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SHWETA ARORA
SP JAIN INSTITUTE, MUMBAI, India

AN EXPLORATORY STUDY TO UNDERSTAND THE FACTORS THAT INFLUENCE PRICE CONSTRAINTS FOR NEW LAUNCHES BY GLOBAL PHARMACEUTICAL COMPANIES IN INDIA

Abstract:

The Purpose of the study is to understand and evaluate various factors that influence price constraints for new launches by global pharmaceutical companies in India. Pharmaceutical companies face the biggest challenge of pricing of new products. Due to high R and D cost patented products have to be kept at higher price so that company can maximize profit globally within the period of exclusivity. High prices often limit volume share of global pharmaceutical companies and restrict them to reach-out to mass consumers. The situation is even challenging in India as major population of patient belongs to self-pay category with limited forward planning for medical health. In addition, infringement cases challenging global pharmaceutical companies also contribute to price constraints. This study will focus on the factors that include financing schemes, Market access-strategies, market liberalization, internet trading and biosimilars on prices, with insufficient discussion identified for the effects of discounts/rebates, profits and price transparency. The outcome of the research is expected to culminate in an innovative model called New Product Pricing Model (NPPM). This model is expected to enable the Global pharmaceutical companies to overcome price as a major constraint for successful product launch in India.

Keywords:

Price constraints, Market access strategies, Market liberalization, Research and development, Biosimilars, Price transparency

JEL Classification: A20

Key Words & definition

Price constraints: Pricing constraints are the factors that limit the latitude of prices that a firm may set. ("Week 9.1 Identifying Pricing Constraints and Objectives," n.d.)

Market access strategies: Strategy that a pharmaceutical company adopt to reach-out to the deeper and broader base of customer in terms of product usages and patient education.

Market liberalization: Liberalization refers to the removal of controls in an industry or market to encourage the entry of new suppliers and thereby, to increase the intensity of competition. ("Market Liberalisation," n.d.)

R&D: Research and development (R&D) includes activities that companies undertake to innovate and introduce new products and services. It is often the first stage in the development process. ("Research and Development (R&D) Definition, Types, and Importance," 2022)

Biosimilars: A bio similar is a biological product that is highly similar to and has no clinically meaningful differences from an existing FDA-approved reference product.

Price transparency: Price transparency refers to the ease with which consumers can obtain detailed price and market information of different products.

Introduction

The global pharmaceutical industry is one of the most dynamic, turbulent, and complex industry which focuses on intense profit development for the nation. In the economic terms, Prices are monetary worth established for a product during transactions between producers, distributers, consumers & regulators. (Borges dos Santos et al., 2019) The equilibrium between product supply & demand are the two important key factors for deciding the product's price.

Factors which determine price of new drugs are relevant for both welfare & economic growth of nation. The following factors controls the pricing strategies of the new launches by global pharmaceutical companies in India.

Research & Development: The Global Pharmaceutical companies are discovering, producing & marketing drugs to improve the patient's quality of life. These drugs are used to treat and cure short- & long-term medical conditions. Clinical trials before require lot of time & expenditure to get safe & efficacious drug in market. Investment in research and development is one of the key factors responsible for entry of high-cost product to achieve good returns within a patented period. **The patient-first business model:** In the current scenario most of the pharmaceutical companies focuses on putting patient first. Providing patients with good quality of life require high quality medication & good awareness level which leads to huge expenditure in terms of new launches. **Introduction of Biosimilars:** The rapid Introduction of biosimilars has made the market ten-fold competitive. Entry of low-priced brands after the patent expiry makes situation of Global pharmaceutical companies more difficult. **Self-Pay or Insured Market:** Major portion of Indian population is not having health insurance and rely on self-pay (Insurance is limited to hospitalization only and a little for medicine). The patients in Indian market have to pay from their own pocket which make them to go for a low cost alternate available brand. Whereas in the western countries most of the population don't need to pay due to health schemes & insurance. **Innovative Products / Unique technology**: Global pharma launches the products which have unique technology. The technology might involve high expenditure which result in high cost of drug. **Focusing on Rare diseases or Common diseases**: Drugs launched for rare disease with niche segment of population will face cost as a major barrier for capturing market share. The drugs for common metabolic diseases like diabetes, hypertension & CV risk etc. focusing larger set of population with excellent efficacy & safety results face lesser price challenge due to serving the common unmet needs of the market.

Materials and Methods

Search strategy and eligibility criteria: The philosophy adopted in the research would be pragmatism. The aim of pragmatism is to take practical point of view of various factors affecting price constraints for new launches by global Pharmaceuticals in India. The research approach for the finding the various price constraints for global Pharmaceuticals will be Inductive.

Data extraction: The study is expected to use qualitative and quantitative mix method approach. This study will employ secondary literature review & other appropriate qualitative approaches to identify and evaluate the major pricing constraints.

Quality assessment & Statistical analysis: The data analysed from these components resulted in the questionnaire items. This survey questionnaire was administered to 53 plus employees across various Global pharmaceuticals in India. The data is collected and analysed by ADANCO. Factors like R & D, Biosimilars, Self-pay market and mass markets; niche markets identified as independent variables .Price act as a dependent variable.

Survey Questionnaire

Research & Development

Q1 Do you think global pharmaceuticals contributes a significant share of money in R & D for the development of products?

Q2 Do you think Huge Expenditure in R & D contributes to the production of life-saving drugs?

Q3 The huge expenditure in R & D contributes to the key factor in deciding the cost of new launches?

The patient-first business model

Q4 In the current scenario does the global pharmaceutical focuses on putting the patient first?

Q5 Providing patients with good quality of life requires high-quality medication & awareness which leads to massive expenditure on new launches?

Q6 Placing patients at the centre will help the organization reimagine care through the patient's eye & find solutions to the prevailing problems & providing good care.

Introduction of Biosimilars

Q7 Do you think Biosimilars are similar in quality, safety & efficacy to already licensed bio therapeutic products?

Q8 Once the innovator brand loses its patent, many pharmaceutical companies launch biosimilars at lower prices?

Q9 Biosimilars don't need to undergo many expensive & lengthy clinical trials resulting in lower prices of biosimilars, reaching the maximum patient population?

Self-Pay/ Insured Market

Q10 India deprived of health insurance or most Indian health markets self-pay?

Q11 Low expenditure by Government on the health results in shifting preference from global company products to generic brands?

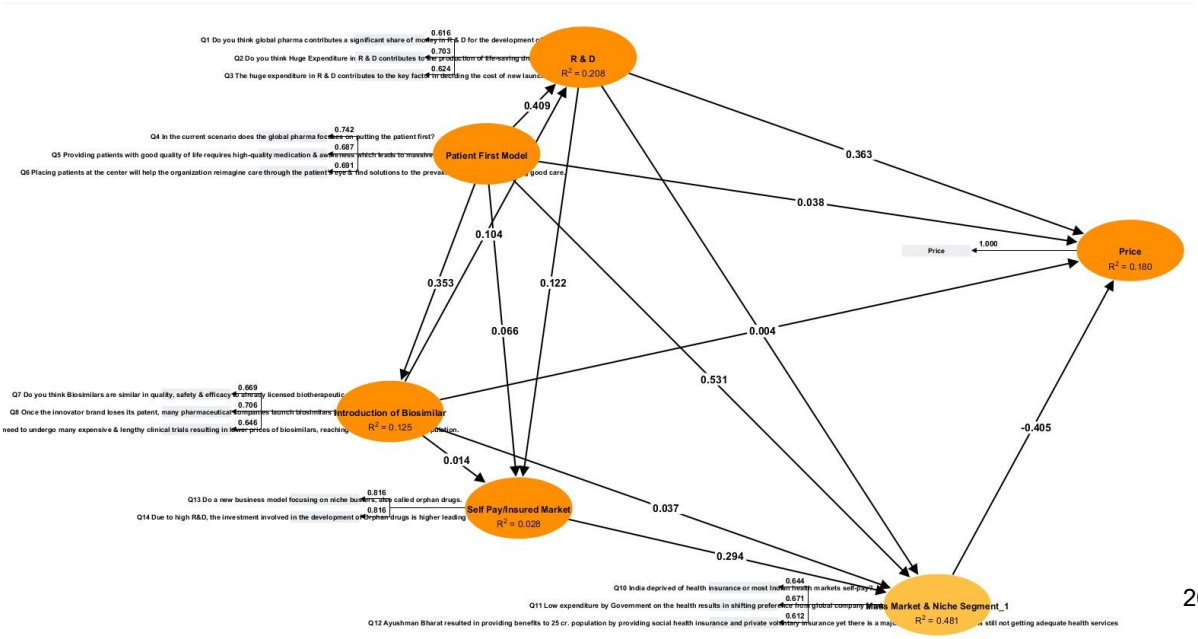
Q12 Ayushman Bharat resulted in providing benefits to 25 cr. population by providing social health insurance and private voluntary insurance yet there is a major patient population that is still not getting adequate health services?

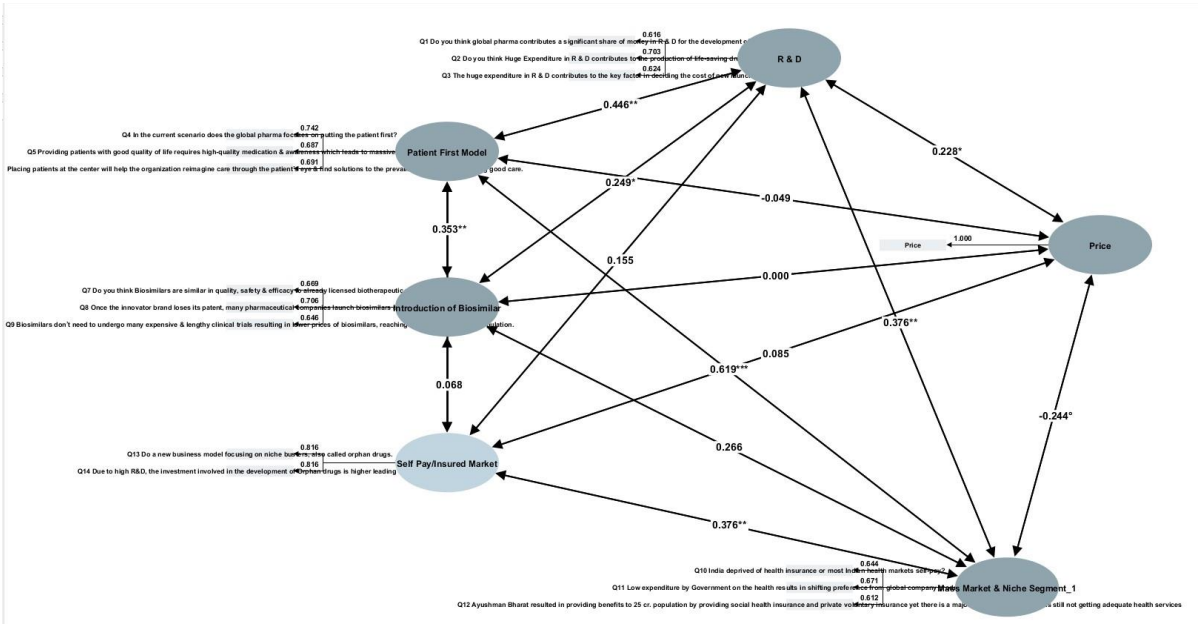
Mass Markets and Niche segments

Q13 Do a new business model focusing on niche busters, also called orphan drugs?

Q14 Due to high R&D, the investment involved in the development of Orphan drugs is higher leading to high prices?

Key outcome: The various factors Factors like R & D, Biosimilars, Self-pay market and mass markets; niche markets identified as independent variables. Price act as a dependent variable.





Results & Conclusion

Price correlation with R & D: When we have seen price correlation with R & D the P value seen to be significant less than 0.05 (significant). T value equal to 2.12 shows 1% significance. Huge expenditure in R & D contributes to the key factor in deciding the cost of new launches in Global Pharmaceuticals.

R & D correlation with patient first model: Providing patients with good quality of life require high quality medication & good awareness level which leads to huge expenditure in terms of new launches. Good quality medication requires high R & D expenditure. As per data analysed T value (3.2) & P value (0.0012) which shows significant results. Good expenditure in R & D provides high quality medicines to patients.

Introduction of Biosimilar Correlation with Self Pay market: The patients in Indian market must pay from their own pocket which make them to go for a low-cost alternate available brand. Entry of low-priced brands after the patent expiry makes situation of Global pharmaceutical companies more difficult. As per the data analysed the T value 2.8 & P value 0.05 seen to be significant. Both the factors do not decide the price of global but correlated with each other. In India biosimilar are mostly successful as the Indian market is mostly self-pay Vs. the Western world with insurance.

Interaction of Niche Market and Price: The current economic situation coupled with huge generic competition has shifted the focus of Global pharmaceutical companies from general medicines to specialty products with new business model focusing on niche busters, also called orphan drugs. As per the data is analysed the T value 1.93 and P value 0.05 it's significant. Orphan drug entry into the market always come with high price .Nice markets impacts price in positive manner

Literature Review

Contributing immensely to global health, the Indian pharmaceutical industry ranked 3rd Largest in the world. In (2021-2022) the global pharmaceutical companies grew by growth of 9-11% which was mainly driven by a push from emerging & domestic markets ("the Financial Express," 2022). During pandemic also the pharmaceutical industry not only contributed to provide covid vaccines but also supported in terms of providing other necessary essentials like sanitation, preventive healthcare & quarantine facilities (Haldane et al., 2021). Going forward to 2022 global pharmaceutical companies will invest maximum in Research and development to provide drugs for various life-threatening diseases. Apart from successful growth and serving community global pharmaceutical companies faced certain challenges during & after the pandemic. As per economic times global pharmaceutical companies are undergoing major transformation in terms of restructuring their business in India by selling brands, closing non-core units, or laying off employees (Somvanshi, n.d.) Multinational pharmaceutical companies do not consider India as a favourable market due to major population with self-pay category on high priced multinational pharmaceutical company's products. The large price variation between the innovator & generic brands creates a confusion in the minds of healthcare professionals & patients whether to select high price innovator brand or to go for much affordable generic brands. The key factors which determine the pricing strategies of the global pharmaceutical companies in India

Research & Development: As per the report from Global trends in R&D 2022, Venture capital deal activity and investment flows in the U.S. accelerated in the past two years as interest in life sciences intensified with more than 2,000 deals and $47 billion of deal value occurring in 2021 ("Global Trends in R&D 2022 - IQVIA," 2022). In addition, the 15 largest pharmaceutical companies invested a record $133 billion in 2021 in R&D expenditure, an increase of 44%

since 2016. ("Global Trends in R&D 2022 - IQVIA," 2022). Huge expenditure in R & D contributes to the key factor in deciding the cost of new launches.

The patient-first business model: Placing patients at the centre will help the organisation to reimagine care through patient's eye & to find solutions to the prevailing problems & providing good care. (Fralick, 2014) Poor-quality care is now a bigger barrier to reducing mortality than insufficient access. High-quality health systems could prevent 2·5 million deaths from cardiovascular disease, 1 million new-born deaths, 900000 deaths from tuberculosis, and half of all maternal deaths each year. (Kruk et al., 2018). High quality health systems require huge investment which result in increasing cost of the molecules.

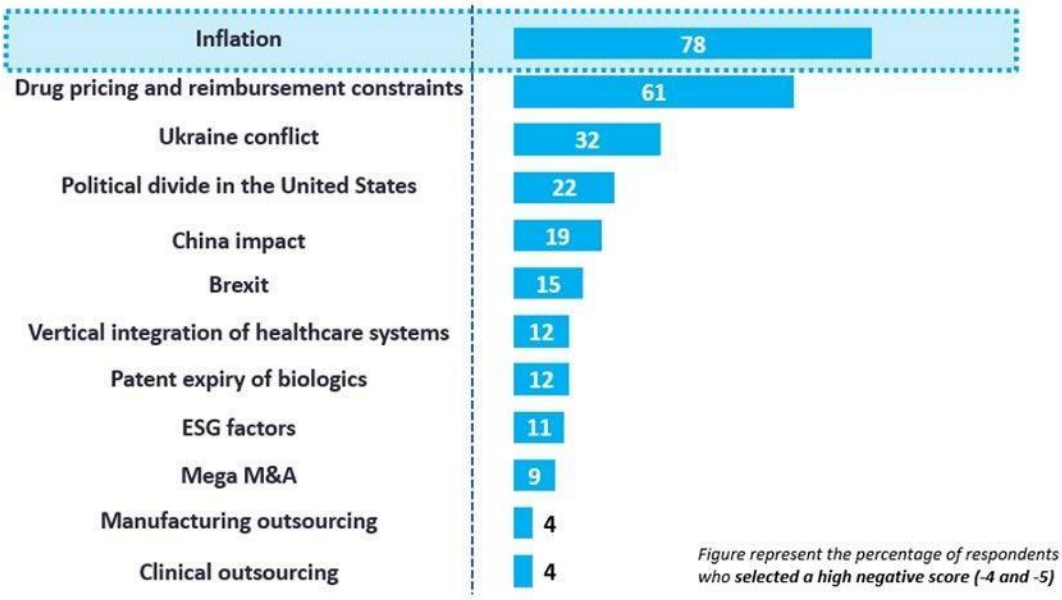
Introduction of Biosimilars: A biosimilar is a medicinal product like another biologic medicine that has been already approved to use. Biosimilars are similar in quality, safety & efficacy to already licensed bio therapeutic product (Knezevic & Griffiths, 2011). Once the innovator brand loses its patent, many pharmaceutical companies launch biosimilars in lower prices, Biosimilars don't need to undergo many expensive & lengthy clinical trials resulting in lower price of biosimilars hence reaching the maximum patient population.

Self-Pay/ Insured Market: As per economic times, In India nearly 20-30% population is deprived of health insurance (Sharma, n.d.). Low expenditure by Government on the health result in shifting preference from global company's product to generic brand. Although Ayushman Bharat resulted in providing benefits to 25 cr. population by providing social health insurance and private voluntary insurance yet there is a major patient population which is still not getting adequate health services.

Mass Markets and Niche segments: The current economic situation coupled with huge generic competition has shifted the focus of Global pharmaceutical companies from general medicines to specialty products with new business model focusing on niche busters, also called orphan drugs. Orphan drugs may help pharmaceutical companies to reduce the impact of revenue loss caused by patent expiries of blockbuster drugs. (Sharma, Jacob, Tandon, & Kumar, 2010). The orphan drug earns maximum profit due to monopoly till its patent expires. The major challenge faced by orphan drugs is the difficult drug development as it acts on rare mechanism & rare receptors. Due to high R&D the investment involved in the development of these drugs is higher leading to high prices.

Inflation: The outlook for global growth continues to deteriorate as inflation continues to significantly exceed the target of 2% in most developed markets. According to Global Data's survey on "The State of the Biopharmaceutical Industry – 2023", fielded from October 26, 2022, to November 23, 2022, approximately 40% of surveyed industry professionals believed that among regulatory and macroeconomic trends, inflation will have the most negative impact on the pharmaceutical sector in 2023 (Figure 1).

Figure 1: Inflation is expected to be the main challenge that the pharmaceutical industry will face in 2023



Q: On a scale of -5 to 5, please rate the anticipated impact of each of the following emerging regulatory and macroeconomic trends on the pharmaceutical industry in 2023. (5 indicates the greatest positive impact, 0 indicates no impact, -5 indicates the greatest negative impact.)
Source: GlobalData © GlobalData

The survey results also indicated that drug pricing and reimbursement constraints will be the second biggest concern, impacting the industry's growth. Throughout the years, legislators and policymakers in various markets introduced new frameworks and laws facilitating negotiations and the regulation of drug prices.

The pharmaceutical industry has long been labelled as a recession-proof—stable demand for medicines and new treatment options acts as a protective barrier. Nevertheless, while pharma is often less harmed by economic downturns, the industry still faces constant challenges such as rising operational costs, industry rivalry, patent expirations, increasing demands to become more sustainable, and huge drug pricing pressures from cost-conscious regulators. This means that the industry will have to navigate a complex balance between

financial and strategic risks, as the emerging regulatory and macroeconomic trends will influence a substantial drop in net drug prices.

To adapt is the only way to thrive. The pharmaceutical sector will need to find new ways to offset regulatory and inflationary pressures. Innovating by modernizing R&D models; addressing environmental, social, and corporate governance (ESG) issues; leveraging emerging technologies; and encouraging cross-functional or cross-company collaborations may be the way to go.

DPCO : DPCO policies have a negative impact on profit margins . As the drugs which come in DPCO are to be sold within a price range. which is mandatory for the company and therefore, the break-even point is sometimes barely reached (Paul, 2018).

Corporate Development: Growth of companies was seen where most drug prices were under the ceiling price, but in contrast, there was a decline in the growth of those companies where most drug prices were above the ceiling price. Many differences were seen between DPCO and the concerned companies because of the adoption of market-based pricing (MBP). However, in MBP, pricing was determined by market share, and according to demand, it was characterized into numerous categories of drugs. Thus, MBP has had an adverse impact on pharmaceutical companies (Narula, 2015)

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Si No	Title	Author	Yr	Key Findings	Primary variable	Secondary Variable	Conclusions	Gaps
1	Factors influencing pharmaceutical pricing - a scoping review of academic literature in health science	(Borges dos Santos et al., 2019)	2019	Pricing of the pharma becoming important	. Pricing factors (i) supply-related, (ii) consumer-related and (iii) product-related; (iv) trading strategies, either buyer's or seller's and (v) regulatory		: Interest in pharmaceutical pricing literature is increasing. Robust evidence-producing study designs for pricing interventions will be a welcome development	Research lags in the literature on factors affecting pharmaceutical pricing include impacts of finan

					approach.			cing schemes, market liberalization, internet trading and biosimilars on prices, with insufficient discussion identified for the effects of disco

								unts/ rebates, profits and price transparency.
2	Health systems resilience in managing the COVID-19 pandemic: lessons from 28 countries	Haldane, V., De Foo, C., Abdalla, S. M., Jung, A. S., Tan, M.	2021	Four salient elements that underlie highly effective national responses and offer recommendations toward strengthening health systems resilience globally.	COVID-19 responses in 28 countries using a new health systems resilience framework.		four salient elements that underlie highly effective national responses and offer recommendations toward strengthening health systems resilience globally. 1 Activate comprehensive responses	system is weakest to demonstrate the interdependencies of a range of health, social and econ

		, Wu, S., . .					2 Adapt Health system capacity 3 Preserve health system function and resources 4 Reduce vulnerability	omic struc tures
3	How the Indian Pharmaceutical Industry is planning to grow in 2022	The Financial Express. (20	2022	Indian pharmaceutical industry will foster a culture of R&D and innovation to enable	innovation funding, continuous regulatory reforms, and infrastructure		The pharmaceuticals industry is already a well-established presence globally and it just needs to increase	

		22, February 23).		rapid drug discovery and development to improve the health outcomes of people worldwide.	and industry - academia collaboration		its efficiency in affordable yet innovative products which cater to the needs of patients worldwide.	
4	Why MNC pharma companies are realigning their India operations	The Economic Times. Retrieved October 15, 2022,	2019	Global pharmaceutical companies are undergoing major transformation in terms of restructuring their business in India by selling brands, closing non-core units or laying off	innovator & generic brands		The profitability ratio by global pharmaceuticals have reduced due to lesser acceptance of new launches in India	Apart from Price other factors should define the reasons for global pharmaceutic

				employees				als in India
5	Global Trends in R&D 2022	IQVIA. (2022, February 10).	2022	Reseach and developent before launch require lot of time & expenditure to get safe & efficacious drug in market	Venture capital deal activity and investment flows in the U.S		2,000 R & D deals and $47 billion of deal value.15 largest pharmaceutical companies invested a record $133 billion in 2021 in R&D expenditure, an increase of 44% since 2016.	
6	Putting patients first in the age of pharma	Fralick, M.	2014	Patients must come first in health care professionals' dealings	Patients and Budget contrains ts		Patients should be key priority for the pharma	Budget constraints are often the

				with drug companies, urge new ethical guidelines.				foil of patient-centred initiatives.
7	High-quality health systems in the Sustainable Development Goals era: time for a revolution	Kruk et al., 2018	2018	High quality health systems requires huge investment which result in increasing cost of the molecules.	quality of care available to people in LMICs across a range of health needs included in the Sustainable Development Goals (SDGs).			Poor-quality care is now a bigger barrier to reducing mortality than insufficient access.

8	Biosimilars – Global issues, national solutions. Biologicals,	Knezevic & Griffiths, 2011	2011	Biologicals & Biosimilars	Biosimilars are similar in quality, safety & efficacy to already licensed bio therapeutic product		Scientific and regulatory challenges faced in developing and evaluating similar biotherapeutic products for global use	
9	Nearly 30% of Indian population don't have any health insurance: Survey - The Economic Times. The Economic Times	Sharma, Y. S.	2022	Health Insurance	As per economic times, In India nearly 20-30% population is deprived of health insurance . Low expenditure by Government on			

					the health result in shifting preference from global company's product to generic brand			
10	Orphan drug: Development trends and strategies	Sharma, Jacob, Tandon, & Kumar, 2010	2010	orphan drugs	Orphan drugs may help pharmaceutical companies to reduce the impact of revenue loss caused by patent expiries		The new business model of orphan drugs could offer an integrated healthcare solution that enables pharma companies to develop newer areas of therapeutics, diagnosis, treatment,	

					of blockbuster drugs		monitoring, and patient support. Incentives for drug development provided by governments, as well as support from the FDA and EU Commission in special protocols, are a further boost for the companies developing orphan drugs	