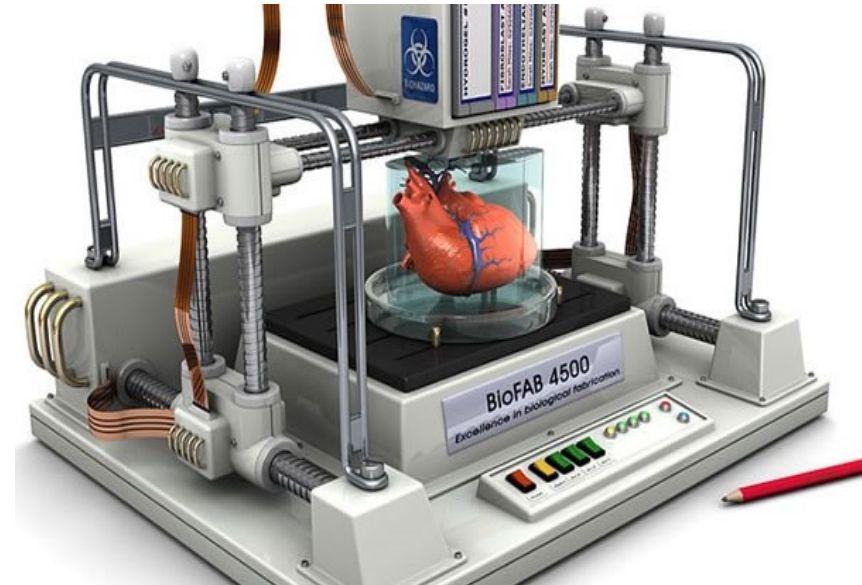
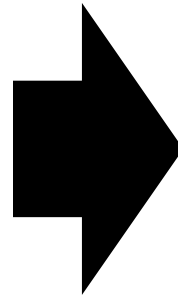
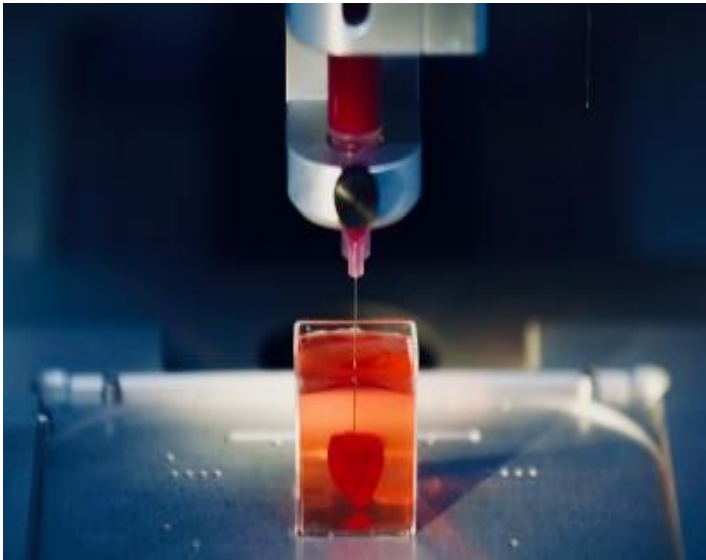
- New trends such as advanced cell and gene therapies, 3D printing of implants will radically personalize health care and have impressive economic potential.
- New products and therapies are challenging the foundations of a regime built around traditional models of sale, manufacturing, pre-market approval, clinical trial evidence and labelling, among other things.
 - For example, personalized medicine means that mass production of health products based on population-level, pre-market evidence will become less relevant.
- Such technology tests the key concepts of "sale" and "manufacture" "therapeutic products" in the *Food and Drugs Act*.



Targeted Regulatory Reviews: Health and Biosciences Sector

- These evolutions in manufacturing and markets create uncertainty about how to identify and manage quality and safety issues through modern regulatory frameworks and approaches.
 - For example, 3D-printed medical devices and non-traditional means of accessing these products (selling and advertising online) challenge existing scientific approaches and oversight mechanisms.
- A new approach is required to enable access to advanced treatments and enhance product safety through stronger post-market controls.

Innovation and the Future of Health Care – 3D Printing of Human Organs



- A. V. Borovjagin et al., *Circulation Research*, American Heart Association, Inc, [From Microscale Devices to 3D Printing: Advances in Fabrication of 3D Cardiovascular Tissues](#), January 6, 2017
- C. S. Ong et al., *Scientific Reports*, Nature Publishing Group, [Biomaterial-Free Three-Dimensional Bioprinting of Cardiac Tissue using Human Induced Pluripotent Stem Cell Derived Cardiomyocytes](#), July 4, 2017
- F. Maiullari et al., *Scientific Reports*, Nature Publishing Group, [A multi-cellular 3D bioprinting approach for vascularized heart tissue engineering based on HUVECs and iPSC-derived cardiomyocytes](#), September 10, 2018
- Global News, [Israeli scientists 3D print a tiny heart complete with blood vessels](#), April 15, 2019
- N. Noor et al., *Advanced Science*, [3D Printing of Personalized Thick and Perfusable Cardiac Patches and Hearts](#), April 15, 2019

Ethical considerations – printing spare body parts and extending longevity



© Photo by Ranald Mackechnie via Getty Images



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Regulatory Experimentation: Design and Challenges



Overview of Regulatory Experimentation



Types of Regulatory Experimentation

No Regulatory Regime Exists

Iterative Co-Development

Could it mean this?

- Working with industry and other stakeholders to identify what instrument, if any, is appropriate for disruptive or innovative process or products.
- Novel approach because of **enhanced** consultation on instrument choice.

Regulatory Regime in Place is a Barrier

Regulatory Sandbox

Could it mean this?

- Existing regulations prevent the innovation or technology.
- Exemptions from specific requirements issued on case by case basis to individual proponents.
- Continued regulator oversight.

Experimentation with Regulations

Pilot Project

Could it mean this?

- Regulations of general application, but of limited scope.
- Not a case by case basis
- May be a subset of other regulations carving out a short term approach for evaluation

Ambiguity in Regulations

Combination of Regulatory Approaches

Could it mean this?

- Co-development with stakeholders to determine where there is fit, if at all
- Exemptions / non-enforcement letters
- Creation of new regulations? Or removal of ambiguity?



Regulatory Sandboxes: Exploration of Best Practices for Design

- 1) Scope of Authority to Exempt – All Rules or Just Some?
- 2) Individual or General Approach – Players in the Regulatory Sandbox
- 3) Eligibility – Criteria for Participation
- 4) Transparency – Applications, Decisions, Results
- 5) Designing the Details of the Sandbox



Regulatory Sandboxes: Exploration of Best Practices for Design

1) Scope of Authority to Exempt – All Rules or Just Some?

If authority to create a “regulatory sandbox” is conferred, what should be its scope to exempt?

- The Act and the regulations?
- Any and all provisions?
- Are some fundamental provisions of the Act or regulations that should not be waived or altered in the regulatory sandbox?
- What are essential “safeguard mechanisms”?
- Imposition of terms and conditions – co-development?



Regulatory Sandboxes: Exploration of Best Practices for Design

2) Individual or General Approach – Players in the Regulatory Sandbox

Innovations (new and emerging technology) or innovative ways to apply existing technology is inherently individual and requires a case-by-case assessment.

- Exemption or waiver powers should be limited to individualized exemptions
- *Cabinet Directive on Regulation, Statutory Instruments Act*
- Capacity (resources, expertise) of the regulator to assess the individual proponents
- Regulatory sandboxes are a form of testing, not intended to enable permanent regulatory waivers or exemptions (OECD)



Regulatory Sandboxes: Exploration of Best Practices for Design

3) Eligibility – Criteria for Participation

Assessment of technologies or innovations – who gets to play in the sandbox?

- Who will establish criteria for participants?
- Should there be standard criteria across the federal government?
- Requirement for a “genuine innovation”?
- Should there be a requirement that a benefit is anticipated? How will we know?
- Should the proponent have to demonstrate that they are “ready”?
- Who should determine if there is a regulatory barrier?



Regulatory Sandboxes: Exploration of Best Practices for Design

4) Transparency – Applications, Decisions, Results

Regulatory sandboxes can confer market advantage and require transparency in:

- Criteria for who is eligible to participate
- Process for application and disposition of proposals
- Publication of decisions to grant or deny permission
- Publication of terms and conditions
- Time limited
- Report on results and accountability



Regulatory Sandboxes: Exploration of Best Practices for Design

5) Designing the Details of the Sandbox

Considerations:

- Can we choose between incumbents and new entries, and do we want to?
- Can we limit the numbers of sandboxes?
- Do regulators have the resources to monitor and adapt?
- Determination of duration
- Revocation and termination principles
- General Act or individual Acts – what will our approach be?



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Case Study of Regulatory Sandbox: Amendments to the *Food and Drugs Act*



Overview of the 2019 Amendments to the *Food and Drugs Act*

1. Give the regulator a new authority to classify a product solely as a food, drug, cosmetic or device;
2. Directly regulate the conduct of clinical trials (to allow more flexible and effective oversight over increasingly complex clinical research); and
3. Create a new, flexible approval pathway for advanced therapeutic products (ATPs).



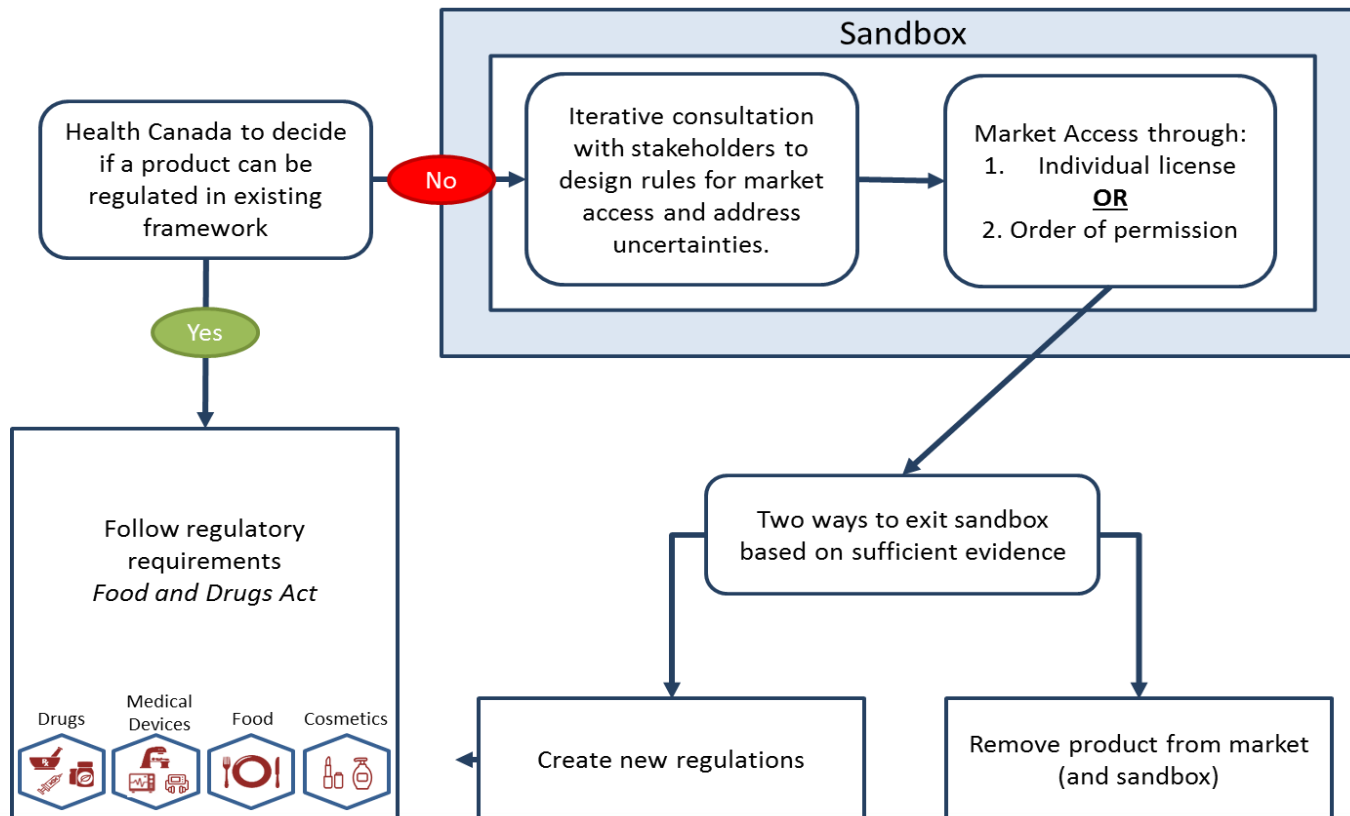


Regulatory Experiment in the *Food and Drugs Act*

- The FDA was amended in 2019 to introduce a new approval pathway for *advanced therapeutic products* in sections 21.9 to 21.96.
- The new approval pathway complements but does not replace existing ones.
- This new scheme is anchored by a prohibition against anyone importing, selling, advertising, manufacturing, preparing, preserving, packaging, labelling, storing or testing an ATP unless
 - the person holds a licence issued to them to do so,
 - they have been authorized under an Order that permits anyone in a class to do so, or
 - they have otherwise been authorized to conduct the activity under the FDR.

Advanced Therapeutic Products

The Advanced Therapeutic Products Pathway – Our Regulatory Sandbox





Advanced Therapeutic Products

- The new ATP prohibition only operates when the Minister has, by Order, added a product to Schedule G of the FDA. The regulator will schedule an emerging or innovative product, or class of products, only if the product needs to be governed by new flexible rules relating to its licensing.
- A drug that is scheduled can still be manufactured or imported in accordance with a DEL and sold in accordance with an NOC without the issuance of a licence or the making of an Order permitting anyone in a class to do so.





Advanced Therapeutic Products

- When a product is listed, its import, sale, advertising, manufacture, preparation, preservation, packaging, labelling, storing or testing can be authorized administratively through the issuance of a licence; by an Order that authorizes persons within a class to do the things; or in accordance with the existing regulations (e.g. via NDS, device licence application).
- ATP licences and orders can be subject to terms and conditions specified in them; they are enforceable in the same way that terms and conditions on clinical trial or therapeutic product authorizations can be.





Advanced Therapeutic Products

- The holder of an ATP licence or Order is exempt from the FDA regulations unless a regulation specifies otherwise. This allows the regulator to take a flexible and iterative approach to regulating these products.
- A product can remain in this flexible regulatory pathway for as long as the regulator determines it is necessary.
- This is the regulatory sandbox that has been created for therapeutic products.





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Next Steps





Activities in the Regulatory Experimentation Space

Centre for Regulatory Innovation (CRI) Partnering with NESTA

Capacity Fund and Support For Regulators

Second Round of Regulatory Reviews: Roadmaps 2021

Canada can be a leader in developing a coherent approach to regulatory sandboxes that respect good regulatory practices



Questions

