Student Electronic Assignment Cover Sheet

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<thead>
<tr>
<th>Course Title</th>
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<tr>
<td>Lecturer Name</td>
<td>Ann Masterson</td>
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<tr>
<td>Module Code</td>
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<td>The global pharmaceutical industry</td>
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# Strategic Customers and their evolution over time

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1. **Global Pharmaceutical Industry in a Nutshell**

According to World Health Organization *(WHO, n.d.)*, global pharma market is currently US$ 300 billion and is expected to grow by US$ 100 billion within 3 years. A worldwide prescription drugs sale in 2015 was US$ 750 billion and is expected to touch US$ 770 billion by 2016. *(Euler Hermes Economic Research, 2016)*

2. **Environmental forces influencing global pharmaceutical industry**

Pharmaceutical business is highly sensitive since it involves in-depth research & development based on science. It plays a unique role in developing new vaccines & life-saving drugs for disease prevention & treatment. Here are key PESTEL drivers that influence & shape this industry globally - *[Appendix I]*

2.1. **Political factors**

Major political factors that have strong effect on global pharmaceutical industry are – government regulations, price control & corruption. Pharma business needs huge capital investment and has much more risk compared to other hi-tech technology sectors. *[Appendix II]*

This industry is heavily regulated by government in most of the countries where it dictates policies like price control, imports required for pharma industry, licensing etc. Since these factors are government specific, they may change dramatically from government to government in democratic countries. *[Scenario 1 - Appendix III]* In case of communist countries, these policies usually remain same for longer period unless those countries opt for liberalization. *(IFPMA, 2016)*

2.2. **Economic factors**

For pharma industry, important economic factors are economic growth, consumer income and exchange rate. *[Appendix II]* Exchange rate is mostly useful for companies that do business internationally. Any fluctuations in their local currencies against US Dollar can have significant impact since it involves revenues & expenses due to imports & exports. It also has major effect on R&D since R&D process in pharma industry is lengthy and expensive. *[Figure 7 in Appendix IV]*

Similarly, economic and pharma industry growth goes hand-in-hand. Recession slows down economic growth and it also brings down average consumer disposable income. So even if government policies favour for foreign direct investment, weak economy forces companies to take cost-cutting measures due to lowering profits. *[Scenario 2 - Appendix III]* This situation may cause reduction in amounts reserved for research or even further expansion plans. One such example is Russia where purchasing power of ordinary Russians has gone down due to currency devaluation which has negative effect on pharma industry there. *(Yablokova, 2015)*

On the contrary, better exchange rate can go in favour of the company. According to Bloomberg Business *(Kitamura, 2015)*, multinational Bayer has expressed positive opinion about its forecast due to improved exchange rate of US Dollar against Euro.
2.3. Technological factors —
Two major technological factors affecting global pharma industry are amount spent on R&D and ability to innovate. [Appendix II] Since pharma industry’s success depends on new inventions through research & development, technology has immense effect. To keep pace with rising expectations about new drugs, company requires most up-to-date technological infrastructure to conduct its research. [Scenario 2 - Appendix III]

R&D requires huge investment [Figure 4 in Appendix IV] & usually begins when researchers or scientists identify chemical compound using 5,000–10,000 sample screening. Then they extensively test that compound to ensure its efficacy & safety and this process can take 10 to 15 years. [Figure 3 in Appendix IV] According to IFPMA (IFPMA, 2016), yearly expenditure of pharma industry in R&D is almost US$ 141 billion.

Another innovation that have changed US pharma industry is E-prescription i.e. doctors now send prescriptions electronically to the pharmacies instead of traditional system where pharmacy dispenses medications to patient only after paper-based prescriptions. (Kaur and Amirfar, 2015)

2.4. Social factors —
Two social factors that have impacted global pharma industry are lifestyle changes and population age demographics. [Appendix II] Apart from business cycles & recession, health awareness has also caused dramatic changes in people’s lifestyle and it has definite impact on pharma industry.

Obesity & Diabetes have become worldwide phenomenon. According to TIME (Sifferlin, 2015), majority of Americans are overweight. So not just US, but global pharma companies also have made strategic decision to focus their research on obesity related drugs. One such example is Danish pharma company Novo Nordisk which has launched obesity treatment in US last year. (Reuters, 2015)

Aging population has a problem in many countries but also an opportunity for pharma companies globally to invest & innovate in healthcare research for aged people. e.g. Japan’s aging population is growing and many pharma companies are finding this market as lucrative. This is because older people need more medications compared to younger people. (Lo, 2015)

2.5. Environmental factors —
Environmental factors that affect global pharma industry are air & water pollution and waste management. [Appendix II] It examines the effects of pharma wastes on local & global environment.

There are many types of industrial waste like antibiotics, steroids etc. generated during drug manufacturing and governments expect companies to follow regulations to avoid polluting air & water. Because of this, people living near pharma manufacturing plant are more prone to all kinds of risks due to faulty waste management mechanism.
(Kapoor, 2015) Many times, this pharma waste is in the form of unused medications, used test strips, chemicals used as ingredients etc. (Grossman, 2015)

2.6. Legal factors –
Legal factors important for pharma industry are - Copyright, patents / Intellectual property laws and consumer protection laws. [Appendix II] Since pharma products are consumed by human beings and due to bio-chemical nature of drugs, any adverse effects on human body can invite legal actions against the company.

In most countries, there are strict consumer protection laws to make sure that pharma companies take precautions about consumer health and promote their drugs in ethical manner. In 2015, Australian Federal Court ordered British pharma company Reckitt Benckiser not to sell its pain-relief products containing Nurofen after complaints of misleading consumers. (Duckett, 2015)

Intellectual Property Rights and Patents constitute significant portion of trade secrets of competitive advantage for pharma companies since their core business depends on inventing new drugs and bring them in market ahead of their competitors. So IPR laws of a country are major decision factor for them when establishing the business. [Scenario 3 - Appendix III]

3. Environmental forces affecting the global pharmaceutical industry

3.1. Porter’s Five Forces
Porter’s Five Forces Analysis helps in analyzing the intensity of competition, attractiveness and profitability of an industry. (Marin, A et al, 2015) Porter referred to these forces as the microenvironment, to contrast it with the more general term macro-environment already dealt with in question 1 above. They consist of those forces close to a company that affect its ability to service its customers and profitability. A change in any of the forces normally requires a company to re-assess the marketplace.
3.2. Industry Analysis using Porter’s Five Forces

- **Bargaining Power of Buyers**
  Pharmaceutical manufacturers may sell drugs to wholesalers, which then sell on to pharmacies, or to healthcare institutions such as hospitals. Mature markets are facing an increase in healthcare costs due to aging populations and governments are therefore putting increasing pressure on prices. Conversely, developing markets are growing in potential and becoming more important for manufacturers.

  Generally, the bargaining power of buyers is moderate due to the following key drivers of buyer power in Global Pharmaceutical Industry as has been addressed in Appendix V.

  - Backward Integration
  - Switching Costs
  - Product Differentiation
  - Buyer size
  - Oligopoly Threat
  - Buyer independence

- **Threat of New Entrants**
  Generally, the threat to new entrants is low due to the following factors which have been fully addressed in Appendix V.
• Capital Entry Requirements
• Regulation and Legal Framework
• Legislation and government action
• Restrictive formalities
• Intellectual Property

✓ Bargaining Power of Suppliers
The bargaining power of suppliers is moderate in the global pharmaceutical due to the following key drivers which are explained in detail in Appendix V
• Backward integration
• Switching costs
• Purchase from numerous suppliers
• Differentiated Inputs
• Importance of quality or cost

✓ Threat of Substitutes - Strong
The main substitutes to branded drugs are generics, Biosimilar (also known as follow-on biologics) and herbal medicines. (Falit, Singh and Brennan, 2015) Manufacturers of generics can offer the same drug at a much reduced price, as they rely on the efficacy and safety data provided by the innovator product, and there is no need to conduct expensive clinical trials. Generics also have low switching cost and offer a beneficial alternative.

✓ Threat of Rivalry among existing firms
The degree of rivalry is very strong. Pharmaceutical industry continues to witness fierce competition; there are a lot of big Multinationals, a lot of Mergers and Acquisitions, strategic alliances, network building, and niche-based acquisition taking place. (Mehta, Hasan and Selvaraj, 2016)

In conclusion, the pharmaceutical industry is not an attractive industry to enter for new players as its highly competitive, the incumbents are well established multinationals who have invested heavily in Research and Development, are enjoying economies of scale. However, Porter’s Five forces model has its limitations (refer to Appendix VII) hence it needs to be applied with some caution.
3.3. How Porter’s Five Forces differ per pharmaceutical industry sector

Below is a table depicting how Porter’s Five Forces differ per pharmaceutical industry sector. Detailed analysis of the key factors is in Appendix VI.

<table>
<thead>
<tr>
<th>Competitive Force</th>
<th>Ethical Drugs</th>
<th>Generics</th>
<th>OTC</th>
<th>Biopharmaceutical &amp; Vaccines</th>
</tr>
</thead>
<tbody>
<tr>
<td>Threat of New Entry</td>
<td>Low</td>
<td>Strong</td>
<td>Moderate</td>
<td>High</td>
</tr>
<tr>
<td>Bargaining Power of Suppliers</td>
<td>Moderate</td>
<td>Moderate</td>
<td>Strong</td>
<td>Low</td>
</tr>
<tr>
<td>Bargaining Power of Buyers</td>
<td>Moderate</td>
<td>Strong</td>
<td>Strong</td>
<td>Low</td>
</tr>
<tr>
<td>Threat of Substitutes</td>
<td>Strong</td>
<td>Moderate</td>
<td>Weak</td>
<td>Low</td>
</tr>
<tr>
<td>Competitive Rivalry</td>
<td>Strong</td>
<td>Strong</td>
<td>Moderate</td>
<td>High</td>
</tr>
</tbody>
</table>

PHARMACEUTICAL INDUSTRY SECTOR LIFE CYCLE

Below is a Pharmaceutical Industry Life Cycle as described by (Johnson, Scholes and Whittington, 2014) is a concept which proposes that industries start small in their development stage, then go through a period of rapid growth culminating in a period of shakeout, maturity and decline. The table below shows where each sector lies based on the underlying factors they are currently experiencing. Refer to Appendix VI for a detailed explanation.

GLOBAL PHARMACEUTICAL SECTORS INDUSTRY LIFE CYCLE

(OTC Pharmaceuticals Industry Profile: Global, 2015)
4. Strategic Groups within the global pharmaceutical industry

4.1. Identification of Strategic Groups within the global pharmaceutical industry

The aim of strategic group analysis is to determine whether groups of firms that have a comparable strategic position exist within an industry or not. Findings of strategic group analysis might further be used to explore the performance implications of strategic group Membership. This analysis has a significant effect on the industry’s profitability, contradicting the industrial organization (IO) Economics’ speculation that an industry members differ only in market share.

Global pharmaceutical industry is monophony with intense level of competition in R&D and property rights (Johnson, Scholes and Whittington, 2014). We have carefully identified top 9 close competitors within the global pharmaceutical industry and have strategically group them based on the following factors:

In the first pillar of strategic grouping by Revenue:

![chart](chart.png)

From the above chart, competitive analysis indicates that GSK, Sanofi, NOVARTIS, MERCK, ROCHES and PFIZER fall into one group since they share a close competitive strategy in the industry while ABBOTT & ASTRAZENECA are into second group with close in strategy, while J&J shows a stand out in terms of revenue. According to Statista report (Statista, 2014) on global pharmaceutical industry, revenue worldwide has reached approximately US$ 1 trillion.

Furthermore, 2015 ranking top 10 biotech and pharmaceutical global companies worldwide, based on revenue by (Statista, 2015) U.S. pharmaceutical company Johnson & Johnson was at the top of chart, with a total revenue of approximately US$ 74.3 billion. From our strategic grouping US pharmaceuticals Johnson & Johnson, Pfizer and Novartis
occupy the leading position which is nearly 45% of the total worldwide pharmaceutical companies.

The second pillar of strategic grouping on Total Market Spending:

In this category, Johnson & Johnson is a leader in the industry based on their market spending of US$ 17.5 billion. The analysis indicates very close clustering between ROCHE, GSK, MERCK and Sanofi, According Porter and Heppelmann (Porter and Heppelmann, 2014), the closer the strategic groups clustered in the chart, the stronger the across group competitive rivalry will be. Roche, GSK, Merck and Sanofi are close rivalry in the market based on their market spending. Johnson & Johnson and Novartis holds high competitive advantage over the above listed. There is also a strategic gap in the chart Pfizer could increase their market spending considering their revenue at US$ 11.4 billion.

Strategic grouping by Percent of Revenue spent on R&D:
R&D is key area for a pharmaceutical industry. The company’s valuation is done not only based on the product it has out in the market but also the products it has in its pipeline. Statista report on R&D spending shows that from 2006 to 2014, there has been continuous increase in R&D spending in the global pharmaceuticals industry. In 2015 R&D in global pharmaceuticals industry dropped by 1%, statistical forecasted on pharmaceutical industry on R&D spending by 2020 is expected to reach 160bn in US$.

Our Strategic grouping analysis indicates that Novartis and Roche are close competitors in the global pharmaceuticals while Merck and AstraZeneca are also close competitors. Johnson & Johnson is high in revenue but in terms of spending in R&D, they have spent lesser than other companies in the industry. From the chart Roche and Novartis are close strategic grouping they invest heavily on research and development. There is a gap between Merck and AstraZeneca.

Although the global pharmaceutical industry is an extremely competitive, strict regulations, with continuous change of government policies, lengthier time to market products, high attrition rate and a limited period of right to intellectual property, huge capitals investment, large market spending and constant involvement on research and development makes it a high stake market, from the strategic group analysis firms can still identify gaps within their environment to adopt.
5. Strategic Customers and their evolution over time

5.1. Business to Business (B2B) strategic customer

The meaning of customer has developed or evolved from "somebody who buys goods or services to someone with whom one must deal, which suggests emphasis on the relationship. The strategic customers in Pharmaceutical industry are the government agencies, wholesalers, healthcare/hospital and pharmacies. Pharmaceutical companies through their sales representative invite doctors, healthcare professionals and pharmacist for discussion on how to use their products, the advantages of the drugs along with free samples. They provide necessary information, new studies, clinical data and new dosing information. Promotion was subject to industry self-regulation (Johnson, G. 2014, P. 555). Below is the communication channel from pharmaceutical industry to their strategic customers and the end users.

Communication Channels in Pharmaceutical Industry- Through Strategic Customers

In developing countries like India and Nigeria, the government is a strategic customer of pharmaceutical industry because they hold some substantial power to dictate polices and regulations. Government controls pharmaceutical market through drug prices (Rxchange CO., 2015). Government has played an important role in shaping pharmaceutical industry by taking some measures to make medicines available to those who cannot afford it. They have subsidized the prices of some drugs such as Anti-Retroviral drugs (drugs for HIV/AIDS).
The US pharmaceutical market is different from the rest of the world since the US government has no price control. So people have to pay more for same drugs compared to other countries (RxChange Co., 2015)

5.2. Business to Consumer (B2C) strategic customer

Pharmaceutical industry is now marketing their product directly to the final consumer which is B2C. B2C is a Pharmaceutical marketing strategy used to promote products and services directly to consumers (the end users). United states of America are the largest market for prescription drug sales (Mackey T, Liang B., 2015). The emergence of Direct to Consumer advertising (DTCA) is a form of pharmaceutical marketing directly advertises prescription drugs and targets the consumer/patient rather than healthcare professionals (Wang B, Kesselheim, 2013).

In March 2014, 235 companies in China have gained Qualification Certificate for Online Drug Trading Services, including 162 online pharmacies (A Berkshire Hathaway Company, 2014). Online drug-stores are getting more attention to pharmaceutical companies as they continue to shape the future of drug purchasing and have created new relationships between patients, retail/wholesale pharmacies. The pharmaceutical industry is predicted to grow 20 percent of total sales coming from online sources by 2020, the highest penetration of all industries (Kaplan, 2015).

5.3. Strategic Customer Evolvement

In past, most of the pharmaceutical industry decisions were heavily influenced by healthcare providers like doctors and medical representatives. This is mainly because insurance companies or government involvement was very limited. Similarly, medical practitioners were insensitive to price but susceptible to the efforts of sales representatives.

At present, this picture has changed to a great extent since technology and globalization have profound effect and government is taking lead role in maintaining control on the industry. Worldwide growth of healthcare sector has also attributed to present scenario where wholesalers are playing role of strategic customer.

In future, government and wholesalers will continue their role as strategic pillars in the industry but consumers will also bring their influence through steady rise in B2C concept which is still limited in few markets only.

5.4. Impact of CSF (Critical Success Factors) on Pharma Industry

Government has focus on reducing spending on health from patient. They believe that savings are to be made by facilitating and increasing the uptake of unbranded drugs (generics) by individual patients and healthcare professional. Branded drugs are more expensive than generic but both do the same function. Government hopes to achieve the increased uptake and substantial cost savings by introducing generic and also opening up price competition among pharmaceutical suppliers.
The generic companies are happy with government policy on the production of generic drugs. The blockbuster drugs are coming off from patent protection, such as Lipitor from Pfizer’s company that is used for lowering cholesterol (Lkshields.ie, 2012). The introduction of generic version of Lipitor has made greater market competition generally affecting demand and pricing at a global scale. The generic manufacturing companies are witnessing strong sector growth in emerging markets.

**Below is the revenue forecast for generic drugs till 2025**

![Figure 3.18 Endo: Generic Drugs Revenue Forecast ($m, AGR%), 2015-2025](image)

*Source: Endo Generics 2015
(International Pharmacy Conference, n.d.)*

**Innovation, Research and Development (R&D)**

Innovative medicines developed by America’s Biopharmaceutical research company have helped many children to survive cancer. In 1970s, 58 percent of childhood cancer survived but today, the rate has increased to 83 percent and have contributed to reducing death rates for patients battling with diseases; for example, HIV/AIDS, heart problems and cancer has reduced 22 percent since 1991 (Phrma.org, 2016) Patients and community as a whole benefit from new drug development innovations.

Pharmaceutical companies remain competitive by expending significant resources to maintain diverse number of drugs in their research pipeline in order to bring new drugs to the market. Refer to figure [Figure 4 in Appendix IV].

**Mergers and acquisition (M&A)**

M&A are very crucial for pharmaceutical industries to achieve growth and realign their portfolios in a competitive market. The pharmaceutical industry enjoys R&D collaboration, often considered to be attractive as they abolish duplication, control development costs, attain increased market share, greater exchange of expertise with merged company and they have wider geographical coverage/market, by introducing new product easily. M&A has results in cost reduction and revenue maximization.
6. Conclusion

At the end, it can be concluded that pharma industry is heading towards growth. In 2015, Novartis was leading pharma industry in terms of manpower [Figure 1 in Appendix IV] while Johnson & Johnson was top company by revenue. [Figure 2 in Appendix IV]

Global prescription drugs sales are expected to reach US$ 987 billion [Figure 6 in Appendix IV] by 2020. (SILVERMAN, 2015) According to Nasdaq report (NASDAQ, 2016), companies will focus more on generic drugs than branded. By 2018, sales of generic drugs worldwide are expected to rise to US$ 442 Billion. [Figure 5 in Appendix IV] Similarly vaccine market is emerging as major revenue source for pharmaceutical companies. It is expected to reach US$ 61 billion by 2020. (Guzman, 2016)
7. Bibliography

Journals/Articles


Books


Websites


Images


## Appendix I – PESTEL Analysis

### Political
- **Factors in this category deal with government related issues like regulations and legal policies. These are important since they can affect a company’s success in the market. Major factors here are tax guidelines, copyright & property laws, political stability, trade & competition regulations and nature of bureaucracy.**

<table>
<thead>
<tr>
<th>Political factors</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Government regulations</td>
<td>Government policies affect business environment directly since it formulates fiscal as well as monetary policy which can be either favorable or against the economic growth.</td>
</tr>
<tr>
<td>Bureaucracy</td>
<td>In most countries, bureaucracy is bane for businesses since it can significantly delay critical strategic decisions of the company thus derailing entire plans so it is one of the critical factors.</td>
</tr>
<tr>
<td>Corruption level</td>
<td>Corruption has become big debating topic now a days and it can affect business environment in adverse way.</td>
</tr>
<tr>
<td>Competition regulation</td>
<td>Political forces can also regulate businesses or trades based on their ideologies. e.g. communist governments prefer tightly regulated markets in which competition becomes almost impossible.</td>
</tr>
<tr>
<td>Trade control</td>
<td>Trade of medicines is usually not controlled unless there are sanctions on the particular nation by UN or such organizations in case of Exports. Domestic trade is controlled as per the FDA laws.</td>
</tr>
<tr>
<td>Import restrictions</td>
<td>To protect domestic industry, governments do restrict some products, raw materials to be imported and quantity is also restricted in some cases. Government may impose restrictions on importing certain items due to quality issues, health hazards (Bird Flu virus).</td>
</tr>
<tr>
<td>Tariffs</td>
<td>Tariffs also play important part in business environment. Higher tariffs usually discourage companies to enter in new countries while business friendly tariffs boost confidence in companies by making the market more attractive.</td>
</tr>
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### Economic
- **Economic factors are used to examine economic issues that can have major impact on company’s success. These factors include growth rate of economy, exchange rates, inflation and interest rates, economic stability, monetary & fiscal policies.**

<table>
<thead>
<tr>
<th>Economic factors</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td>Economic Growth</td>
<td>Economic growth does have positive impact on pharma industry. Stronger economy enables companies to invest for research and manufacturing drugs.</td>
</tr>
<tr>
<td>Exchange rates</td>
<td>Exchange rates play vital role in trading pharma products within two countries since it directly affects import duties due to conversion.</td>
</tr>
<tr>
<td>Labor costs</td>
<td>Labor costs are directly associated with company’s profit margins since cheap labor helps the business improve profit margin due to cost-cutting.</td>
</tr>
<tr>
<td>Monetary policies</td>
<td>Monetary policies mean actions taken by a government to control supply of money with country’s economic market to monitor inflation &amp; interest rates to make sure that there will be price stability and people will have faith in their currency.</td>
</tr>
<tr>
<td>Fiscal policies</td>
<td>Fiscal policies are related to revenue collection by government in the form of taxes and also related to its spending. Government fiscal policies are influenced by economic conditions like recession or inflation.</td>
</tr>
</tbody>
</table>
Consumers’ disposable income | Consumer disposable income depends on local as well as global economy. Recession can pull down this income which forces consumers to spend less to face unwanted situations.

| Socio-Cultural – These factors help to analyze market conditions from demographic & cultural perspective. They can determine consumer needs & forces behind their behavior patterns. Among the items that should be examined are demographics, population growth rates, age distribution, religious beliefs, lifestyle changes, educational and environmental issues and health consciousness. |
| Lifestyle changes | Changes in people’s lifestyle have definite impact on overall economy since it fuels competition among companies to create and satisfy demands depending on lifestyle changes. |
| Population growth rate | High population growth also creates new opportunities for emerging markets. |
| Age distribution | Average age of population determines the market trends and thus influences lifestyle changes. High percentage of youth attracts business that target products for young generation. |
| Attitudes toward product quality and customer service | A society with high awareness about product quality & customer service is always challenging for companies since they need to monitor their business processes continuously. |
| Social classes | Most markets in the world have to cater three broad social categories of consumers –
1. Rich & affluent
2. Middle class with average income
3. Poor living on bare minimum wages |

| Technological – These factors deal with issues related to technology to determine how it impacts an organization in delivering its product or service to the marketplace. Some of the major technological factors are technological advancements, government funding for technology research, life cycle of existing technology etc. |
| Basic infrastructure level | Technology plays a major role while entering & setting up the Industry. Lack of basic infrastructure has negative impact on businesses. |
| Rate of technological change | Market has to respond changes in technology otherwise companies within that market will become obsolete and will be flooded by new entrants. |
| Spending on research & development | Governments have to encourage companies to invest in research activities if they want to promote technology based businesses. |
| Access to newest technology | Country’s technical progress also depends on how quickly the businesses get access to developments in technology. |
| Innovation | Companies have to be innovative in their business strategies to stay ahead of competitors in terms of technology. |

(Shah, Jamil and Kazmi, 2015)

<p>| Environmental – These factors study impact of various environmental factors like climate change, weather, waste management, energy consumption etc. |
| Weather | Climatic conditions are considered very seriously to ensure the smooth operations while setting up an industry |
| Climate change | Country should have provisions to deal with factors affecting by the |</p>
<table>
<thead>
<tr>
<th></th>
<th>climate change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Air and water pollution</td>
<td>Companies have to follow strict norms on emissions during manufacturing process so that it doesn’t violate air &amp; water pollution regulations.</td>
</tr>
<tr>
<td>Recycling</td>
<td>Waste water recycling is compulsory.</td>
</tr>
<tr>
<td>Waste management</td>
<td>It indicates adoption of techniques to manage industry waste in a way that will be safe for the society.</td>
</tr>
<tr>
<td>Environmental Law</td>
<td>It involves stringent laws and regulations to ensure that any industry does not harm or pollute the environment.</td>
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</table>

**Legal –** These factors include studying challenges in market due to legal aspects. These include IPR laws, patent laws, Data protection laws, consumer protection policies etc.

<table>
<thead>
<tr>
<th>Copyright, patents / Intellectual property law</th>
<th>Copyright infringement is common in some countries, which poses great risk for companies. Similarly, companies try to protect their inventions through patents. So if a country doesn’t offer adequate protection to patents then it becomes huge risk for businesses involved in research.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consumer protection</td>
<td>Consumer protection laws are important in business environment since it protects consumers from getting sub-standard products &amp; services.</td>
</tr>
<tr>
<td>Employment law</td>
<td>These laws make sure that employees are paid appropriate wages as per minimum wages laws.</td>
</tr>
<tr>
<td>Health and safety law</td>
<td>Health insurance and safety laws are necessary for employees &amp; laborers to create safe working environment.</td>
</tr>
<tr>
<td>Data Protection</td>
<td>Data protection policies of government ensure that companies can do their business without information theft worries.</td>
</tr>
</tbody>
</table>

*(Mind Tools, n.d.)*
### Appendix II – Identifying Key Drivers

Assign uncertainty level to important PESTEL factor affecting pharmaceutical industry –

<table>
<thead>
<tr>
<th>PESTEL Factor</th>
<th>Category</th>
<th>Uncertainty Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Government regulations</td>
<td>Political</td>
<td>High</td>
</tr>
<tr>
<td>Price control</td>
<td>Political</td>
<td>Low</td>
</tr>
<tr>
<td>Corruption</td>
<td>Political</td>
<td>Low</td>
</tr>
<tr>
<td>Economy Growth (Business cycles)</td>
<td>Economic</td>
<td>High</td>
</tr>
<tr>
<td>Consumers’ disposable income</td>
<td>Economic</td>
<td>Low</td>
</tr>
<tr>
<td>Exchange rate</td>
<td>Economic</td>
<td>Medium</td>
</tr>
<tr>
<td>Lifestyle changes</td>
<td>Social</td>
<td>High</td>
</tr>
<tr>
<td>Age distribution</td>
<td>Social</td>
<td>Low</td>
</tr>
<tr>
<td>Innovation</td>
<td>Technological</td>
<td>Medium</td>
</tr>
<tr>
<td>Spending on R &amp; D</td>
<td>Technological</td>
<td>High</td>
</tr>
<tr>
<td>Air and water pollution</td>
<td>Environmental</td>
<td>Low</td>
</tr>
<tr>
<td>Waste management</td>
<td>Environmental</td>
<td>Low</td>
</tr>
<tr>
<td>Copyright, Patent &amp; IPR laws</td>
<td>Legal</td>
<td>High</td>
</tr>
<tr>
<td>Consumer protection</td>
<td>Legal</td>
<td>Low</td>
</tr>
</tbody>
</table>

Determine key drivers having high uncertainty levels and higher impact on the environment in future –

i. Government regulations
ii. Economic growth
iii. Lifestyle changes
iv. R&D Spending
v. Copyright, Patent & IPR laws
Appendix III – Scenarios based on Key Drivers that have high uncertainty level and high impact in future

**Scenario 1**

<table>
<thead>
<tr>
<th>Low Government regulations</th>
<th>High Government regulations</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Low Economic growth</strong></td>
<td>Medium to High risk for further investment due to recession</td>
</tr>
<tr>
<td><strong>High Economic growth</strong></td>
<td>Pharma market ideal for investment due to economic growth &amp; low regulations</td>
</tr>
</tbody>
</table>

**Scenario 2**

<table>
<thead>
<tr>
<th>High R&amp;D Spending</th>
<th>Low R&amp;D Spending</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Low Economic growth</strong></td>
<td>Companies can suffer financial losses due to high expenses during recession</td>
</tr>
<tr>
<td><strong>High Economic growth</strong></td>
<td>Aggressive approach to target potential markets by boosting research due to economic boom</td>
</tr>
</tbody>
</table>

**Scenario 3**

<table>
<thead>
<tr>
<th>Low Government regulations</th>
<th>High Government regulations</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Strict IPR laws</strong></td>
<td>Market is favored by pharma companies since it provides protection against IP theft</td>
</tr>
<tr>
<td><strong>Lenient IPR laws</strong></td>
<td>Pharma companies will stay away from research in this market since it doesn’t provide protection against counterfeit</td>
</tr>
</tbody>
</table>

(Fotr et al., 2015)
Appendix IV – Figures

Figure 1 - 2015 ranking of top 10 global biotech & pharma companies by employees

2015 ranking of the global top 10 biotech and pharmaceutical companies based on employee number

(Statista, 2016)

Figure 2 – 2015 ranking of top 10 global biotech & pharma companies by revenue

2015 ranking of the global top 10 biotech and pharmaceutical companies based on revenue (in billion U.S. dollars)

(Statista, 2016)
Figure 3 – Biopharmaceutical R&D Process

From drug discovery through FDA approval, developing a new medicine on average takes at least 10 years and costs $2.6 billion. Less than 12% of the candidate medicines that make it into phase I clinical trials will be approved by the FDA.


(2015 biopharmaceutical research industry profile, 2015, p.45)

Figure 4 – Pharma companies’ expenditure on Marketing and R&D

(Olson, 2015)

Figure 5 – Predicting Global Sales - Branded vs Generic Drugs

(NASDAQ, 2016)
Figure 6 – Worldwide Prescription Drug Sales by 2020

(EvaluatePharma, 2015)

Figure 7 – Front-End Innovation (FEI) process in pharma research

(AAGAARD, 2015)

Figure 8 – Johnson & Johnson Pharma vs Medical Devices Revenue

(Koons, 2016)
Figure 9 – Pharmaceutical Wholesalers in Fortune 500 List

<table>
<thead>
<tr>
<th>Company (stock symbol)</th>
<th>2014 Revenues ($B)</th>
<th>Revenues, % vs. 2013</th>
<th>2015 Fortune 500 Rank</th>
<th>Profit as % of Revenues</th>
<th>Profit as % of Assets</th>
<th>Annualized Return to Investors (2004-2014)</th>
<th>Total Return to Investors (2014)</th>
</tr>
</thead>
<tbody>
<tr>
<td>CVS Health (CVS)</td>
<td>$139.4</td>
<td>9%</td>
<td>10</td>
<td>3%</td>
<td>6%</td>
<td>16%</td>
<td>36%</td>
</tr>
<tr>
<td>McKesson (MCK)</td>
<td>$138.0</td>
<td>12%</td>
<td>11</td>
<td>0%</td>
<td>2%</td>
<td>21%</td>
<td>29%</td>
</tr>
<tr>
<td>AmerisourceBergen (ABC)</td>
<td>$119.6</td>
<td>34%</td>
<td>16</td>
<td>0%</td>
<td>1%</td>
<td>21%</td>
<td>29%</td>
</tr>
<tr>
<td>Express Scripts Holding (ESRX)</td>
<td>$100.9</td>
<td>-8%</td>
<td>22</td>
<td>2%</td>
<td>3%</td>
<td>24%</td>
<td>20%</td>
</tr>
<tr>
<td>Cardinal Health (CAH)</td>
<td>$91.1</td>
<td>-9%</td>
<td>26</td>
<td>1%</td>
<td>4%</td>
<td>8%</td>
<td>23%</td>
</tr>
<tr>
<td>Walgreens (WBA)</td>
<td>$76.4</td>
<td>5%</td>
<td>35</td>
<td>2%</td>
<td>5%</td>
<td>8%</td>
<td>35%</td>
</tr>
<tr>
<td>Rite Aid (RAD)</td>
<td>$25.5</td>
<td>0%</td>
<td>117</td>
<td>1%</td>
<td>3%</td>
<td>7%</td>
<td>48%</td>
</tr>
<tr>
<td>Omnicare (OCR)</td>
<td>$6.6</td>
<td>4%</td>
<td>414</td>
<td>2%</td>
<td>2%</td>
<td>8%</td>
<td>22%</td>
</tr>
</tbody>
</table>

(Fein, 2016)

Figure 10 – Americans pay more for same drug due to no price control

<table>
<thead>
<tr>
<th></th>
<th>Average price of Nexum (heartburn medication), USD</th>
</tr>
</thead>
<tbody>
<tr>
<td>USA</td>
<td>$295</td>
</tr>
<tr>
<td>Switzerland</td>
<td>$500</td>
</tr>
<tr>
<td>Spain</td>
<td>$568</td>
</tr>
<tr>
<td>England</td>
<td>$442</td>
</tr>
<tr>
<td>Netherlands</td>
<td>$223</td>
</tr>
</tbody>
</table>

(The Fight to prevent Price Gouging for Prescription Drugs, 2015)
Appendix V – Porter’s Five Forces for Pharmaceutical Industry

1. **BUYER POWER (Moderate)**

Pharmaceutical manufacturers may sell drugs to wholesalers, which then sell on to pharmacies, or to healthcare institutions such as hospitals. Mature markets are facing an increase in healthcare costs due to aging populations and governments are therefore putting pressure on prices. Conversely, developing markets are growing in potential and becoming more important for manufacturers.

- Except for OTC and similar drugs, prescriptions are normally required in order to obtain pharmaceutical products. Marketing of prescription drugs is therefore largely directed at Doctors, with whom they wield a substantial influence. With the exception of United States, advertising such products directly to consumers is usually unlawful. Depending on the medical ailment, there may be several different medications available and product differentiation in these circumstances weakens buyer power. Differentiation can consist of efficacy, ease of use, side effects, and cost-effectiveness. Genetic and genomic research, gives rise to the opportunity of personalized medicine, which is also likely to decrease buyer power. Conversely, where generic equivalents to a branded drug exist, differentiation is decreased and buyer power increases.

- Private Health Insurance or government usually fund medicine purchases, e.g. National Health Service in United Kingdom or may refund all money/funds utilized on medication. Buyer Power is enhanced in the process. In a monophony market, this is one of the price control mechanism by government.

- Governments may prescribe prices to be charged, any price differences may be deemed illegal. Where governments are responsible for refunding consumers, they may set a very low refund price for existing or new drugs. Reference pricing systems, in which refund levels are set, by comparison of the price of a drug in peer group state and/or therapeutic types, are common. Where a therapeutic grouping contains generics, the effect may be to push down the reference price for on-patent drugs in the same group. A similar effect can occur where peer group countries have lower incomes than the country making the comparison.

- The US and Germany, are trending towards a value-based pricing system in which the price of drugs is centered on health outcomes rather than cost of development. Profit controls may exist whereby a limit is set a limit for the drug which may be sold in the country or to the amount of profit that can be realized by a Company from a drug anything above, the manufacturers must offer either compensatory disbursements to government or reduce price. Import tariffs are also used to motivate manufacturers to locate in a given economy. Such arrangements may be regarded as market alterations. However, where they are in practice it is because policy makers consider that the social benefits of low-cost drugs, such as better access to healthcare, compensate the social harms, such as a possible reduction in pharmaceutical companies’ ability to invest in Research and Development.

- Factors lessening buyer power include the high significance of pharmaceuticals in healthcare. This is apparent in systems such as the United States, where several people are
individually responsible for significant co-pays and personal insurance premiums. But even in the United Kingdom, where the National Health Service is financed entirely by taxation and free at the point of use, it would be politically risky for a government to abandon healthcare. Although the ultimate patients, to use the drugs interact with the pharmaceutical market through political endeavors rather than a direct value chain, they still have a substantial impact on the purchasing procedure. Increase in Buyer power recently has been due to increasing healthcare costs, state austerity policies, and the increasing accessibility of generics.

- The cost of switching-Buyers will have extensive choice if they want to buy paracetamol from superstore or pharmacy and it is low risk and buyer power is high compared to a patient or doctor looking to switch patient’s cancer treatment may have little choices as there are fewer suppliers specializing in that treatment – risk is high and buyer power is low

Overall, buyer power is assessed as moderate.

2. THREAT OF NEW ENTRANTS

Regulation and Legal Frameworks

The pharmaceutical sector plays a crucial role in the medical and health field (Shabaninejad et al., 2014). The pharmaceutical market is heavily controlled in many countries because of the unique nature of demand and supply in this section. According to the characteristics of the competition in the drug market, governments must keep in balance both clinical and economic interests. (Mehralian, Zarenezhad and Rajabzadeh Ghatari, 2015)

Legal frameworks and Regulation can affect the easiness of market entry in several ways. Firstly, drug manufacturers wishing to market its products must show that its drugs are safe and effective, to the satisfaction of the regulating body. Examples of regulators would be Food and Drug Administration in USA, Agence Française de Sécurité Sanitaire des Products de Santé in France, and the Pharmaceutical and Medical Devices Agency in Japan.

Capital Requirement of Entry

A start-up company that intends to develop an entirely new biotech drug will need substantial up-front cash outlay, often from venture capital companies, and this must be accessible for the time it takes to develop and test the product.

Legislation and government Action

Meeting regulatory requirements takes a lot of time about 10-15 years to bring a drug to market. Pharmaceutical Research and Manufacturers of America trade group indicated that out of 5,000 to 10,000 screened compounds, only 250 entered preclinical testing phase, out of which five only enter human clinical trials, and only one will be approved by the Food and Drug Administration (FDA). In 2011 and 2012, the FDA approved only 35 new drugs per year. In addition to investing a significant amount in research and development, manufacturers
also incur significant expenses on marketing, which further increases the investment required by new entrants. (IBEF, 2016)

On the other hand, entering a specific drug market with an existing drug is probably going to be easier, provided the licensing authority in that jurisdiction is satisfied.

**Restrictive formularies**

Another regulatory barrier to entry is use of restrictive formularies: for instance, in a specific therapeutic category, only certain medications may be listed as preferred. This does not imply that non-formulary options are unsafe or ineffective. Rather, they can only be recommended in special conditions with prior approval from the relevant body or with more substantial co-pays from the patient. The potential market for non-formulary drugs will consequently be smaller than the size of the therapeutic market.

Another restraint is imposition by government by ‘prescribing guidelines’ offered by relevant bodies such as the National Institute for Clinical Excellence in the UK. Such guidelines may be recommendations or compulsory, and typically include prescriptions of special therapeutic interventions, substitute brands, and so on.

**Intellectual Property**

New Entrants in a drug market are also affected by the strength and nature of intellectual property protection, which is currently restrictive. However, pressure from developing countries to increase technology transfer and make intellectual property matters more favorable are likely to benefit new entrants

3. **SUPPLIER POWER (MODERATE)**

**Backward integration**

Suppliers to the pharmaceutical industry are manufacturers of API’s, which form a sub-sector of the chemical industry. A number of leading pharmaceutical entities have backward integration into chemical manufacturing, providing them with a degree of self-reliance and this reduces supplier power to an extent.

**Switching Costs**

APIs operate on contractual basis with pharmaceutical companies which are likely to risk high switching costs if they consider taking their business elsewhere. In turn, pharmaceutical companies engage sourcing managers to minimize costs and to lessen supplier power. The development of new therapeutic agents involves the sourcing of newer APIs, for which chemical manufacturers can charge pharmaceutical companies higher prices. If the new drug successfully reaches the market, the supplier of the API can make enormous amount of money.
Purchase from numerous suppliers

Drug manufacturers tend to purchase their raw materials from various suppliers, reducing their dependence on any specific company. In general, laboratory equipment and chemicals show little differentiation between suppliers, with customers utilizing a wider choice in order to obtain the best quality and cost, reducing supplier power.

Differentiated Input

Nevertheless, there are cases where specialized facilities or raw materials are required, for instance sterile processing of biological materials. In such instances, supplier power is very strong. It is unlikely that suppliers would pursue forward integration into the pharmaceutical market; however, their competencies in chemical synthesis make them perfect candidates for forward integration into manufacturing of generic drugs. Recently larger pharmaceutical companies have resorted to producing their own chemicals in an attempt to enhance their profitability, however smaller entities lack the resources enabling them to do this and remain dependent on API manufacturers.

Pharmaceutical companies usually outsource their drug testing services and clinical trials to third party service providers. Given the significance of these trials for regulatory approvals, these companies are also important suppliers.

Overall, supplier power is moderate.

4. THREAT OF SUBSTITUTES (STRONG)

Patients may choose traditional remedies Homeopathy and Ayurveda as substitutes for pharmaceuticals (IBEF, 2016). Physicians may opt for non-drug treatments if they consider them most suitable. Successful drugs whose patents are expiring also allow buyers to purchase generic drugs.

Switching costs for patients here are relatively low. However, they may be more substantial for the ultimate buyers, the healthcare providers. For instance, a national primary healthcare system reviewed the clinical evidence and decided that a chronic condition that had been treated by patient taking drugs in his lifetime could actually be treated by a simple surgical procedure. This would be a beneficial and economical alternative. However, it might require more surgical teams to be trained and more construction of operating theatres, which the healthcare system would also need to fund. These would be switching costs.

The main substitutes to branded drugs are generics and biosimilar (Falit, Singh and Brennan, 2015). Manufacturers of generics can offer the same drug at a much reduced price, as they rely on the efficacy and safety data provided by the innovator product, and there is no need to conduct expensive clinical trials. In the US, generics are approved provided that they can show a similar level of availability in the bloodstream as that of the innovator.
Similarly, there is a growing threat from biosimilar. In Europe, there is an easier pathway for approval of biosimilar that are deemed sufficiently comparable to the innovator product. In March 2009, the US introduced an Act for Pathway for Biosimilar which also allows submissions for approval of biosimilar to be based on license for biologics. Since comparable effectiveness is assumed, generics and biosimilar score highly as beneficial substitutes, and there are few switching costs involved in using them.

Overall, the threat of substitutes is strong

5. **COMPETITIVE RIVARLY (STRONG)**

Pharmaceutical companies are expected to grow in next few years with many drugs going off-patent in the USA and other countries thus intensifying competition. *(IBEF, 2016)*

The global pharmaceutical industry is dominated by multinational companies, smaller firms such as biotech players focused on a small number of new products offerings; generics companies are also in existent.

There is some evidence of consolidation, mainly during a period in which major players have huge cash reserves and are seeking to obtain new blockbuster drugs. This eases competition as players diversify their product portfolio in order to replace drugs that are soon going off-patent or to increase geographical spread. For instance, Perrigo completed its acquisition of Elan in FY2013 to obtain a license for multiple sclerosis drugs and to assist with international expansion due to the low tax system in Ireland. The pharmaceutical industry continues to witness severe competition regarding M & As, strategic alliances, network building, and niche-based acquisition. *(Mehta, Hasan and Selvaraj, 2016)* However, market concentration overall is not very high in most countries.

**Differentiation**

Products can be highly differentiated through their clinical effectiveness. eg, one company may have a patented drug like Lipitor which is highly effective in reducing cholesterol levels. It would be cumbersome to compete directly with such a player, although other entities will no doubt be managing development pipelines in order to exploit this market when the drug becomes off patent.

Research-based pharmaceutical companies are similar to media companies, in that they rely on creating valuable intellectual property incurring an exorbitant cost, which can then be used to make mass-produced products at a low cost. The ability of generics companies to be profitable while selling the same molecule at a reduced price than the originator, following patent expiration, shows that instituting high-quality manufacturing processes is not excessively costly. A secondary effect of this is that it is relatively easy for research companies to expand output, e.g. through licensing agreements with other entities, without the need to scale up their own manufacturing facilities. Given the increasing connections between regulatory authorities and the greater chance of a drug being approved in multiple countries, this tends to increase rivalry.
It is reasonably easy to exit the market. Most assets are ‘weightless’ – patents, trademarks, synthetic methods, and so on – and can be traded relatively easily. Many of the production and R&D facilities and equipment will have uses outside pharmaceutical research or manufacturing.

Overall, the degree of rivalry is strong (OTC Pharmaceuticals Industry Profile: Global, 2015)
Appendix VI – How Porter’s Five Forces differ per industry sector and industry life cycle

BIOPHARMACEUTICAL PLC (GROWTH)

The biopharmaceutical industry is characterised by a high growth rate and a strong pipeline of drugs (Ramasamy, Titchener-Hooker, and Lettieri, 2015) The industry is important for global health as it is a main supplier of affordable new therapies, achieved through the genetic manipulation of living organisms.

According to the Generic Pharmaceuticals Market—A Global Analysis report, “This is trending towards less competitive, yet commercially attractive segments such as difficult-to-produce generics, specialty generics and Biosimilar.

Biosimilar are new versions of generic pharmaceuticals, introduced in the market following the patent expiry of generics. Biosimilar may act differently from their predecessors due to differences in molecular structures and preparation methodology. The biosimilar market is expected to have a decent growth rate due to impending patent expiry of many blockbuster drugs.

Biosimilar are currently growing at the rate of 40.0 per cent and are projected to grow at a compound annual growth rate of (CAGR) 79.0 per cent between 2010 and 2017.

Porter’s Five Forces for Biopharmaceuticals

**Barriers to entry** are very high in the biotechnology and drug industry; reasons being high costs of research and development and the length of time required for a drug to go through clinical trials and obtain approval by the governing agency; hence, this is a capital intensive venture which has very high start-up costs and delayed incomes.

**The threat of substitutes** is the lowest among the Porter Five Forces. The ability for biotechnology and drug companies to patent their compounds and corresponding technologies, companies are able to protect their revenues from branded drugs and their respective technology platforms. Various treatments for the same problem, which will only differ in delivery method, will compete for the same market as substitutes.

**Supplier Power – Low to Moderate** Due to limited number of new entrants, suppliers do not have many new customers that require their raw materials supply from production equipment to biochemical raw materials; Low level of differentiation also affects supply of inputs necessary for research and development. There are over 100 suppliers, who have a low bargaining power on biotech or drug entities.

**High Competitive Rivalry** Biotechnology/pharmaceutical companies utilizes discovery of drugs and delivery process which has an extremely high cost for research and development, the rivalry among companies is extremely high.

**Buyer Power – Low but Increasing** The buyers are patients, hospitals, and pharmacies, who have low buyer power as there exist few if any substitutes and these drugs are at times a
necessity for life. Buyers have low bargaining power as they must get the drug prescribed to them and once they start a drug regime it is problematic and sometimes dangerous to switching drugs. The buyers do have strong bargaining power whenever they purchase large volumes e.g. hospitals) or when products become standardized after off-patents (generic drugs).

ETHICAL DRUGS (DECLINE)

The traditional big pharma is facing a difficult time with patent cliff, generic drugs threat, and low research and development (R&D) productivity. Multinational Pharmaceutical companies, currently facing problems have been systematically externalizing R&D and some even incorporate their own corporate venture capital so as to diversify to exploit their market position with more shots on goal, with the hope of accomplishing higher success rate in their compound pipeline. (Ku, 2015)

Prescription branded drugs: Patents’ expiration puts sales at risk as competitors can manufacture generic drugs at lower costs. (Euler Hermes Economic Research, 2016)

OVER THE COUNTER (OTC) (SHAKEOUT)

Market value and forecast

The performance of the market is forecast to decelerate, with an anticipated CAGR of 3.6% for the 5-year period 2014 - 2019, which is expected to drive the market to a value of $165.7bn by the end of 2019 an increase of 19.1% since 2014. Comparatively, the European and Asia-Pacific markets will grow with CAGRs of 2.7% and 4.7% respectively, over the same period, to reach respective values of $50.6bn and $61.2bn in 2019. The CAGRs of the market in the period 2014–19 is predicted to be 3.6%. Refer to Table 6 below.
**Moderate Buyer Power:** Pharmacies have less buyer power than the large supermarkets, due to their smaller operational size. The drivers of power in the global OTC pharmaceuticals market are depicted in figure 8 below.

![Figure 8: Drivers of buyer power in the global OTC pharmaceuticals market, 2014](image)

*(OTC Pharmaceuticals Industry Profile: Global, 2015)*

**Strong Bargaining Power of Suppliers:** Suppliers for OTC are Active Pharmaceutical Ingredients (API). These ingredients are usually supplied to pharmaceutical companies under contractual arrangements, increasing switching costs and increasing the power of suppliers. The factors driving the power of suppliers in the global OTC market are shown in figure 9 below.

![Figure 9: Drivers of supplier power in the global OTC pharmaceuticals market, 2014](image)

*(OTC Pharmaceuticals Industry Profile: Global, 2015)*
**Moderate Threat to New Entrants:** Market entry is more difficult as some OTC manufacturers highly invest in new product development which involves exorbitant product development costs. The requirement to obtain approval for products from the regulatory authorities also creates barriers to entry for the new players wanting to join the market as it can prove very costly and time-consuming.

The factors that influence the likelihood of the new entrants in the global OTC market is depicted in figure 10 below.

![New entrants](image)

**Weak Threat of Substitutes:** Prescription drugs are the main substitute, but the threat they render is weak as they are often only used in situations where no suitable OTC remedy exists.

The factors influencing threat of substitutes are depicted below in figure 11.

![Threat of substitutes](image)

*(OTC Pharmaceuticals Industry Profile: Global, 2015)*
**Moderate Competitive Rivalry:** Leading players in this market are large diversified multinationals, which moderates the degree of rivalry in this industry.

(OTC Pharmaceuticals Industry Profile: Global, 2015)

**VACCINES (GROWTH)**

The market is highly concentrated with 5 main players with total market share of 85%. The exit and entry barriers are high in terms of:

- Specialised skills required in manufacturing,
- Complex clinical trials required
- Managing surveillance programmes
- There is a high development success rates at lower risk of generic entry than conventional medicines
- Offers blockbuster potential

The vaccine technology market is projected to reach $57,885.4 million by 2019 from $33,140.6 million in 2014, at a CAGR of 11.8%. Major factors attributable to the growth of vaccine technology market include rising incidence of diseases, increasing government initiatives for increasing immunization across the globe, increasing company investments in vaccine development, and intensification of initiatives by non-government organizations for vaccinations. However, low accessibility to vaccines in remote locations and rigorous regulatory procedures are expected to restrain the growth of market. Emerging economies e.g China and India present a number of opportunities for this market. North America dominates the vaccine market, with the U.S. accounting for a majority market share. However, Asia is poised to grow at the utmost CAGR during the forecast period owing to the initiatives by government, increased focus of major players on the Indian vaccine technology market, and increasing immunization initiatives by international bodies like World Health Organization and GAVI in these regions. (Marketsandmarkets.com, 2016)

Moreover, the strict formalities for regulatory approvals and the high cost associated with research to discover and develop new vaccine are likely to influence market growth in a negative manner during 2011 to 2016.
GENERIC (MATURITY)
By 2019, the generic drug market is forecast to reach USD84.6bn, up from USD66.9bn in 2014, growing at a compound annual growth rate (CAGR) of 4.8%. Through to 2024, the market is likely to see fairly steady growth, with a CAGR of 4.8% projected over 10-year period (Refer to Market forecast Table below)- although still more than double the rate of the overall pharmaceutical market.

Generic medicines: Market growth potential in demand will result from patent expiration of branded drugs. Parallel increase in biosimilar sales corresponds to branded biotechnological drugs going off-patent. (Euler Hermes Economic Research, 2016)

Competitive Rivalry - Strong: The level of competition in the generics market is increased somewhat by the presence of large, multinational coupled with high fixed and exit costs.

Strong Bargaining Power of Buyers is supported by the combination of the lack of brand loyalty and large degree of selection available to buyers. However, the ability for forward integration into the production of generic drugs strengthens the power of supplier where manufacturers of API’s are concerned.

Moderate Threat of Substitutes: Patented drugs and holistic therapies are the main substitutes to generic drugs. However, the benefit of such substitutes for consumer use is widely disputed as in the case of holistic therapies and costlier patented drugs.

Strong Threat to New Entrants: Entry barriers are usually lower in this market than those of the wider pharmaceutical industry. Current market players, with whom new entrants must compete, are well-established entities who benefit from economies of scale. (OTC Pharmaceuticals Industry Profile: Global, 2015)

Appendix VII – Limitations of Five Porter’s Model
- The model is based on concept of fierce competition in an industry and completely ignores the amount of collaboration industry players are using these days beside being competitors e.g. strategic alliances, mergers and acquisitions, virtual enterprise networking and sharing of information of different companies on the value chain.
- The model is used at the broader level of an entire industry; and it is not designed to be used at a smaller market level.
- Porter’s model is inherently static, depicting only aspects of the present day.
- It is not designed to deduce optimal industry attractiveness with certainty, as such the criteria used might be subjective
- The model assumes an existence of a perfect market forgetting all regulatory restrictions that falls into place in an industry
- Model is most suitable for only an analysis of simple static market structures – narrow focus on particular segment bears the risk of leaving out important elements.