CAPRA 2024 PHARMACEUTICAL SYMPOSIUM

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Innovative Medicines Canada

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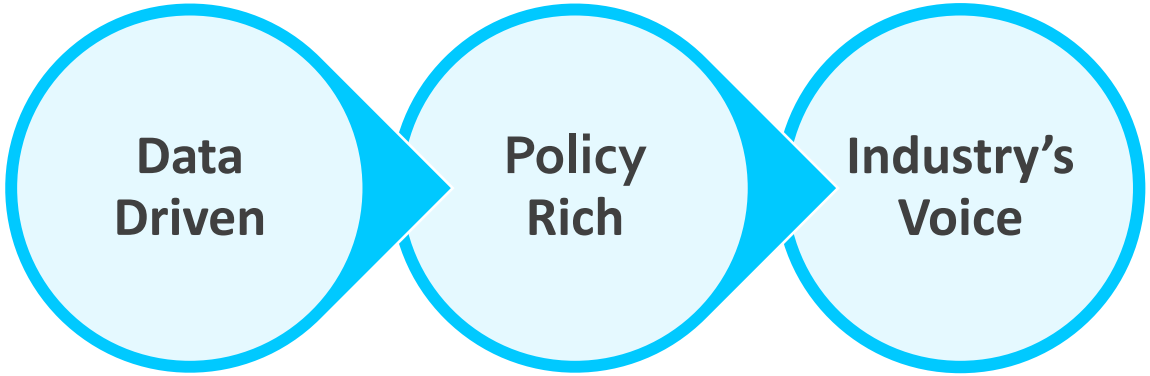
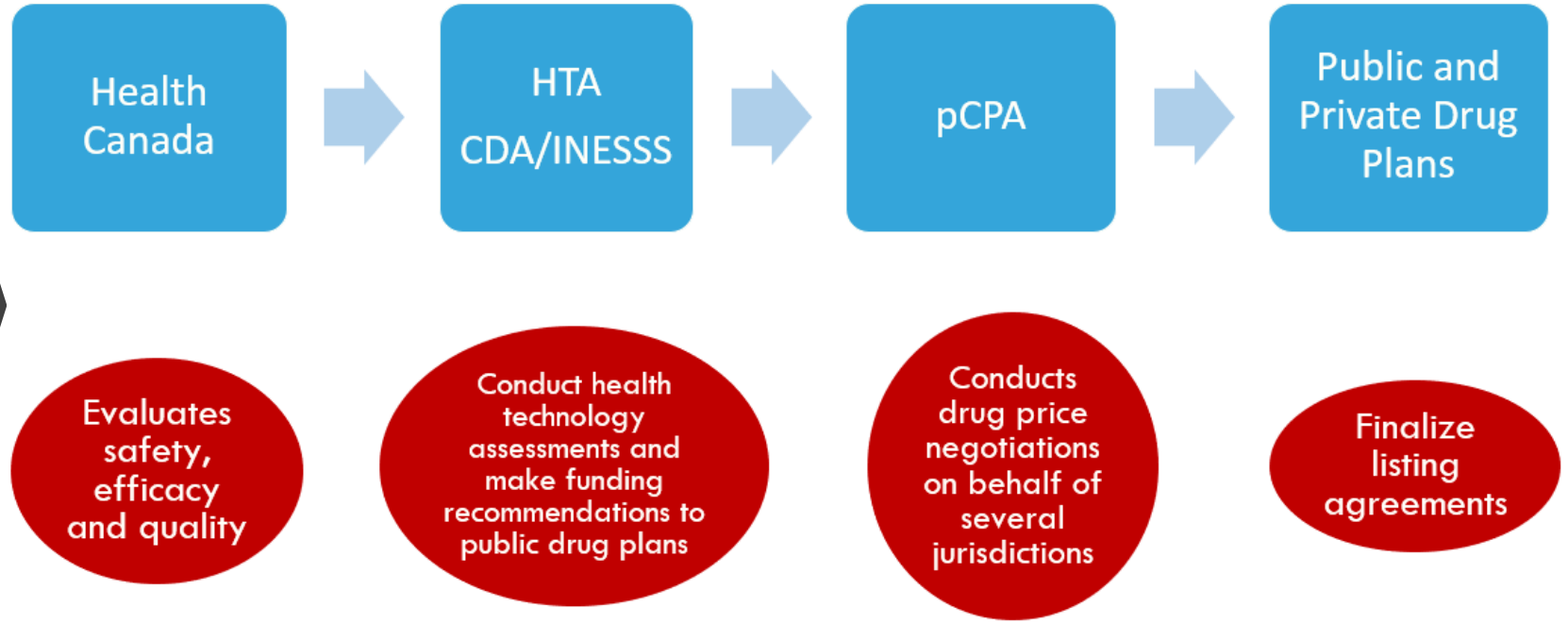
Who and What Does IMC Represent



41 Full Members	8 Life Sciences Associate Members
Committed to being valued partners in Canada's healthcare system.	
Form effective alliances, support policies, improve Canada's regulatory environment, widen access to innovative medicines and ensure the effective protection of intellectual property.	

Industry's Economic Impact

Canada's drug approval and reimbursement



Health Canada Regulatory Updates

- Access Consortium
- Reliance/Recognition/Use of foreign decision pathway
- Rollings Reviews/acceptance of new relevant data during review
- Drug Shortages
- Pilot Pediatric Program

Access Consortium

- A five-member coalition of like-minded health regulatory authorities focusing on regulatory information and work sharing initiatives to provide faster access to safe, effective and novel medicines.
- The five members are:
  - Therapeutic Goods Administration (TGA) - Australia
  - Health Canada - Canada
  - Health Sciences Authority (HSA) - Singapore
  - Swissmedic - Switzerland
  - Medicines and Healthcare products Regulatory Agency (MHRA) – UK joined October 2020

Access Consortium - survey

- Survey developed by trade associations of the five Access Consortium countries – Results published in March 2024
- Specific recommendation to Health Canada:
  - **Consider eliminating or minimising rolling questions;** several affiliates believe rolling questions make planning difficult and find them challenging to manage.
  - **Ensure prompt responses and feedback to affiliates**, especially during the EoI phase.

Reliance / Recognition / Use of foreign decisions

Forward Regulatory Plan 2023-2025: Precision Regulating

"Health Canada is exploring instruments that would help address market gaps and vulnerabilities with precise tools to support the availability of health products and food, such as infant formula and other food for a special dietary purpose. This would enable Health Canada to rely on decisions of trusted foreign regulatory authorities, where appropriate, or to temporarily waive regulatory requirements to address market issues. These authorities would be carefully crafted to respect the health and safety requirements of the Food and Drugs Act and its associated regulations, ensuring that health products and food remain safe and effective while ensuring that people in Canada have access to the products they need"

"Stakeholder engagement and consultation have been ongoing since 2017, including as part of Health Canada's response to the COVID-19 pandemic. Further policy consultations will occur with a view to bring forward the new authorities in spring 2024"

Reliance / Recognition / Use of foreign decisions

Budget 2024 : Legislative Measures

Improving Health Product Regulations: In Budget 2024, the government proposes to amend the *Food and Drugs Act* to provide the Minister of Health with the authority to rely on information or decisions of select foreign regulatory authorities in specific instances to satisfy requirements in the *Food and Drugs Act* and/or its regulations.

Reliance / Recognition / Use of foreign decisions

Foreign regulatory decisions. New ministerial authority to rely on information and decisions from select foreign regulatory authorities to satisfy FDA/FDR requirements on therapeutic products (defined as drugs and devices) and food. These amendments are high-level and do not specify any specific foreign regulatory jurisdictions or triggering events. Before issuing such an order, the Minister must be satisfied that it is necessary for health, safety or the public interest and unlikely to result in unacceptable health risk or safety.

Reliance / Recognition / Use of foreign decisions

- IMC has been doing work on understanding reliance and recognition pathways in other jurisdictions.
- Reliance vs Recognition:

  Reliance: RA in one jurisdiction may take into account and give significant weight to assessments performed by another authority or trusted institution in reaching its own decision. The relying authority remains independent, responsible and accountable regarding the decisions taken.

  Recognition: Acceptance of the regulatory decision of another regulator or trusted institution.

- Propose to Health Canada a framework to implement the use of foreign decisions pathway (reliance vs recognition) as well as the type of submissions or lifecycle of the product (i.e. post approval changes such as CMC).

Rolling Reviews/acceptance of new data during review

- Amendments to the *Food and Drugs Regulations* (Agile Licensing) – CGI 2023
  - Rolling reviews for certain drugs
    - Allows manufacturers to file drug submissions with some but not all the information necessary for the regulator to assess the safety and effectiveness of a drug – missing information would need to be provided within a reasonable time

- June 11, 2024 update from Health Canada
  - Removing rolling reviews from CGII

- Working with Health Canada on potentially allowing the acceptance of new relevant data during review at least in some situations such as Access Consortium and Project Orbis submissions

Drug shortages

- Notice of Intent to amend the FDR to address health product shortages in Canada: published June 25 – submission due July 25
- Publication of amended regulations in Canada Gazette Part I – Fall 2024
- Publication of a list of drugs that are critical and vulnerable to shortages should also be published.

Pilot pediatric program

- Launched in February 2024
- Health Canada would like members to submit their available pediatric studies and/or pediatric development plans – voluntary
- IMC supports Health Canada's intent to develop pediatric regulations and a pediatric study submission policy that will encourage the generation and submission of pediatric data in Canada
- Policies and regulations must not impede the registration and availability of innovative medicines by creating Canada-specific regulatory requirements or significant regulatory burdens
- Practical and financial incentives are crucial for the future success of pediatric policy in Canada

Thank you!

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