Online Course Report

DRUG COMMERCIALIZATION

by

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Course Name - DRUG COMMERCIALIZATION

Introduction

This course (Drug commercialization) will provide an overview of entire process from target identification and commercialization.

This course covers topic ranging:

- Pharmacoeconomics
- Intellectual property and freedom to operate
- Managed market
- Marketing strategy
- Portfolio management & business model

Objective

- How to launch a product in market and sell the product as well as many other facts in the commercial aspect of making a drug successfully.

Course Contents

WEEK 1

Pharmacoeconomics

Pharmacoeconomics is a field that is used by health care payers to compare the **COST VS. BENEFIT** of alternative drug for population of patient.

- Balancing cost and outcomes of pharmaceutical therapies and services.

Objective

- Define basic type of pharmacoeconomic analysis
- Describe value proposition for pharmaceutical using direct cost, indirect cost and quality of life data.

Pharmacoeconomic analysis:

Pharmacoeconomic research is used to identify, measure, and compare the costs, risks, and benefits of programs, services, or therapies and determine which alternative produces the best health outcome for the resources invested

Cost / Outcome =Analysis

Types of pharmacoeconomic analysis:

- Cost of illness (COI)
- Cost minimization (CMA)
- Cost Effectiveness (CEA)
- Cost benefit (CBA)
- Cost utility (CUA)

Value of pharmaceutical framework:

Economic (Resource Utilization)	Clinical	Humanistic
Direct Costs e.g. Drug Physician visits Hospitalization Nursing time Transportation	Safety e.g. Headaches Nausea Stroke	Quality of Life Health-Related vs. Overall, Global
Indirect Costs Lost days of work Reduced Productivity Patient, Provider, System	Efficacy e.g. Reduced Symptoms Cured Patients Saved Lives Years Gained	Patient satisfaction e.g. With Treatment With Provider
		Patient preferences e.g. Treatment Mode Disease State

Direct cost: Schizophrenia patient before vs. after Residone therapy initiation change in hospitilazation.

		Change in Hospitalization
No. patients	Months	↓ # Days/year
36	> 7 months	25% (5.7 to 4.2 days)

Change in Costs (mean per patient/yr)			
↑ Drug	↓ Hospital	↓ Other	↓ Total (%)
$1322 ↑ Risperidone $1889 ↓ Other psychotropic $567	$762	$868 Residential, day out patient, & case management	$308 (3)

Indirect cost: this cost deals with the **productivity & margin.**

Mean	Customary	Naratriptan
# Attacks/pt	35.2	35.2
Duration (hrs)	608.4 hrs.	***383 hrs.***
Work time lost (hrs/Can $)	51.4 hrs. ($851)	***32.8 hrs.*** ($544)
Unpaid work time lost (hrs/Can $)	19.9 hrs. ($228)	***12.6 hrs.*** ($145)
Leisure time lost (hrs/Can $)	46.2 hrs.($0)	***29.6 hrs.*** ($0)
Total	117.50 ($1,080)	***75.00*** ($689)

Week 2

Intellectual property strategy and Biosimilars:

Intellectual property and Patent provide legal protection for inventors in order to prevent the other people from making use of their ideas. It's basically an exclusive right for that invention. It's granted primarily by states and government to the inventor. The inventor can be either a company or an individual. And the holder as the sole right over the invention.

Acts which are major changes in patent law:

- America invents Act (A.I.A.)
- Bayh-Dole Act
- Hatch-Waxman Act

BIOLOGICS MARKET:

- **Difference between biologics and conventional Drugs:**

New Molecular Entity Drugs	Biologics
Small Molecules (~500 molecular weight)	Large molecules (>5000 molecular weight)
Chemically synthesized	Biotechnologically produced or isolated from living sources
Simple well-defined structure	Complex structure/mixtures (tertiary structure, glycosylated)
Less target specificity	High target specificity
Oral administration possible (pills)	Generally parenteral administration (intravenous)
Generally not or unpredictably antigenic	Can stimulates the production of an antibody

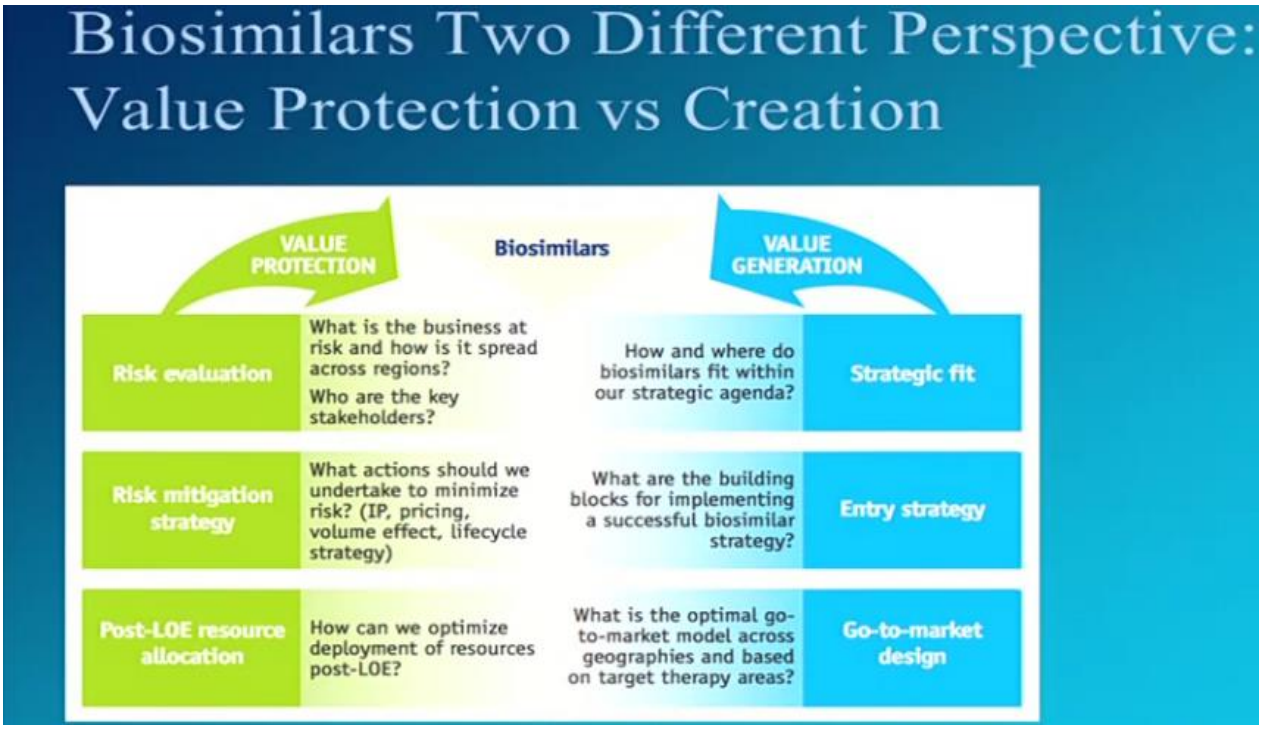
BIOSIMILARS:

Biosimilar is a biological product that is highly similar to a US-licensed reference biological product notwithstanding minor differences in clinically inactive components. And for which there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product

the Biosimilar User Fee Act:
the Biosimilar User Fee Act, it is very important because it's basically amending. It authorized the FDA to assess and collect fee. To expedite the review process of biosimilar biological products. So that's very interesting because supposedly if you are a biosimilar manufacturer, well you want your drug to be approved quickly. You don't want it to sit on the shelf if you are doing what is required. And, you know the reason for that, that this went through is because there is a very important public health benefit. A lot of these drugs, especially in Oncology, have improved survival rates. In RA, they have improved quality of live substantially in terms of rheumatoid arthritis.

Biosimilars & follow on biologics some of the players:

- **Teva in Israel**
- **DR. Reddy, Ranbaxy, Biocon in India**
- **Sandoz (Novartis), Bedpartners in Switzerland**
- **Merck, Pfizer in US**
- **Stada in Germany**



WEEK 3

Pharmaceutical Marketing & Biotech Drugs

Objective:

- Pharmaceutical traditional marketing: The 4Ps
- FDA: Regulatory Rules
- Pharma new business Model
- Novel Approach: The 4Cs

Pharmaceutical Marketing

- What makes a drug success?
- Marketing's role is to increase SALES
- The 4Ps (Product, Place or market, Price, Promotion)
- Element of the "ideal Drug Profile"
- Design Marketing Plan
- Product Positioning
- Market shift: pharma change strategy
  *Move from general practitioner and family practice market to speciality market.
  * portfolio moving from small molecule to biologics and macromolecule.
- Pricing strategy and elasticity

- Launching the drugs: Promotion

- Market share and share driven
- FDA: Office of Prescription and Promotion and advertising
- Managed market and sales strategy
- Sales targeting

Relationship of sales and marketing strategy:

WEEK 4

Business model and portfolio management in the pharmaceutical Industry

Objective:

- Top 3 business models in the pharmaceutical industry
- 3 Key strategies to refuel the pipeline

The Pharma Business models:

1. Inventor business model
2. Generic business model
3. OTC business model

How to refuel the Pipeline:

- First, the pipeline needs to be balanced between Short Term and Long-Term projects.
- In-house R & D.
- In-licensing.
- Company acquisition.

Conclusion

A successful product launch depends on the strategic implementation of fully integrated project, program, and portfolio management into the product commercialization life cycle. However, while most pharmaceutical companies have talented functional resources, organizations often lack the dedicated expertise and discipline needed to lead the matrix structure and interdependencies essential to the success of a commercialization program.

The value of project and portfolio leadership for a drug commercial launch program has become increasingly evident as more pharmaceutical organizations leverage this expertise to maximize organizational capabilities and capacity to launch new drugs with speed, efficiency, and effectiveness. Implementing such expertise enables the pharmaceutical company to transform its vision into an actionable road map, compress time to market, and streamline operations to accelerate benefits for the patient and value for the company.

Learning Methodology

Web session was conducted by **Williams S. Ettouati, Pharm.D.**, Director, Industrial Relations & Development; Health Sciences Associate Clinical Professor, N.S. **Joseph D. Ma**, Associate Professor of Clinical Pharmacy Two days in a week from 1 June to 5 July 2020 and some data were given to learn and to analyze it.

Key learning

- How to make and sell a product successfully
- Basics of Pharmacoeconomics
- Intellectual property and freedom to operate
- Marketing strategy
- Portfolio management & Different type business model