Health Canada Santé Canada

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Promoting Reliance to enable information sharing between authorities: Health Canada's experience

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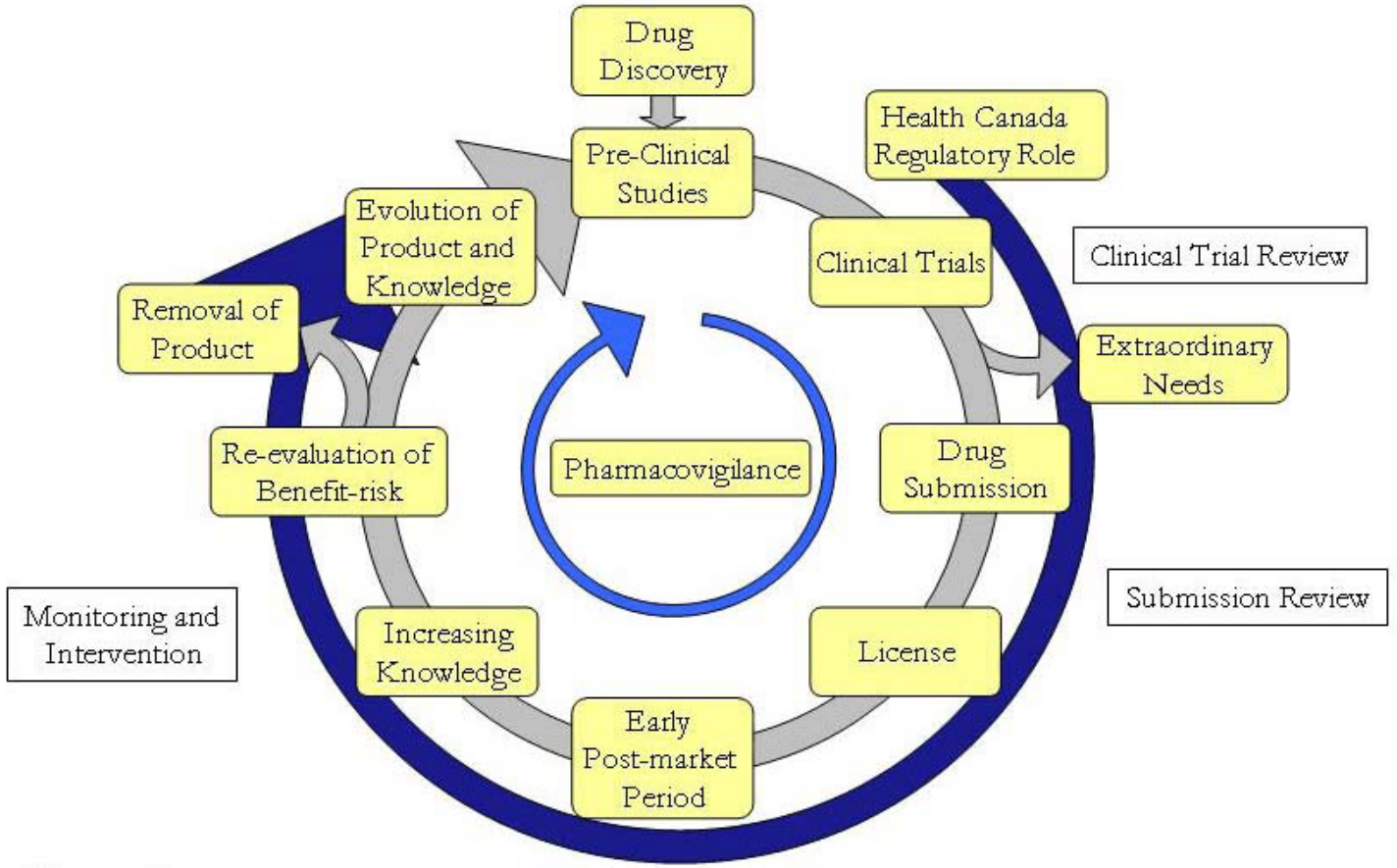
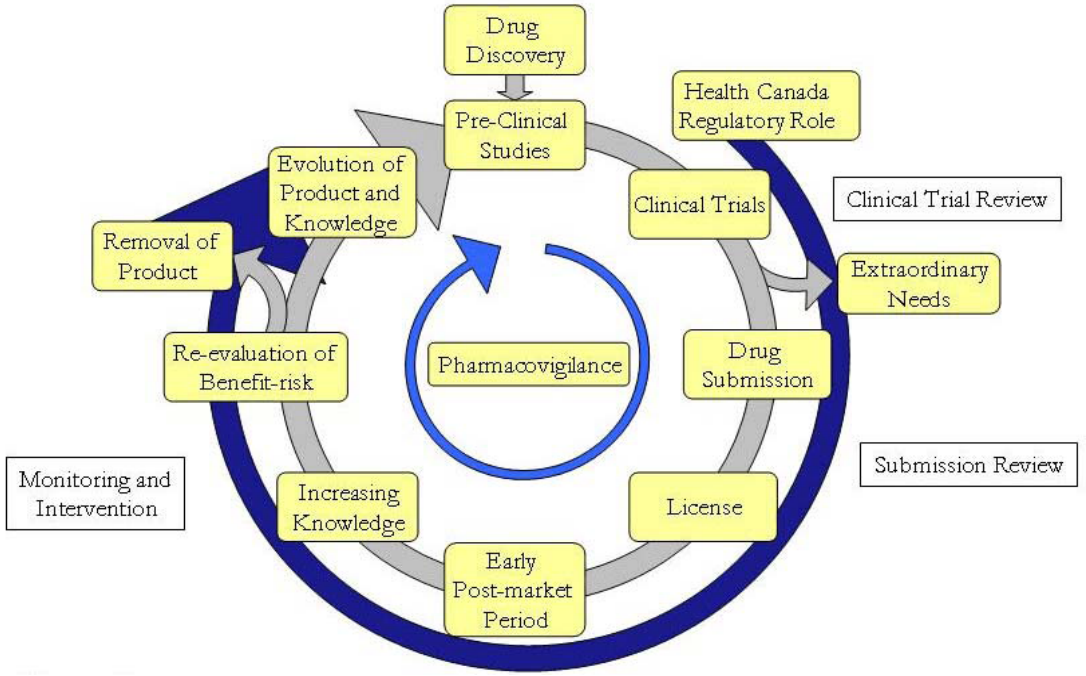
YOUR HEALTH AND SAFETY... OUR PRIORITY.

The Regulatory Reality: Lifecycle Management



Source: The Progressive Licensing Framework Concept Paper for Discussion, Health Canada, 2006; www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/prodpharma/proglic_homprog_concept-eng.pdf.

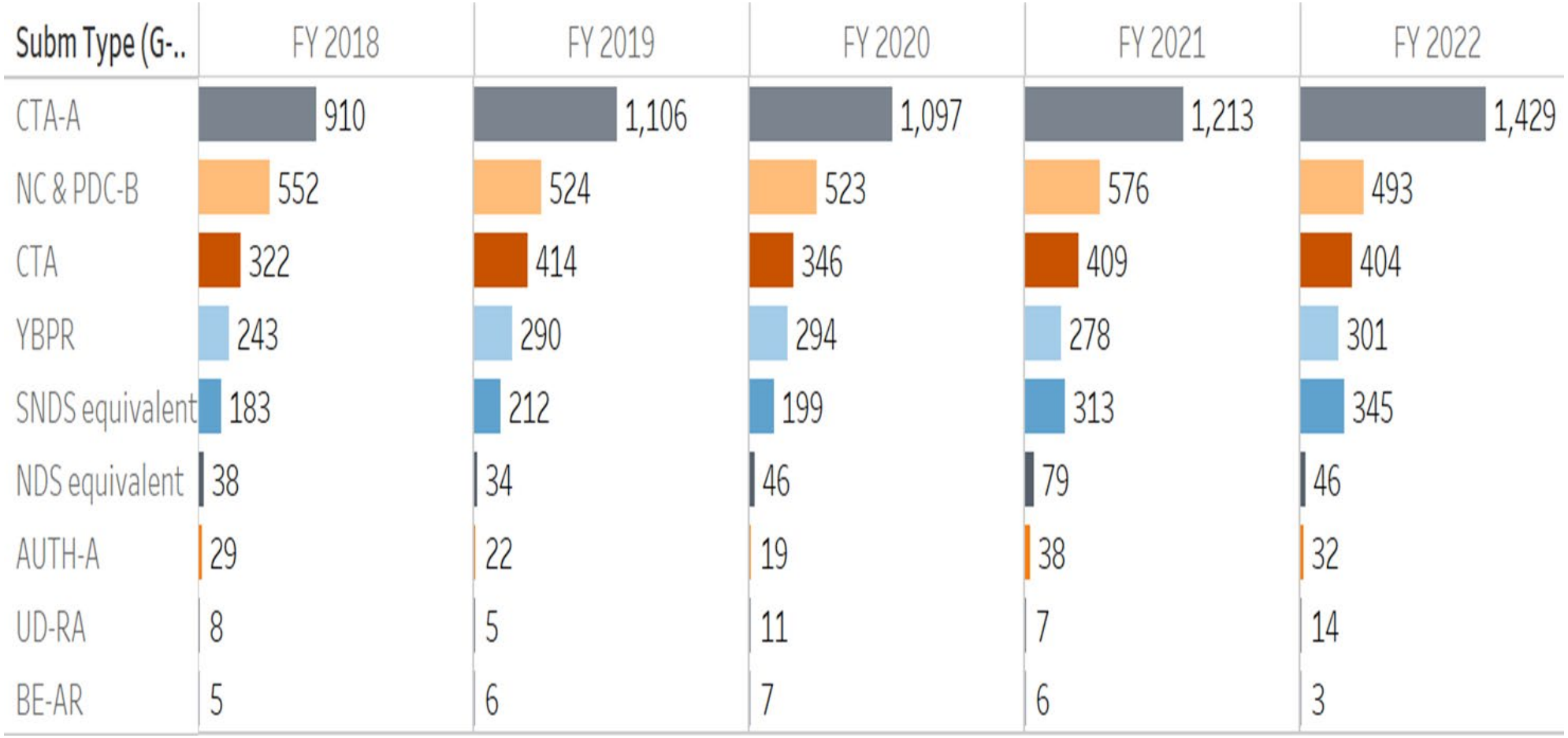
The Regulatory Reality: Lifecycle Management



Provide citizens timely access to safe, efficacious and high quality health products

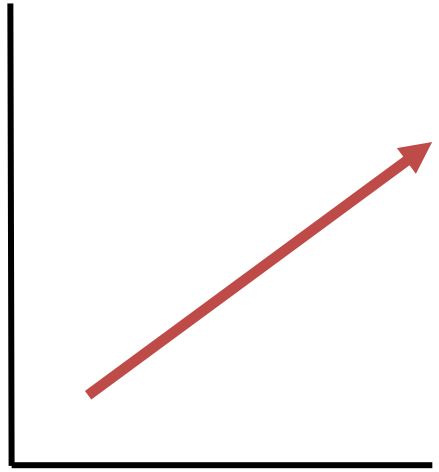
Source: The Progressive Licensing Framework Concept Paper for Discussion, Health Canada, 2006; www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/prodpharma/proglic_homprog_concept-eng.pdf.

Submissions Received in BRDD* by Fiscal Year

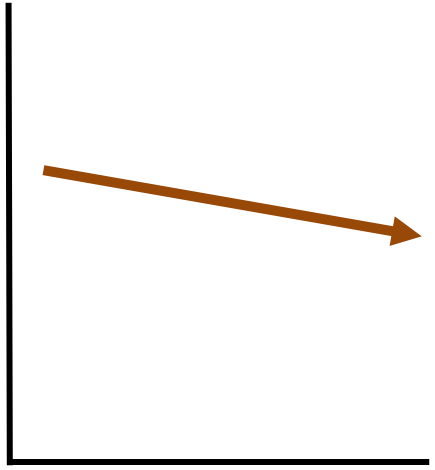


*Biologic and Radiopharmaceutical Drugs Directorate

The Regulatory Reality: Increasing Workload



Workload



Relative Resources

"I absolutely guarantee your workloads will not increase."

The Regulatory Reality: Risk of Increasing Workload

Provide citizens **TIMELY ACCES** to safe, efficacious, and high quality health products

Need to find efficiencies!!!!

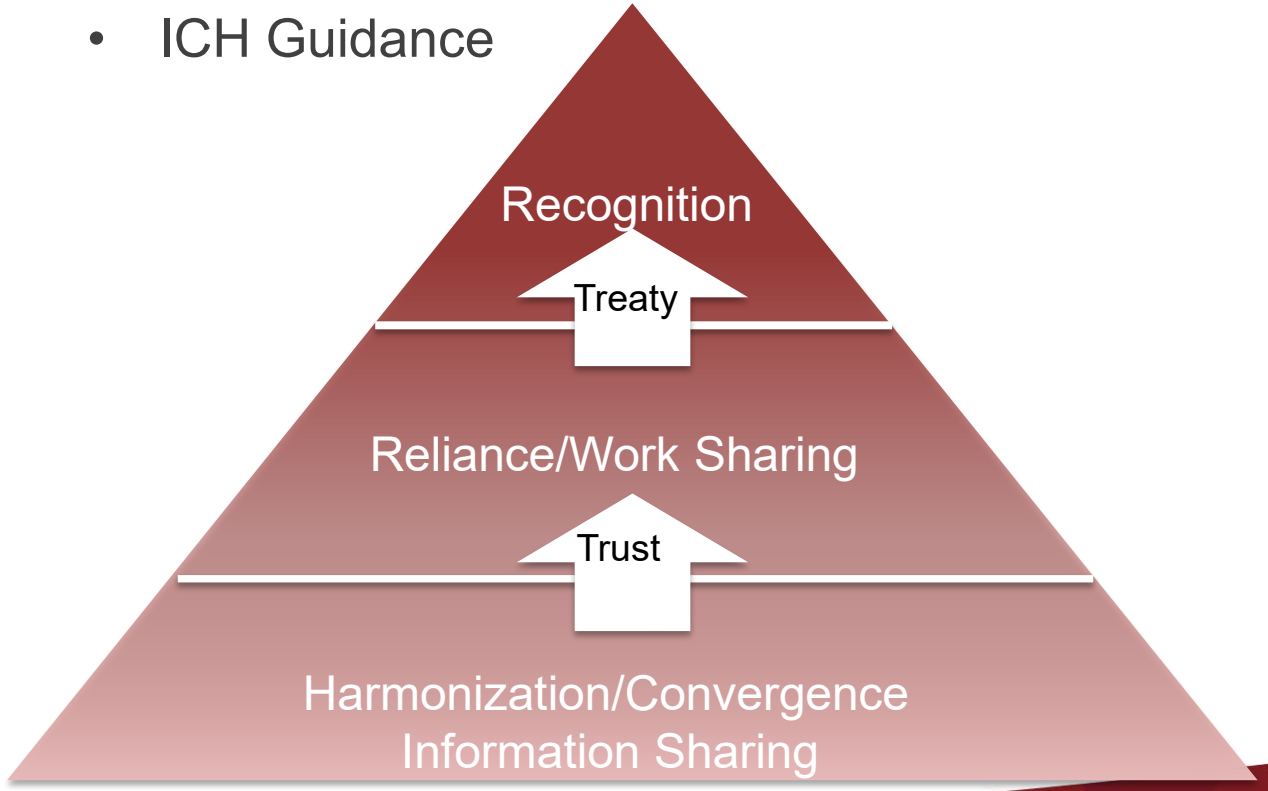
Health Canada: Reliance and Recognition

Information Sharing/Reliance

- ACCESS Consortium
- ORBIS
- OMCL
- EDQM
- WHO Pre-qualification Testing
- PIC/S
- ICMRA
- RELIANCE (Pilot project)
- Tri-cluster Meetings (EMA, FDA, HC)

Recognition

- GMP inspections
- ICH Guidance



Health Canada experience with information/work sharing during COVID pandemic

- Clinical and Non-Clinical
  - ACCESS Guidance
    - HC, the UK's MHRA and the other ACCESS Partners aligned with the non-inferiority immunogenicity/superiority considerations (www.icmra.info/drupal/en/covid-19/24june2021)

    - The ACCESS Partners also aligned regarding cross-platform immuno-bridging
      - Relevant animal challenge studies and demonstration of effectiveness against variants of concern (VOCs)
      - Characterization of comparative immunogenicity profiles
      - Characterization of comparative in vitro neutralization against VOCs;
      - Safety data with a median follow-up of at least two months post-final dose; and,
      - Post-authorization effectiveness studies.

  - Collaborative meetings amongst NRAs important for discussing and aligning on concepts of common clinical assays, reference standards, specifications etc.
  - Decisions made in quick time → reports shared amongst NRAs
  - More general alignment amongst NRAs when data not available

*Not always complete concordance amongst NRAs, however more general consensus than if decisions made in isolation

Health Canada experience with information/work sharing during COVID pandemic

- Quality (CMC)
  - ACCESS Consortium Guidance/Statements
    - ACCESS Consortium Points to Consider https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/drugs-vaccines-treatments/access-guidance-vaccines-strain-changes.html#a3)
      - Strain Change
    - ACCESS Consortium statement on COVID-19 vaccine evidences (https://www.tga.gov.au/access-consortium-statement-covid-19-vaccines-evidence)
  - Sharing of documents and technical discussions on COVID-19 vaccines
  - Sharing of Q&As with EMA and FDA → reduced duplication of workload for regulator and sponsor
  - Collaborative meetings between NRAs important for discussing and aligning on concepts of specifications, analytical assays, process validation, leveraging of platform technology etc

*Not always complete concordance amongst NRAs, however more general consensus than if decisions made in isolation

Key Points

What went well

- Evolution of sponsors permitting NRAs to talk/discuss a particular submission and share information
  - Improved harmonization of approach and outcome of decisions
  - More consensus on key clinical and quality issues (indications, specifications, assays)
  - Reduced duplication of workload for sponsors and regulators
- Collaborative discussions with jurisdictions that received submissions early

What could be done better

- Same information provided to NRAs at the same time when an issue impacts multiple jurisdictions
  - Situations where sponsor provides some information to a NRA and not the other
- Improve the flow/sharing of information
- Joint meetings between NRAs and sponsors

Factors influencing degree of Reliance

- Many factors impacting NRA final decisions, and these factors vary between jurisdiction (different Risk - Benefit)
  - Public Health considerations (public perception, vaccine access, status of pandemic)
  - Robustness of Health Care system
  - Political direction
  - Urgency to make national regulatory decisions prevented better align amongst NRAs
    - Pandemic versus non-Pandemic context (easier to reach consensus when not in pandemic mode)

Health Canada Non-Public Health Emergency History with Reliance

- Since October 2011, Health Canada has implemented the pilot project on the Use of Foreign Reviews
- *Draft Guidance Document: The Use of Foreign Reviews by Health Canada* prepared in 2012 (https://www.canada.ca/content/dam/hc-sc/migration/hc-sc/dhp-mps/alt_formats/pdf/prodpharma/applic-demande/guide-ld/for_rev-exam_etr/draft_foreign_rev_ebauche_exam_etra-eng.pdf)
- Objectives:
  - enhance the quality of Health Canada regulatory assessments; and
  - assist Health Canada in meeting performance targets for regulatory assessments while maintaining;
  - the integrity of Health Canada's regulatory review process; and
  - **Canadians' timely access to safe, efficacious and high quality health products.**

Examples:

- HC/FDA/PEI → New Drug Submission: Vaccine (completed)
- ORBIS (HC/FDA) →New Drug Submission: Cancer Therapy (completed)
- ACCESS partnership (HC/TGA) → New Drug Submission: Vaccine (ongoing)
  - HC review CMC and TGA review clinical
- RELIANCE Pilot Project with Sanofi Pasteur → Post-market CMC change: Vaccine (ongoing)
  - HC reviewed submission (recently completed)
  - Approval recommended
  - Report to be shared with many relying NRAs

Conclusions

- The concepts of Reliance were applied during the recent Public Health Emergency
- Reliance facilitated more convergence and harmonization amongst stakeholders → quicker access to medicines
- Information/Work Sharing reduced duplication of work → benefits to all stakeholders
- Continued Information/Work Sharing will be necessary to off-set the current trajectory of workload outpacing resources
- Experiences highlight areas of strength and areas of improvement → continued experience leads to continued improvement

Many thanks to all Health Canada colleagues!

Questions?