

DRUG SAFETY AND EFFECTIVENESS NETWORK

The View from the Pharmaceuticals Industry

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About 3Sixty Public Affairs

- Who we are:
 - Political and policy experts
 - Subject matter expertise on health / pharma issues and products
 - Research and analysis
 - Strategy PLUS implementation
 - Network in provincial capitals
- Disclosure:
 - Not presenting on behalf of or under contract with a manufacturer
 - Current and past clients include many of the innovative pharmaceutical manufacturers

Drug Safety and Effectiveness Network

1. Environmental Shifts
2. Global and Canadian Pharmacovigilance
3. Industry's Value(s) and Role in DSEN





ENVIRONMENTAL SHIFTS

Environmental Shifts

Pipeline Changes - Specialty Drugs

- Post-patent cliff
- Biologics and precision-medicine

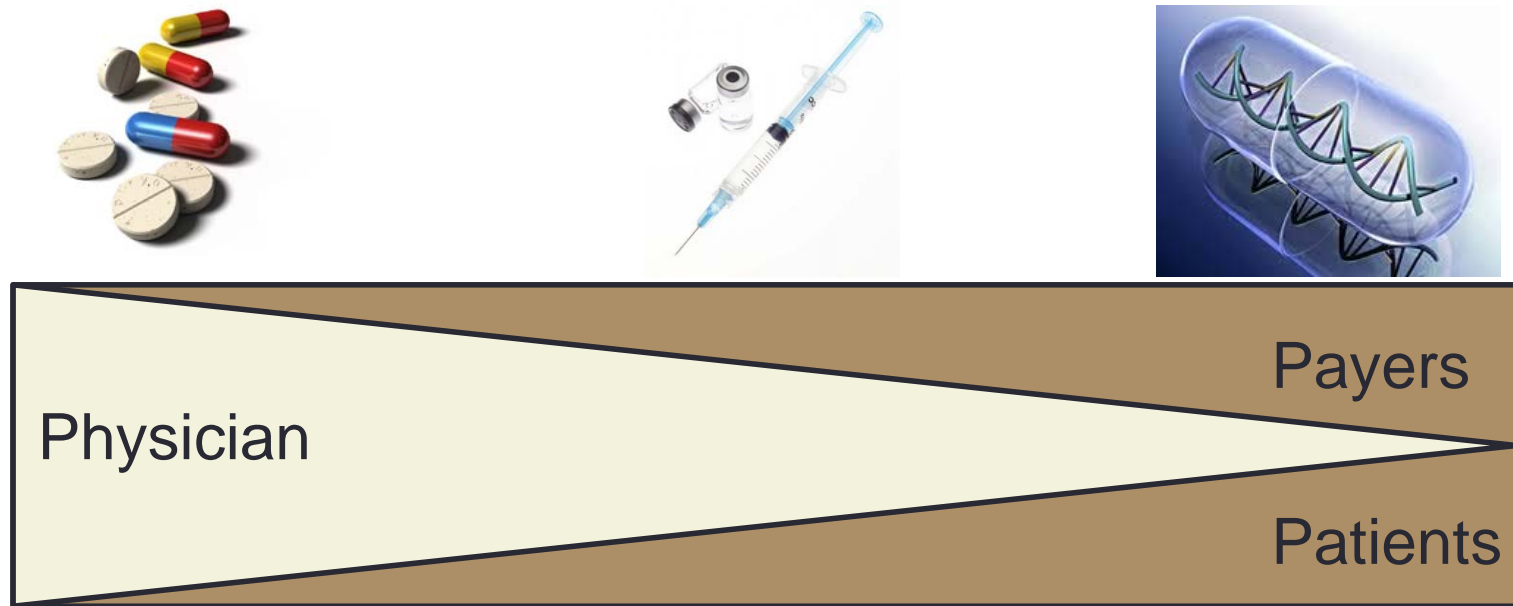
Challenging Regulatory and Payer Environment

- Heightened safety focus
- Challenging fiscal environment

Information and Communication Technology

- Patients Like Me
- Big Data and Web 3.0

Environment / Market Impacting Pharma



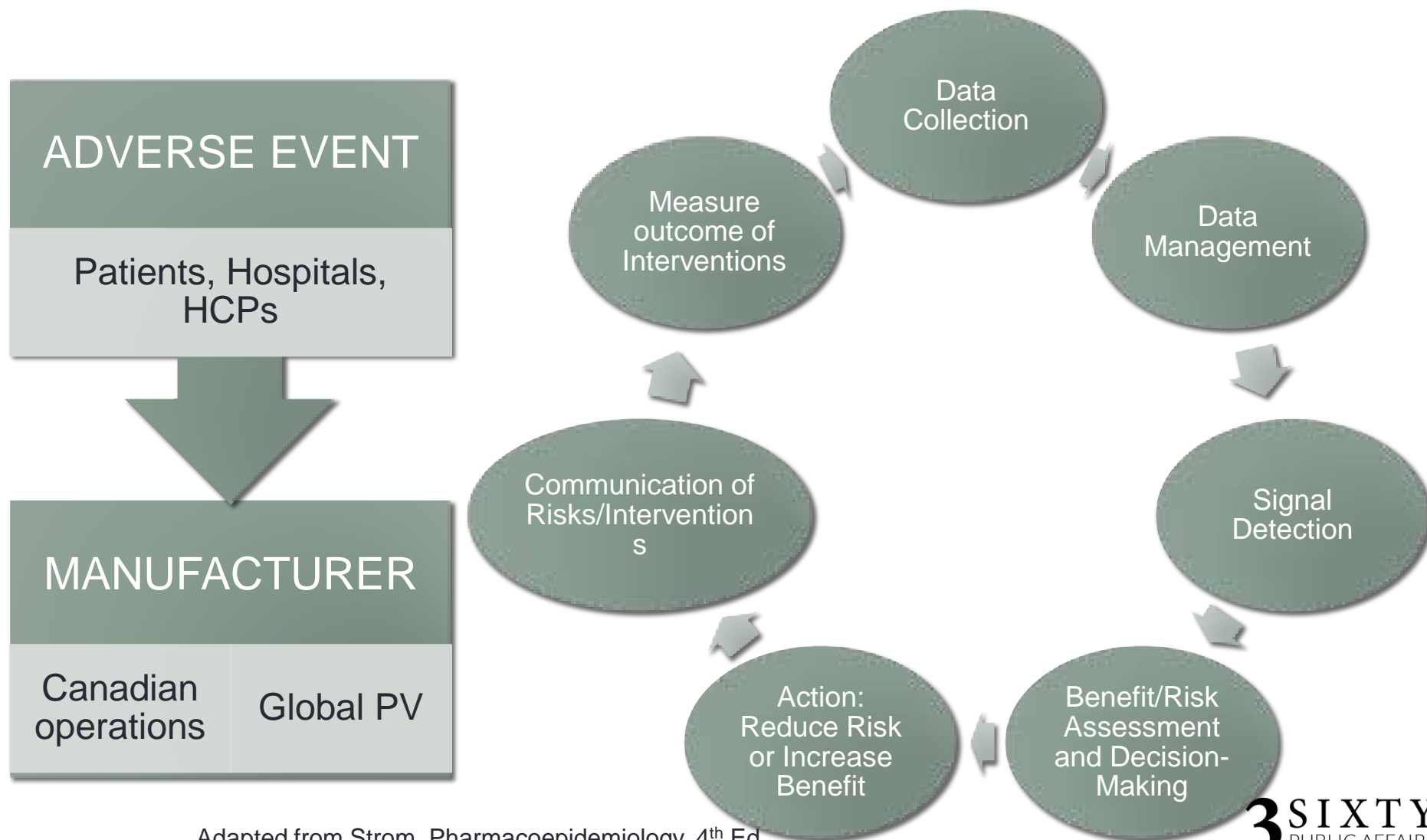
Adapted from Ernst & Young's Pharma 3.0 Analysis

- Number of industry stakeholders expanding
- Constant collaboration, dialogue, feedback



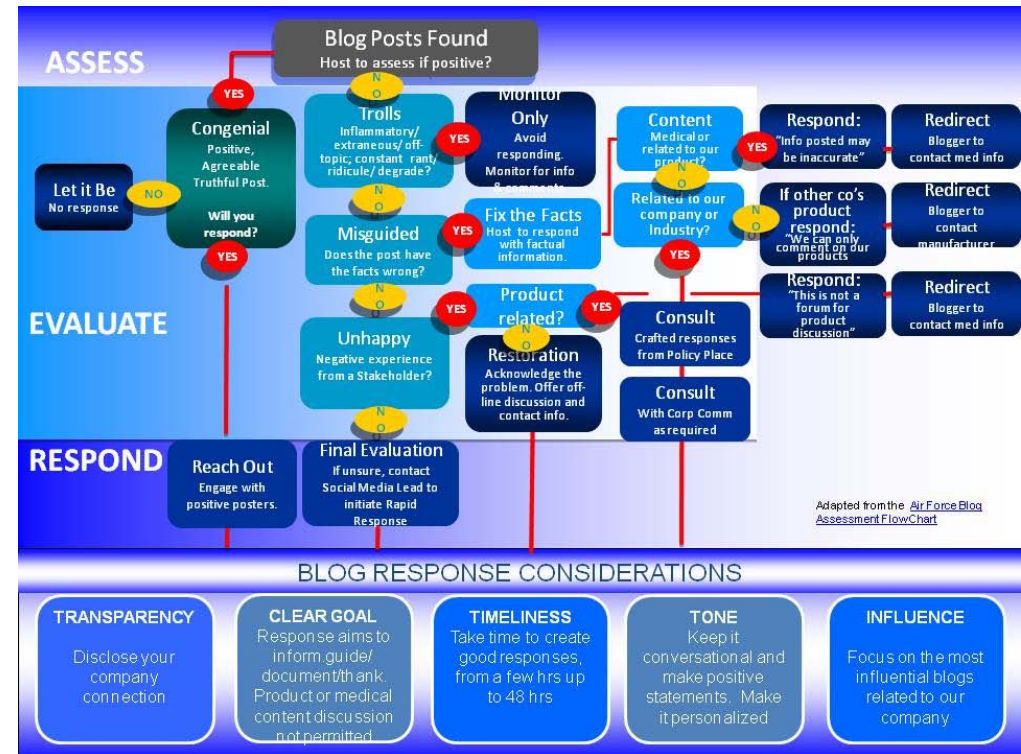
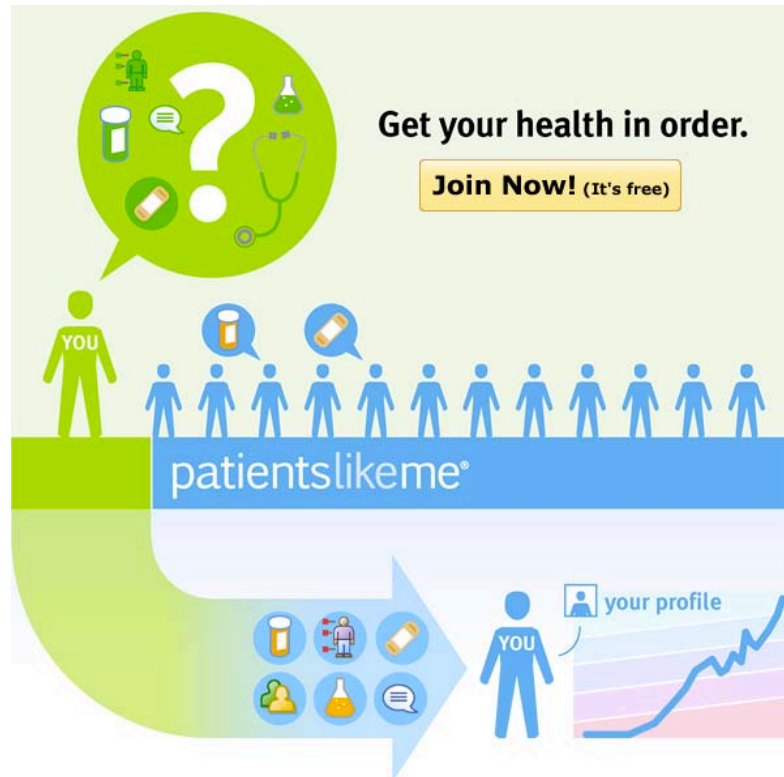
GLOBAL AND CANADIAN VIGILANCE – ROLE

Pharmacovigilance Process



Adapted from Strom, Pharmacoepidemiology, 4th Ed.

Consumer / Patient Power and ICT



Pfizer Canada; <http://marketing4health.ca/wp-content/uploads/2011/01/pfizer-social-media-response-guard-rails-dec-10-2.jpg>

Drug Safety Tools for Consumers

iPhone App

We've developed Canada's first and only app that will help you keep track of your medicine and health related information easily and accurately. Use it to record medicines that you and your family members are taking. Use it to remind you to take your medicines on time. All information stored within the app can only be accessed by yourself and those you wish to share it with. Bring this app with you to all of your medical related appointments. This will ensure that your healthcare providers have the necessary information to make the best decisions regarding your health.



Download App



Features:



Medication/Immunization Record

Up-to-date medication list with you at all times



Multiple Patient Profiles

Easy access to your and your loved one's health information



Dose/Refill Reminder

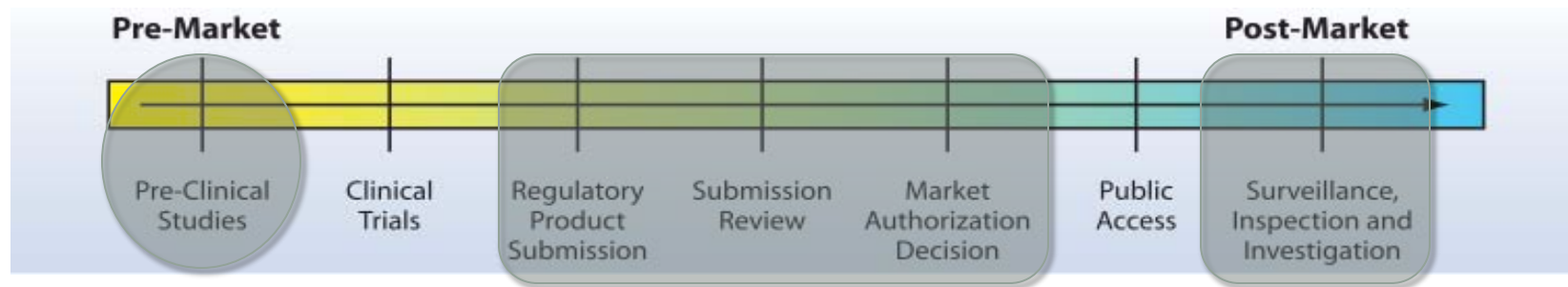
Reminds you to take your medications on time and when they need to be refilled



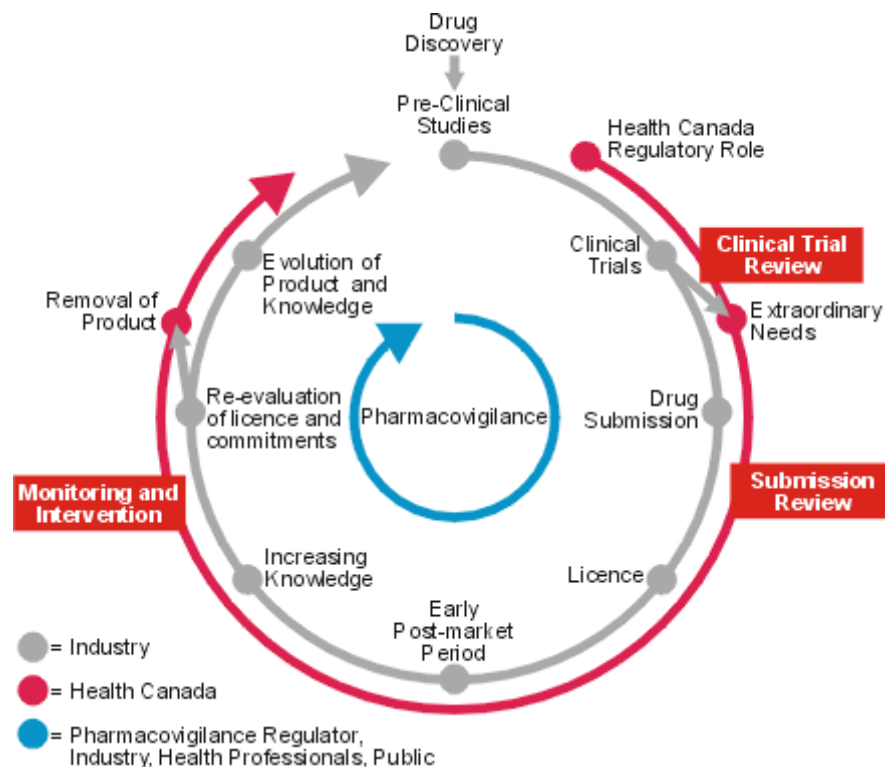
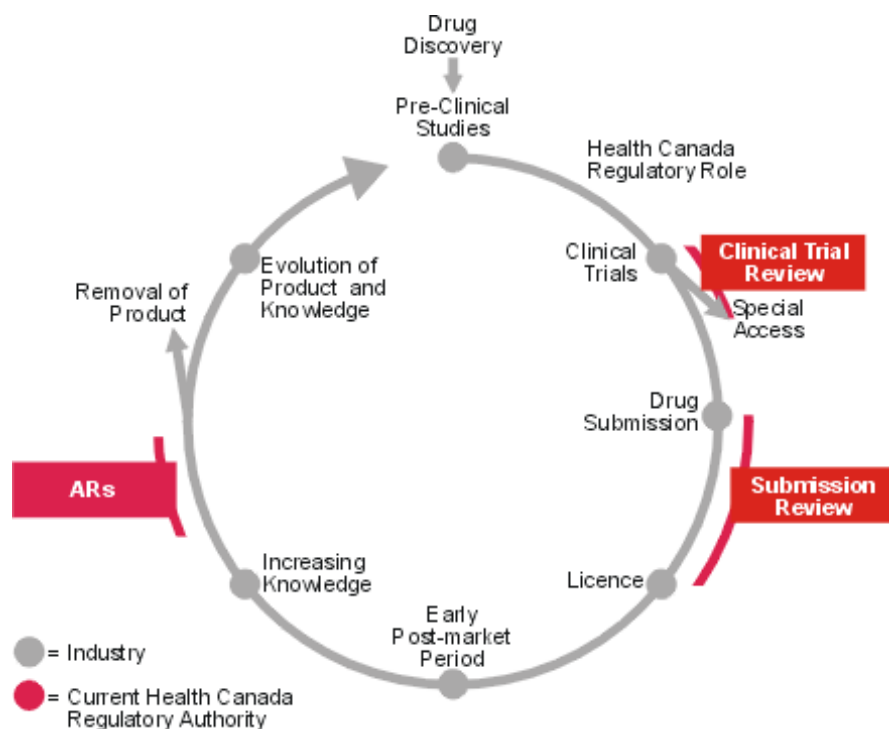
Email Information

Keep your healthcare team, family etc. up-to-date by sending them information directly

Government's Evolving Approach

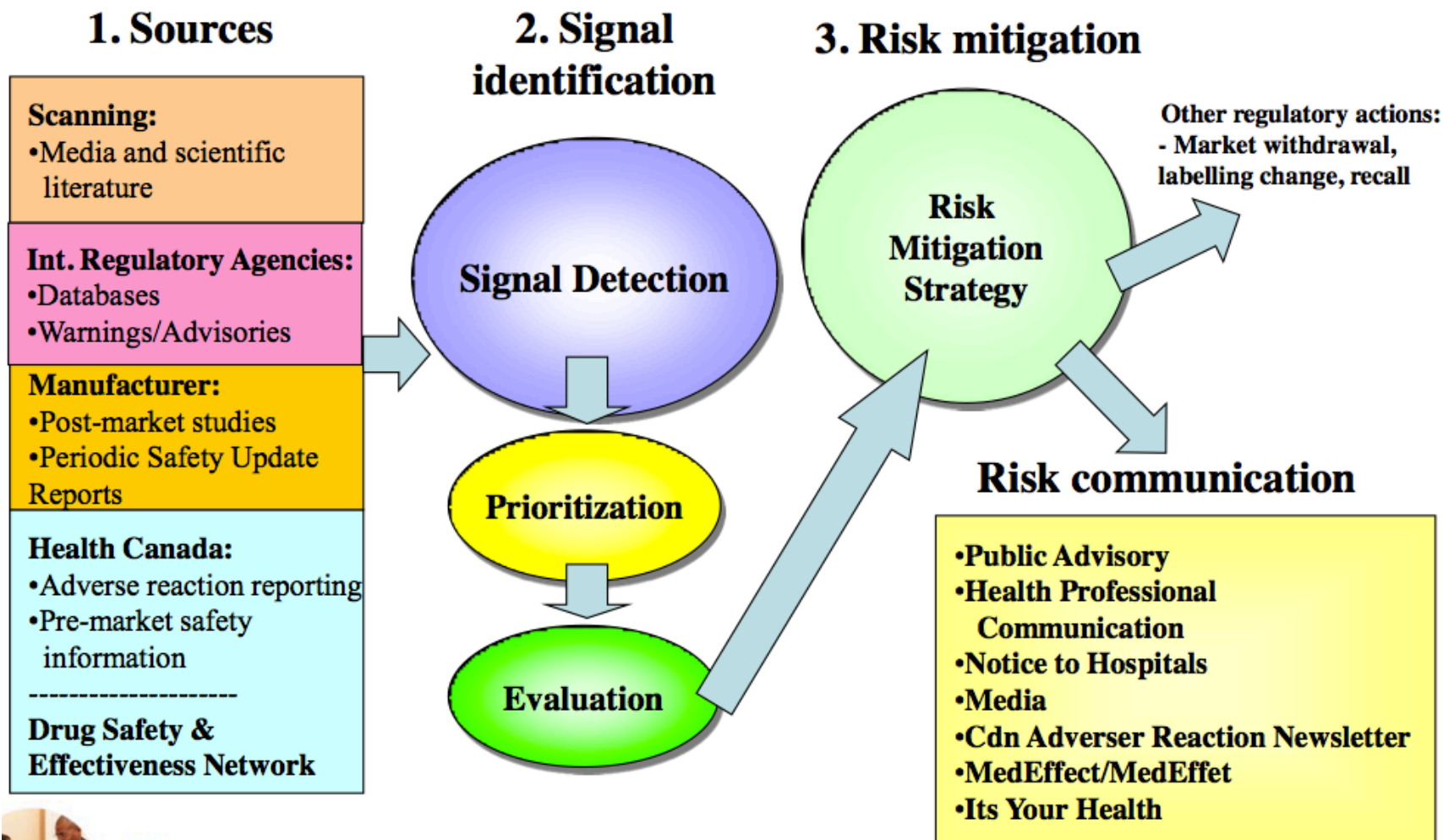


Government's Evolving Approach



Government's Evolving Approach

Health Product Vigilance Process Overview



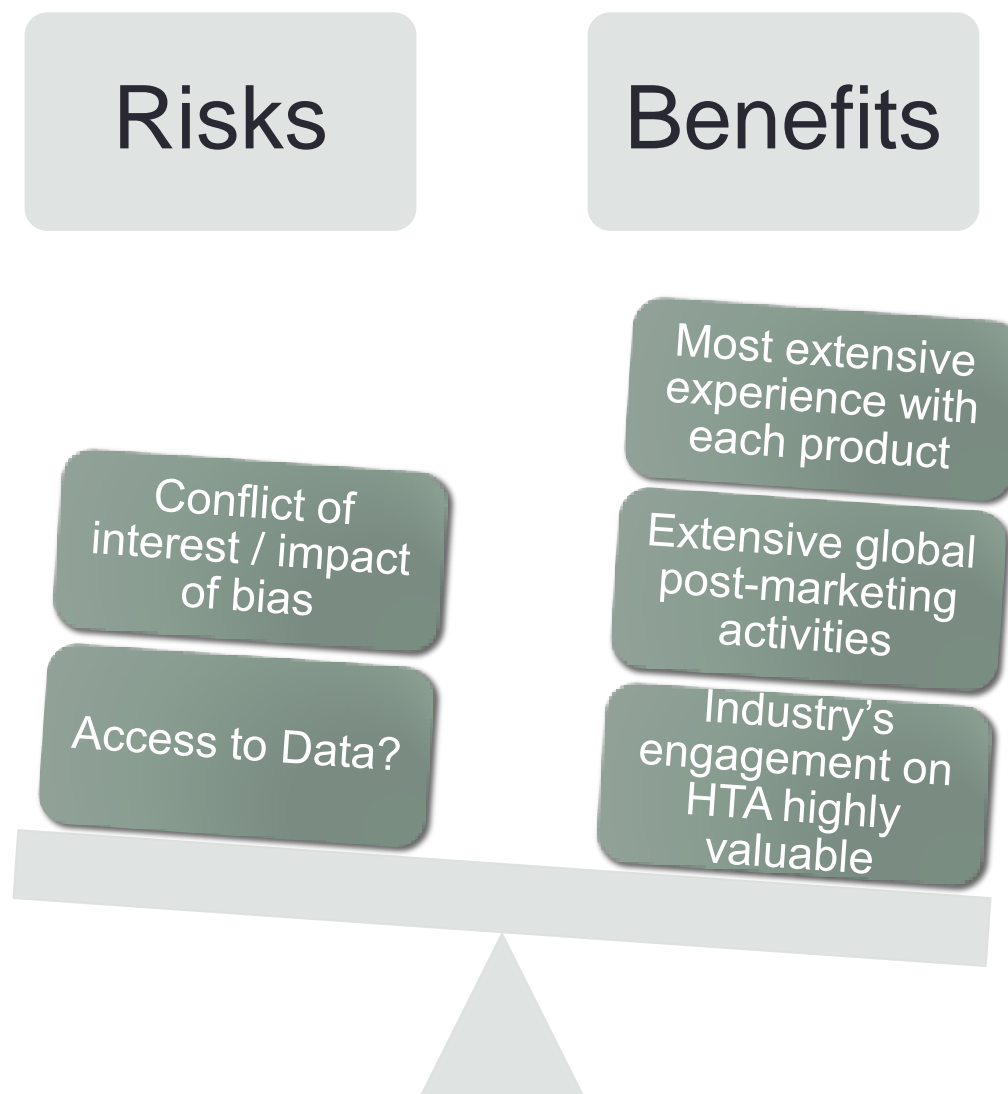
Industry's "Shared Responsibility"

- Health Canada Draft Health Product Vigilance Framework
 - **Responsibility:** "The maintenance and improvement of health and safety is understood to be a **shared responsibility**."
 - **Stakeholders:** "In addition to government and regulated industry, health professionals, patients, consumers and their respective associations play an important role in reporting health product safety related issues."
 - **Shifting focus:** "Health Canada is shifting its focus in the direction of encouraging and monitoring industry's good product vigilance practices reflecting the fact that industry is responsible for the safety and efficacy of their products."
 - **Health Canada's role:** "At the same time, Canadians expect Health Canada to be involved in minimizing the risks associated with these products."
 - **Need:** As a result, there is a need for a robust yet transparent product vigilance system that will **seek the appropriate level of involvement from the participants and stakeholders in the system.**



INDUSTRY'S VALUE(S) AND ROLE IN DSEN

Risk/Benefit Assessment of Industry's Role



Discussion

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