

IMPACT OF FEDERAL PRIORITIES ON REGULATORY POLICY

CAPRA Education Day

June 16, 2016

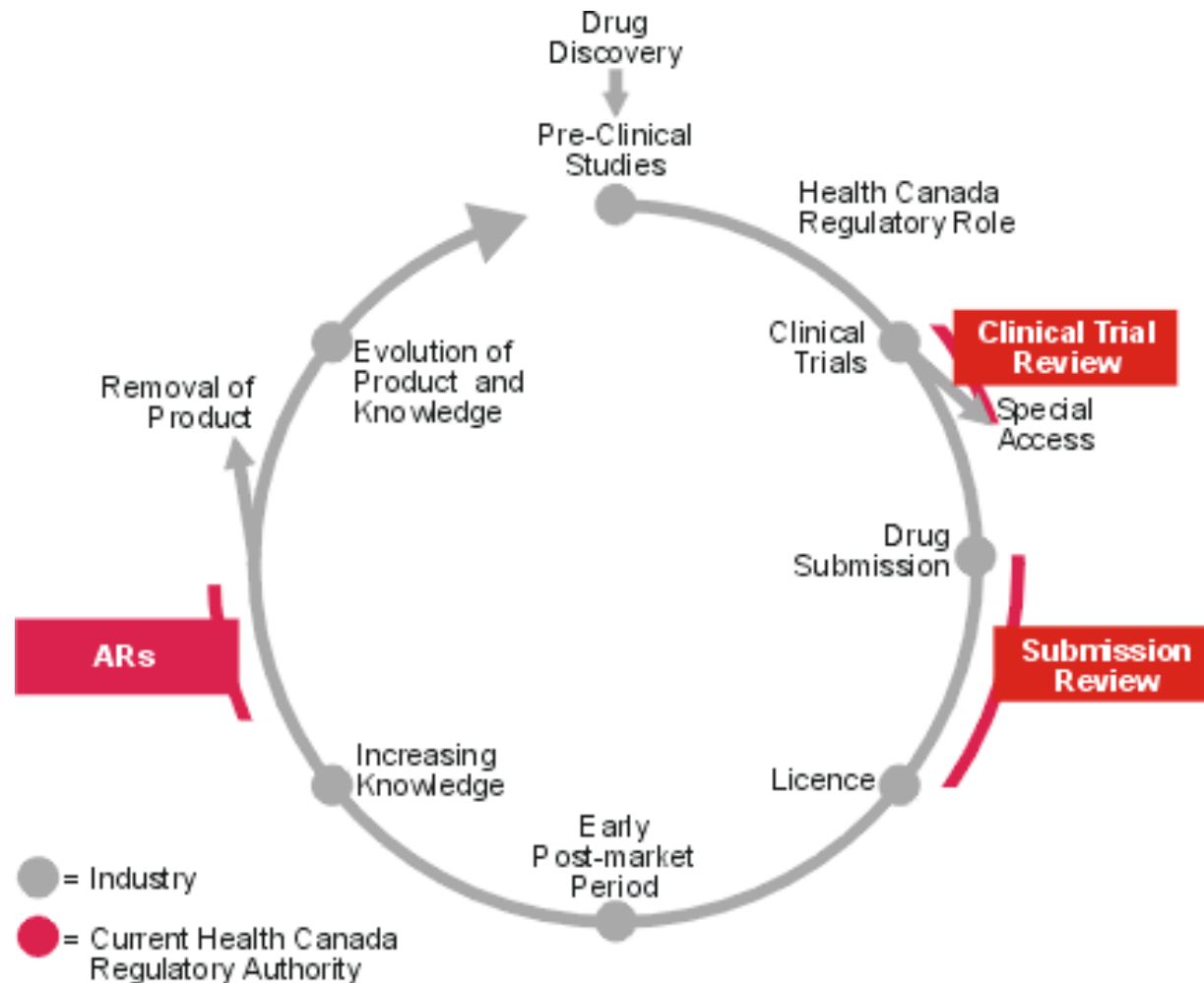
Toronto, ON

OBJECTIVE

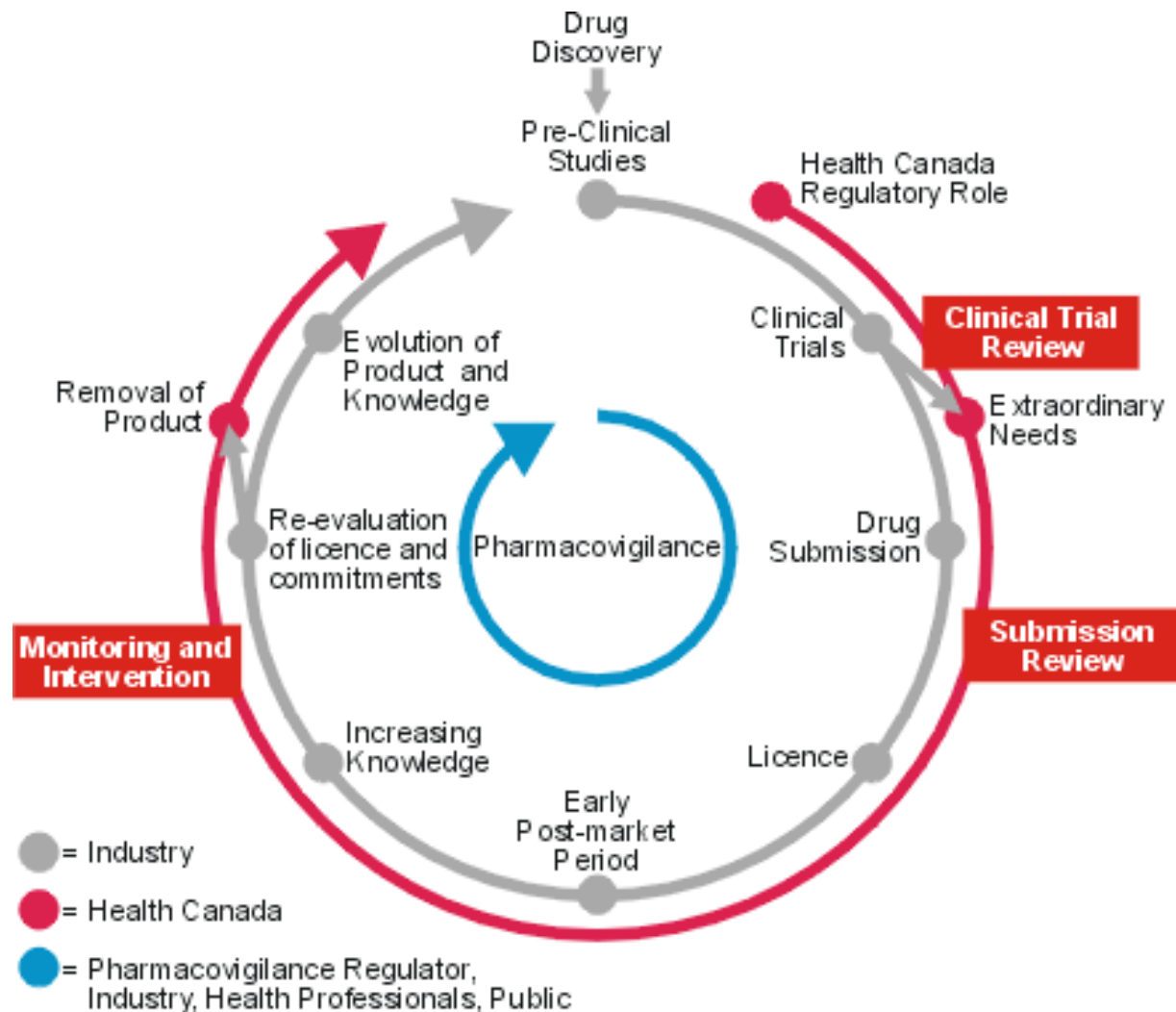


Understand the impact of federal priorities on regulatory policy as the approach to regulating health products increasingly focuses on post-market monitoring and intervention.

Regulatory Reform



Regulatory Reform



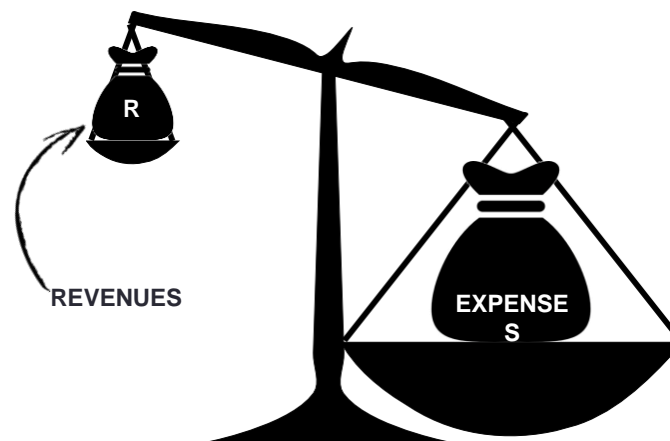
Broader context



Canadian election 2015 hands Justin Trudeau and the Liberals a majority government **NATIONAL POST** Oct. 20, 2015

Dr. Jane Philpott Appointed as
Canada's New Health Minister

Nov. 4, 2015



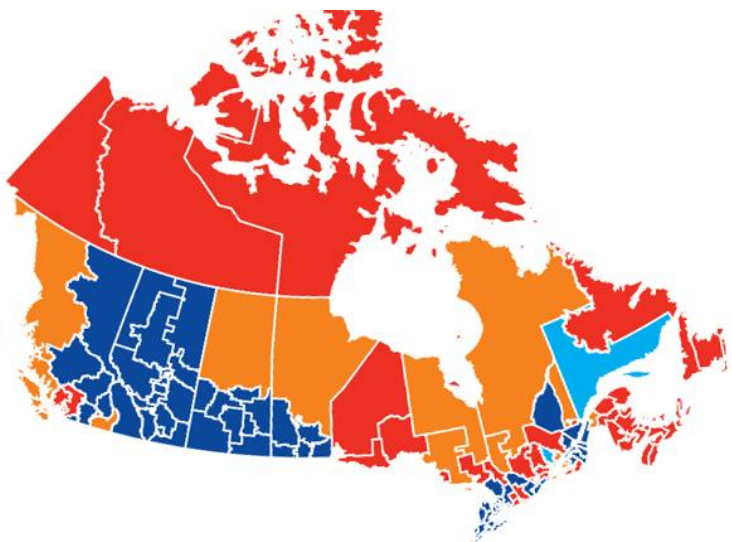
Election promises...

- **Engagement with provinces** and renew health accord
- Address the **affordability of Rx medicines**
- “Immediate commitment:” \$3 billion over 4 years for **home care**
- High quality **mental health** services
- A “pan-Canadian collaboration on **health innovation**”
- New “**innovation agenda**” - \$200M per year
- Modest, short-term **deficits** < \$10B per year for two years



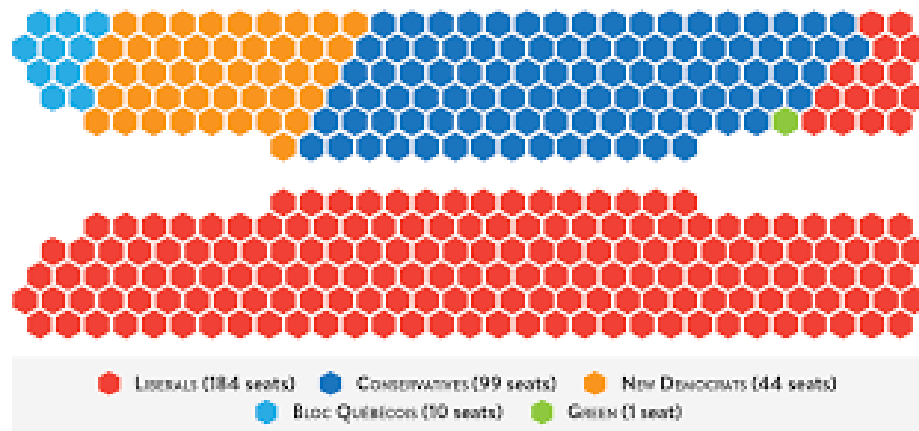
Strong majority - representation from every province

LPC	CPC	NDP	BQ	GREEN
183	98	44	10	1



PARLIAMENT BREAKDOWN

Source: Elections Canada / Graphs by Pierre A. Lapointe



1 seat is currently vacant

1 seat is currently represented by an independent MP

New cabinet and mandate letters

To Health Minister Philpott:

Office of the
Prime Minister



Cabinet du
Premier ministre

- “I expect you to work with provincial and territorial governments to support them in their efforts to make home care more available, prescription drugs more affordable, and mental health care more accessible.”
- Development of a multi-year Health Accord: home care, digital health technology, mental health and bulk purchasing / exploring national formulary
- Public health: vaccination, healthy food, concussion awareness



Health Minister Jane Philpott 'anxious' to sign new health accord by year's end **CBCnews** | Politics Apr 16, 2016

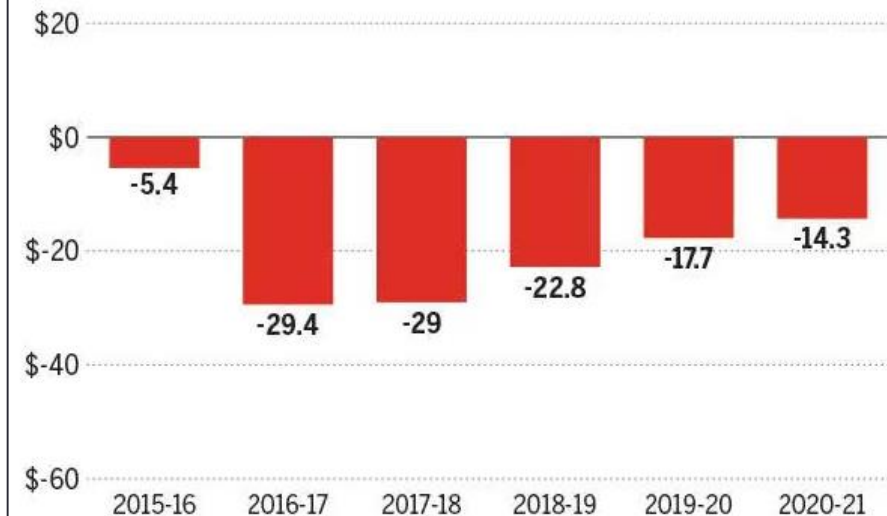
2016-17 budget – March 22

- \$29.4 billion deficit for 2016-17
- Deficits until at least 2020-21
- Focus on debt to GDP ratio

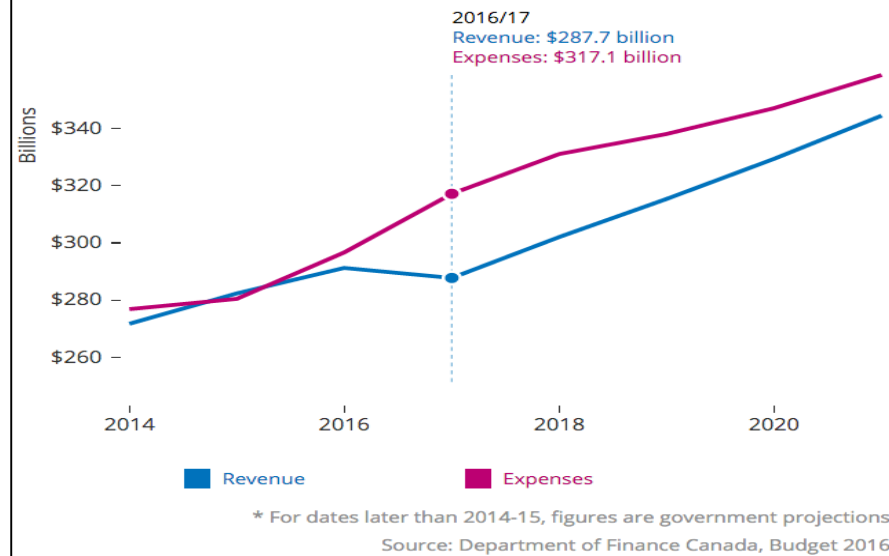


PROJECTED BUDGET DEFICITS

BY FISCAL YEAR, IN BILLIONS OF DOLLARS

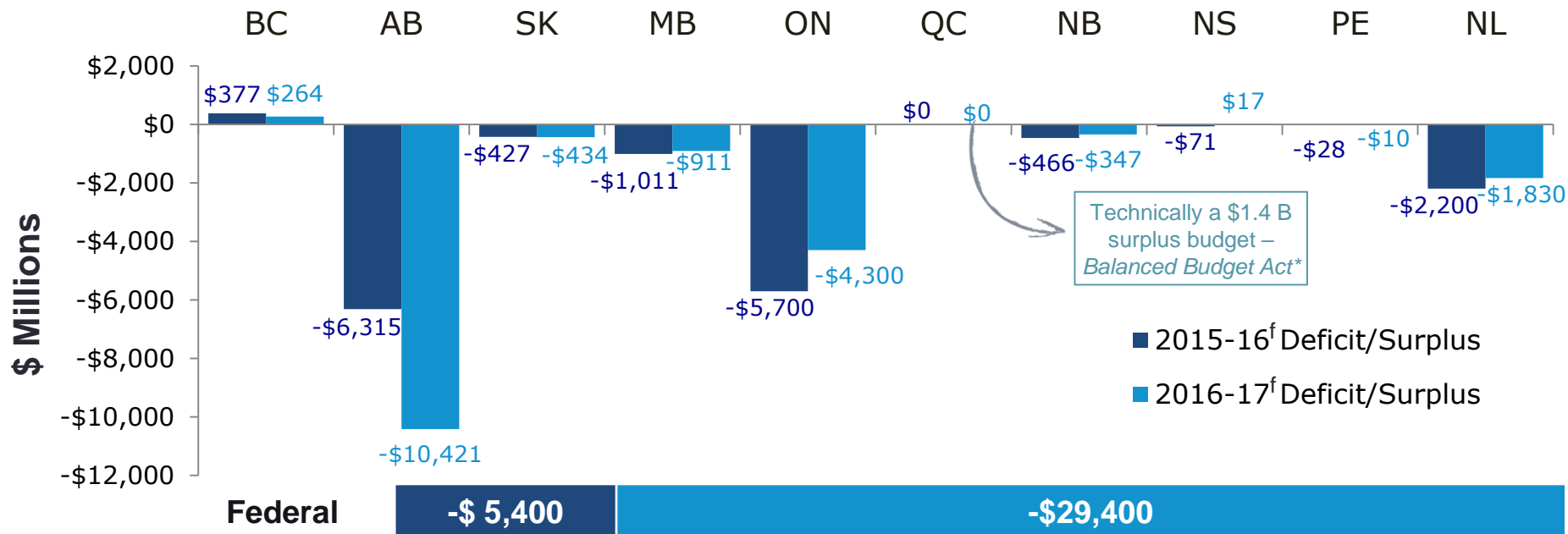


Projected government revenue and expenditures (2013/14 to 2020/21)



Canadian Fiscal Realities

Government Budget Balance: 2015-16^f vs. 2016-17^f (\$ Millions)



2016-2017^f Government Debt

	FED	BC	AB	SK	MB	ON	QC	NB	NS	PE	NL
Debt (C\$ billions)	648.7	42.2	10.0	9.1	23.1	308.3	188.6	13.5	15.2	2.2	14.7

^f Forecast

* *Balanced Budget Act** in QC stipulates that the government can redirect money that would normally go into the “general fund” into the “Generations Fund” which is used to repay the gross debt.

Source: Government budget documents & RBC Economics – Canadian Federal and Provincial Fiscal Tables (Jun. 1, 2016)

Federal Priorities



Health
Canada

Santé
Canada

Organizational priorities

- Health Accord negotiations
 - Better access to home care access
 - Innovative practices to improve patient / health outcomes
 - Improved access to affordable prescription drugs
 - Better access to high-quality mental health services
- Indigenous health and wellness
- Health promotion / illness prevention
 - Restricting marketing to children: “unhealthy” food and drinks
 - Eliminating trans fats, cut sodium in processed foods, improve food labels

Federal Priorities



Health
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Santé
Canada

Regulatory priorities (RPP 2016-17)

- New authorities under Bill C-17
- Implement Regulatory Transparency and Openness framework and Action Plan (March 2018)
- Change food safety and nutrition policy - e.g., sodium / trans fats (March 2017)
- Pesticide regulations re cost recovery
- Implementing plain packaging for tobacco (TBD)
 - May 31: World No Tobacco Day – announcement
- Supporting:
 - Regulation and legalization of marijuana by Minister of Justice (Regulatory approach: Spring 2017)

Federal Priorities



Health
Canada

Santé
Canada

Health Products and Food Branch (HPFB) priorities

- **Pharmaceutical Drugs**
 - Stewardship of antimicrobials in animals
- **Biologics and Radiopharmaceuticals:**
 - Regulatory guidance on emerging technologies – personalized medicines & cellular therapy
- **Medical Devices**
 - Continued alignment with international regulators re MD applications
 - Develop and implement Medical Device Single Audit Program
- **NHPs / Cosmetics / Non-Rx drugs / Consumer drugs & health products**
 - Develop new approach for “consistent and aligned regulation”
- **Substance Use and Abuse**
 - Prescription drug abuse

Federal Priorities



Health
Canada

Santé
Canada

Forward Regulatory Plan 2016-18

Amendments to Food and Drug Regulations

- Antimicrobial resistance to vet drugs
- Commercial compounding
- DIN requirements for radiopharmaceuticals
- Mandatory drug shortage reporting
- Therapeutic products
 - Terms and conditions
 - Mandatory Label Change
 - Foreign Risk Communications
 - Tests and Studies
 - Reassessment
 - Recalls
- Consumer Health Products Framework
- Orphan Drugs for Rare Diseases

Amendments to Controlled Drugs and Substances Act

- Changes to Schedules
- Licences and permits

Canada Gazette



Contextual issues for HPFB

- Intergovernmental collaboration
 - Health Accord
 - FPT First Ministers: Canada's Premiers
 - Health Care Innovation Working Group
 - pCPA
 - FPT Health Ministers
- Orphan drugs
- Closer collaboration with HTA (CADTH)
 - Adaptive licensing / reimbursement
- Affordability / national pharmacare
- DSEN

Health Minister Jane Philpott says the new Health Accord will be a 'fundamental change.'  THE HILL TIMES



CADTH

Key Themes

- Liberal government still getting its sea legs
 - Consultation mode
- Fiscal challenges
 - Diverse priorities
 - Could impact timelines of LRM
- Dynamic health and life sciences policy environment
- Role of regulatory experts evolving





DISCUSSION

Thank you!

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