Health Canada Santé Canada

Canada

Access Pathways for Novel Therapies

Health Canada

ISCT 2018

YOUR HEALTH AND SAFETY... OUR PRIORITY.

Legislative and Regulatory Authorities

- *Food and Drugs Act* provides overall legislative framework
- Specific detailed regulatory frameworks in place for:
  - Blood
  - Cosmetics
  - Drugs (prescription, including biologics and non-prescription)
  - Medical devices
  - Cells, tissues and organs for transplantation
  - Natural health products
- Additional policy direction provided in guidance documents
- Guidance available from the regulator

Regulatory Pathways to Drug Access -1

- **Pre-CTA Meetings (and Pre-pre CTA meetings)**
  - Opportunity to seek regulatory advice for CTA
- **Clinical trial application (CTA)**
  - Phase I, II, III trials to be conducted in Canada
  - 30 day default review
- **Pre-submission meetings**
  - Currently most commonly held late in development
  - Familiarize reviewers with data package
  - Some end of Phase II meetings used to seek advice on development plan
  - Opportunity to seek regulatory advice for submission content and pathway

Regulatory Pathways to Drug Access -2

- **New Drug Submission**
  - Target review time – 300 days, focus of review: safety, efficacy, quality
  - Complete data package
  - No rolling submission of data, other than new safety data

- **Supplementary New Drug Submission**
  - Most commonly used to add new indications to an approved drug
  - May be clinical data only
  - Target review time - 300 days

Regulatory Pathways to Drug Access -3

- **Priority review policy**
  - Unmet medical need, serious, life-threatening or severely debilitating disease
  - Requirement for “substantial” evidence of effectiveness
  - Target review time – 180 days

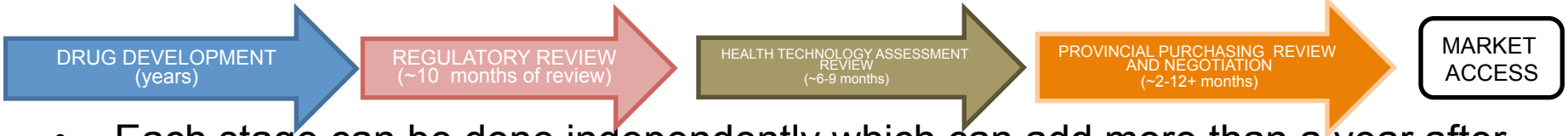
- **Notice of Compliance with Conditions policy**
  - Unmet medical need, serious, life-threatening or severely debilitating disease
  - “Promising” evidence of effectiveness
  - Target review time – 200 days
  - Manufacturer agrees to conduct **confirmatory studies**

Post-market authorities

- Required reporting from manufacturers:
  - Serious Canadian adverse drug reactions
  - Serious unexpected adverse drug reactions
  - Most submitted electronically, data mining project for signal detection in development
- Annual summary reports (PSURs/PBRERs) – required to be developed, submitted upon demand
- Ability to request analysis of a safety issue, submission of case reports
- Ability to require label change or package modification – if necessary to prevent injury to health

Beyond Regulatory Approvals

- Federal regulatory role vs provincial health care delivery role
- After Health Canada approvals:
  - Health technology assessment (clinical and cost effectiveness)
    - Canadian Agency for Drugs and Technologies in Health
    - Institut national d'excellence en santé et en services sociaux
  - Reimbursement decisions
    - Provincial purchasing negotiations (Pan-Canadian Pharmaceutical Alliance) and payment reviews
    - Private drug plans



- Each stage can be done independently which can add more than a year after authorization before a drug is available in provinces and reimbursed by public drug plans

Health Canada's Plan for Transformation – Regulatory Review

- **Objective: An agile regulatory system that supports better access to therapeutic products based on healthcare system needs**

Expanded collaboration with health partners

•Alignment of the Health Technology Assessment (CADTH) Review with Health Canada Review

•Implementing a Mechanism for Early Parallel Scientific Advice

•Use of Foreign Reviews/ Decisions

•International Collaboration and Work Sharing in Reviews

More timely access to drugs and devices

- Expansion of Priority Review Pathways
- Improving Access to Biosimilars and Biologics
- Improving Access to Generic Drugs
- Building Better Access to Digital Health Technologies
- Pre-Submission Scientific Advice for Medical Devices
- Special Access Programme (SAP) Renewal

Enhanced Use of real world evidence

•Leveraging Data for Assessing Drug Safety and Effectiveness

•Strengthening the use of real world evidence and regulations for medical devices

Modern and flexible operations

Updated System Infrastructure

Appropriate cost recovery framework

Public Release of Clinical Information

Selected Projects supporting improved access

Alignment of the Health Technology Assessment (HTA) Review with the Health Canada Review

Alignment of HTA and HC review to:

•Share information between organizations

•Reduce overall time to completion of these two steps along the drug access chain (Maximum time saved could be up to 6 months from current timelines)

- Note – process is submission-driven, and relies on sponsor opt-in

Progress to date:

•Successful pilot project with oncology pharmaceutical products

•Significant industry interest in participating

•Expanding now to include biologics and make a part of standard business

Early Parallel Scientific Advice

Providing technical advice early in drug development to:

•Support manufacturers in developing clinical trial programs that meet the needs of the regulator and HTA organization

Progress to date:

•HC and CADTH attending meetings to understand processes

•Early consultations with external stakeholders (industry, healthcare professional associations, academics, healthcare professionals and patients)

•Policy development in progress

Expansion of Priority Review Pathways

Evaluating the criteria used to prioritize rapid reviews to:

- Consider health care system needs
- Other considerations?

Progress to date:

- Initial consultations held to scope out possible priority review criteria
- Targeted consultation ongoing to gather more information on prioritization criteria and possible process for identifying system needs

Expected outcomes of regulatory review

- Enhanced predictability and flexibility of the therapeutic product review system
- Faster access to therapeutic products that better respond to the needs of the health care system
  - Early engagement with industry
  - More agile pathways to market
- Greater alignment and collaboration with other players in the drug access chain throughout the product lifecycle
- Enhanced post-market monitoring of therapeutic products

Thank you

Regulatory Review Communications- Webpage and Consultations

- Dedicated webpage includes project summaries, timelines and upcoming opportunities for consultation

- Webpage is being updated regularly, providing a single point of contact for the initiative

https://www.canada.ca/en/health-canada/corporate/transparency/regulatory-transparency-and-openness/improving-review-drugs-devices.html

- Guidance for Industry: Management of Drug Submissions https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/management-drug-submissions/industry.html

- Guidance for Industry - Priority Review of Drug Submissions https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/priority-review/drug-submissions.html

- Guidance Document: Notice of Compliance with Conditions (NOC/c) https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/notice-compliance-conditions.html

Guidance Document: Preparation of Clinical Trial Applications for use of Cell Therapy Products in Humans

http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/clini/cell-therapy-therapie-cellulaire-eng.php

Guidance Document For Clinical Trial Sponsors: Clinical Trial Applications

http://hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/clini/ctdcta_ctddec-eng.php

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