Strategic planning in Regulatory Affairs

A presentation by Christine Degeling, Head of Regulatory Affairs, Teva Pharmachemie
Learning Outcomes

- Understand the importance of a regulatory strategy
- Understand which factors play a role in designing a regulatory strategy
- Understand how current trends in pharmaceutical industry may influence the regulatory strategy
In This presentation we will cover

- What is a regulatory strategy?
- Why and when is a regulatory strategy needed?
- The aspects of a regulatory strategy
- What are the current trends in pharmaceutical industry?
- How will these trends in pharmaceutical industry affect the regulatory strategy?
What is a Regulatory Strategy?

- **Strategic planning:**
  - Process of defining strategy or direction
  - Making decisions on resources to pursue this strategy.
  - Control mechanisms for guiding the implementation of the strategy.
  - Involves many parties and research sources in the analysis of the goal, the organization and its relationship to the environment in which it competes.
What is a Regulatory Strategy?

- Regulatory Strategy:
  - Plan for developing the product with the goal of obtaining regulatory approval in desired markets
  - Plan for lifecycle management/maintenance post approval
Why a Regulatory Strategy?

- For alignment of development, commercial and regulatory goals:
  - Development: CMC, non-clinical and clinical development plan
  - Commercial: key product label attributes and positioning
  - Regulatory: scientific advice, procedure, legal basis, exclusivity
Why a Regulatory Strategy?

- Understand the regulatory landscape
  - Guidelines
  - Stakeholders
  - Emerging policies
  - Precedence
  - Drive the development and identify hurdles so they can be solved proactively
Why a Regulatory Strategy?

Tracking tool: summarize key agreements with project team and with authorities
Planning tool: documentation of timelines and topics to be discussed with health authorities
Risk register: keep track of issues that may affect timelines, costs or commercial value
When a Regulatory Strategy?

- Always......
  - Development: new molecular entities (chemical and biopharmaceutical), drug rediscovery
  - Lifecycle management: maintenance of existing products, new indications, new API suppliers, new markets, line-extensions, site transfers
When a Regulatory Strategy?

- Start early in development, e.g. before regulatory non-clinical studies
- Start with the end in mind, e.g. with a target product profile
- Regulatory strategy should be a living document
Aspects of a Regulatory Strategy

- Overview of guidelines and precedents: covered in the lecture on regulatory intelligence
- Plan for interaction with authorities: covered in the lecture on scientific advice
- Knowledge on requirements in the regions of interest
Aspects of a Regulatory Strategy

- Key product label attributes
- External influencing
- Global submission strategy: know the requirements in each region
- Pharmacoeconomics
- Target submission and approval dates
- Options for accelerated approval pathways: covered in the lectures for the various regions
Aspects of a Regulatory Strategy

Provides guidance on how to work with other disciplines: covered in the lecture on project management
Aspects of a Regulatory Strategy

What is designing a regulatory strategy about?

or

or
Design of a regulatory strategy requires the regulatory professional to have:

a certain degree of technical and scientific know-how

AND

Soft skills:

• Negotiation skills
• Problem-solving
• Creativity and flexibility
• Understanding of and insight in interests of stakeholders
Trends in Pharmaceutical Industry

- Personalised medicine
- Shift to emerging markets
- Unmet medical need: Alzheimer’s disease, obesity/diabetes type II
- Need for prevention of diseases versus treatment (vaccines for developing countries, e.g. malaria)
- Companion diagnostics
Trends in Pharmaceutical Industry

- Mergers and acquisitions
- In- and out-licensing
- A big pharma company handles the strategic planning differently than a small enterprise
Effect of Trends on the Regulatory Strategy

• For personalised medicine, a different regulatory strategy is needed when compared to a blockbuster.

How?
Effects of trends on the Regulatory Strategy

- Emerging markets are also in the picture for development and manufacturing activities hence requiring management skills.

What are the specifics in the regulatory strategy?
Effects of Trend on the Regulatory Strategy

- A drug is developed for an unmet medical need.

What are the strategically important aspects?
In This presentation we covered

- Why and when is a regulatory strategy needed?
- The aspects of a regulatory strategy
- What are the current trends in pharmaceutical industry?
- How will these trends in pharmaceutical industry affect the regulatory strategy?
Recommended references

- TOPRA Regulatory Rapporteur February 2014
- Worldwide Update, FDA and NIH heads outline plan for personalised medicine; RAJ Vol 21 No 8 August 2010, page 520
Take home message

- Regulatory strategy is indispensable
- As a regulatory professional you are in a unique position:
  - You can influence company policy
  - You are an active stakeholder in company policy, development and life cycle management
  - You contribute to the success of your company!
  - You have added value
- It is an underestimation to consider the regulatory profession only as filling out forms and shoving paper around.
QUESTIONS?
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