Pharmaceutical Drug Commercialization: Strategy & Practice
Fall 2017 B Term (5.45 to 9.00 pm on Wednesdays)
Healthcare and Pharmaceutical Management Program
Columbia Business School

Faculty
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Course Overview
This cross-functional course focuses on ‘real-world’ issues for commercializing pharmaceutical drugs in a rapidly changing and complex global business environment. This course will highlight the influential role external stakeholders (governments, regulators, payers, purchasing organizations, hospitals, physicians, pharmacies, patients, care givers and advocacy groups) and internal functions (early development, late stage development, data management, manufacturing, medical affairs, market access and commercial teams) play along a brand’s lifecycle, driving commercial success. Key topics to be explored include:

- Market dynamics, competitive strategies, clinical practices, regulatory issues, access challenges and lifecycle planning
- Internal and external stakeholders who influence the commercialization of the brand
- Brand strategy plans, brand forecasts, inputs into strategic clinical development options, science and communications strategies
- Strategies for pricing, market access and reimbursement in multiple geographies

Students who are interested in gaining insight into this increasingly complex market environment, and desire to learn how to navigate the influencers and set the stage for commercialization of pharmaceuticals, will benefit from the curriculum. This course will assist students interested in careers in pharmaceuticals, biotechnology, and healthcare, as well as management consulting and the financial industry, given the large and growing pharmaceutical practices of such firms.

Deliverables
Learning is driven through readings, class discussion and a series of guest speakers representing a wide range of global commercialization issues. Evaluation is based on class discussion, case study reports and a group project.

Course grades will be based on participation, case reports and a written brand plan
- Class Participation 20%
- Case Write-ups (EpiPen and Metabical) 30%
- Team Project Presentation 50%

Class Participation
Each session, students are expected to review the background readings and come to class prepared to discuss the assigned readings and cases. Students should focus on the quality of the contributions to class discussions versus the quantity of contributions.
**Case Write-Ups** - Each team is required to analyze the two assigned cases and develop recommendations. The team will then submit a written report that contains an *executive summary* and *analysis* not exceeding a total of four pages that describe *the team's recommendations* and *rationale* for those recommendations. Use the discussion questions as a guide in developing your recommendations. The case write-ups are due in class on **day** of the case session. The teams will consist of 4 members, preferably with varying backgrounds. Please contact us if your team consists of a fewer or greater number of members. This component accounts for **30%** of your course grade.

**Team Project (Written Presentation)**
Each team will be asked to choose a pharmaceutical brand (from those identified by Professors) and develop a written “annual” brand plan presentation, theoretically to be delivered to Senior Executives from Pharma Companies.

**Guest Speakers**
Prominent guest speakers from the pharmaceutical and biotechnology industry will provide additional real-world insight on key industry challenges and trends.

Students will develop their competencies in the analytic and systematic use of pharmaceutical marketing concepts and methods to develop commercialization/launch plan for a brand.
Class Schedule and Topics

Session 1 – October 25: Pharmaceutical Industry Overview & the Evolving Customers

- Course Introduction & Student Introductions
- Review of assignments, due dates and expectations

Biopharmaceutical Industry Overview

- Key market dynamics
  - Size and projections of the pharmaceutical industry
  - Revenue and geographic trends
  - Where is Pharma focusing and why?
  - R&D spend vs. advertising to healthcare professionals & consumer
  - Competitive strategies, clinical practices, regulatory issues and access challenges in key pharmaceutical markets

Customer Expectations

- New business customer
  - The value driven proposition.
  - Implications on B2B – the power shift
- New healthcare consumer
  - The consumer/patient experience of today
  - Implications on B2C
  - Variation in levels of patient knowledge and motivation
  - Shifts from treatment to prevention and wellness

Suggested Readings:

- 2016 PhRMA Profile
- EvaluatePharma World Preview 2016, Outlook to 2022
Session 2 – November 01: Drug Commercialization & Company Culture

Essentials of Commercialization

- Environment: intellectual property regime and established ownership over complementary assets such as manufacturing expertise or distribution channels
- Strategy Framework: benefits and costs of alternative strategies for securing profits and competitive advantage through innovation
- Types of scientific innovation and its significance in drug commercialization

Pharma Marketing

- Accountabilities of marketing
  - P&L and cost centers
  - Differences between pharma marketing and consumer goods marketing
  - The four “old” 4 “P’s” & the four “new P’s”
- Pharmaceutical marketing constraints
  - Ethical considerations & public-policy scrutiny
  - Promotional regulations and impact

Is culture the culprit in pharmaceutical companies?

- Understanding the rationale and differences, as well as the strengths and weaknesses of three different cultures in the pharma industry:
  - Sales
  - Product Innovation
  - Market-led
- EpiPen Case

Guest Speaker: Game-Changing Advances in the Healthcare Industry: Big Data Implications for Pharmaceutical Commercialization

Suggested Readings:

- http://www.pharmexec.com/new-four-ps-marketing
- EpiPen Case

Case write up due
Session 3 – November 08: Building Brand Strategies for commercialization success

Creating actionable insights - the driver of competitive differentiation
• Patient Flow: quantifying a brand’s market potential by analyzing patient population data & dynamics
• Patient Journey: gaining insight from the patient’s interaction with his/her environment

Developing Brand Strategic Plan:
• What is a strategic choice and how does it apply to the marketing of pharmaceuticals?
• What are the brand realization drivers?
• Why patients / physicians / payers choose brands?
• What are the stages of the prescription adoption process?
• Where to play? The SWOT analysis
• How do you get customer information?
• Segmentation / Positioning / Marketing Mix / ROI trap
• How to forecast sales?

Launch Strategies
• Archetypes
• Guiding Principles & Recipe
• How launches perform against expectations?

Case Review:
• HBS Case Collection | July 2010 - Metabical: Positioning and Communications Strategy for a New Weight Loss Drug by John A. Quelch and Heather Beckham

Suggested Reading:
• IMS White Paper: Patient Journey
• Beyond_the_storm_Launch_excellence_in_the_new_normal: McKinsey Article, 2013

Case write up due
Session 4 – November 15: How cross-functional teams impact commercialization?

Companies are usually organized in multiple customer-facing and/or functional silos and in a world where these organizational functions have converged, how is commercialization best managed?

**Internal ecosystem:** How internal stakeholders influence commercialization?
- R&D
- Medical affairs
- Market research
- Market Access & HEOR
- Manufacturing, supply chain & distribution
- Sales & operations
- CRM, Consumer & Media Buying
- Finance
- Legal
- Regulatory
- IT
- Government Affairs & Advocacy

**External ecosystem:** How to work together with external partners?
- Competitive Intelligence
- Contract Research Organization
- AOR - Digital
- Promotional & Medical Coms (and the difference between the two)
- Market Research
- Public Relations / Investor Relations

**Guest Speaker:** TBD

**Suggested Readings:**
Session 5 – November 29: How Marketing Interfaces with Three Key Functions – deep dive

Marketing Input into R&D
- How Unmet Medical Need and Disease Market Attractiveness help prioritizing areas of R&D and drive R&D strategic decisions
- Establishing the Target Product Profile based on competitive landscape analysis

Marketing-Medical Interface
- The impact of the migration of clinical data dissemination from the marketing to the medical function
- Role of Medical Affairs: offer new value-added patient-centric services for customers

Marketing & Market Access
- Strategies for pricing, market access and reimbursement in multiple geographies
- Best-practice in developing a market access plan and the role of marketing therein
- Understanding how the supply chain plays a role in access to medicines

Guest Speaker: TBD

Suggested Readings:
- R&D Annual Report 2016: Pharma Projects
- Pharma_Medical_Affairs_2020_and_beyond: McKinsey Insights, 2014
Session 6 – December 6: Economic Implications for Commercialization

Each stakeholder has different interests and interacts in different ways, at different points of the value chain, with diverse motivations. Understanding the collective impact of the interplays across these differences is essential for the commercial success of a brand.

Internal Profit Levers
- Multiple decision makers, often with competing economic interests
- R&D Efficiency: Past-Present-Future
- Expense evaluation, cost cutting, extension of the period of market exclusivity and real-world evidence

External Profit Levers
- US - GTN – impact on net revenue & profitability
- Patient Assistance Programs & Co-pay Card
- Global practices

Guest Speaker: TBD

Final Project Presentations Due