Coordination of Pre-launch Activities between Regulatory and Key Functional Areas

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Regulatory Drivers for Coordination of Pre-Launch Activities

- Launching Product *as soon as* NOC is received
- Conditions of Approval meet needs of Key Stakeholders
  - Product Monograph
  - Chemistry and Manufacturing information

Key Deliverables for Launching a Product

- NOC
- Ready to ship product in the warehouse
- Promotional materials
- Trained sales force

Product Launch

- Successful Product launch requires thorough pro-active planning
- Product launch is a cross-functional activity
- Regulatory is involved in interactions with a number of functional areas

Standard Practice: Management of Pre-launch Activities

- Product launch is generally managed by a cross-functional launch team represented by different areas:
  - Marketing, Regulatory, Clinical, Materials Management/ Logistics, Quality Assurance, Market Access, Corporate/ Government Affairs and Drug Information

- Should be formed at least 9-12 months prior to launch

Role of Regulatory in Pre-Launch Activities

- Many team activities are driven by Regulatory input
- Manage expectations around Regulatory issues: NOC timing, Labeling, CMC data etc.
- Be realistic on the deliverables
  [*over promised/under-delivered vs. under-promised/over-delivered*]

Role of Regulatory in Pre-Launch Activities Cont'd:

- Critical business decisions (e.g. sales force expansion, scheduling launch meeting) are made around regulatory information
- Regulatory acts as an interface between local and global teams
- Recognize needs and sensitivities of different groups

Role of Regulatory in Pre-Launch Activities Cont'd

- Maintain active communication with key functional areas on critical feedback from Health Canada in final stages of review process
- Ensure participations of all key groups especially marketing (both local and global) throughout the Product Monograph review process
- Circulate key Regulatory documents to key stake holders and ensure to record the comments

Coordination Activities: Marketing

- Preparation of Promotional Materials
  - Detail Aid
  - Journal Ad
  - Dear Health Care Professional Letters

Coordination Activities: Marketing

- Promotional materials prepared prior to finalization of the Product Monograph
  - Early and on-going Regulatory involvement in the development of promotional materials
  - Critical feedback on the data to support promotional statements

Coordination Activities: Marketing

- Assistance in PAAB negotiations
  - Initial PAAB review could be based on the draft monograph
  - Early Regulatory feedback on PAAB review leads to faster resolution of issues

Coordination Activities: Marketing

- Sales Training:
  - Review of training materials
  - Product launch meeting
    - Presentation
    - Assistance in practice detail

Coordination Activities: Market Access

- Product Monograph
- Pricing: PMPRB Strategy
- Formulary Submission
- Retrospective pharmacoeconomic analysis

Coordination Activities: Quality Assurance

- Documentation for product testing and release
  - Approved Specifications
  - Test Methods
- Post Approval Stability Protocol
- Completing Global QA documentation for local product shipment/release

Coordination Activities: General

- Labelling:
  - Amount of text
  - Size
  - Changes during the review
- Translation:
  - Process for Product Monograph translation
- Clinical:
  - Impact of initiating new studies during the review on Canadian approval
  - Phase IV commitments

Coordination Activities: General

- Drug Information: Review of launch materials
- Materials Management:
  NOC timing, risk printing of labels
- Corporate Affairs:
  Press release, media briefing

Summary: Role of Regulatory in Pre-Launch Activities

- Regulatory involvement is not limited to obtaining NOC alone in the product launch process
- Regulatory provides key strategic input in pre-launch activities
- Regulatory professionals require technical expertise as well as political savvy to manage cross-functional pre-launch activities