

Overview of the Federal Landscape



HIV/AIDS Treatment Access Advocacy Workshop Series



Canadian Treatment Action Council



Conseil canadien de surveillance et d'accès aux traitements

Workshop Overview

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1. Introductions
2. What is the federal government's role in access to treatment?
 - What federal bodies play a role?
 - How do their activities affect access?
3. What do you expect to learn?
4. Evaluation: Did we meet your expectations?



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What is the federal government's role in access to treatment?

What are the federal government's **exclusive** roles?

What roles do they **share** with provincial and territorial governments?



What are the federal government's 4 exclusive roles?

Review for approval

Access to drugs not available in Canada

Regulation

Monitoring of pricing

Real world safety and effectiveness

Funding research



*What role does the federal government
share with the provinces and territories?*

Common Drug Review



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The Federal government's exclusive roles



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*What are the federal government's **exclusive** roles?*

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Review for approval

Pharmaceutical drugs

- Patented
- Generic
- Over-the-Counter (OTC)



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Federal Activities

Review for approval of New Pharmaceutical Drugs

Where?

Therapeutics Products Directorate (TPD), Health
Canada



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Federal Activities

Impact on Access:

- Availability of drugs for sale in Canada
- The length of time required to approve new drugs



*What are the federal
government's **exclusive** roles?*

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Review for approval

Medical Devices



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Federal Activities

Review for approval of new medical devices

Where?

Medical Devices Bureau, Therapeutics Products Directorate (TPD), Health Canada



Federal Activities

Impact on Access

- Availability of medical devices for sale in Canada
 - The length of time required to approve new medical devices



*What are the federal
government's **exclusive** roles?*

Review for approval

Biologics and genetic therapies



Federal Activities

Review for approval of New Biologics and Genetic Therapies

Where?

Biologics and Genetic Therapies Directorate
(BGTD), Health Canada



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Federal Activities

Impact on Access:

Few (if any) HIV/AIDS-related medications have been submitted to the BGTD in the past



*What are the federal
government's **exclusive** roles?*

Review for approval

Natural Health Products



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Federal Activities

Review for approval of Natural Health Products

Where?

Natural Health Products Directorate (NHPD),
Health Canada



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Federal Activities

Impact on Access:

Authorization of products for sale in
Canada



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*What are the federal
government's **exclusive**
roles?*

Access to drugs not available in Canada



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Federal Activities

Special Access Programme (SAP)

Where?

Under the Therapeutics Products Directorate
(TPD), Health Products and Food Branch,
Health Canada



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Federal Activities

Impact on Access:

Access to a promising but still experimental drug that has not been approved for sale in Canada.



*What are the federal
government's **exclusive** roles?*

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Monitoring of Pricing



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Federal Activities

Monitoring of Pricing of Patented Medicines

Where?

Patented Medicine Prices Review Board
(PMPRB), Industry Canada



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Federal Activities

Impact on Access:

- Monitor initial price set by company
 - Monitor price increases
- Provide information to consumers



*What are the federal government's **exclusive** roles?*

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Real World Safety and Effectiveness (Post-Approval Surveillance)



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Federal Activities

Real World Safety and Effectiveness (Post-Approval Surveillance)

Where?

Marketed Health Products Directorate (MHPD)



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Federal Activities

Impact on Access:

- Remove drugs from the market if there are serious concerns about safety, efficacy or quality
 - Provide information to consumers



Federal Activities

Federally Funded Research

Where?

Canadian Institutes for Health Research (CIHR)



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Federal Activities

Impact on Access:

Improves our knowledge of HIV and leads to the development of medications to fight the disease.



What are the federal government's ³⁰ exclusive roles?

The federal government is also responsible for delivering health care to:

- First Nations and Inuit
- Military personnel and veterans
 - Prisoners
 - RCMP
- Refugee claimants



What are the federal government's exclusive roles?

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Review for approval

Access to drugs not available in Canada

Regulation

Monitoring of pricing

Real world safety and effectiveness

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Contact us:

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