



Health  
Canada

Santé  
Canada

# Therapeutic Products Directorate

Health Products and Food Branch

# Direction des produits thérapeutiques

Direction générale des produits  
de santé et des aliments



## Challenges and Opportunities in the Pharmaceutical Arena Keynote Speech at CVG 2007



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# Outline of Presentation

- Key Activities
  - Therapeutic Products Directorate (TPD)
  - Bureau of Pharmaceutical Sciences (BPS)
- Challenges and Opportunities
  - Scientific Dimension
  - National Dimension
  - International Dimension
- Priorities and Achievements

# Key Activities

## Therapeutic Products Directorate (TPD)

- Pre-market assessment of pharmaceutical submissions and medical device applications
- Administration of patented medicine (NOC)
- Development of legislation, regulation, policies and guidance
- Provide support to Directorate and liaise with Branch on strategic international initiatives

## Key Activities

### Therapeutic Products Directorate (TPD) *(cont'd)*

- Provide information, education and outreach to stakeholders through summary basis of decision, product monograph, NOC database, and Drug Product Database enhancement
- Monitor safety, quality and therapeutic effectiveness and health hazard evaluation

# Key Activities

## Therapeutic Products Directorate (TPD) *(cont'd)*

- Risk management and communication (media interviews, emergency preparedness)
- Transparency, public accountability and stakeholder relationship
- Consultation, bilateral association meetings and advisory committees
- Litigation support

# Key Activities

## Bureau of Pharmaceutical Sciences (BPS)

- BPS is responsible for the review of the:
  - Quality (Chemistry and Manufacturing) portion of all:
    - New Drug Submissions (NDSs), and
    - Abbreviated New Drug Submissions (ANDSs) including subsequent changes);
  - Biopharmaceutics portion of all ANDSs, as well as those BE/BA studies contained in NDSs and DINs;
  - prescription Drug Identification Number (DIN) submissions

# Key Activities

## Bureau of Pharmaceutical Sciences (BPS) *(cont'd)*

- BPS also has a research laboratory which:
  - Conducts studies for enhanced international scientific collaboration;
  - Develops research projects to support policies and the assessment of pharmaceutical products (innovator and generic drugs).

# Challenges and Opportunities

## Scientific Dimension

- ICH Q8: Quality by Design (QBD) and Design Space \*
- Functionality-related tests for excipients
- Manufacture of a product at commercial scale with consistency and quality
- Latest generation of analytical tools (colour analysis)
- Reverse osmosis versus distillation (water for injection)
- Genotoxic impurities
- Use of process analytical technology (PAT)
- Leachables and Extractables

# Challenges and Opportunities

## Scientific Dimension

- ICH Q8: Quality by Design QBD and Design Space \*
- The concept of QBD is not new to industry
- QBD principles will improve the ways of developing pharmaceutical products and manufacturing processes
- Provide new regulatory approaches to the review of submissions and to post-approval changes

# Challenges and Opportunities

## Scientific Dimension *(cont'd)*

- ICH Q8: Quality by Design QBD and Design Space \* *(cont'd)*
  - Gain better understanding and opportunities of regulatory flexibility
  - Expected to reach Step 2 by October 2007 at the ICH Yokohama meeting

# Challenges and Opportunities

## National Dimension

- Access of medicine regime (Bill C9)
- Progressive licensing project – product life cycle
- Certification, use of CEP
- USP verification program (under consideration)
- Increased workload of generic submissions
- Integrated review process

# Challenges and Opportunities

## National Dimension *(cont'd)*

- Implementation of Q7A
- Post-notice of compliance changes: Quality document

# Challenges and Opportunities

## International Dimension

- International cooperation and synergy in quality issues
- Partnership in combating of counterfeit medicine
- Participation in WHO pre-qualification program
- Collaborative efforts among industry, scientific organizations, governments and academia (PQRI)
- Import safety on products coming from developing countries (e.g. China, India)
- Reverse osmosis versus distillation for injectable products

# Challenges and Opportunities

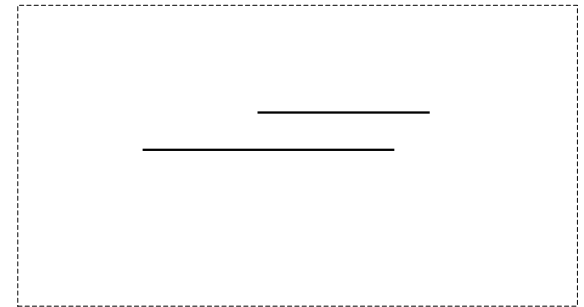
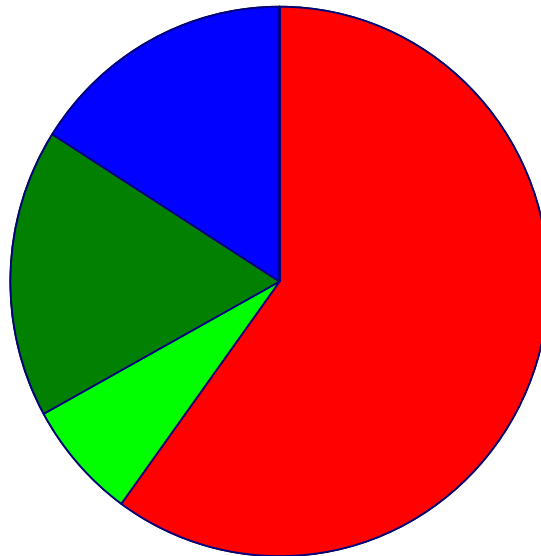
## International Dimension

- Innovation is emerging in global scene
- India and China emerging centres of excellence
- Eastern Europe will offer low-cost clinical trials
- US is more towards innovation for growth
- Canada's excellence in basic research
- Global quality problems?\*

# Challenges and Opportunities

## International Dimension (*cont'd*)

Is quality of pharmaceuticals a problem?



# Priorities and Achievements

## Priorities

- Establishment of a modern regulatory framework
- Performance sustainability
- Training programs
- Relationship management

# Priorities and Achievements

## Achievement

- Exceeded 90% review time for submissions (Q1)
- Amendment to the patented medicine notice of compliance regulation (CG II)
- Clinical trial registration and disclosure – final report 2006, HC website
- MOU signed on March 20, 2007 with EDQM on CEP
- Special Access Program – operational review completed

*Thank you*