Opportunities, challenges and learnings in running a Code

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Rx&D: Who We Are

• The voice for the pharmaceutical industry in Canada since 1914

Mission

Advocate for policies that bring the best innovative medicines & vaccines to Canadians in a timely and appropriate manner.

Improve Canada’s global competitiveness.

Make Canada a world leader in attracting pharmaceutical and biotechnology investments, which are key components of the knowledge-based economy.
Opportunities-Challenges-Learning’s
Rx&D’ s Code of Ethical Practices

Get to know your Code
2012 Code of Ethical Practices

The Code is the foundation for relationships with the healthcare community and our stakeholders.

This Code encompasses all member companies and their employees.

Rx&D has updated the Code of Ethical Practices. The updated Code will be in effect on March 31, 2012.
Why was a Code created in 1988?

- Established in 1988 -Marketing Practices Task Force Headed by the former PMAC Director Leon Jacobs (Ciba-Geigy)

  *In the words of the Chairman Leon Jacobs:*

  “The marketing practices of the industry are under attack both nationally and internationally. It is therefore imperative that we demonstrate to all segments of our publics, a responsible attitude in every aspect of our marketing practices.”
The Code – 25 Years Later

• Promotes Reputation and Builds Trust

• Demonstrates the value and builds the reputation of the industry with key stakeholders

• A Code helps us communicate the high standards we set ourselves as an industry
Scope of the Code

2010 Code:
• Largely applied to relationships between sales representatives and Health Care Professionals (HCPs)

Revised Code:
• To expand the Code to include interactions with many different stakeholders and all member employees
Applies to ALL Member Employees
Many Stakeholders

- Nurses
- Government officials
- Doctors
- Pharmacists
- Hospital Administrators
1. The health and well-being of patients and all Canadians is our first priority.
2. All interactions with Stakeholders are to be conducted in a professional and ethical manner. We must be cognizant of potential conflicts of interest and manage them appropriately.
3. All interactions shall be in accordance with all applicable laws and regulations.
4. We must adhere to the Code in both the spirit and the letter and, as such, we must ensure that all relevant Member Employees and agents acting on our behalf are appropriately trained in the requirements of the Code and abide by it.
5. We are committed to engaging in relationships that are trustworthy and credible.
6. All clinical (phase I to IV) trials and scientific research sponsored or supported by Members will be conducted with the intent to develop knowledge that will benefit Canadians and advancement of science and medicine. We support transparency in the presentation of research and study results.
7. We will ensure that Canadian Stakeholders have access to education and information about the appropriate uses of our products and services. All product information provided to Stakeholders must be accurate and fair balanced.
8. We will not give or offer any payments or inducements that are either unlawful or improper, directly or indirectly, to any individual stakeholder.
Complaints Procedure

Complaint to Rx&D Canada’s Research–Based Pharmaceutical Companies

Industry Practices Review Committee

Complainant Advised of Ruling

- Accepted
- Appealed

Respondent Advised of Ruling

- Appealed
- Accepted

Appeal Board
Infraction published in Rx&D Update and on website

- Member is placed on a 12-month probationary period for 5 or more infractions/year or 3 or more/year for 2 years
- Infractions during probation period may result in expulsion

CEO appears before the Board of Directors to explain infractions and provide a comprehensive written action plan to ensure remediation.
Awareness and Outreach

• Broaden awareness and leverage support for the Code

• Take the opportunity to help spread the message about the Rx&D Code

• Ensure that Stakeholders are aware of our Code, its benefits, and the high standards to which members of Rx&D hold themselves and their employees.
eLearning:

- Rx&D is proud to issue an integrated learning module to aid in the dissemination and training of employees and stakeholders on the revised Code.

- Companies, stakeholders and individuals interested in taking this e-learning Course can contact Rx&D directly for more information.
Rx&D’s Global Participation
International Federation of Pharmaceutical Manufacturers & Associations (IFPMA)
A Code of Practice

A Code is

• A model of self-regulation

• IFPMA Code: a condition of membership to the IFPMA

The IFPMA Code:

• Established in 1981, latest revision 2011, launched in 2012 with global effective date on 1 September 2012

• Requires that promotional activities be carried out in a responsible, ethical and professional manner
In December Russell Williams presented to the Global IFPMA Council a proposal to adopt changes to the IFPMA Code.

- Changes included:
  - A New set of Guiding Principles
  - Expanded scope to include interactions with patient organisations and medical institutions
  - Section on CME, fees for services, clinical trials transparency and interactions with patient organisations
  - Clarity on the complaint mechanism and adjudication process
Why APEC Focused on Business Ethics

Unethical behavior hurts economies:
- Negative impacts on inflation
- Decreased GDP
- Currency depreciation
- Reduced foreign investment
- Undermined health systems

Unethical behavior hurts individual businesses:
- Increases the costs of doing business (through bribes and penalties)
- Lowers sales growth and productivity
- Lowers the ability to enter new markets
- Constricts access to capital
- Over the long term undermines a company’s financial growth

Source: Presentation by Dr. Philip Nichols (Professor of Legal Studies and Business Ethics at the Wharton School of Business) at the APEC Business Ethics for APEC SMEs Workshop in Gifu, Japan – September 2010.
Corruption Perceived as a Major business obstacle

Corruption perceived as a major business obstacle by SMEs and large companies (in per cent)

- According to the Business Environment and Enterprise Performance Survey (BEEPS):
  - More than 70 per cent of SMEs in transition economies perceive corruption as an impediment to their business.
  - Almost 35 per cent of Small companies perceived corruption as a major business obstacle.
APECs work in Developing Voluntary Codes of Ethics

- **Benefits APEC member economies**
  - Provides a platform for effective industry self-regulation
  - Supports government enforcement and anti-corruption efforts
- **Benefits businesses, especially resource-constrained SMEs**
  - Provides companies with clarity and harmonization in rules and practices
  - In the case of the biopharmaceutical and medical device sectors, facilitates ongoing innovation
- **Benefits patients (in the case of the biopharmaceutical and medical device sectors)**
  - Ethical collaborations fuel advances and promote access to life-saving medicines
  - Ethical collaborations ensure that decisions are made in the best interest of patients
The Kuala Lumpur Principles

The first industry-specific initiative in APEC to lay out a series of voluntary, self-regulatory guidelines for organizations to assist in the creation and alignment of their own codes of ethics.

Drafted by Expert Working Group in Kuala Lumpur composed of 37 experts representing 18 APEC member economies (small & large industry, government, academia & civil society)

www.apec.org/.../The%20Kuala%20Lumpur%20Principles.ashx
The Mexico City Principles

- Recognizes that appropriate and ethical interactions help ensure medical decisions are made in the best interests of patients

- Calls upon the **entire** biopharmaceutical sector to embrace aligned standards for ethical interactions, including:
  - Companies and industry associations
  - Healthcare professionals and organizations
  - Government regulators and anti-corruption enforcement authorities
The Mexico City Principles (cont’d)

- On behalf of the Canadian Pharmaceutical Industry, Mr. Russell Williams co-chaired this exciting initiative on ethical business practices.

- Drafted by 36 Expert Working Group Members from industry, government, civil society and academia from 14 APEC Economies in September 2011.

- APEC multi-year funding awarded to implement The Mexico City Principles.
Conclusion

• Innovation is the key to the future productivity of our country, our workplaces, our communities and our citizens
• Rx&D has taken a leadership position in ensuring universal standards of ethics
• Good governance and compliance are a joint responsibility
• The Code must provide a clear guide to real life situations
• In so doing, the Code will help to build more trust and understanding amongst stakeholders and improve reputation amongst our stakeholders
Thank You

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