WINNING THE WORLD OF BIOSIMILARS: COMMERCIAL STRATEGIES FOR EUROPEAN MARKET

Dissertation submitted for the partial fulfillment of the MBA in Pharmaceutical Management

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INSTITUTE OF HEALTH MANAGEMENT RESEARCH

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Theme

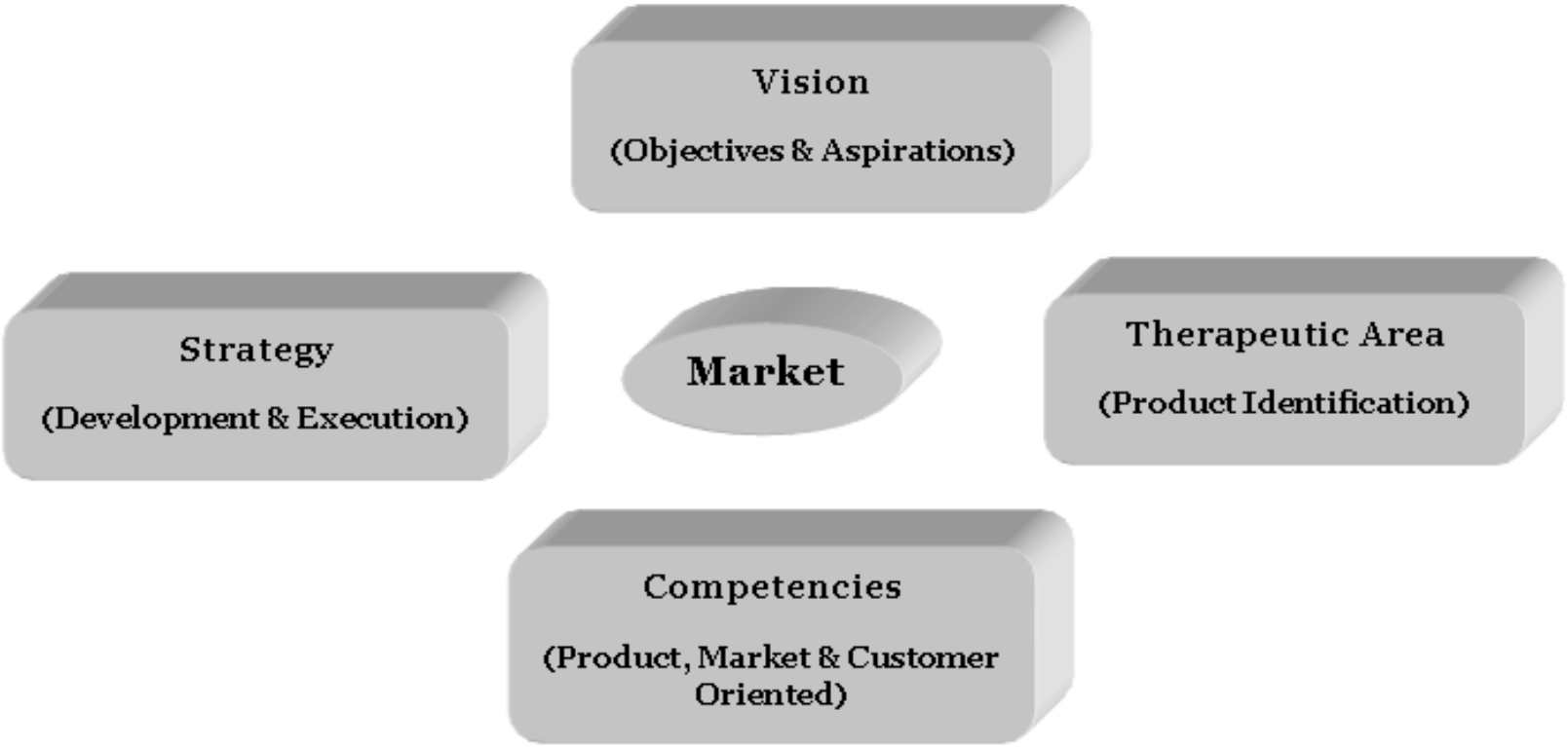
European Union delivers the immense potential of Biosimilars market to be tapped as a stride towards the Healthcare economical substantiality of the EU Member States. As the uptake of Biosimilars varies considerably by therapeutic area and case basis across the European Nations, the Companies striding towards the EU should postulate its Go-to-Market considerations with the perspectives of Stakeholders and Policies of the market. Thereby, unlocking the potential of Biosimilars across the EU necessitates an integrated approach of Regulatory and Commercialization strategies to counter the gray areas in the path and to edge the sustainable market space across European Union.

Background

- Biologics have transformed the clinical outcomes for patients across Europe.
- Biosimilars renders Patient access to treatment and are economical for European Healthcare systems.
- EMA paved the establishment of Regulatory guidelines and Market for Biosimilars in 2005.
- Journey 2006-2017 (March): 29 Biosimilar products, in the basket of the EU market.

Need and Scope of the Study

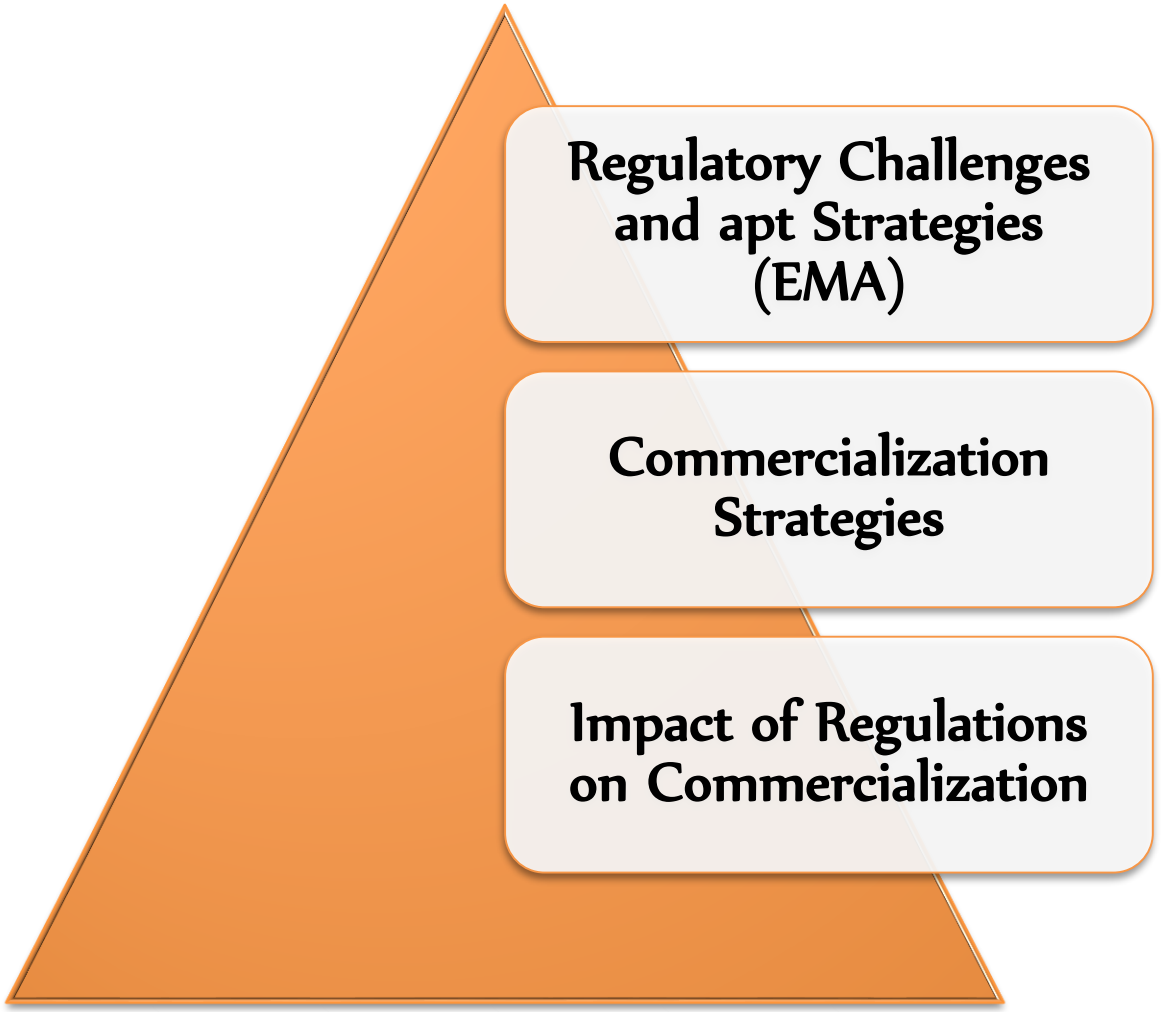
- The European Commission has acknowledged the call for better patient access as a part of reducing healthcare budget of Biologics.
- The substantial benefits associated with biosimilars are achieved only if sustainable mechanisms are available to strengthen the entry into the market.
- **Market Choice Strategy Cascade** Model – addresses both strategic and tactical set of choices associated with the Market.



Market Choice Strategy Cascade Model

- Along with it, the requisite regulatory stipulations and an integrated commercialization strategy approach via stakeholders prospective across EU is essential to edge the market space.

Objective


Regulatory Challenges and apt Strategies (EMA)
Commercialization Strategies
Impact of Regulations on Commercialization

Methodology

- Study Design

  Exploratory study with Qualitative outfit.

- Study Duration

  3 Months period (February 6, 2017 to May 5, 2017)

- Data Collection Procedure & Content Analysis

  The **Dual approach system** is deployed to establish the objectivity of the research sphere.

  - 1st step - retrieval of entropy of the information from various data sources.
  - 2nd step - the **Discussion-Framework technique**, with the panel of experts of the domain to have a qualitative content emphasis and is transcribed to objective insight.

Study Findings

Regulatory Challenges

- **Establishing Biosimilarity** in line with Reference Biologic

  i.e. **Comparability** is the core of Biosimilarity

- **Immunogenicity**

Strategies to counter the Regulatory challenges

- **Totality-of-Evidence** approach by endearing streamlined **ABCE** path of biosimilars and **Data package** imbibed in Registration Dossier for Marketing Authorization.

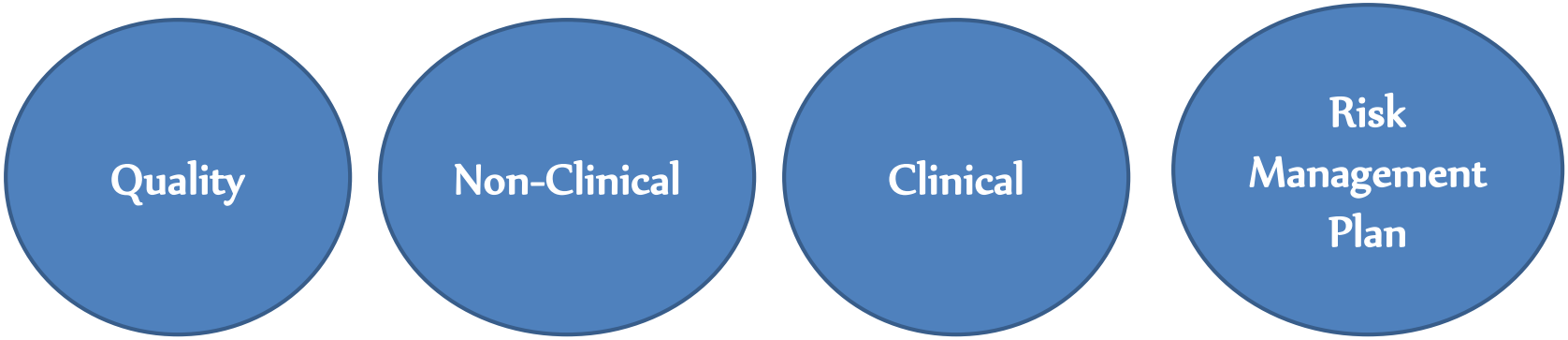
A - Accuracy of Analytics (Analytical demonstration and Biological characterization)

B - Bridging of Clinical data points

C - Curb the expectation of Clinical trials in every indication

E - Embrace Extrapolation.

ABCE of Biosimilars

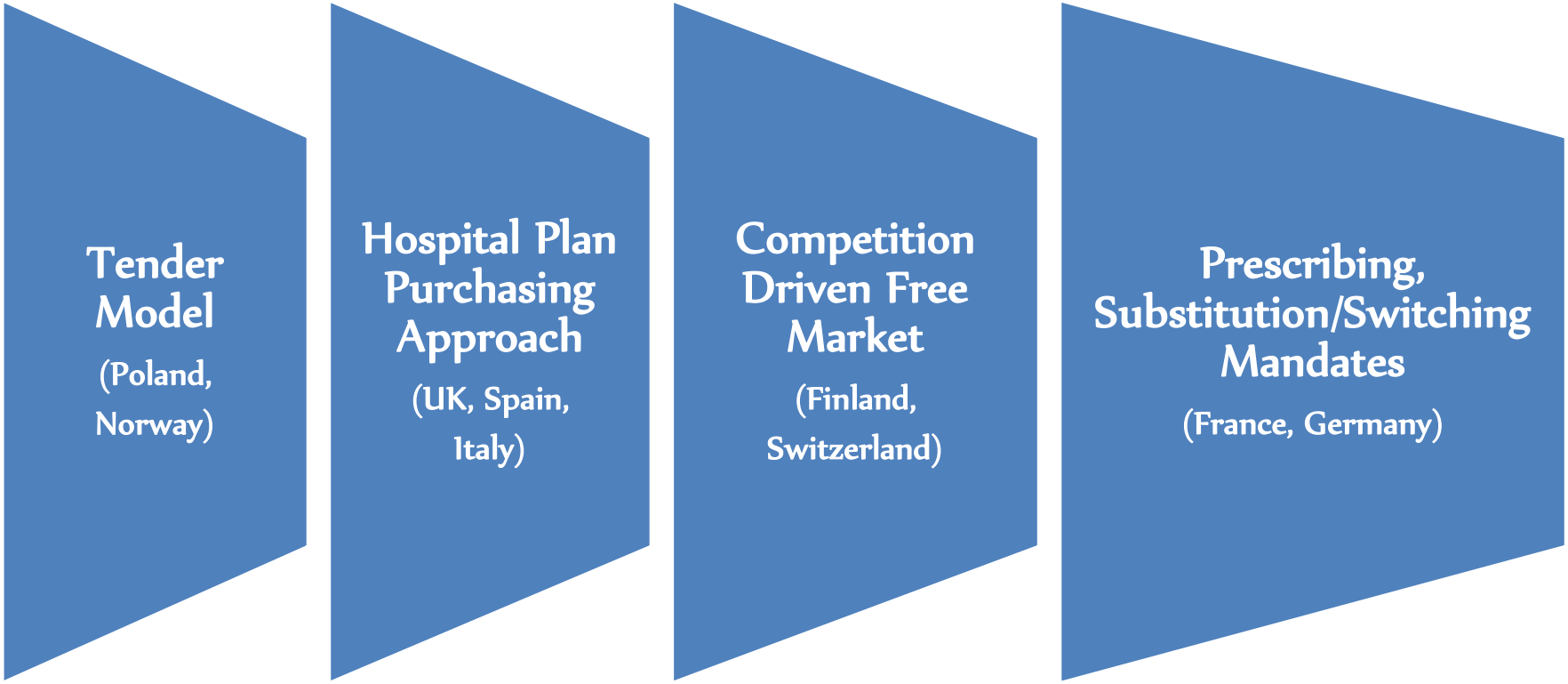


Data Package

"Risk Management Plan – Pharmacovigilance part"

Commercialization Strategies (with Perspective of Stakeholders in view of Go-to-Market considerations)

- **Payer Environment** – 4 models across EU.



- **Physician**

  Physicians at the **Heart** of Decision-Driving.

  - Physicians are part of Procurement decision panel (LIS – Norway)
  - KV (Physician associations - Germany) are proactive in building the Biosimilars concept via Insurers/Payers.

- **Patient**

  Awareness and Decision making towards biosimilars are crucial.

Biosimilar Pricing range with relative to Reference Biologic across EU5

- France: -(15-20%)
- UK: Free Pricing
- Germany: Free Pricing
- Spain: -(25-30%)
- Italy: -(20%)

- In UK & Germany, the Companies should adhere to the Pricing policies of Payers.
- "-" Price range cut/Price discount

Pricing and Market Access policies employed for sustainable Biosimilar Market

UK

- Four Regional Tender system
- National/Regional Guidance – NICE and CCGs
- Gain sharing – CCGs and Hospital level.

Germany

- Target Agreements – Biosimilar Quotas
- Bio-like initiative – Information & Education program by Physician associations (KV)
- Gain sharing – at the Physician level.

- "Gain sharing in terms of Non-Financial credits".

Reimbursement Agencies across EU5

- Germany – SHIs (Statutory Health Insurance system)
- France – CNAM (National Health Insurance Fund)
- United kingdom – NICE
- Spain – Spanish Reimbursement Council
- Italy – CTS

- Reimbursement Agencies - HTA committee governed by NHS the Ministry of Health.

Gray areas of Commercialization

- **Interchangeability (across EU5)**
  - France – Automatic Substitution (but with informed choice of Patient)
  - Germany, UK and Spain – Not allowed (but switching depends on Physician)
  - Italy – Not allowed
- **Name game**
  - Prescription with only **Trade name** of Biological products is accepted across EU.
- **Labeling**
  - **Black Triangle** symbol
- **Pharmacovigilance**
  - **Immunogenicity** and any other therapeutic issues.

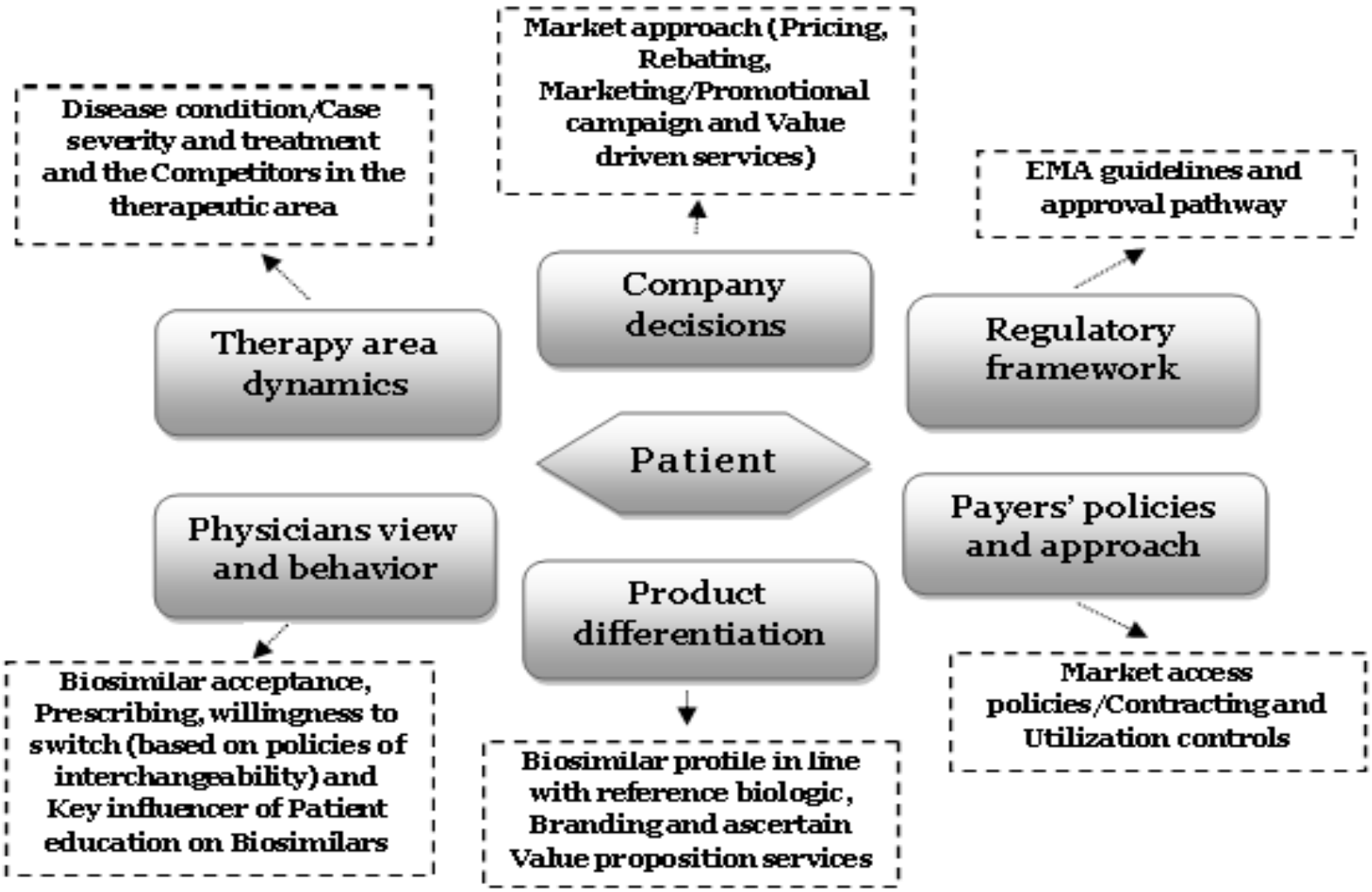
- **Patent &Trade Secrets issues**
  - Patent extension and Data exclusivity

  ex: Infliximab – Biosimilar launch delay because of Patent extension for Pediatric indication for 6 months across EU.
- **Innovator Market orientation**
  - Bio-Better version

  ex: Gazyva®

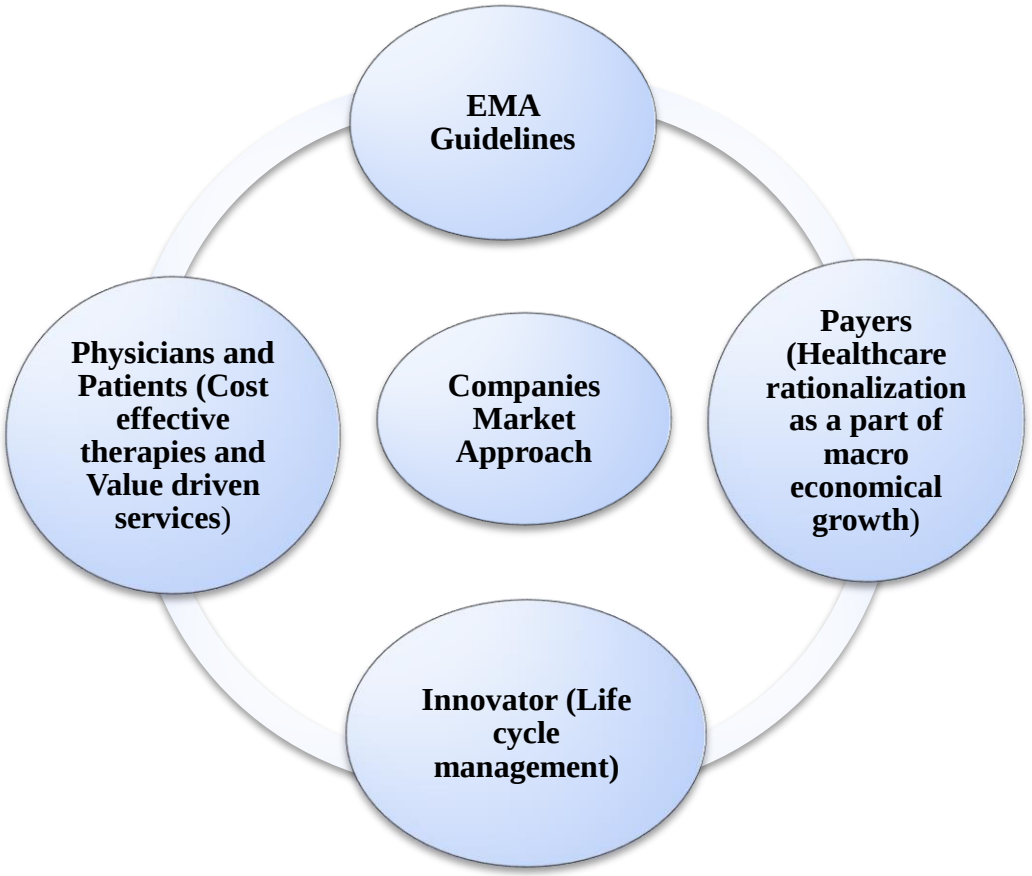
Commercial Success Approach Model for Biosimilars

The model attributes the performance of biosimilar companies and drives the market space in view of stakeholders' perspectives with the company specific market oriented approach to derive space in the EU biosimilars market.



Commercial Success Approach Model for Biosimilars in EU

Conclusion



Stakeholder Advocacy of Biosimilars in Europe

- Ultimately, the successful commercialization approach integrated with the regulatory roadmap for marketing authorization from EMA and collaborating the Go-to-Market phenomenon by countering the gray areas of commercialization, enacts as the winning strategy for a company to gain the access in the market space across the European nations.

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Annexure

Discussion Framework approach

- Discussion Framework approach implies the systematic interactions with the team of experts in Biologics, as to have the insights from the companies' prospective towards the Regulatory and Go-to-Market considerations with the Stakeholder alignment prospects across EU.
- Overview of the subject matter (Biosimilars) entails;
    - Streamlining of Clinical Development process
    - Real World Evidence (RWE) as a base for Totality-of-Evidence approach

- Commercialization considerations/strategies
- Stakeholders' Prospects across the EU
- Sustainability factors
- Gray areas to counter for EU market space
- Commercial Success framework.

- The information incurred is transcribed and formulated in to the study theme.