The Strategic Role of Regulatory Affairs within the Biopharmaceutical Business

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Disclaimer

- Lorella Garofalo is an employee of Pfizer Canada Inc.
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Overview

- “Traditional” role of regulatory
- Continuous evolution of the regulatory function within dynamic internal and external environments
- How a strategic, high performing regulatory organization adds great value to the business

Regulatory Affairs: Fundamental "Raison d'être"

- Secure market approval for medicines and maintain their lifecycle
  - Quality
  - Safety
  - Efficacy

- Compliance

What most understand about Regulatory Affairs: prepares and submits regulatory dossiers to authorities

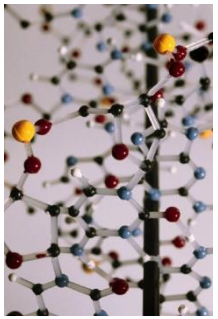
Scientific data

+

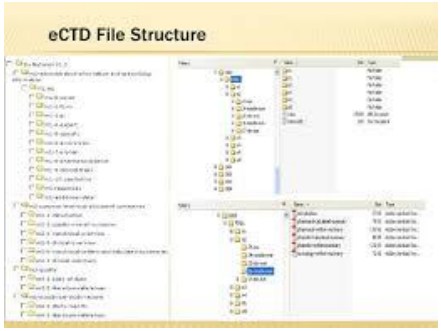
Guidelines

+

Legislation



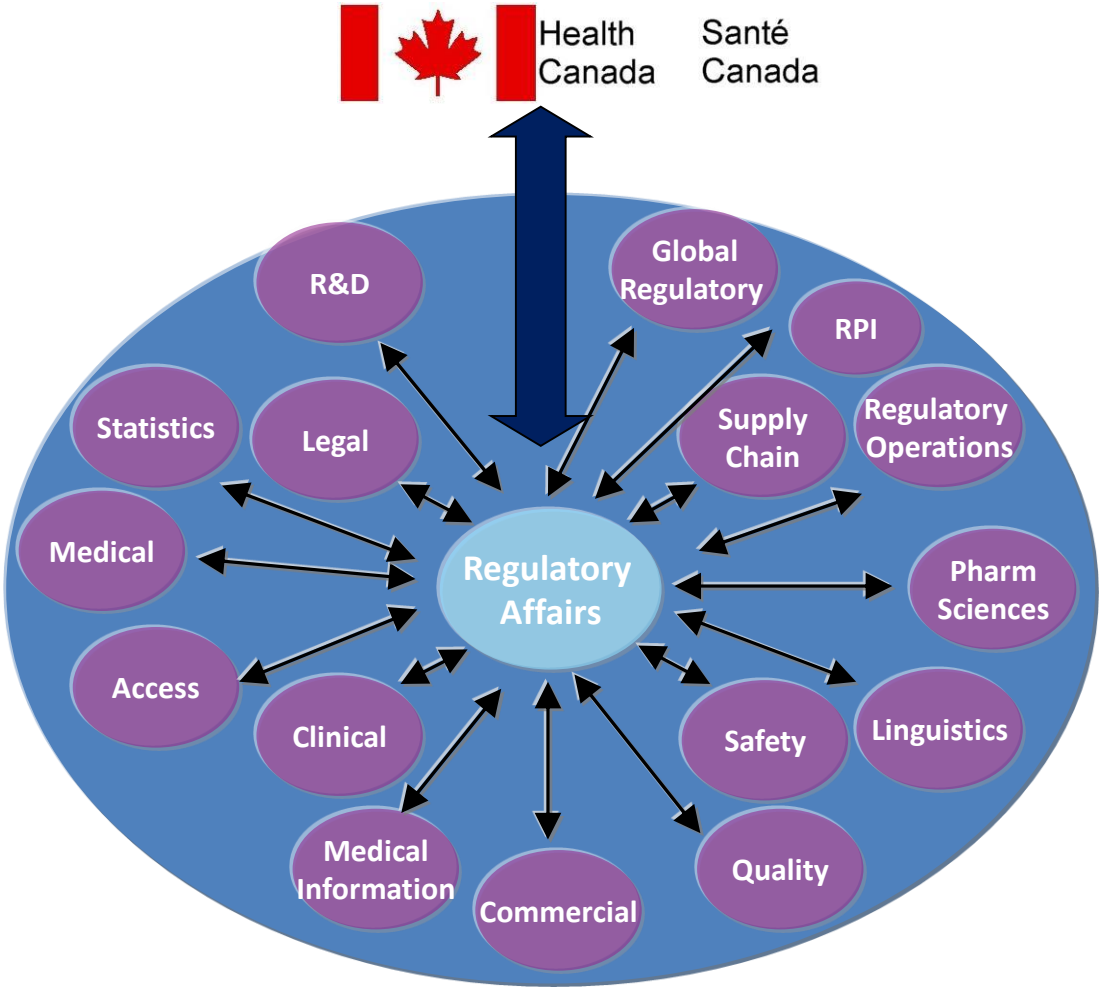
Regulatory



Regulatory Submissions

Approval

Regulatory Affairs is the Company's "face" to Health Canada



Broad Scope and key member of cross functional teams

A Biopharmaceutical company's value and corporate decision points are dependent on critical regulatory milestones

- Underscores the importance of regulatory's strategic contribution to the business

- Corporate success relies on achievement of product:
  - development milestones
  - manufacturing
  - registration milestones
  - …. and many additional factors….

- Driven by achievement of regulatory goals
  - Importance of precision planning

Regulatory is increasingly recognized as a central role and as a strategic partner to several business functions

Commercial

Clinical / Medical

HEOR / Access

Legal

Others..

Product Development and Lifecycle

Regulatory Policy and intelligence

Intellectual Property Protection

A Dynamic Environment: Internal and External Pressures

INTERNAL

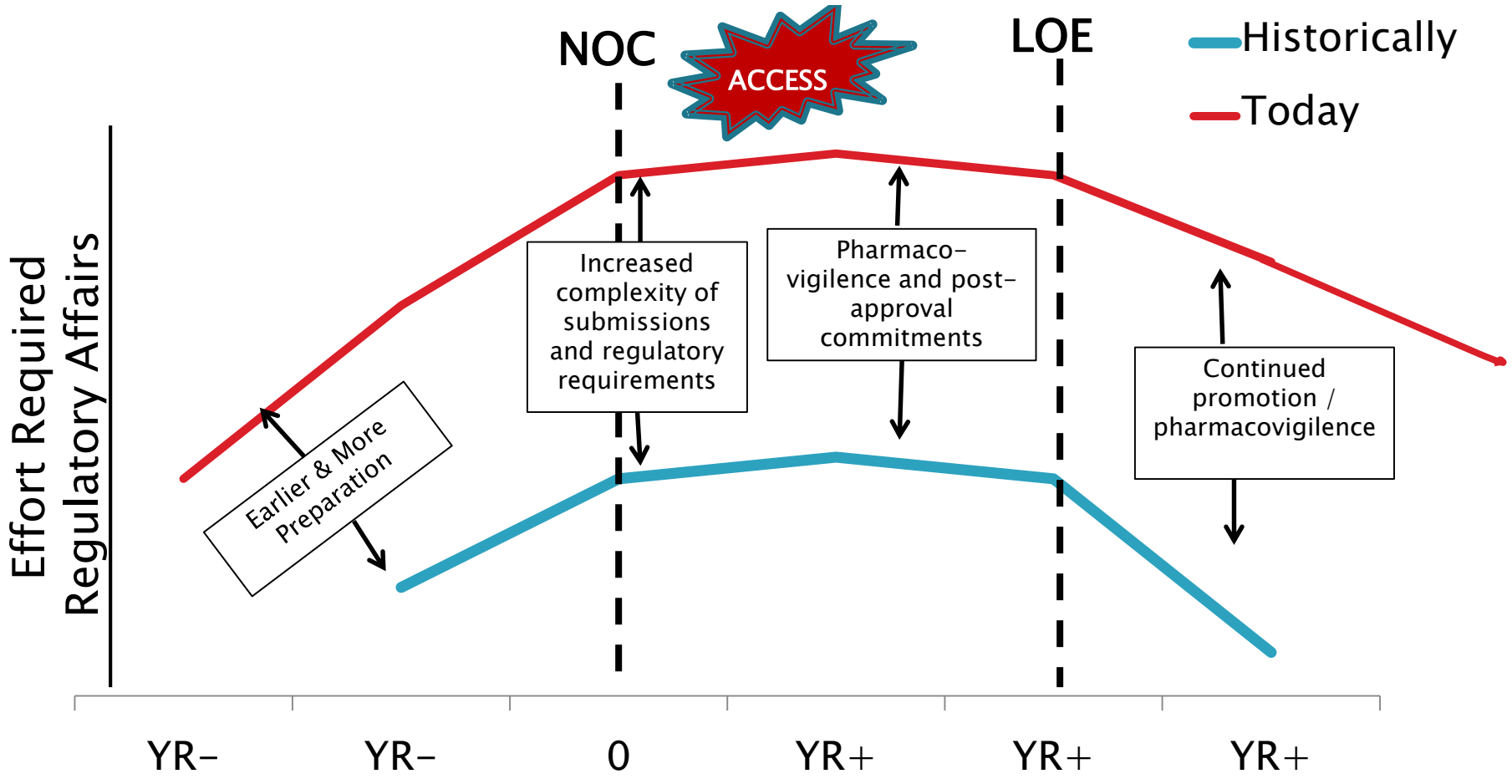
- Focus on Continuous Improvement
- Resource limitations
- Trend towards centralization and outsourcing (contractors/Alliance Partners/CROs)
- Dynamics of Product Portfolio
- Complexity of Products

Biopharmaceutical company

EXTERNAL

- Rapidly evolving regulatory environment (Bill C-17; transparency, etc..)
- Increasing Regulatory Hurdles
- Greater Public and Media Scrutiny
- Proliferation of Policy Issues
- Developing / Competing Submission and Data Standards

Lifecycle Portfolio Management



Challenging and Complex Path to Access in Canada

NOC: Market Authorization

HTA: Market Commercialization

Development programs need to address HTA requirements to ensure best opportunity for early, positive reimbursement decisions and optimize commercial success

Regulatory: Adds Knowledge and Value Across the Lifecycle

DISCOVERY/
PRE-CLINICAL

Preparing regulatory strategies

- Identity potential regulatory risks
- Create mitigation plans

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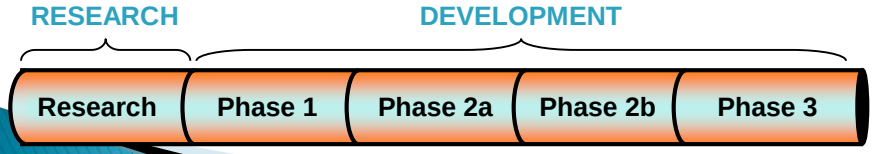
PHASE I-III

- Filing and maintaining CTAs
  - Raise awareness /ensure alignment of business re: clinical programs in Canada
- Health Authority meetings to obtain regulatory advice
- Leading provision of regulatory guidance to project teams
- Label development
  - Cross-functional discussions (medical, commercial, access)
- Licensing drug due diligence
- NDS filing strategies



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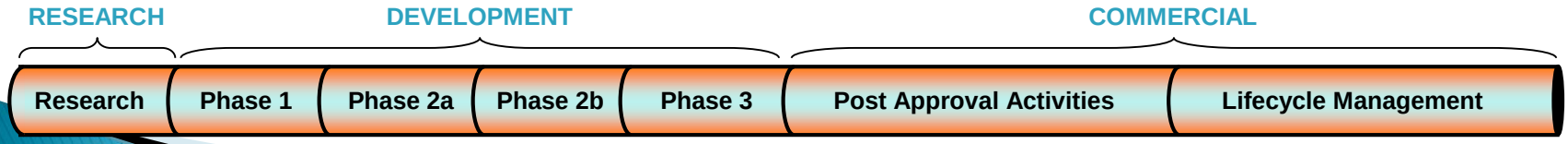
REGISTRATION

- Pre-submission meetings with Health Authorities
- Delivery of Marketing Applications
- Submissions coordination
- Rapid Response teams
- Labelling discussions
- QA review of submissions
- Trend analyses on regulatory review practices & competitors



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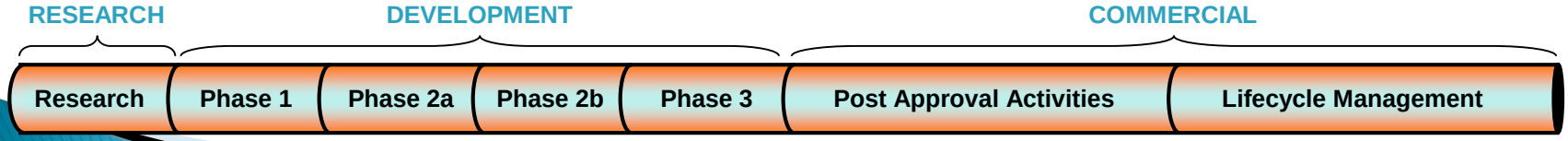
POST-APPROVAL

- Supplemental submissions for line extensions (new indications, new formulations)
- Responses to Health Authority queries
- Product lifecycle management
- Maintenance of market authorization (Safety Updates, CMC enhancements/changes)



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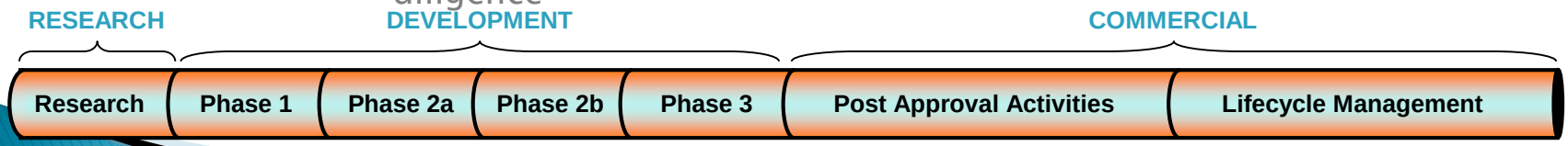
Policy Development and Advocacy



POLICY

- Regulations and guidelines are constantly evolving, increasing in number and importance.
- The regulatory environment is becoming ever more complex, more challenging.
- Health Canada recognized as a key regulatory authority globally – influence increasing
- The companies that are best positioned to understand the uncertainties, anticipate and plan for evolving changes, plus *influence* the environment, will have a competitive edge

Regulatory Policy: Significantly impacts the business

- Regulatory
  - monitors external environment
    - changes in regulatory guidelines, requirements, policy shifts, competitive intelligence
    - analyzes impact and provides timely communication to company stakeholders
    - is the internal advisor on interpretation of regulations, guidelines, agency policies
  - coordinates the development of company positions/comments to shape appropriate content of draft guidelines/regulations
    - communicates views to regulatory agencies and trade associations and works to ensure continued favorable regulatory environment for the business
  - represents company on key trade association regulatory committees

Communication to key internal stakeholders regarding anticipated changes in industry trends, policies, and regulations that could have a local/global impact on the development and lifecycle strategies of company products is of great strategic value to the business

Important Changes to Canadian Regulatory Environment

Bill C-17
HC Openness and Transparency Framework

- Disclosure submission information
- Summary of actions (PAAT) posted
- Safety reviews initiated & SSRs posted
- Label Safety Updates posted
- Inspection Reports (GMP, GCP, GVP) posted
- Advertising Compliance disclosed
- Drug Shortages – mandatory reporting
- Orphan Drug Regulations

- Increased need for regulatory to anticipate issues and manage risk
- Proactively update local and global business on important emerging information
- Advise cross-functional teams of information disclosed about our products and that of key competitors
- Partner with Communications team and other cross functional team members to address media/public enquiries
- Enhance competitive intelligence

Life-Cycle Management and Post-marketing

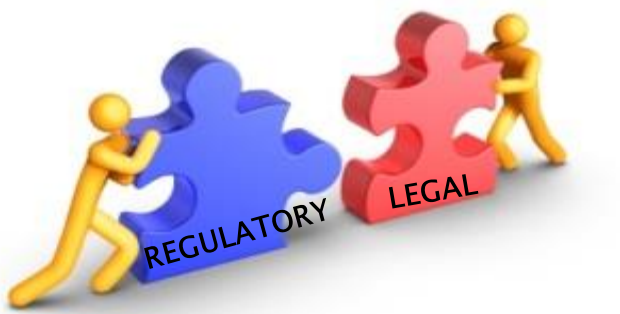
- Strategic input to product lifecycle optimization
  - Define regulatory pathway and prioritization
  - New indications, formulations, dosages
- Pro-active risk minimization and management
- Support competitive product differentiation
  - Maintenance of optimal product information and labeling
  - Ensure competitive promotional/advertising materials that meet regulatory requirements

Intellectual Property Protection

- Patent protection only becomes effective once the patent is listed on the Health Canada Patent Register (as per PM(NOC) Regulations)

- Ensuring pediatric exclusivity data protection

    - An **additional 6-month period** is available for innovative drugs that have been the subject of clinical trials designed and conducted for the purpose of increasing the knowledge of the use of the drug in pediatric populations, **filed within the first 5 years** from NOC.



Regulatory Affairs: Critical partner to advance business strategy

Regulatory has a strategic role From Bench to Bedside and Beyond…

Bench

FIH/Clinical Trials Applications / Submissions / Agency Meetings / Market Authorization / regulatory review process

Life Cycle Optimization/Product supply/Label Optimization

Regulatory Affairs

Compliance to post-marketing commitments

And Promotional / Advertising regulations

Bedside

Regulatory approval / Patient Access / timely information for patients/doctors supporting continued appropriate use of medicines

Thank you !