Business Processes of Indian Vaccine Manufacturers

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ABSTRACT

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The vaccine industry, or vaccine manufacturing, is a highly sophisticated and niche area in the field of biopharmaceuticals or biotechnology, which forms part of the pharmaceutical industry. Biopharma is defined as "any pharmaceutical product derived from biological sources, especially one produced by biotechnology." The vaccine segment is one of the most important parts of the Biopharma offering, with a high emphasis on the preventive management of diseases. Unlike the pharmaceutical industry, the vaccine industry is highly regulated, highly capital-intensive, and requires sophisticated manufacturing facilities to manage biological materials and standardize output as per regulatory norms. Strength in advanced research and research platforms in the field of vaccines and biotechnology gives the manufacturer an edge in the industry.

India is one of the highest-quality and lowest-cost manufacturers of vaccines in the world, accounting for more than 60% of the world's requirements. Although vaccine manufacturing facilities require equipment to manage viruses, bacteria, and other microorganisms, the industry has specialized fields in human and animal (veterinary) vaccines. Indian vaccine manufacturers have grown over time to do active research, introduce newer vaccines, and design manufacturing facilities based on technology. Such new vaccines give an advantage to the manufacturers as first movers to gain premium in the retail market, and later, when the product finds more manufacturers or is adopted by state-run programs, the premium advantage of the vaccine ceases to exist. Vaccines manufactured in India are low-cost in nature, and UNICEF usually ropes in these manufacturers for worldwide supplies to reduce the cost of procurement of vaccines. The Indian vaccine industry has always been a subset of the pharmaceutical industry, and hence, business processes and other methods of evaluation of the vaccine industry

in India have always followed the pharmaceutical business template. Hence, this research aimed to examine the vaccine industry and its business processes. Further, this research is to explore the attributes that are related to the pharmaceutical and vaccine business processes.

This is an **exploratory and explanatory study** to accomplish the research objectives by exploring insights in the Indian vaccine industry. Research studies include publications (research studies, paper publications, news, and articles), magazines, questionnaires (Google Forms) for important personnel in the industry, personal discussions, data from profit and loss statements, balance sheets of companies, progress of select companies through historical data, progress of technology, business model evaluation, existing literature, and both qualitative and quantitative evaluation of the Indian vaccine industry. Out of the total estimated 32 vaccine manufacturing companies, about nine are state-run companies, and hence 25% of the samples were drawn from the remaining twenty-three companies. Seven companies responded, which include two multinational companies and one PSU, in line with the research design and proposal.

Collected data, key information, and patterns were analysed. Research produced key findings through various questionnaires and analyses related to the objectives.

1. The inherent factors that influence the vaccine business and business models are unlike the pharma business model.
2. practices in the industry to sustain business models and identify the customer selection compulsions of the manufacturer.
3. Classification of the vaccine industry is also vital, given the diversified nature of variables and
4. Parameters set by rating agencies such as CRISIL for each company based on their in-house metrics However, due to inherent risks and long lead times in delivering vaccines, rating agencies should find additional parameters to set ratings and suggest ratings for the vaccine industry other than the conventional ones.

The key inferences or conclusions drawn from this research imply the stark differences between the vaccine industry operated in India and the selection of customers, which cannot be

compared with pharmaceutical industry models. Consequently, the research findings and recommendations will help further refine the new classifications, rating systems, and evaluation systems for the vaccine industry in India.

KEY WORDS

Indian vaccine industry, vaccine business process, customers, Indian vaccine customer, business models, ratings, classification of vaccine manufacturers, technology in vaccines.

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GLOSSARY

Adult vaccine	Vaccinations are readily available for such common adult illnesses as influenza (flu), pneumococcal disease, herpes zoster (shingles), human papillomavirus (HPV), pertussis (whooping cough), hepatitis A and hepatitis B.
Antigen	Any substance that causes your immune system to produce antibodies against it.
Anti-Rabies vaccine	Rabies vaccine is a vaccine used to prevent rabies. Rabies vaccines available that are both safe and effective. Vaccine used for preventing rabies before, and for a period of time, after exposure to the rabies virus, due to dog bite or a bat bite.
BCG Vaccine	Vaccine for tuberculosis (TB) disease
Bioeconomy	The share of the economy based on products, services, and processes derived from biological resources (e.g., plants and microorganisms)
Biologicals	That class of medicines which grown and then purified from large-scale cell cultures of bacteria or yeast, or plant or animal cells.
Biopharmaceuticals	complex medicines made from living cells or organisms, often produced using innovative biotechnological methods.
Biotechnology	technology that utilizes biological systems, living organisms or parts of this to develop or create various products.
Cell Culture	One of the most important techniques in cellular and molecular biology since it provides a platform to investigate the biology, biochemistry, physiology (e.g., aging) and metabolism of wild-type cells and diseased cells.
Companion animals	Dogs, cats, horses, rabbits, ferrets, birds, guinea pigs and select other small mammals, small reptiles, and fish.
CRISIL	A global analytics company (S&P company)
Enumeration	The act or process of making or stating a list of things one after another.

Epidemic	A large number of people or animals suffering from the same disease at the same time.
Gene therapies	A technique that uses a gene(s) to treat, prevent or cure a disease or medical disorder.
GP	General Practitioner
Immunology	Immunology is the study of the immune system and is an important branch of the medical and biological sciences.
In Ovo	In medical usage it refers to the growth of live virus in chicken egg embryos for vaccine development for human use, as well as an effective method for vaccination of poultry.
In-license	the process of creating a contract that allows another firm to provide capital to the development and launch process, thus taking on fiscal responsibility.
Livestock	Domesticated animals raised in an agricultural setting in order to provide labour and produce diversified products for consumption such as meat, eggs, milk, fur, leather, and wool.
Microbes	Organisms that are too small and cannot be visible without using a microscope.
Micro-organisms	An organism that is microscopic.
mRNA	mRNA stands for messenger Ribonucleic Acid and is the single stranded molecule that carries the instructions to make proteins.
Multiple sclerosis	A long-lasting (chronic) disease of the central nervous system.
Oncology	Oncology is the study of cancer.
Pandemic	An epidemic occurring on a scale that crosses international boundaries, usually affecting people on a worldwide scale.
Pathogen	An organism causing disease to its host, with the severity of the disease symptoms referred to as virulence.

Pharmaceuticals	Substance used in the diagnosis, treatment, or prevention of disease and for restoring, correcting, or modifying organic functions.
Plasmid	A small circular DNA molecule found in bacteria and other microscopic organisms.
Poultry	Domesticated avian species that raised for eggs, meat and/or feathers
Prophylaxis	Preventive.
PSU	Public Sector Unit
Tetanus vaccine	Tetanus vaccine, also known as tetanus toxoid, is a toxoid vaccine used to prevent tetanus.
Therapeutic	Having a beneficial effect on the body or mind.
Travellers' vaccine	Vaccines that you may need to get for the first time or boosters before you travel.
Urological	A part of health care that deals with diseases of the male and female urinary tract.
Vaccine	A preparation that used to stimulate the body's immune response against diseases.
VLP	Virus like Particles

CHAPTER-1: INTRODUCTION

1.1 BACKGROUND OF THE STUDY

Biopharmaceuticals is one of the most sophisticated and niche areas in the pharmaceutical industry. Biopharma is defined as "any pharmaceutical product derived from biological sources, especially one produced by biotechnology." The vaccine segment is one of the most important parts of the Biopharma offering, with a high emphasis on the preventive management of diseases. Unlike the pharma industry, the vaccine industry is highly regulated, requires sophisticated facilities to manage biological materials, and has standardized output. Advanced research and research platforms in the vaccine and biotechnology industries give manufacturers an edge. Vaccine companies in India develop vaccines through collaborative research and demonstrate their efficacy to get regulatory clearance and, subsequently, to market the products. External (Pedro Garcia-del-Barrio, 2012) economies of scale are helped by governments to implement inexpensive vaccination programs. However, business revenues and profitability depend on efficiencies in operations and antigen yields.

A typical business model consists of three components: value proposition, value chain structure, and revenue generation. India is regarded as a vaccine manufacturing hub in the world, contributing to almost 60% of the global vaccine supply (Khan Sharun, 2021). Indian vaccine manufacturers are classified in terms of research, product development, manufacturing, and marketing (Viren Konde, 2008). The high-cost effectiveness of immunization and its unparalleled contribution to the reduction of infant and child mortality in the world need greater recognition (Children's Vaccine Initiative, Bellaglo, 1997). India is one of the most high-quality and low-cost manufacturers in the world. Human vaccines are classified into childhood and paediatric vaccines; adult vaccines; and traveller's vaccines. Paediatric vaccines remain the cornerstone among all vaccines covered under the Universal Immunization Programme (UIP). All over the world, paediatric vaccines are executed by large institutions or states. However, in advanced nations, vaccines are administered by hospitals and not necessarily by the state per se. Indian vaccine manufacturers have grown over time to do active research to introduce newer vaccines and design manufacturing facilities based on that. It is also a known fact that vaccines

introduced in India as novel or new vaccines later find place in state-run programs, especially for childhood immunization candidates. Such new vaccines give an advantage to the manufacturers as first-movers to gain premium, and later, when the product finds more manufacturers or is adopted by state-run programs, the premium advantage of the vaccine ceases to exist. In India, most manufacturers initially started their business with the technologies required to produce vaccines for the state. These vaccines are low-cost in nature, and UNICEF usually ropes in these manufacturers for worldwide supplies to reduce the cost of procurement of vaccines.

Animal vaccines are classified into livestock and poultry vaccines (cattle, buffalo, sheep, goats, pigs, camels, and poultry) and companion animal vaccines (dogs, horses, mules, and cats). Delhi, N. (n.d.). Indian Council of Agricultural Research (April' 2020)

Vaccine manufacturers are allowed to market their products after establishing field trials and satisfying the regulatory framework. This required a research and medical services wing. Manufacturing facilities must meet the regulatory norms to manage various viruses, bacteria, and cells to develop vaccines, unlike simplified norms for formulations.

1.2 BIOPHARMACEUTICALS IN INDIA

The Indian pharmaceutical industry ranks third globally in pharmaceutical production by volume and is known for its generic medicines and low-cost vaccines. The sector contributed to around 1.32% of the gross value added (in 2011–12 constant prices) of the Indian economy in 2020–21. The total annual turnover of pharmaceuticals in the fiscal year 2021–22 was Rs. 3,44,125 crore (USD 42.34 billion), according to the Annual Report of the Department of Pharmaceuticals, 2023. The vaccine industry in India is a part of the life sciences or biopharmaceuticals industry, which in turn forms part of the Indian pharmaceuticals industry. Pharmaceutical companies operating in India are defined as a 'therapeutic class.' The regulatory set-up, scale, and promotional aspects of the pharmaceuticals industry are quite different from those of the vaccine industry, which is a 'prophylactic class.' Hence, when we study business models, customers, promotional methods, and regulatory scrutiny, it is important to examine the vaccine industry. The expenditure in the pharma industry for promotional aspects or

marketing is higher than that in the vaccine industry, which is about 17%, while in the pharma industry it is higher than 35% (Calnan, M., & Douglass, T., 2020). Initial exploration suggests that there are stark differences in India between pharma industry business models and vaccine industry business models.

In the pharmaceutical industry, products are further classified into archetypes such as access drivers, therapy leaders, brand builders, and specialty players (IQVIA, November 2018). The pharmaceuticals industry has therapeutic products classified in terms of general practitioner (GP) focus and brand focus.

Fig-1: Archetype of Pharma products classification

Source: IQVIA, November 2018

This product classification is done keeping in view of the method of promotional activity that companies intend to pursue while choosing customers for a certain set of products. For example, "Therapy Leaders" have a specialty product that is a large brand with less competition and a lesser risk of replacement. These companies typically employ a moderately large field force in a SBU (~300–600) in India, as the business focus is on its ability to have reach, covering both GPs and specialists. In the "Brand Builders" category, the products are usually highly priced, and companies focus on building brands. As a case in point, GSK Pharma focuses on brand-building its vaccine portfolio. However, the Indian vaccine industry in the pre-COVID era is expected to be more balanced for study purposes. Hence, we also chose to collect and collate

data from the pre-Covid era to have a realistic assessment of vaccine manufacturers' sales. In the COVID era, sales zoomed, and in the very subsequent year, they crashed due to the presence or absence of sales from the COVID vaccine.

Traveller's vaccines are used on a preventive basis for people to travel or get travel visas for countries. This is also not available in an ad hoc manner or over the counter since these vaccines are not used in India regularly, viz., the yellow fever vaccine. Whoever wishes to travel from India to Africa must mandatorily use the vaccine to get a travel visa for any African nation. However, since this disease is not prevalent in India, it is not available in any pharmacy; rather, it is available in a very select few government hospitals, and they demand proper documentation before administering the vaccine.

Adult vaccines are used for certain specific conditions. The tetanus vaccine is administered normally after any injury, during pregnancy, or during surgeries. This vaccine is used as a routine dose in childhood immunization. Anti-Rabies vaccine (post-animal bite) is used or administered for all age groups; BCG vaccine is used in certain urological conditions.

Childhood immunization is a mandatory exercise by the state, covering more than 89% (Universal Immunization Program, India, 2023). while the private sector covers only 8.4% of the children in India.

During 2021–22, total pharmaceutical exports stood at Rs. 1,74,955 crore (USD 23.5 billion) in India, while the domestic market was about Rs. 1,69,170 crore (USD 18.84 billion). The government procurement of pharmaceutical products, including vaccines, is less than Rs. 22000 (or less than USD 3 billion). Eye on quality and price, the government plans to use a single platform to source medicines (Times of India, March 2022). However, the vaccine market is estimated at around less than USD 1 billion. It is also strange that market research organizations conduct prescription audits, retail audits, and wholesale audits to publish annual reports on pharmaceutical product markets, market share of key products, and companies. However, the procurement patterns of states or governments and their detailed market size, share, and other classifications are not found on professional research platforms. Hence, there are unreliable sources who make estimations on the government procurement of the pharma or vaccine

industry in India. However, there are professional vaccine companies that enumerate the government market by collating the market dynamics in the government segment for internal purposes. The estimated market size of the vaccine industry is significantly lower in India, estimated at Rs. 5800 crore (USD 0.7 billion). The vaccine business model cannot function in parallel, as per the product classification done for the pharmaceutical industry for promotional expenses and attributes of the industry. Vaccine business in India is driven by exports and state procurement, and a smaller section is private market driven. In a post-COVID scenario, the customer decision-making process also impacted India (Verma, M., & Naveen, B. R. 2021). Business compulsions to select customers therefore drive the business model, especially customer selection, and therefore warrant a classification of the Indian vaccine industry.

1.3 THE IMPORTANCE OF THE RESEARCH

Business Process: The classification of the vaccine industry is not available in its structural form and is more often drawn in lines with the pharmaceutical industry. The cost of setting up a vaccine company can range beyond $1 billion USD or more due to the complexity and cost of vaccine manufacturing (Plotkin, S., Robinson, et al., 2017). This is significantly higher than setting up a pharmaceutical manufacturing unit in the USA. In India, it is ironic that to establish a pharmaceutical company, it takes a very modest amount of Rs. 20 lakhs ($25,000 USD), whereas a vaccine manufacturing unit is expected to cost at least 50 million USD. It may cost higher or lower depending on the place and the microbes to be handled and the antigen capacity that has to be produced. As mentioned in the introduction, the regulatory aspect is very stringent for vaccines, especially how viruses, bacteria, and protozoa are managed in the facility. There are systematic audits to ensure that it does not cause any environmental hazards or trigger any leaks leading to epidemic situations. Hence, vaccine manufacturers, vaccine businesses, and vaccine costs are always different. Even the way vaccines are promoted through advocacy is quite different from that of the pharmaceutical industry. Although vaccine business done properly is hugely rewarding, it is difficult to demonstrate the consistency that pharmaceutical business with regular field promotion activity could actually achieve. The vaccine business is

capital-intensive and has long delivery lead times, making it significantly different in all aspects.

The delicate balance between innovation, government support, industrial expertise, and market forces has led to the establishment of a robust vaccine industry that will continue into the future (Vaccine Industry Samant, 2014).

According to the DICHS Market Access Study (2022), the pharmaceutical business is divided into distinct categories, such as,

- Vaccines
- General Medicines (such as Cardiovascular, Diabetes, or Respiratory)
- High-volume specialty (such as multiple sclerosis, immunology, or hepatitis C)
- Oncology
- Rare diseases include cell and gene therapies.

The vaccine business always stood out, and the approach to the vaccine business model is not the conventional pharmaceutical business model, which aims at generating prescriptions and use in hospitals.

A customer funnel was created for each vaccine on the market and then triangulated with publicly available penetration figures and validated with market size obtained from industry interviews. Structural barriers hinder growth and penetration across vaccines and segments, resulting in drop-offs across the customer funnel (transforming India's vaccine market). Saving lives creates value (Kinsey, 2012). Further, as per this report, a number of factors have subdued the growth and penetration of vaccines in India, both in the public and private markets. They include difficulties in introducing new vaccines into the country's massive universal immunization program (UIP), a lack of awareness and understanding of vaccines among the health community, limitations in affordability and access, and constraints on manufacturing and supply. The vaccine business constitutes 1.58% in terms of value and 0.05% in terms of volume (PHFI estimation from the PHARMATRAC Database, July 2020). Hence, most studies and business models use pharmaceutical businesses as the basis instead of studying the intricacies

of the vaccine industry. During the COVID period, studies were made on the business environment, and they depicted the pharmaceutical industry and not specifically the vaccine business at work.

1.4 AIM AND OBJECTIVES

The Indian vaccine industry has all it takes to be a global hub for vaccine manufacturing and can scale up capacities to meet the demand of protecting the world from pandemics and regular diseases. In such a situation, a clear-cut process is essential. India is still a volume builder with low-cost vaccines. This study aimed to understand the business process in the vaccine industry. Research objectives drive the research questions, or vice versa. In this case, we have objectives that are necessary for research. The vaccine industry is time-consuming, capital-intensive, and vulnerable to technological and regulatory changes.

1. Understand the customer selection process that drives the business process.
2. The classification of vaccine manufacturers will bring out the vulnerability of the vaccine industry and could provide guidelines for medium- and long-term corrections.
3. Stand-alone vaccine manufacturers are guided by diversification or other methods to sustain the industry.

It should create parameters for each company to move forward and develop the industry as an attractive incubating hub for investment for aspiring entrepreneurs.

1.5 RESEARCH QUESTIONS

As the India story is emerging, it has a long way to go to holistically develop a thriving and hugely profitable vaccine industry. Hence, more specifically, the following research questions were addressed:

- A clear classification of the customers, especially in India (as we are going to study the Indian vaccine industry), and choices of customer selection, whether it is through promotional efforts in the retail industry, through state procurement, exclusive international business, or a combination of one or more, This will give a quite simple and clear picture of the customer choices that our study intends to make as one of the research questions.

- Exploring methods to classify the companies on the basis of research, products, business processes or business models, revenues, customers, and new products.
- This paper will explore a rating system by classifying the companies or a system that will guide the vaccine industry to move ahead in the ladder systematically.

This will also explore methods to classify the marketing approaches in India for vaccines as compared to pharmaceutical products.

1.6 RESEARCH APPROACH

This subject has a mix of both exploratory and explanatory research. Under both circumstances, it is important to conduct open interviews with industry leaders and new entrants based on the sample strata picked up. Questionnaire survey, personal interviews or discussions, and analysis of hard data such as balance sheets and profit and loss statements. Besides publications, government data, or any other data published by consultants or research papers, technology progression is expected to corroborate the study. Both qualitative and quantitative evaluations of the industry were attempted with the data during the study.

CHAPTER 2: PROBLEM STATEMENT

2.1 APPROACH TO PROBLEM

During the COVID-19 pandemic, the priority of all vaccine manufacturers in developed countries such as the US, UK, EU, etc. was to supply the vaccine immediately and use technology platforms to deliver the vaccine faster. Governments were also desperate to get the vaccines and hence allowed emergency use to bypass the stringent regulatory mechanism to save lives. This move by vaccine manufacturers aimed to make better profit margins instantly (Chiranjib Chakraborty et al., 2021). On the other hand, despite vaccine manufacturing facilities present in developing nations such as India, there is a lack of technological know-how to make a new vaccine to instantly serve the needs of the respective countries. In India, during COVID times, most companies have in-licensed (bringing technology, process know-how, or complete outsourcing) vaccine making and start doing development work, and subsequently get the product cleared through regulatory agencies on an emergency use basis. Only one vaccine candidate was internally developed in India by the Indian Council of Medical Research (ICMR) and has been manufactured by one Indian vaccine manufacturer, 'Bharat Biotech International Ltd.' Unlike the routine lead times of at least 5–6 years that it takes to get a new vaccine rollout, the COVID outbreak has forced regulators to compress timelines due to the emergency that the pandemic posed. COVAX (co-led by Gavi, the Coalition for Epidemic Preparedness Innovations (CEPI), and WHO) has been the world's most prominent effort to ensure equitable access to SARS-CoV-2 vaccines (Felix Stein, 2021). It is interesting to note that Indian vaccine manufacturers have come of age and could roll out vaccines in quick time. This is not a normal phenomenon, and this does not happen in the everyday life of a vaccine manufacturer. This stand-alone windfall should not stand as testimony to the vaccine industry's general trends over the years. How are these business models and processes so amenable to pandemics? Are the vaccine manufacturers already following any business processes that make this possible instantly? It is therefore important to revisit business processes, redefine business models, revisit assumptions, and draw a system in India that is classified into different models distinctly from pharmaceutical models. It is imperative to discover a common thread that drives the

vaccine industry. Right now, there has been an unprecedented alignment between the priorities of vaccine manufacturers and public health following the outbreak of SARS-CoV-2 (Jennifer Shulman, Rowena Ahsan, and Kayleigh O'Malley, KPMG Canada, 2019).

Unlike vaccine manufacturers in advanced countries, Indian companies opt for technologies that can help roll out the vaccine quickly and find a larger customer base who can consume the product. These vaccines are low-cost in nature, and UNICEF, the Indian State, or general exports to other developing nations are usually roped in by these manufacturers for supplies to reduce the cost of procurement of vaccines. Vaccine manufacturers are allowed to market their products after establishing field trials and satisfying the regulatory framework. This required a research and medical services wing. Manufacturing facilities must meet the regulatory norms to manage various viruses, bacteria, and cells to develop vaccines, unlike simplified norms for formulations. Establishment cost, infrastructure, longer lead times, and not entirely an off-the-counter product profile make vaccine positioning unique.

In India, enumeration of pharmaceutical and vaccine products is done through sample surveys across all the stakeholders, such as pharmacies, wholesale distributors, and other stakeholders. However, there is no such organized enumeration done for supplies made to the state or large institutions. Attempts have been made to just enumerate the vaccine industry (other than state) and find out the actual revenues, market share, and even striking differences between the pharmaceutical and vaccine industries (R. Gordon Douglas and Vijay B. Samant, 2020). The sales-to-equity ratio in the vaccine industry is similar to that of the pharma industry. Which is not the case. The pharmaceutical industry spends more (35%) as compared to the vaccine industry (24%) on sales, marketing, and administrative expenses. While India accounts for 60% of the total vaccine supplies in volumes under the Expanded Programme of Immunization (Khan Sharun, 2021), more than 80% of revenues come from Western companies, which have a sheer higher value.

The Indian vaccine industry is coming of age. (COVER STORY 17, www.biospectrumindia.com) This magazine regularly publishes the revenues and ranking of the industry based on revenues. This is always in the form of news, and it does not classify the

industry. Investments in pharmaceuticals before and after TRIPS (Trade Related Aspects of Intellectual Property Rights) in 2005 were quite late compared to other developing and developed countries (Kyle, M. K., & McGahan, A. M., 2012). The world is divided into high-income countries (HIC), middle-income countries (MIC), and low-income countries (LIC). In such a classified world of global vaccine economics, R&D is of significant importance as it could potentially influence Indian vaccine manufacturers. (Jennifer Shulman, Rowena Ahsan, and Kayleigh O'Malley, KPMG Canada, 2019) projected that the vaccine demand for the global vaccine market will be $ 62 billion by 2027. However, the volume of vaccines expected to be consumed in low- and middle-income countries would be ahead of that in high-income countries. This sheer volume and economies of scale are expected to attract investment opportunities in developing nations such as India, which has the potential to produce low-cost vaccines. The perils of vaccine making are that new vaccine development takes not less than 10 years, and only 12% of all the vaccines under development actually enter the clinical trial stage. The percentage success rate in vaccine research is extremely low and highly regulated. High-income countries constitute 80% of the global vaccine market in terms of value, while they only consume 20% of the volume. The pricing of the vaccine is another interesting aspect that divides the world. High-income countries charge almost 10 times the price of the vaccine, just for the low volumes as compared to low-income countries. Multinational companies such as MERCK, GSK, SANOFI, and PFIZER—the big four—generate 80% of the global vaccine revenues. A typical classification of large vaccine manufacturers and small biotech companies by KPMG, Canada (Shulman J et al., KPMG Canada, 2019) leaves a gap in the classification sought in this research study. DCVMN (Developing Countries Vaccine Manufacturers Network) is an association of vaccine manufacturers from developing nations such as India, China, and Brazil. Indian vaccine manufacturers make up a large part of the DCVMN group. But not all Indian vaccine manufacturers are members of DCVMN since multinational companies operating in India are not part of it, and some small biotech companies are yet to become members.

Multinationals have large and diverse portfolios of products besides originally developed vaccines, while DCVMN companies in developing nations have smaller portfolios. Countries normally shape the demand and are the end users of the vaccines, seeking to vaccinate as much of their populations as possible. This paper (S Jadhav, M Gautam, and S Gairola, Serum Institute of India, 2021) refers to vaccine portfolios. According to Michael Kremer (2002), low-income countries (LICs) and middle-income countries (MICs) have limited resources with which to buy vaccines and seek low prices but have large populations. Whereas high-income countries (HICs) are able to pay higher prices but have smaller populations, There are also various international actors, such as GAVI (Global Alliance for Vaccine and Immunization), USAID (United States Aid Agency), the Bill and Melinda Gates Foundation, COVAX, and UNICEF, that shape procurement policies and funding mechanisms using different market-shaping tools. Interestingly, a characterization of vaccine manufacturers is done from a global perspective, but India-specific classification is missing, which makes a case for further study. The societal benefits of improved product development and manufacturing are expected to be remarkably high (Pradeep Suresh, Prabir K. Basu, 2008). The probability of developing a marketable vaccine is low under subsidy programs, especially through a university. (Jason C. Hsu, Eduardo S. Schwartz, 2003). An early defence against the claim that excess profits were realized was that high average returns were necessary to induce investment in high-risk research and development (F. M. Scherer, 1993). While India is known as the vaccine capital and pharmacy of the world, it was put to a severe test during the COVID pandemic. India has to answer criticism of adopting "Vaccine Nationalism" and putting the COVID pandemic in a slow recovery mode (Chatterjee, N., Mahmood, Z., & Marcussen, E., 2021). A list of specific diseases for which more than 99 percent of the burden falls in low- and middle-income countries, which include malaria, schistosomiasis, and leprosy (Lanjouw and Cockburn, 2001). This calls for all the low- and middle-income countries to spend more on disease control, which obviously becomes the responsibility of the government or state, and that is the key challenge. That means it is the responsibility of the international community to chip in for the global good (Kremer, 2001). That is how the "India Story" has emerged, and private entrepreneurs struggled

initially to set up facilities for vaccines, wait for long regulatory clearances, and fight Intellectual Properties to stop exploitation of the very high-priced vaccines coming from the HIC or developed nations. As a logical consequence, Indian vaccine manufacturers have slashed prices. Indian companies started investing in the vaccine business and set up plants, and each such company has adopted different product groups to cater to national or international requirements, albeit with collaborations and partnerships. (Frew S. E. et al., 2007). The authors tried to inform readers of the status of each vaccine company in India and their collaborations, R&D, and other financial sources, with a recommendation for the future.

The case in question is a new industry in the west that has mushroomed to develop new vaccines and transfer the knowledge to the LIC and MIC for the benefit of these countries, of course for a fee. A case in question is the patent buyout of the Human Papilloma Virus (HPV) (Mario Songane, Volker Grossmann, 2021). The choices that the vaccine industry makes are driven by innovation, and a contrary paper published by JPRI found that there is an increase in spending on R&D in India, and an increase in spending on R&D in pharmaceuticals leads to innovations (Sethi et al., 2021). Now in the new world order where the Indian vaccine industry is recognized to fulfil the larger population of this planet, different projects undertaken by different vaccine manufacturers are listed out to ascertain the intense activities of the vaccine industry in India (S. Jadhav, M. Gautam, and S. Gairola, 2021). This displays the contribution of developing countries' vaccine manufacturers' objectives and goals and how these companies are committed to being part of the global good by saving millions of lives. An early success story of the Indian vaccine industry started with the Serum Institute and Shanta Biotechniques. The success story lies in leveraging the strengths of Indian craftsman ship with technology. This low-cost model shook the industry (Chakma, J., et al., 2011), and Shanta Biotechniques has made giant strides to expand the product basket after the success of Hepatitis B. Business model classifications for biotechnology companies in India were done earlier from a distinct perspective about product manufacturing, marketing, research, etc. (Viren Konde, 2008). However, this perspective had its limitations.

Therefore, by conducting this study, it will provide a clear understanding of the customer selection process in the vaccine industry and how the business process dovetails according to the compulsions. This will further lead to classifying the vaccine industry and suggesting rating systems.

2.2 INTRODUCTION TO THE STRUCTURE OF THE REPORT

The thesis consists of sections that will build the structure of the research. Introduction with aim and objectives; Literature Review; Methodology of Research; Analysis of Data Collected; Discussions; Conclusions and Recommendations as Per Research Questions.

2.3 STRUCTURE OF THE THESIS

Chapter -1 Introduction

The introduction chapter gives a write-up on the idea of having a vaccine manufacturing unit in India, given the circumstances of the industry and being a part of the larger pharmaceutical industry. Precisely, the introduction is trying to characterize and differentiate the vaccine industry from the pharmaceutical industry. It drives the point of the research question, aims, and objectives of the study. Hence, this chapter gives a flavour of how the topic was discussed and shaped up for further studies.

Chapter-2 Problem Statement

A problem statement is expected to define the issue raised by the researcher and explain the problem and its trigger for various forms of research.

Chapter-3 Literature Review

Literature reviews are a principal factor in understanding how the Indian vaccine industry, its business, and customers are addressed, from research publications, magazine articles, news reports, government data, books, and websites.

Chapter-4 Research Methodology

In this chapter, there is discussion on the methods used for carrying out the research study and the implementation of the methods. Research strategy, design, and justifications for using specific methods are discussed. Ethical considerations, reliability of the data, and measures to ensure the reliability of the research were ensured.

Chapter-5 Results

Data analysis: outlining the findings after the data collected from questionnaires, industry data, and government reports for the vaccine industry in India, given the complexity of the business, constraints, and business operations.

Chapter-6 Discussion and Analysis

This chapter will discuss the results and try to interpret the outcomes of the research. This will also provide opportunities for further research, if any.

Chapter-7 Conclusion

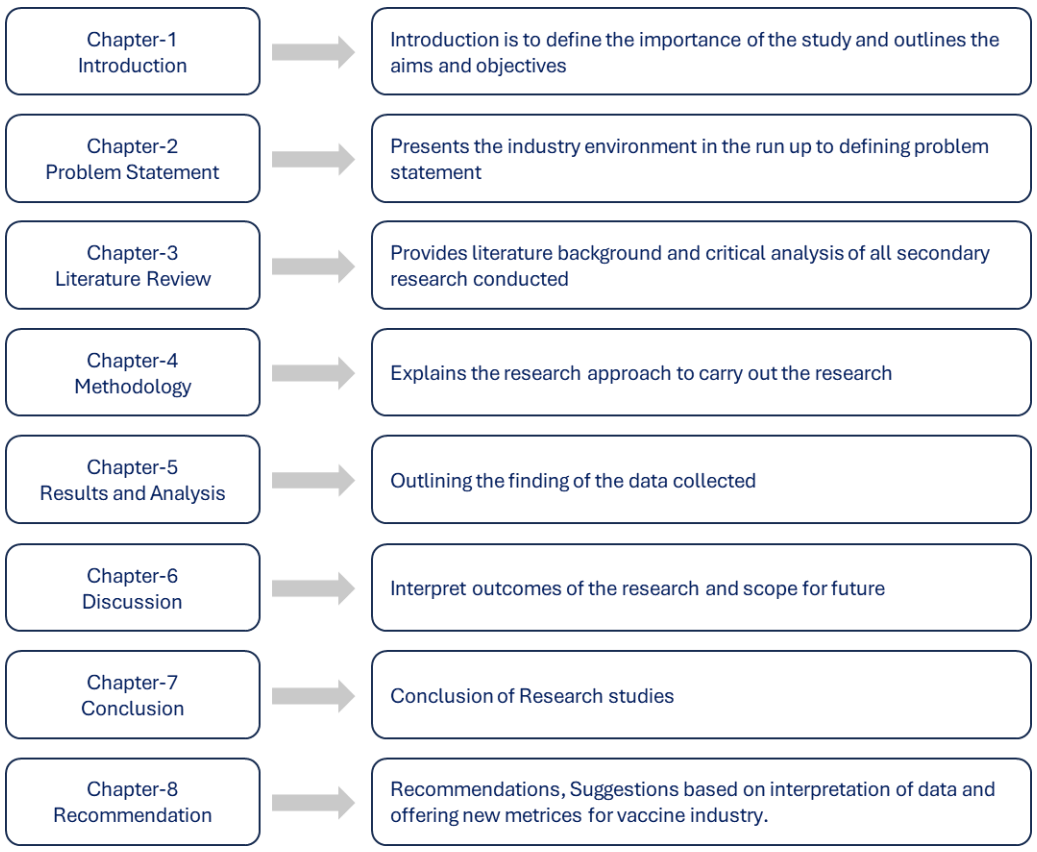
This chapter concludes the study by giving a summary of research studies.

Chapter-8 Recommendation

This is an important chapter considering the recommendations made by designing the new metrics on rating systems, business processes, and recommended classifications of the vaccine industry in India.

A pictorial representation of the flow of thesis given below:

Fig-2: Flow of Thesis

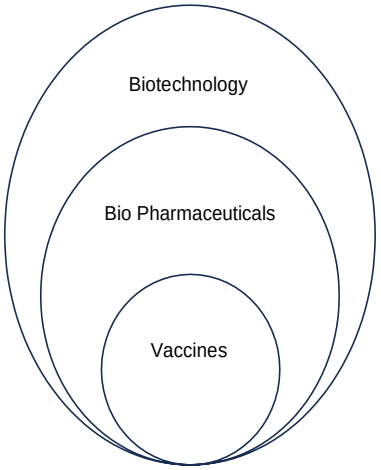


CHAPTER 3: LITERATURE REVIEW

3.1 INTRODUCTION

Biotechnology, biopharmaceuticals, and vaccines are often used simultaneously. Hence, it is important that the literature research, although attempting to cover strictly the topic of vaccines, refer to the overall biopharmaceuticals and other aspects to derive the context. Figure 3 below will give an overall glimpse of the broader understanding of vaccines as a part of the biotechnology industry.

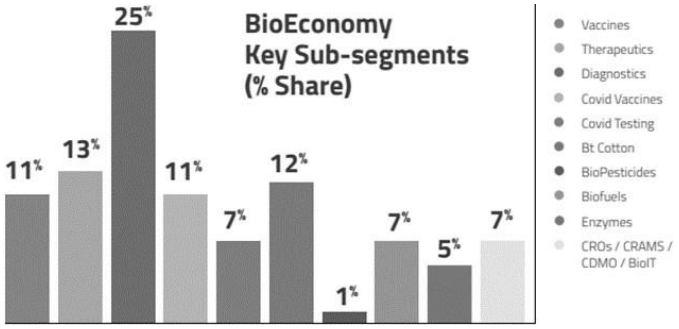
Fig-3: Vaccines part of Biotechnology



Source: Researcher

According to the INDIA BIOECONOMY REPORT 2022 (June 2022), the bio-industrial segment's contribution to the bioeconomy witnessed 202 percent growth in 2021 in India. India's bioeconomy will cross the $80 billion mark in 2021. The nation has set an ambitious target for the bioeconomy to touch the $150 billion threshold by 2025. The segment is estimated at $10.27 billion. The primary driver is the government's decision to concentrate on renewable energy, especially blended fuels. Biofuels contributed $5.97 billion in value. The other important sub-segment of Bio-Industrial, the enzymes market, reached $4.3 billion.

Fig-4: Contribution of Vaccines to Biotechnology



Source: India Bioeconomy Report 2022

Hence, it is abundantly clear that the vaccine component is only 11% of the bioeconomy, and hence, the rules applicable to vaccines are different from others. You may notice that COVID vaccines also contribute a separate 11% of the bioeconomy but are shown separately since this will interfere in the general evaluation of vaccines since COVID vaccines are not a consistent phenomenon.

The preliminary literature review aimed at finding relevant data on the Indian vaccine market. Especially the customer selection and marketing parameters, business models, classification, and other information meet the research objectives. Regarding the classification of the vaccine industry, work done in this area (although in limited numbers and in publications by consultancies such as KPMG) and while evaluating the parameters found that there is a sufficient gap in commercial and marketing links to the overall organization structure. There are papers dwelling on the global vaccine industry, and hence, India-specific analysis is required to create a new parameter, which has not been comprehensively covered as yet.

There are published papers on the Developing Countries Vaccine Manufacturing Network (https://dcvmn.org) and attempts made to define the vaccine business. This has a broader perspective, and there are no papers on new entrepreneurs, start-ups (although it is difficult to have vaccine manufacturers start up, although possible), or space for these vaccine manufacturers in the industry. Bio Spectrum, a renowned monthly magazine on biotechnology, publishes an annual article on the revenues of Indian biopharma companies

(www.biospectrumindia.com), which rates or classifies vaccine companies, but it does not link that with classification and other parameters, which are not clearly identified.

Hence, it is necessary to conduct more Indian vaccine industry-specific research and bring about the necessary data, which might help the industry at large and new entrants in particular.

3.2 DEFINING BUSINESS PROCESS

As per Adam Smith's "An Enquiry into the Nature and Causes of the Wealth of the Nations" (1827), almost two centuries ago, he attempted first to define the business process. One man draws out the wire; another straightens it; a third cuts it; a fourth points it; and a fifth grinds it at the top for receiving the head. "To make the head requires two or three distinct operations—to put it on is one; to whiten the pins is another—and therefore, the important business of making a pin in this manner is divided into about eighteen distinct operations, which, in some manufactories, are all performed by distinct hands, though in others the same man will sometimes perform two or three of them."

As per Gartner (www.gartner.com), business process management (BPM) is a discipline that uses various methods to discover, model, analyse, measure, improve, and optimize business processes. A business process coordinates the behaviour of people, systems, information, and things to produce business outcomes in support of a business strategy. Processes are either structured and repeatable or unstructured and variable.

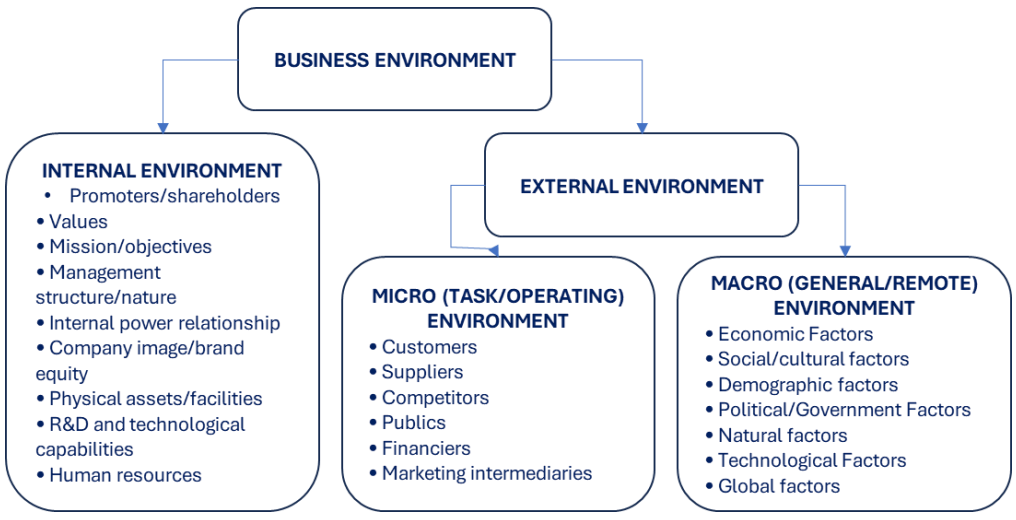
A business process is a compilation of tasks performed by stakeholders that work to deliver a goal, such as a service or product. The tasks are either triggered or automated by an event and result in the delivery of the final output for the customer. A business process is so pertinent in businesses because it's a building block of everything that happens, from day-to-day operations to the setup of automated workflows (www.SloveXia.com).

As per MSMEX (www.msmex.com), a business process is defined as a set of tasks and activities that eventually lead to the completion of a business goal. Depending on the business and its objectives, business processes tend to shift, alter, and mould since the final goal of every organizational task is different and unique. However, there are things common in every business process: clearly defined inputs, instructions, and a clearly defined final goal.

A business process is a structured, measured set of activities designed to produce a specific output for a particular customer or market. It implies a strong emphasis on how work is done within an organization, in contrast to a product focus's emphasis on what. A process is thus a specific ordering of work activities across time and space, with a beginning and an end and clearly defined inputs and outputs—a structure for action. Taking a process approach implies adopting the customer's point of view. Processes are the structure by which an organization does what is necessary to produce value for its customers (www.processand.com).

The business process is determined by the business environment in the pharmaceutical industry. According to Biswas, I., Singh, R. K., Chauhan, H., and Professor, A. 2002, the business environment is defined as "all those factors which have a bearing on business, i.e., factors which influence business decisions and impact business performance." Just like the development of an organism depends on its adaptability to the environment, the sustenance and growth of an organization depend on the resources of the organization and how those resources are favourable to the development of the organization.

Fig-5: Business Process relationship with Business Enrinment



Source: Business Environment-Indian Pharma Sector, Biswas, I., Singh, R. K., Chauhan, H., & Professor, A. (2020), Institute of Management, Nirma University

According to the above studies, all the employees of a pharma company (whether they work independently or are governed by any functional team or union) are considered internal stakeholders. Stakeholders who have a role in the success of the company, like suppliers,

regulators, and politicians, are considered input stakeholders. Stakeholders who are in between the final consumer (patient) and the pharma industry, mostly comprising doctors and medical university professors, are considered intermediaries. The consumers comprise the patient, then families, and advocacy groups.

3.3PHARMACEUTICALS INDUSTRY

3.3.1 WHAT IS A PHARMACEUTICAL PRODUCT

The vaccine industry is part of the pharmaceutical industry, and it is therefore important to understand the definition of pharmaceuticals and vaccines/biologicals. Pharmaceutical products are actually chemical ingredients, also called drugs, used for the treatment or prevention of disease. Pharmaceutical products, or drugs, are for treatments and are hence called therapeutic products.

- Pharmaceutical means a manufactured chemical product that is intended to be inhaled, ingested, injected, or topically applied for use in the diagnosis, cure, mitigation, treatment, therapy, or prevention of disease or injury in humans or other animals, according to Law Insider (lawinsider.com/dictionary/pharmaceutical).
- Pharmaceutical products consist of active ingredients combined with additional materials (excipients) selected to control dosage delivery, enhance performance, and facilitate manufacture (G.V. Rex Reklaitis, 2017).
- A drug, or pharmaceutical, is a substance used to prevent or cure a disease or ailment or to alleviate its symptoms. (James Chen, 2022)

3.3.2 WHAT IS THERAPEUTIC

A general understanding of medical treatment that is used for curing or controlling an ailment is therapeutic, which is also meant as a branch of medicine that is concerned specifically with the treatment of disease. The therapeutic dose of a drug is the amount needed to treat a disease.

- Within the domain of everyday language, the adjective therapeutic means “what relates to the treatment of disease or disorders by remedial agents or methods;” it is synonymous with the two terms “curative” and “medicinal” (Rakel, 2021).

- Therapy is defined as the treatment of physical or mental disorders. The therapy definition is broad and includes treatments for several types of conditions. Physical conditions treated with therapy include sports injuries, back and neck pain, headaches, vertigo, limited range of motion, muscular dystrophy, and others. Mental disorders are conditions that affect a person's mood, thinking, feelings, and behaviour. There are different mental disorders, including depression, bipolar disorder, anxiety, eating disorders, addiction, and personality disorders. (www.study.com)

3.3.3 WHAT IS VACCINE

Vaccines are injections (shots), liquids, pills, or nasal sprays that you take to teach your body's immune system to recognize and defend against harmful germs. For example, there are vaccines to protect against diseases caused by:

- Viruses, like the ones that cause the flu and COVID-19
- Bacteria, including tetanus, diphtheria, and pertussis (MedlinePlus, 2nd Edition, 2007)

There is a stark difference between a pharmaceutical drug and a vaccine. Pharmaceutical drugs are meant for the treatment of disease or prevention, and hence, pharmaceutical drugs in general are called therapeutic drugs. On the other hand, vaccines are completely different.

- A vaccine is a substance used for the production of antidotes in the body and provides immunity against one or a few diseases. In biological terms, a vaccine is defined as a biological and formulated preparation to provide acquired immunity for a particular disease (vedantu.com).
- A vaccine is an agent that contains a weakened or killed form of the disease-causing agent, its surface, or its toxins. When this solution is introduced to the human body, the immune system is able to identify the threat and destroy it. More than this, the human body will recognize the threat and can initiate an appropriate response in the future (vedantu.com).
- Vaccines differ from other medical drugs in two important ways. The first is that they were designed to prevent disease rather than treat it. They do this by priming a person's

immune system to recognize a specific disease-causing bacteria, virus, or other pathogen. This “memory” can last years, or in some cases, for life, which is why vaccination can be so effective, stopping people from getting sick rather than waiting until disease occurs. The second is that vaccines, by their nature, tend to be biological products rather than chemical ones like most drugs. This not only means that the processes involved in making them are usually more complex and expensive, but also that they tend to be less stable than chemicals and more vulnerable to temperature changes. Because of this, vaccines normally need refrigeration to keep them within a specific temperature range. The type of vaccine will determine how low a temperature the vaccine needs for storage. Most vaccines need to be kept refrigerated or frozen, but intranasal vaccines are now being developed that can be stored at room temperature (https://www.gavi.org/vaccineswork).

- Vaccines reduce the risk of getting a disease by working with your body’s natural defences to build protection. When you get a vaccine, your immune system responds (who.int).
- Vaccination is a simple, safe, and effective way of protecting you against harmful diseases before you come into contact with them. It uses your body’s natural defences to build resistance to specific infections and make your immune system stronger (who.int).
- Vaccines train your immune system to create antibodies, just as it does when expose to a disease. However, because vaccines contain only killed or weakened forms of germs like viruses or bacteria, they do not cause the disease or put you at risk of its complications (who.int).

Vaccines, by definition, are biological agents that elicit an immune response to a specific antigen derived from an infectious disease-causing pathogen. (Jennifer Czochor and Audrey Turchick, 2014)

3.3.4 WHAT IS PROPHYLAXIS

A measure taken to prevent a disease or condition. Prophylaxis is any medical or public health procedure whose aim is to prevent rather than treat or cure a disease (www.pmlive.com).

Since preventive measures can take different forms and prophylaxis is used to prevent, arrest, and reduce diseases, it is divided into three types:

- Primary Prophylaxis: In this process, prevention or increasing resistance to diseases happen. These diseases have not yet occurred in individuals. It comprises routine medical checkups, vaccinations, mammograms, pap smears, and other forms of testing. These tests are conducted when the patient appears well without any symptoms of any disease. If a disease is known to be present, then that screening is no longer primary prophylaxis.
- Secondary Prophylaxis: This screening is done to prevent the recurrence of a disease that has already occurred in a patient. A few examples are taking statins to prevent recurrent heart attacks and changing the work environment to stop re-injury.
- Tertiary Prophylaxis: This prophylaxis is done to reduce the impact of chronic diseases. Such diseases might induce long-lasting effects. So, programs like disease management programs or stroke rehab programs for heart diseases are undertaken as part of this prophylaxis.
- Quaternary Prophylaxis: The main idea of this prophylaxis is that excessive medical treatment should be avoided for patients who do not seem to benefit from medical treatments. For example, if a cancer patient does not respond to the first round of chemotherapy, then another round is not done using the same medicines. (https://www.riverwalkdentalorthodontics.com/what-are-the-different-types-of-prophylaxis).

Even there is a term called prophylaxis treatment, which means, “Prophylaxis means preventative, derived from the Greek term ‘PHYLAX’ which means to guard or watch. Prophylactic treatment is a medical term for any precautionary measure taken to prevent the onset of a disease. These measures could be in the form of medicine, therapy, or other

procedures. There are several types of prophylactic treatments. These include surgeries, antibiotics, vaccines, and dental treatments (www.hganalytics.com).

3.3.5 **DIFFERENCE BEWTEEN VACCINE AND PHARMACEUTICAL DRUG**

Differences between medicines and vaccines start right from the research and development process, safety tests and requirements, production process, certification process, and user groups. Vaccines are given to healthy people to prevent disease. There are fewer vaccine manufacturers but more vaccine recipients. A single defective batch can therefore cause massive problems for populations (a considerable risk for all of us). Only a few countries manufacture their own vaccines, while other countries import vaccines, which involves long-distance transport, resulting in cold chain issues (Levon, B., 2020). There are differences between medicines and vaccines.

When doctors or veterinarians are prescribing or administering a drug, their goal is to achieve the desired concentration of the drug in a targeted tissue. Drugs are transported in the bloodstream and diluted across all of the tissues in the body, not just the desired tissue. The drug(s) will then be flushed from the body over time, usually by the liver and/or kidneys. Most of the body is water, so if you can imagine colour dyeing one end of a pool by placing dye in another end of the pool while the pool filter is running, you can start to visualize how, as your pool starts to get bigger, you're going to need a lot more dye to get the job done. This is why drug doses will change depending on the weight or size of the patient receiving them.

Vaccines work by exposing the body to a set amount of pathogen proteins or something that looks close enough that the immune system cannot tell the difference. These proteins do not distribute through the body the way drugs do. Instead, the immune system reacts locally, learns about that disease, and then sends trained cells and antibodies throughout the body. The dose of vaccine administered, therefore, is not determined by the patient's body size but rather by the amount of protein required to mount an effective immune system response, which does not change with patient size. (www.lavittanimalhospital.com).

Biotechnology and pharmaceutical companies both produce medicines, but the medicines made by companies in the biotech industry are derived from living organisms, while those made by pharmaceutical companies have a chemical basis (www.investopedia.com).

3.3.6 TYPES OF VACCINES

Vaccines can be injectable, oral, or in aerosol form. Vaccines are produced on technology platforms, and each has its own delivery mechanism and manufacturing process. The main types of vaccines that act in diverse ways are:

- attenuated vaccines
- Inactivated vaccines
- Subunit, recombinant, conjugate, and polysaccharide vaccines
- Toxoid vaccines
- mRNA vaccines
- Viral vector vaccines (news-medical.net)

3.3.7 VACCINE SEGMENTS

There are human and animal vaccines in the country. Although the regulatory rules to operate a vaccine manufacturing plant are similar, this segment will give a better understanding of the classification.

As pointed out in the Introduction chapter, human vaccines are further sub-characterized as adult vaccines, childhood vaccines, and traveller's vaccines. Whereas animal vaccines are further sub-characterized as livestock, poultry, and companion animal vaccines, (Roth, J. A., 2011). Veterinary Vaccines and Their Importance to Animal Health and Public Health *Procedia in Vaccinology*

3.3.8 DIFFRENCE BETWEEN ANTIBIOTICS AND VACCINES

Table-1: Difference between Antibiotics and Vaccines

	Antibiotics	Vaccines
Definition	Antibiotics are small molecules or compounds that are effective in treating	Vaccines are dead or inactivated organisms or compounds used to provide

	infections caused by organisms such as bacteria, fungi, and protozoa.	immunity to a particular infection or disease.
Types	Antibiotics classified according to their structure and mechanism of action into 3 classes: cyclic lipopeptides, oxazolidinones & glycyl cyclins. The first 2 targeted at Gram positive infections and the last one is a broad-spectrum antibiotic	Vaccines are of distinct types-live and attenuated (vaccines against chicken pox), inactivated (BCG vaccine), subunit (Hepatitis C), toxoid, conjugate, DNA, recombinant vector vaccines and other experimental vaccines.
Side effects	Antibiotics may have side effects like diarrhoea, nausea, and allergic reactions.	Vaccines may cause allergic reactions.
Source	Antibiotics derived from natural, semi-synthetic and synthetic sources.	Sources of vaccines include live or inactivated microbes, toxins, antigens.
Function	Antibiotics used to treat bacterial diseases.	Vaccines prevent bacterial and viral diseases.
Examples	E.g., tetracycline, sulphonamides, cephalosporins	MMR, Tdap, DTaP, HPV vaccine, polio vaccine

Source: www.diffen.com

Antibiotics and vaccines are both used to fight germs, but they work in unusual ways. While vaccines are used to prevent disease, antibiotics are used to treat diseases that have already occurred (www.diffen.com).

There is adequate demonstration of significant differences of pharmaceutical drug and the vaccine or biologicals. The composition is different, process sis different, purpose is different, and the administration and results are different. It is therefore imperative that we need to study the business process which gives different dimension.

3.3.9 PHARMACEUTICALS BUSINESS PROCESS

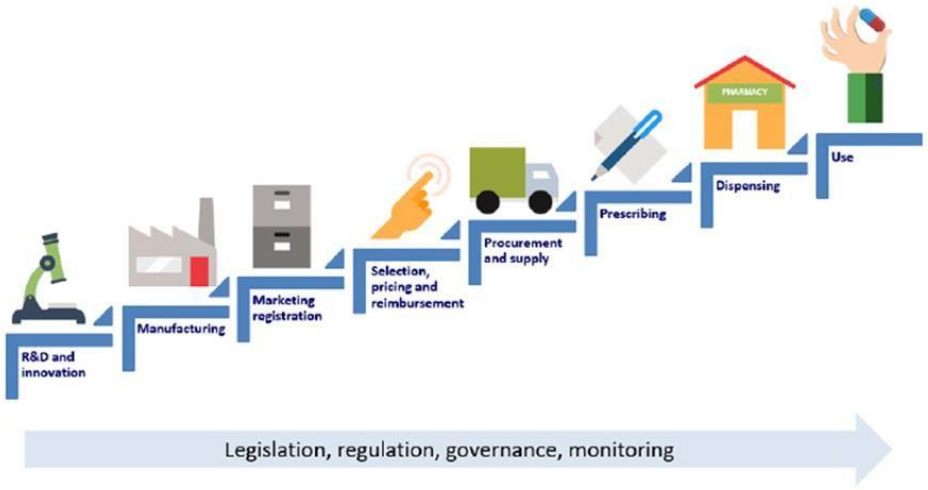
Vaccine industry invariably categorised under pharmaceuticals industry, yet comes under

- Different purpose compared to pharmaceutical drugs.

- Different technology compared to pharmaceutical drugs.
- Different and stringent Manufacturing process
- Capital intensive and time taking process for vaccine.

Business Process for Pharmaceutical products given as under.

Fig-6: Business Process for Pharmaceuticals



Source: United Nations Tool Kit on Synthetic Drugs

(https://syntheticdrugs.unodc.org/syntheticdrugs/en/access/pharmaceutical/index.html)

The business process for a pharmaceutical product ends up with prescription of the product by a doctor and finally a patient is the consumer who either buys from a retailer or consumes in a hospital. India's retail pharmacy market is about $18.89 Bn in 2022 as against $20 Bn USD market which is significant (www.insights10.com). The Indian pharmaceutical industry ranks third globally in pharmaceutical production by volume and is known for its generic medicines and low-cost vaccines. The sector contributed to around 1.32% of the Gross Value Added (at 2011-12 constant prices) of the Indian Economy in 2020-21. The total annual turnover of Pharmaceuticals in the fiscal year 2021-22 was Rs. 3,44,125 crore (USD 42.34 Bn). Major segments of Indian Pharmaceutical Industry include generic drugs, OTC medicines, bulk drugs, vaccines, contract research & manufacturing, biosimilars and biologics. India is a global leader in the supply of DPT, BCG, and Measles vaccines. India is one of the biggest suppliers of low-cost vaccines in the world. India accounts for 60 percent of global vaccine production,

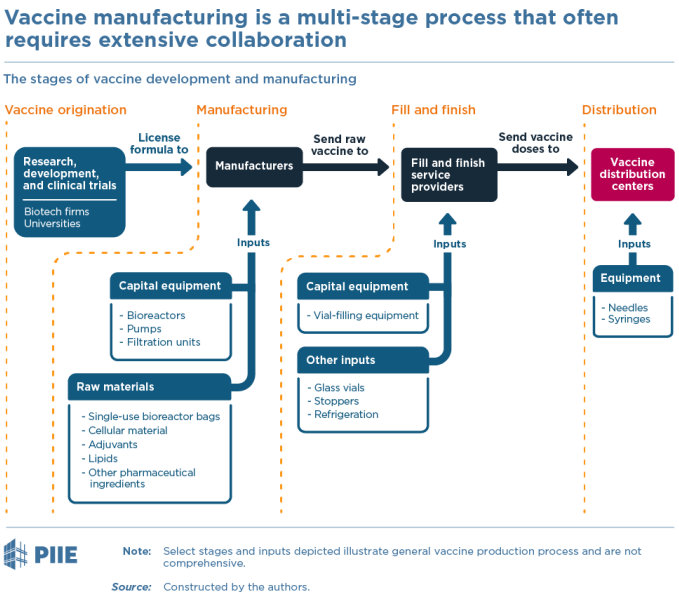
contributing 40 to 70 percent of the WHO demand for Diphtheria, Tetanus and Pertussis (DPT) and Bacillus Calmette–Guérin (BCG) vaccines, and 90 percent of the WHO demand for the measles vaccine. There are 500 API manufacturers contributing about 8% in the global API Industry. India is the largest supplier of generic medicines. It manufactures about 60,000 different generic brands across sixty therapeutic categories and accounts for 20% of the global supply of generics. Access to affordable HIV treatment from India is one of the greatest success stories in medicine. Because of the low price and high quality, Indian medicines preferred worldwide, making it "pharmacy of the world," (Department of Pharmaceuticals, Government of India, Annual Report, 2022-23).

Hence, the prescription drug market in India is significantly high due to pharmaceutical drug sales either through sales through prescriptions or sales through over the counter in retail segment.

3.3.10 VACCINE BUSINESS PROCESS

There are processes defined for manufacturing and it does not capture entire process. However, a prototype of the vaccine manufacturing process, given as under.

Fig-7: Vaccine Manufacturing process



Source: Monica de Bolle, Maurice Obstfeld, and Adam S. Posen, April 2021

It is pertinent to move the customer choices, classifications, and business process for the Indian vaccine industry.

3.4 BUSINESS MODELS AND CLASSIFICATION OF VACCINE INDUSTRY

3.4.1 BUSINESS MODEL

According to (Konde, V., 2009). Biotechnology business models: An Indian perspective. Journal of Commercial Biotechnology defines business process and models as not homogeneous; divided into three to four groups such as the Platform, Product, Vertical and Hybrid models.

1. The Platform-based companies develop a set of tools or integrated technologies and provide these for use in different applications. One advantage of this business model is that revenue generated quickly.
2. The Product business model represented by conducting basic and preclinical research, developing products in defined therapeutic areas, venture capital funding through preclinical development, public investors to support clinical trials, and licence away 'first-born 'products. Very few companies succeeded with this business model.
3. The combination of product – platform business models lead to what is known as 'hybrid models' in which technology platforms combined with services and the creation of products. The Hybrid business model represents the company characteristics like breadth of integrated technologies, proprietary biology, focused therapeutic interests and capabilities, longitudinal product development, and renewable source of products along with contract research and services for the generation of revenue.
4. In the fully-or-vertically integrated biopharmaceutical company or Vertical business model, the drugs developed up to end of clinical studies or up to approval, which means that the creation of value pursued till the end of value chain. On the other hand, integrated pharmaceutical companies, only small number of employees focused on a specific area; other business areas outsourced to external partners. It is simply an office-based company, dealing exclusively with project management and outsourcing all steps

along with the practical value creation work, from ADME tests (Absorption, Distribution, Metabolism, and Excretion), animal experiments to clinical studies.

This paper from (Konde V., 2009) has been the closest to the contemporary business models. But it is short of defining vaccine industry process and 'customer centric decision making' in India. This classification is based on Business models or basic structure of the organization, not as per the outcomes or performance of the organization.

MNCs in human vaccine business have pulled out of the low-margin vaccine business, thereby shrinking number of players from 26 in 1967 to 8 in 1996 and finally to 4 players in 2003. The reasons include price controls, liability fears and opportunity costs. But the demand for vaccines is growing and developing country firms are increasingly exploiting recent technologies to tap this niche market, (Lewis-Lettington, R., & Grace, C., 2004). Issues paper-Access to medicines The Effect of Changing Intellectual Property on Pharmaceutical Industry Prospects in India and China Considerations for Access to Medicines.(www.healthsystemsrc.org). This report goes on to emphasise the "Cooperative business model," while changing legislation and technological capacity are pushing Indian firms to consider new ways of competing, there is also a pull from MNCs encouraging the same firms to achieve their growth targets through co-operative strategies. This 'pull-factor' stems from the research based MNC's increasingly pursuing the need to cut costs and boost productivity, and the consequent search to invest an increasing amount in external collaboration, 20% outside the company on a contract or part investment basis. This is true not only for manufacturing, but also for research. As an alternative (or, in noted exceptions, in addition) to the competition models described in the previous section, some of the Indian companies, having recognised an opportunity to meet the needs of the MNCs, have chosen to follow a more service provider/partnership-orientated model. Although the co-operative business model is a well-established in other Indian sectors. This business model otherwise called as "Contract Manufacturing" / "Contract research." This model is prevalent as MNCs, or top Indian companies are getting their products manufactured in third party / contract manufacturing facility and marketing the product by adding value. Now this phenomenon is

also quite common in western countries and Indian companies are either manufacturing for MNCs in the west or marketing their own products in west with production centre in India.

It is also possible that the globalization of biopharmaceutical innovation will have deleterious effects on domestic industries in the emerging markets, and on access to health technologies in the developing world. Failure to sufficiently adapt to new realities could, for instance, lock emerging market firms into low-value segments of the innovation value chain for years to come, and/or limit their growth prospects by preventing access to recent technologies. These areas deserve further study and continued vigilance to minimize adverse impacts on emerging market industries and pharmaceutical access, according to (Rezaie, R., McGahan, A. M., Frew, S. E., Daar, A. S., & Singer, P. A., 2012).

The union government, in addition to various state governments, have been playing a key role in the development of biotechnology sector right from its inception. Research institutes established by the Indian Government during the past two to three decades. All these institutes dedicated to medical, industrial, scientific and/or agricultural biotechnological research and development. The Government also increased budgetary allocation for the Department of Biotechnology (DBT) in 2002–2003, *Biotechnology in India – Emerging Opportunities*, (Himanshu Parmar, 2005).

Most Indian Contract Research Organizations (CROs) are moving towards ICH/GCP (International Conference on Harmonisation / Good clinical practice) compliance norms to find international acceptance for their services. This sector expected to play a key role in India's biotech future, (Palnitkar, U., & Young, E., 2004).

This explains how the paradigm has shifted from "manufacturing and marketing" the product into a "Contract / Cooperative Manufacturing" and "Contract research" for larger MNCs for Indian Pharma companies.

3.4.2 PRODUCTS AS PER EXPORTS REQUIREMENTS (REGULATORY)

There are regulatory classifications within vaccine industry which is important for any vaccine industry to choose the markets accordingly. For example, if any vaccine is WHO-PQ (World

Health Organization – Pre-Qualified) then, vaccine manufacturer has greater chance to register its products outside the country and tap international markets faster. This classification also acts as entry barriers for the manufacturers who do not have such certifications.

1. WHO-Pre-Qualified Product: If a vaccine has undergone thorough evaluation of relevant data, testing of samples and WHO inspection of relevant manufacturing sites — and the outcome is positive — it is included in the WHO List of Prequalified Vaccines (www.who.int). This means that it:

- meets WHO standard for vaccine quality, safety, and efficacy standards, as endorsed by the WHO Expert Committee on Biological Standardization (ECBS)
- It is suitable for the target population (in accordance with the recommended immunization schedules) and for use with appropriate concomitant products.
- It meets the operational specifications for packaging and presentation of UN organizations interested in procuring that vaccine. (Blaschke, T. F., Lumpkin, M., & Hartman, D., 2020). The World Health Organization Prequalification Program and Clinical Pharmacology in 2030.

A WHO- Pre-Qualified vaccine is mandatory today to export or supply vaccines to UNICEF programme and becomes an easier tool to get the vaccine registered in various other countries with that certification, (Global Vaccine Market Report Overview, 2018). However, this is also an entry barrier for companies who do not have a WHO Prequalification to enter into export markets. On the contrary, vaccine companies operating in India do not need WHO-Prequalification to market products in India. To market products in India, WHO-GMP certification is good enough and countries are also exempting WHO Prequalification and accept WHO GMP for specific vaccines, viz., Anti-Rabies vaccine.

2.WHO-GMP Product: Good Manufacturing Practices (GMP, also referred to as 'cGMP' or 'current Good Manufacturing Practice') is the aspect of quality assurance that ensures that medicinal products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the product specification (www.who.int).

Here manufacturers can easily market their products in India and in certain countries who do not insist WHO-PQ for registration.

3. Import License of Finish Product: Companies without a manufacturing facility, who import vaccines under CDSCO (Central Drugs Standard Control Organization, Government of India) registration. These companies simply import the product and sell in the open market as per requirements.

3.4.3 PRODUCT TYPES (ARCHETYPES)

In pharmaceutical business the archetypes broadly classified as – "Access Drivers," "Therapy Leaders," "Specialty Players," and "Brand Builders." (IQVIA, 2018). This is based on pharmaceutical products aiming for 'brand building' and 'prescriptions.' Since, vaccines are in prophylactic (preventive) category, the word "Therapeutic" is little in common with pharmaceuticals and vaccines. With the exception of vaccines such as the anti-Rabies vaccine and the Tetanus toxoid vaccine, used after incidence. However, these vaccines are commonly used as prophylaxis. Hence, the prophylaxis category, or archetype, could be replaced with another archetype. While the export segment is a common factor for all manufacturers, it is the focus of the Indian market that defines the archetypes.

3.4.4 REVENUES & PROFITS

- As per Bio spectrum India magazine (a popular magazine for the biotech industry) (www.biospectrumindia.com), biotech companies and vaccine companies are rated as per revenues and growth of the company. Revenues of leading vaccine companies and pharma companies are enclosed in Appendices 9, 10, and 11. Bio spectrum ranks the vaccine and biopharma industries.
- The researcher could get the "Profit and Loss" statements and "Balance Sheets" of leading vaccine companies and pharma companies from authorized sources and try to analyse the pattern. Enclosed in Appendices 9, 10, and 11
- CRISIL (a S&P company) engaged in rating organizations and developed criteria for rating pharmaceutical companies. While the broader criteria of manufacturing companies apply to entities in the pharmaceutical sector as well, CRISIL Ratings'

analysis of government policies and regulatory issues and the market position and operating efficiency of pharmaceutical companies determines the rating system. (Vemuri, S., Karunakaran, R., Patel, R., & Nehulkar, C. (n.d.)) Criteria contacts. CRISIL-Ratings-criteria-pharmaceutical.)

3.4.5 TECHNOLOGY BEING AN EDGE

The evolution of vaccines (e.g., live attenuated, recombinant) and vaccine production methods (e.g., in Ovo, cell culture) is intimately tied to each other. As vaccine technology has advanced, the methods to produce the vaccine have advanced, and new vaccine opportunities have been created. These technologies will continue to evolve as we strive for safer and more immunogenic vaccines and as our understanding of biology improves. The evolution of vaccine process technology has occurred in parallel to the remarkable growth in the development of therapeutic proteins as products; therefore, recent vaccine innovations can leverage the progress made in the broader biotechnology industry. (Josefsberg, J. O., & Buckland, B., 2012). Vaccine process technology. In Biotechnology and Bioengineering (Vol. 109, Issue 6, pp. 1443–1460) Product classification Licensed vaccines

1. Adjuvant Live attenuated virus (Smallpox, polio, measles, mumps, rubella, chicken pox, rotavirus, shingles, influenza, and yellow fever)
2. Inactivated purified virus (Inactivated polio, Japanese encephalitis, hepatitis A, Influenza (seasonal and pandemic), and rabies)
3. Live attenuated bacterium (Tuberculosis and typhoid)
4. Whole inactivated bacterium (Whole cell pertussis, Purified protein Acellular pertussis)
5. Purified protein toxoid (Tetanus, anthrax, and diphtheria)
6. Purified virus-like particles (VLPs)- (Hepatitis B and human papillomavirus)
7. Purified polysaccharide (Pneumococcal for adults and typhoid)
8. Polysaccharide conjugated to carrier protein (Pneumococcal for infants, haemophilus type B, and bacterial meningitis)
9. Plasmid DNA (In development)

10. Adenovirus DNA delivery (In development)

- And there is mRNA technology for various vaccines including Covid19 vaccine.

3.4.6 MARKETS

A Ghosh, P. K. (n.d.). *Indian Vaccines Industry Addressing Human Health Challenges Forum for Indian Science Diplomacy* FISD. www.ris.org.in classifies the Indian vaccine market as per customer or consumer in three main categories such as,

1. Doctor's prescription – retailer
2. Government / State / Institutional procurement
3. Exports market

However, the fourth segment, such as "Contract Manufacturing"—the last-mile manufacturing of vaccines: recommendations for scaling up production of COVID-19 vaccines in Africa, (2021), United States Pharmacopoeia (USP).

There is abundant data on the pharmaceutical and export business as market research is carried out and enumeration is done by various agencies and research firms. Periodically, the data is published or sold to subscribers. However, it is important to mention that market research organizations and industry watchdogs do not have any systematic enumeration or research done on procurement by the state or government. There is no segmentation done by the pharmaceutical industry about procurement by government agencies.

3.4.7 CAPABILITITES

The larger the capability, the better the economies of scale. Capacity building for the manufacturing of vaccines in developing countries has always been an area of paramount importance, and more so in a pandemic situation. (Kumraj, G., et al., 2022). Capacity Building for Vaccine Manufacturing Across Developing Countries

One would monitor the bottlenecks reported by the private sector participants and identify measures governments can take to support the development and strengthening of the capabilities needed to manufacture and distribute vaccines at scale. In turn, support for such capability development in low- and middle-income countries is provided through aid programs and technical assistance. (Evenett, S. J., Hoekman, B., Rocha, N., & Ruta, M., 2021). The

COVID-19 Vaccine Production Club: Will Value Chains Temper Nationalism? This white paper released by the World Bank indicates that support should be provided to lower-middle-income countries (such as India) to scale up vaccine manufacturing capabilities. It is obvious that the world needs India to have higher capabilities for production, which can in turn serve the world in quick time.

The setting up of vaccine manufacturing units, the grant of permission for clinical trials, and the final licensing and marketing authorization for vaccines in India are provided by the Central Drug Standards Control Organization (CDSCO), which is a National Regulatory Authority (NRA) in the country. The regulatory control over the quality of drugs in the country was exercised through the Drug and Cosmetics Act, 1940. Schedule Y of this act regulates clinical and preclinical testing of the products. As per the Act, vaccines and other biological products are considered to be 'new drugs' and thus governed by all rules and regulations applicable to a new drug. India is a major global vaccine manufacturer and supplies vaccines to developing countries. The World Health Organization has a standard mechanism for assessing the quality of vaccines and that of manufacturing units and provides prequalification of vaccines for procurement for United Nations supply (Lahariya C, 2020). A brief history of vaccines and vaccinations in India

CDSCO, the government regulatory agency in India, does not certify the products with WHO-prequalification, done by WHO itself. However, WHO-GMP certification for the vaccine manufacturing unit issued by the CDSCO.

3.5 COMPLEXITIES IN VACCINE BUSINESS

The vaccine business is a capital-intensive business that requires considerable ongoing investment in manufacturing assets, facilities, and people to maintain compliance with ever-increasing regulatory directives. The recent departure of Baxter and Novartis from the vaccine industry is an ominous sign that reflects the continued financial pressure on the remaining four major vaccine makers. Further consolidation of this business is likely (Vaccine Industry Samant, 2014). Vaccine development is difficult, complex, highly risky, and costly and includes clinical development, process development, and assay development. The risk is high because

most vaccine candidates fail in preclinical or early clinical development, and less than 1 in 15 vaccine candidates entering Phase II achieve licensure. The high failure rate is the result of a variety of reasons, including:

1. Not fully understanding the biology of protection.
2. There is a lack of good animal models to predict vaccine behaviour in humans.
3. Unpredictability of human immune system reactions to antigens as it relates to immunogenicity or safety.
4. The unpredictability of the impact of combining multiple components in a vaccine

According to Tripathy, S., Kumar Ray, P., & Sahu, S. (2011). Performance measurement of R&D is a vaccine for innovation capability: evidence from Indian manufacturing organizations In Int. J. Electronic Transport (Vol. 1, Issue 1). This paper interviewed many R&D scientists and found that the results indicate that technical competency and TQM index are the key drivers to encourage the performance of R&D, which enhance the effectiveness of R&D in manufacturing sectors in the Indian scenario. A new dimension to success is deep diving (Konde V., 2009) in his classification.

India's R&D spending is just 0.7% of the GDP as compared to the global average of 1.8%, with Israel spending the highest at 4.95% of GDP.

As per Chakma, J., Masum, H., Perampaladas, K., Heys, J., & Singer, P. A. (2011). Indian vaccine innovation: The case of Shantha Biotechnics Globalization and Health: The initial success of Shanta Biotechnics in India, attributed to home-grown companies in the developing world, is becoming a source of low-cost, locally relevant healthcare R&D for therapeutics such as vaccines. Such companies are compelled by market forces to focus on products relevant to diseases endemic in their country.

Evidence (Mullard, 2020) suggests that only 6% of vaccines that begin development successfully come to fruition in the market. A new vaccine takes, on average, 10 years to develop. These timelines and rates of success obviously pose a risk for those investing in vaccination research and development. This is an important parameter that defines the progressive future of the organization (Calnan, M., & Douglass, T., 2020). Hopes, hesitancy,

and the risky business of vaccine development In Health, Risk, and Society (Vol. 22, Issues 5–6, pp. 291–304). Routledge. https://doi.org/10.1080/13698575.2020.1846687. A vaccine against HIV has been a work in progress for the past 40 years.

The activities and features that characterize the vaccine industry are described, for instance, in Gordon and Samant (2008): “The vaccine industry is composed of companies that are engaged in any of the following activities: research, development, manufacture, or sales, marketing, and distribution of vaccines. Vaccine development is difficult, complex, highly risky, and costly and includes clinical development, process development, and assay development.”

According to Gordon and Samant (2008), about one-half of vaccines for children in the US are exchanged on the private market. It means that there is a significant share of the market where price-setting takes place under a free market regime. The rest was then delivered through organizations of public character at a reduced price.

Building a Successful Vaccine Manufacturing Business in Lower- and Middle-Income Countries: Lessons from Industry Leaders and Innovators Building a SUCCESSFUL Villa According to the United Nations Industrial Development Organization's (2021) publication, “Building a Successful Vaccine Manufacturing Business in Lower- and Middle-Income Countries: Lessons from Industry Leaders and Innovators," It has interesting things to mention about the vaccine industry.

Table-2: Difference between Small Molecule Pharmaceuticals and Vaccine / Biologics

Small Molecule Pharmaceuticals	**Vaccine / Biologics**
Relatively Simple Structures	Intricate and Complex Structures
Easily modelled	Not easily modelled or designed.
Synthesized through chemical reactions	Produced in living cells via synthesis pathways

Chemical reactions required to make the product well understood	Production pathways rarely completely understood
Purity of final product predicted with high accuracy and assessed analytically	Purity and efficacy cannot be completely determined using analytical lab tests
Identically produced pharmaceuticals in different facilities assumed to act identically	Only authentic way to determine their comparability or similarity to other vaccines is to run trials in humans to ensure they are equally safe and efficacious

Source: UNIDO

One single company can make the same vaccine with the same process and equipment, but at two different sites, which can turn out to be noticeably different. It is then up to the company to prove if the product from the new site has a sufficiently similar safety and efficacy profile to the product that originally underwent clinical trials and regulatory approval.

When the vaccine manufacturing process is so much different compared to pharmaceuticals in terms of sophisticated manufacturing processes, lead times, it therefore warrants a different approach. There is simply no substitute for experience and building deep experience for any new vaccine. manufacturer will take decades, not months or years. The first step is to learn from those who have successfully navigated and will continue to navigate the industry and its continually changing landscape.

While it can be very profitable, the vaccine market is also extremely complex and interconnected, reflecting the difficulties of vaccine market research and development (R&D), the importance of intellectual property, and the intricacies of supply and demand that are created and influenced by vaccine market players., (Shulman, J., Ahsan, R., O'malley, K., & Canada, K. 2019) GLOBAL VACCINE ECONOMICS AND RESEARCH AND DEVELOPMENT. High-income countries (HICs) constitute 82 percent of the global vaccine market in terms of dollar value, but only about 20 percent of the annual volume of vaccines consumed (i.e., vaccine

demand). Low-income countries (LICs) and middle-income countries (MICs) together account for about 18 percent of the dollar value of the global vaccine market but approximately 80 percent of the annual volume (World Health Organization, 2018).

The WHO notes robust evidence of price tiering based on income level, with HICs paying prices that are more than five times higher than MICs on average (see Figure 6) (World Health Organization, 2019, b p. 8). At the same time, it is important to note inconsistencies in this pattern for individual countries and specific vaccines. Although there is less demand for HICs, they are more profitable for vaccine manufacturers. This becomes a determinant for Indian vaccine manufacturers to estimate the export potential and fairly assess the classification. The vaccine business heavily depends on economies of scale and needs a manufacturing facility that continuously runs to meet WHO standards, irrespective of whether any production activity is going on. Hence, it is in the interest of the vaccine manufacturers to continuously feed business to keep the plant engaged to get economies of scale and get the desired cost for better profitability. Prices are at least five times higher in HICs as compared to MICs. However, vaccine manufacturers in DCVNM countries (Developing Countries Vaccine Manufacturers Network) are the largest contributors to the world, and India alone accounts for meeting more than 60% of global vaccine supplies to UNICEF (United Nations Children's Education Fund). UNICEF makes advance market commitments and gives contracts to DCVMN countries such as India, further aided by the Bill and Melinda Gates Foundation and GAVI (Global Alliance for Vaccine and Immunization).

The complex global vaccine market is characterized by multiple actors with different goals and multiple markets with diverse needs. Manufacturers, both multinational corporations and DCVMN companies, seek profits but do so in diverse ways, with the former looking to lower-volume, higher-margin markets and the latter looking to higher-volume, lower-margin markets. In 2017, the procurement budget of vaccines for the Government of India was Rs. 3587.1 crore, which covers 89% of children in India (Chatterjee et al., 2016) in terms of the current costs and projected financial needs of India’s universal immunization program. Indian Journal of Medical Research

3.6 VACCINE REGULATIONS

There are many references as per CDSCO and other guidelines that the new vaccine development takes at least 10 years for approval (https://www.pfizer.com/news/articles/how_are_vaccines_developed) and the introduction of existing vaccines by another company (already registered) will take at least five years, subject to all clinical trials and adequate demonstration of tests and documentation of safety, efficacy, and potency. There are systematic audits for the vaccine facility in manufacturing, biosecurity, microbial handling, and storage; process controls; batch records; quality inspection; and testing audits on an annual basis to permit the vaccine manufacturing facility to be up and running.

The Central Drugs and Standards Control Organization (CDSCO) is the National Regulatory Authority (NRA) in India. CDSCO is headed by the Drugs Controller General (India) [DCGI]. CDSCO approves vaccines that are subsequently introduced in the country, grants permission to conduct clinical trials, registers and controls the quality of imported vaccines, and lays down standards for updating the India Pharmacopoeia. It also approves licenses as the Central License Approving Authority (CLAA) for the manufacture of vaccines, coordinates the activities of the States, and advises them on matters relating to the uniform administration of the Act and Rules. The Central Drugs Laboratory (CDL), Kasauli, performs lot release for all imported vaccines as well as locally produced vaccines (National Vaccine Policy, 2011), Ministry of Health and Family Welfare, Government of India. That means, unlike pharmaceutical companies, vaccines are evaluated at the manufacturer's place but also cleared by a government-approved lab (CDL) for any manufacturer to market the product.

3.7 VACCINE BUSINESS & EXPENSES

The presence of external economies of scale permits that tax-subsidy schemes are always designed in such a way that they improve the welfare status of all the economic agents involved in the matter. Besides this, the model designed for the redistributive policy is self-financing. Moreover, if the transfer was properly arranged, it always led to Pareto-improving situations. (Garcia-Del-Barrio, P., 2012). External economies of scale, government purchasing commitment, and welfare improvements in the vaccines industry. European Journal of

Government and Economics, 1(2) This is an example of how the government extends help in the EU.

Governments acknowledge the need for partnerships and are working to enlist help from the private sector to pull through promising innovations. When public policy is embedded in an innovation ecosystem, this can encourage firms to devise business models that meet strategic goals aligned with those of policy where market incentives are weak, but needs are pressing (Li, J. F., & Garnsey, E., 2014). Policy-driven ecosystems for new vaccine development. Tec novation.

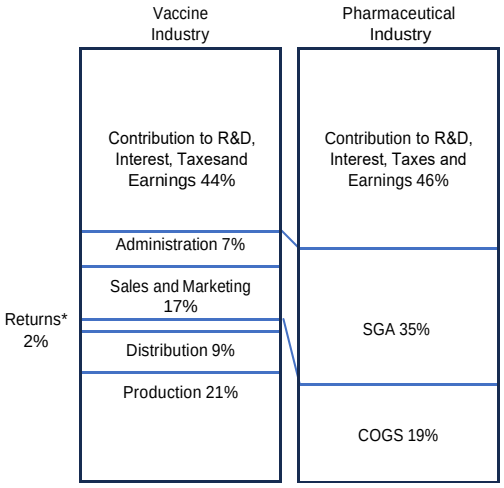
www.biospectrum.com publishes ratings of the biopharma industry on the basis of turnovers and revenues. However, there are no metrics to evaluate these companies on the basis of technology, product pipeline, products marketed, or scale of operation to determine the classification.

Certain financial parameters are used to evaluate the performance of a biotech company, as per Manjunatha, T. (2017), Performance Evaluation of Biotechnology Companies in India. The financial parameters are given as follows:

1. Current Ratio = Current Asset/Current Liabilities
2. Quick ratio = (Cash Marketable Securities Accounts Receivable) / Current Liabilities
3. Gross Profit Margin = Gross Profit/Net Sales
4. Net Profit Margin = Net Profit / Net Sales
5. Debt-to-equity ratio = total debt/total equity
6. Debt to Asset Ratio = Total Debt/Total Asset
7. Asset Turnover Ratio = Cost of Goods Sold / Total Assets
8. Debtors Turnover Ratio = Total Sales/Debtors + Bills Receivable

According to (Vaccine Industry, Samant 2014), there are distinct differences in the way the vaccine industry and the pharmaceutical industry operate and incur expenditure. The table below is in the context of the US market. But worthwhile inferences can be drawn from this reference.

Fig-8: Difference in Expenses between Pharma and Vaccine industry



Source: Vaccine Industry, Samant (2014)

These studies in the United States showed that the contributions to R&D, interest, taxes, and earnings after expenses were similar for the two industries (44% vs. 46%, respectively). However, the marketing expenses were quite different. Significantly more money was spent on production and distribution (32%, which includes production, distribution, and returns of product) in the vaccine industry compared with the pharmaceutical industry (19%), whereas the pharmaceutical industry spent more than the vaccine industry on sales, marketing, and administrative expenses (35% vs. 24%, respectively). Consequently, within companies, there is an expectation that sales-to-expense ratios for vaccines will be similar to those of other pharmaceutical products and that revenues will increase every year. Although this increase is accomplished with sales volume, prices stabilize as vaccine products mature, and increased revenues are no longer possible; hence, the requirement for a steady rollout of new products. However, unlike pharmaceuticals, old vaccines continue to be profitable for a variety of reasons, including:

1. The absence of a regulatory pathway for generic vaccines deters potential entrants from engaging in a complex and expensive approval process.
2. In most cases, access to knowledge, such as proprietary cell lines, virus strains, and internally developed processes, is far more valuable than patent protection.
3. The birth cohort is renewable, providing an ongoing unmet need for vaccines.

3.8 CHALLENGES IN BUSINESS PROCESS

Key issues are considered as a prelude to this.

1. The vaccine business is just 1.58% of the total pharmaceutical business in India, PHFI (2020), in value and 0.05% in volume. (Competition Commission of India, 2021)
2. There are only 34 vaccine brands out of 2871 total pharmaceutical brands in India.
3. In India, there are about 3,000 pharmaceutical companies, whose products are manufactured in over 10,563 industrial units and supplied through 65,000 stockists, with a strong penetration of private retail chemists numbered at about 9 lakhs. Whereas the total number of commercial vaccine manufacturers is only 24.
4. Like other technology-driven and highly regulated industries, vaccine manufacturing is capital-intensive, and long-term product costs are driven primarily by development and production-related economics. (Plotkin, S., Robinson, J. M., Cunningham, G., Iqbal, R., & Larsen, S., 2017). The complexity and cost of vaccine manufacturing: an overview
5. Lead times in manufacturing vaccines range from 3–4 months as compared to medicines, which could be as low as 2–3 weeks.
6. Childhood immunization is done mandatorily by the state, covering more than 89% of the Universal Immunization Program. India, 2023, while the private sector covers only 8.4% of the children.

It is apparently evident that the vaccine business process in India has not been specifically highlighted, and manufacturers have dubbed it on par with the pharmaceutical and medicinal product industry processes. The value chain, supply chain, and business processes of the pharmaceutical industry are more skewed towards retail promotion. On the contrary, the vaccine process is different and hence needs an understanding of the business process.

3.9 CHALLENGES IN CLASSIFICATION

There is already a classification method recommended by Konde (2009) on the basis of activities done by the vaccine industry. However, a classification in a commercial sense has evolved.

3.10 SUMMARY OF LITERATURE REVIEW

This can be segregated based on the following parameters, keeping in view of the research study:

3.10.1 Vaccine Industry

It is quite often misspelled that biotechnology, or, as a matter-of-fact biopharmaceutical, is the same as the vaccine business. The vaccine business, although classified in the same segment, has its own inherent challenges and limitations. Especially in the context of its regulatory, research, and financial framework, besides its business processes in India, which are not very explicitly covered in the literature review.

3.10.2 Business Process

It is understood that the business process of the vaccine business is different from that of the pharmaceutical business. The business process is defined from the beginning to the end of the value chain. In the pharmaceutical business, the process can broadly be mentioned as follows:

Fig-9: Business Process in Pharma industry (another illustration)

Source: Bolineni, P (2016)

This is a general template as defined by (Bolineni, P., 2016) Scholar Works on the Indian Pharmaceutical Industry's Supply Chain Management Strategies. This is dependent upon prescriptions from the doctors and product availability at the retailer, which is managed extensively by the marketing and promotional field force across the country. However, in the pharmaceutical industry, the largest consumer of the product is through the doctors-retailers network, while in the vaccine industry, the government consumes almost 88%–90%, hence the value chain is different and needs to be defined separately. Research articles have defined processes, not as explicitly as they should have been in the case of vaccines, and most often the processes are similar to those of pharmaceuticals. Hence, there is a need to study this.

3.10.3 Business Models and Classifications

Few have attempted to classify the business models of Indian vaccine manufacturers, and they are classified in the broader sense of research to market. This needs to be studied further in the context of government-driven business in India. A compilation of all such classifications and gaps identified should make a comprehensive one.

3.10.4 Complexities in the Vaccine Business

The need to evaluate the complexities in the vaccine business stems from the fact that it is not similar to that of the pharmaceutical business, although the process is quite often defined as similar. It is established that the challenges in the vaccine business, its regulatory framework, and its business process are different from those in the pharmaceutical industry. The inherent complexities in the vaccine business are quite telling of its highly capital-intensive and time-consuming process.

3.10.5 Vaccine Regulation

It is an established fact that dealing with biologicals, live viruses, bacteria, etc. is extremely regulated compared to dealing with simple pharmaceutical chemical compounds. It therefore attracts biosafety and epidemiological evaluations, besides constant audits of the facilities to keep them up and running, according to the Indian CDSCO. India supplies more than 60% of the world's vaccine requirement in terms of volume, and it is pertinent that the systems are robust and constantly evaluated by the WHO and other international agencies. This is a significant departure from the way pharmaceuticals are evaluated.

3.10.6 : Vaccine Finance

Vaccine Finance has several parameters. Firstly, financing research, vaccine manufacturing, and capital-intensive operations; Secondly, expenses to market the product; and thirdly, financial deliverables such as Profit Before taxes, assets, and revenues. Although risk elements are high in the vaccine business, the financial earnings are assumed to be higher than in the pharmaceutical business. Its expenses, especially marketing expenses, are way below those of the pharmaceutical business. It is all the more important that financial risk mitigation and long-term investments, handholding or investment, or grants from governments, stakeholder groups, and agencies are highly desirable.

3.11 LIMITATIONS

There are several limitations to the information available.

1. Most studies are done outside India, and India-specific information is limited to the vaccine business and business process.
2. The vaccine industry is a part of the pharmaceutical industry in India, and due to the low salience of the overall industry, the process and customer selection options are not being defined properly.
3. Business process flow for the vaccine and pharmaceutical industries is interconnected, and hence, divergent process flow is not captured in the publications reviewed.
4. The total number of vaccine companies limited in India, which includes the state-run units, However, state-run units are not considered for evaluation since they do not operate as commercial units.

CHAPTER 4: RESEARCH METHODOLOGY

4.1 INTRODUCTION

Research methodology was used by the researcher to explore the business process in the vaccine industry and conventional perceptions of reaching consumers based on experience in the pharmaceutical process. This chapter will explain the selection of research methods, including the data collection analysis through questionnaires, interviews with some key personnel as defined by the objectives, and other qualitative approaches.

4.2 AIM OF THE RESEARCH

The aim of the research was to answer the research questions identified in the introduction section and consider the vaccine industry separately to evolve a new classification and rating mechanism as identified in the literature review.

4.3 RESEARCH PROCESS

According to (Sakyi, K. A., Musona, D., & Mweshi, G., 2020). Research Methods and Methodology Advances in Social Sciences Research Journal, 7(3), 296–302. Exploratory research is conducted where the scope of the research is not known, and the topic of research is a fertile area that was discovered as a literature gap. Exploratory research is also known as grounded theory, and it is applicable in most social sciences and the humanities where some phenomena are not deterministic.

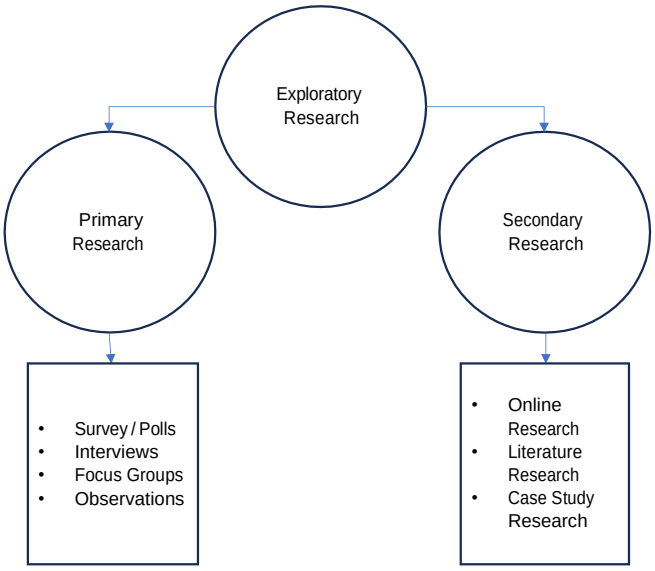
Exploration can begin with a literature search, a focus group discussion, or case studies. If a survey is conducted for exploratory purposes, no attempt is made to examine a random sample of a population; rather, researchers conducting exploratory research usually look for individuals who are knowledgeable about a topic or process. Exploratory research typically seeks to create hypotheses rather than test them. Data from exploratory studies tends to be qualitative. Examples include brainstorming sessions, interviews with experts, and posting a concise survey to a social networking website (Sage Publications Book on Research Models).

Exploratory research is defined as research used to investigate a problem that is not clearly defined. It is conducted to gain a better understanding of the existing research problem but will not provide conclusive results. For such research, a researcher starts with a general idea and

uses this research as a medium to identify issues, which can be the focus for future research (Adi Bhat, Question Pro, 2023). This exploratory research is further classified into two parts.

1. Primary Research
2. Secondary Research

Fig-10: Exploratory Research Design



Adapted from Question Pro (2023), and Sage Publications

1. Primary research – Survey, Polls, Interviews, Observations are part of the Primary Research.
2. Secondary Research – This consists of Online research to find relevant information and data, Literature research and case studies if any.

The objectives of the research are to explore the following:

- To examine the vaccine industry from the perspective of business processes and customer selection assumptions and compulsions
- To understand the common nature of the vaccine business in India.
- The classification of vaccine manufacturers will bring out the vulnerability of the vaccine industry and could provide guidelines for medium- and long-term corrections.

- Stand-alone vaccine manufacturers will be guided by diversification or other methods to sustain the industry.
- The business models of existing players will require a revisit and structure of their models towards more authentic research instead of in-licensing or other contemporary methods.
- It should create parameters for each company to move forward and develop the industry as an attractive incubating hub for investment for aspiring entrepreneurs.

4.3.1 RESEARCH PHILOSOPHY

In their 2017 British Journal of Management article, Cunliffe and Scaratti aim to reimagine the relevance of management scholarship by exploring a new form of participatory action research they call 'engaged research'. This form of research, they say, focused on being 'socially useful' by enabling a dialogue between conceptual and practical forms of knowledge and ensuring that an exchange of ideas between practitioners and academic researchers shapes the whole research process (they call this 'dialogical sensemaking'). Cunliffe and Scaratti explain that, methodologically, engaged research means continuously crossing many traditional research boundaries, involving much movement between researchers and participants, and many types of data: conversational, artefactual, textual, visual, etc., depending on how various research participants negotiate, reinterpret, and reconfigure their practical knowledge (Saunders et al., 2019).

- **INTERPRETIVISM**

Typically, inductive. Small samples, in-depth investigations, and qualitative methods of analysis, but a range of da ta can be interpreted. Interpretivism emphasizes that humans are different from physical phenomena because they create meanings.

- **PRAGMATISM**

Following research problems and research questions Range of methods: mixed, multiple, qualitative, quantitative, action research Emphasis on practical solutions and outcomes. Pragmatism asserts that concepts are only relevant where they support action (Kelemen and

Rumens 2008). Pragmatism originated in the late-nineteenth- and early-twentieth-century USA in the work of philosophers Charles Pierce, William James, and John Dewey. It strives to reconcile both objectivism and subjectivism, facts and values, accurate and rigorous knowledge, and different contextualized experiences.

- **CRITICAL REALISM**

It is important not to confuse the philosophy of critical realism with the more extreme form of realism underpinning the positivist philosophy. The latter, sometimes known as direct realism (or naïve empirical scientific realism), says that what you see is what you get: what we experience through our senses portrays the world accurately. By contrast, the philosophy of critical realism focuses on explaining what we see and experience in terms of the underlying structures of reality that shape the observable events. Critical realism originated in the late twentieth century in the work of Roy Bhaskar as a response to both positivist direct realism and postmodernist nominalism (discussed later) and occupies a middle ground between these two positions (Reed 2005).

4.3.2 RESEARCH APPROACH

The extent to which your research is concerned with theory testing or theory building raises an important question regarding the design of your research project. This is often portrayed as two contrasting approaches to the reasoning you adopt: deductive or inductive, although we alternatively term this abductive. Deductive reasoning occurs when the conclusion is derived logically from a set of theory-derived premises, with the conclusion being true when all the premises are true (Ketokivi and Mantere, 2010).

Table-3: Research Approach

Source: Saunders, Lewis, and Thornhill (2012)

Research using an inductive approach to reasoning is likely to be particularly concerned with the context in which such events take place. Therefore, the study of a small sample of subjects might be more appropriate than a substantial number, as with the deductive approach. Researchers in this tradition are more likely to work with qualitative data and to use a variety of methods to collect this data in order to establish different views of phenomena.

Therefore, critical realism and pragmatics are required for carrying out research on the vaccine industry in India with an inductive and abductive approach to draw qualitative inferences and design models fitting to this research topic.

4.3.3 RESEARCH STRATEGY

Numerous factors are considered while evaluating the vaccine industry process, especially business journals, publications through literature reviews, personal discussions with industry, experience dealing with industry, and surveys. The ways adopted in the exploratory research methods are:

- Literature Review (Publications, Books, Journals, Magazines, Articles, News)
- Surveys, personal discussion, and interviews
- Profit and loss statements, balance sheets, government sources, and relevant websites

With such a topic researched, it will yield different results for different countries, and even within the same country, results will differ for different regions and distinct categories of

students in different social groups, among others. Exploratory research may yield some insights for further wide-scale research. Sakyi, K. A., Musona, D., & Mweshi, G. (2020).

4.3.4 RESEARCH CHOICES

Exploratory or qualitative research is conducted to enhance understanding of individuals' cultures, beliefs, and values, human experiences, and situations, as well as to develop theories that describe these experiences (Creswell, & Plano Clark, 2011; Munhall, 2012; Wuest, 2012; Holloway & Galvin, 2016). This research approach emerged from the behavioural and social sciences as a method of understanding the unique, dynamic, and holistic nature of human beings (Hogan et al., 2009; Maxwell & Mittapalli, 2010; Creswell, 2014). Unlike a quantitative research approach that utilizes numerical data to access information about the world, qualitative research does not transform verbal symbols into numerical data; rather, the participants' and/or researcher's words are used to describe the phenomenon being studied (Hogan et al., 2009; Sarantakos, 2013; Holloway & Galvin, 2016). In understanding the vaccine industry and its customer choices, value chain, and business process, it is important to infer the overall outcomes of the questionnaire and research survey.

Qualitative research tries to get to the heart of what exactly happened to the participating individuals, what led them to the decisions that they made, and how the choices they made came to take the form that they eventually did (Curry et al., 2009; Yin, 2015). However, the trustworthiness of qualitative research is often questioned by some readers and quantitative researchers because the traditional concepts of validity and reliability are addressed differently between the two research approaches (Shenton, 2004; Ritchie, 2013). This article presents an exploratory analysis of the essential elements in qualitative research that, when properly and objectively utilized, can enable the readers of qualitative work to judge it as good research. The article is structured as follows:

- Firstly, a brief cursory commentary on what makes qualitative research good research is outlined.
- Secondly, an in-depth consideration of some of the key elements within the qualitative disciplines, including research topic and research appropriateness, research question,

theory, research design, methods of data collection and analysis, sampling, generalization, and ethical consideration These elements, if transparently utilized, can improve the chances of the readers of qualitative work recognizing a piece of qualitative research as good research.

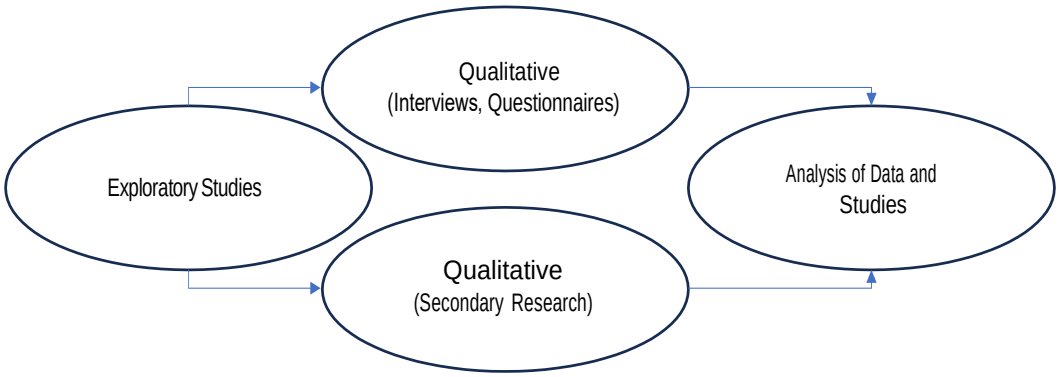
- Thirdly, a conclusion to the article is given.

The orderly establishment of clarity and responsibility is made evident by constantly being reflexive in the decisions made regarding all the elements used in the research. Therefore, transparency, accountability, and reflexivity should show through in the process of:

- Choosing the research topic
- Defining the research question
- Justifying the research
- Stating the adoption of the theory
- Outlining the research design,
- Choosing the sample and sampling strategy
- Methods of data collection
- Data analysis
- Applying consideration to research ethics.
- Demonstrating data trustworthiness
- Reflexivity

Studies were done to explore the vaccine industry, its financial strength, and its link with progression and business processes. Hence, a simple exploratory study comprising the above characteristics was done.

Fig-11: Research approach



Source: Researcher

4.3.5 TIME HORIZON

The research onion (moving from the outer layers to the core) was developed by Saunders, Lewis, and Thornhill (2016) for business studies. It is widely used in the social sciences to construct a theoretical framework for research. In numerous studies, the layers proposed in the research onion model have been modified and changed according to the field of study. The research onion consists of six main layers: research philosophy, approach to theory development, methodological choice, strategy, time horizons, and techniques and procedures including data collection and analysis (Melnikovas, 2018: 33; Sahay, 2016: 1). The researcher will undertake to complete the research before the academic timelines and the time horizon adopted by the studies. characteristics were done.

4.3.6 DATA COLLECTION

For the purpose of the study, qualitative data was collected from industry forums and discussions with relevant authorities, and quantitative data was collected from questionnaires and analysis of the key parameters of the balance sheets and profit and loss statements of some key organizations engaged in manufacturing vaccines. However, for the studies, the period of data was chosen from 2016–17 to 2020–21. It is important for the researcher to get homogenous data since data pertaining to 2021–22 is expected to be skewed due to COVID outbreaks, and worthwhile analysis may not be possible from manufacturing organizations.

4.3.6.1 SECONDARY DATA

It is important to understand the domain data from secondary sources, which helps analyse and infer the patterns of the vaccine industry and the influences on the vaccine industry.

- Data from the literature review is to be used for the purpose of analysis, and the business models suggested in the publications are viewed for the purpose of arriving at the business process.
- Balance sheets and profit and loss statements of select vaccine manufacturers manufacturing in India.
- Government and non-government data on the vaccine industry, right from licensing to economics.

4.3.6.2 QUESTIONNAIRE

According to (Sekaran, 2003, p.236), questionnaire is an efficient method for data collection and defines a questionnaire as "a pre-formulated written set of questions to which respondents record their answers, usually within rather closely defined alternatives". A questionnaire survey was undertaken within the limited set of vaccine manufacturers present in India. As defined in the research methodology, eight questionnaires were filled out by key personnel from seven different vaccine manufacturers in India.

4.3.6.3 FORMAT OF QUESTIONNAIRE

While designing the questionnaire, the researcher evaluated several types of situations and limitations for being a part of the vaccine industry and sought answers from the competition for its research studies. While a broad consensus was expected from the questionnaires, we hence reached the conclusion that a self-administered online questionnaire would be suitable for the study. The challenge in this situation is more about access to key personnel who are willing to share information than the information per se. Since this survey is expected from only key personnel from any vaccine manufacturing company in India, a telephonic discussion followed by the sharing of the questionnaire was to bring them to an ordinary understanding of the subject. The online method suited the veracity of the topic and brought authenticity. Since we are not expecting participation from all manufacturers due to various official protocols, this hybrid method of discussion along with questionnaire sharing was appropriately suited. Several

types of questionnaire formats were evaluated, and finally, a Google Forms questionnaire was used.

Due to the low administrative cost and the fact that a self-administered online questionnaire can reach participating vaccine manufacturers, it is pertinent that the respondents take time out and answer responsibly instead of using interview formats over the phone, which might not give enough time to think or ponder.

4.3.6.4 QUESTIONNAIRE DESIGN

A questionnaire is a tool that can be used in any type of research. It is good practice to 'pilot' or pretest your questionnaire with a small sample of respondents. Before using it to check people's understanding and ability to answer the questions, highlight the areas of confusion and look for any routing errors, as well as provide an estimate of the average time each questionnaire will take to complete.

There are about four distinct types of questionnaires designed for a survey. They are applied according to the purpose of the survey. 1. Contingency questions/Cascade format 2. Matrix questions 3. Closed-ended questions 4. Open-ended questions (S Roopa, MS Rani, 2012). The ideal requirements of a questionnaire should be:

- Be composed of a simple and specific language.
- Demand one answer on one dimension.
- Yield a truthful and accurate answer.
- Accommodate all contingencies of a response.
- Have mutually exclusive response options.
- Produce variability in response.
- Minimize social desirability.

As per (Ellen Taylor, Powell, Carol Hermann, 2000), there are five main survey methods: mail, telephone, face-to-face, handout, and electronic. Each method has its advantages and disadvantages. No single method is superior to another. Each needs to be assessed in terms of the survey content, respondent characteristics, timeline, and available resources. An important part is the survey content.

- What types of questions are asked? How complex or sensitive are they?
- Would people be more likely to understand and respond to questions presented in print or orally? Anonymously or in person?

One of the key considerations while designing the questionnaire is the sensitivity of the information, which is difficult for the vaccine industry to share. Either it is done through a personal, unrecorded interview or through an unrecorded telephone conversation. This was followed by the questionnaire to validate part of the survey.

A questionnaire has a component of closed-ended questions to get definitive answers. Although there are advantages and disadvantages to closed-ended questions, (Siniscalco, M. T., Auriat, N., & Ross, K. N., 2005). Questionnaire design: Module 8; Quantitative research methods in educational planning.

Table-4: Advantages and Disadvantages of Closed ended questions

Advantages	Disadvantages
• The respondent is restricted to a finite (and therefore more manageable) set of responses, • They are easy and quick to answer, • They have response categories that are easy to code, and • They permit the inclusion of more variables in a research study because the format enables the respondent to answer more questions at the same time required to answer fewer open-ended questions.	• They can introduce bias, either by forcing the respondent to choose between given alternatives or by offering alternatives that otherwise would not have come to mind, • They do not allow for creativity or for the respondent to develop ideas, • They do not permit the respondent to qualify the chosen response or express a more complex or subtle meaning, • They can introduce bias, where there is a tendency for the respondent to tick systematically either the first or

	last category, to select what may be considered as the most socially desirable response alternative, or to answer all items in a list in the same way, and • They require skill to write because response categories need to be appropriate, and mutually exclusive.

Source: (Siniscalco, M. T., Auriat, N., & Ross, K. N., 2005)

Since the research expectation is sensitive for the vaccine industry, most of the questions are designed closed ended. This is preceded by telephonic discussions.

The researcher used Google Forms as the mode to distribute Questionnaire. To complete the electronic survey of questionnaire, the participants have to introduce themselves with an identification form and carry on with their responses to the questions. This questionnaire was sent either through e-mail or through personalised post in their social media account. The introductory message was to build ease of questions and the topic that they have been dealing with since several years. After due telephonic conversation and initial discussion on the survey, this formal questionnaire was sent to get data or a statistical outcome of the topic. Since the questionnaires were to be filled by top executives of vaccine industry, they were followed up through phone calls and messages and some of them took internal approvals to respond to the questionnaire which took almost 45-60 days' time. Raw data was collected after sizeable response was observed as per the research methodology, from the existing number of vaccine manufacturers.

4.3.6.5 PILOT QUESTIONNAIRE

The online pilot questionnaire helps to refine questions so that the participants are coordinated with the topic and worthwhile responses can be generated. Hence, the researcher conducted a pilot questionnaire with one respondent at the director level from a vaccine manufacturing organization, who took his time out of his busy schedule to not only provide valuable feedback

in correcting some questions but also respond to my questionnaire after the corrections were carried out. A survey questionnaire is appended to Appendix 1.

4.3.6.6 GROUPING OF QUESTIONNAIRE

After conducting the final questionnaire, the researcher modified the spelling and language of a few questions and grouped the questions into four sections. Although the first section is introductory in nature, the following sections are arranged to give perspective on the topic.

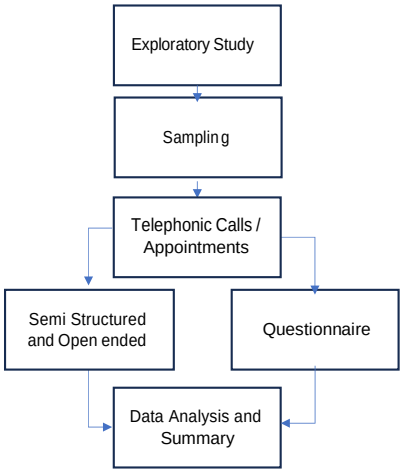
4.4 DATA ANALYSIS

The researcher followed the below methods for data analysis.

4.4.1 TELEPHONIC CONVERSATION

The telephonic conversation objective was to prepare the key executives of the vaccine manufacturing company to acquaint themselves with the importance of the survey questionnaire that is going to be followed, followed by the major expectations from the conversations that the research aims to get. Broadly structured questions are in Appendix 2.

Fig-12: Telephone Interviews as part of exploratory study



Source: Researcher

4.4.2 QUESTIONNAIRE DATA

Responses to the questionnaire were collected using the Google Forms platform and analysed using descriptive analysis. The outcomes were interpreted and validated along with other responses. Using visual graphs and a data matrix, the responses were captured for better

understanding. Descriptive analysis was applied to give participants an overall response. Questionnaire declaration sheet in Appendix 4.

4.5 SAMPLING METHOD

Sampling Unit Description

- Target population: This is a larger population; the results from a representative sample can be generalized to this level.
- Study population: This is the accessible part of the target population from which the sample was selected.
- Sampling frame: This is a list of all the members of the study population (which may not be available in all cases).
- Sample Members of the study population who are selected for the study should be representative of the study and target population. The vaccine manufacturer list and participant details are in Appendix 3.

According to (Omair A., 2014). Sample size estimation and sampling techniques for selecting a representative sample Journal of Health Specialties, 2(4), 142; due to the low size of the target population, we sampled members of the study population who were selected for the study.

4.5.1 SAMPLE SELECTION

In this study, the researcher chooses to select samples from distinct categories of vaccine manufacturing units, such as Indian companies engaged in vaccine manufacturing in India and multinational companies engaged in vaccine manufacturing in India, besides representative samples from animal vaccine units and human vaccine units. State-run units, especially those not registered under the Companies Act of India, were exempted from the study since these organizations largely neither have any profit motive nor structured financials.

4.5.2 SAMPLING TECHNIQUE FOR QUALITATIVE DATA

One of the key features distinguishing what is commonly referred to as qualitative from quantitative inquiry is the kind of sampling used (Sandelowski, M., 2000). While qualitative research typically involves purposeful sampling to enhance understanding of the information-

rich case (Patton, 1990), quantitative research ideally involves probability sampling to permit statistical inferences to be made (purposive sampling methods).

Stratified purposeful sampling is another kind of combination of sampling techniques where the researcher wants to ensure that certain cases varying on preselected parameters are included. This strategy can potentially be used in any of the design templates shown in Figure 1. Although this kind of sampling is—from a probability sampling standpoint—statistically nonrepresentative (Trost, 1986), it is, from a purposeful sampling standpoint, informationally representative. Each case represents a prespecified combination of variables, the distinctive confluence of which is the focus of the study. The researcher wants to explain how these variables come together to make a case the case that it is.

4.5.3 SAMPLING TECHNIQUE FOR QUANTITATIVE DATA

According to Singh, A. S., & Masuku, M. B. (n.d.). International Journal of Economics, Commerce, and Management SAMPLING TECHNIQUES AND DETERMINATION OF SAMPLE SIZE IN APPLIED STATISTICS RESEARCH: AN OVERVIEW http://ijecm.co.uk;

Sample size is important, principally due to its effect on statistical power. Statistical power is the chance that a statistical test will indicate a significant difference when there truly is one. Statistical power is analogous to the sensitivity of a diagnostic test (Browner and Newman 1978), and one could mentally substitute the word ‘sensitivity' for the word ‘power’ during statistical conclusions.

In our study, most of the quantitative data, which are balance sheets and profit and loss statements, are representative of the total target vaccine manufacturers. (Ministry of Corporate Affairs, Government of India).

4.6 RESEARCH LIMIT AND BIASES

The researcher took care of minimizing the limitations and maximizing the authenticity of the information through the validity of the findings. According to (Saunders, Lewis and Thronhill, 2007), reliability refers to the extent to which data collection techniques or analysis procedures will yield consistent findings each time. Validity is concerned with whether the findings are really about what they appear to be about.

4.6.1 LIMITATIONS OF TELEPHONIC DISCUSSIONS

This apparent bias against telephone interviews contrasts with a growing interest in electronic qualitative interviews. Research is needed to compare these modalities and examine their impact on data quality and their use for studying varying topics and populations. Such studies could contribute evidence-based guidelines for optimizing interview data. Novick, G. (2008). Telephone interviewing reduces these costs (ADAMS, KHAN, RAESIDE &WHITE, 2007; CARR & WORTH, 2001; CHAPPLE, 1999; DINHAM, 1993; GARBETT & McCormack, 2001; IRVINE, DREW & SAINSBURY, 2012; LECHUGA, 2012; NOVICK, 2008; PRIDEMORE, DAMPHOUSSE & MOORE, 2005; STURGES & HANRAHAN, 2004; VOGL, 2013). First, the time needed to travel is eliminated (ELMIR, SCHMIED, JACKSON, & WILKES, 2011). This led TRIER-BIENIEK (2012) to describe telephone interviews as "a more time-efficient and researcher-friendly tool for conducting interviews" (p. 630). Oltmann, S. M. (n.d.). Qualitative Interviews: A Methodological Discussion of the Interviewer and Respondent Contexts

4.6.2 LIMITATIONS OF QUESTIONNAIRE

One of the main limitations of the questionnaire is that the response levels are limited, and in this study, the researcher is relying on top executives of the company to respond as a sample framework, hence the need for several follow-ups. Some respondents choose not to answer due to information security and strict standard operating procedures (SOPs) for information flow. Although the study captures various aspects of the vaccine industry in different contexts that manufacturers are in that are representative of the vaccine industry, the all-round coverage within the limited vaccine manufacturers would be desirable. Questionnaire grouping details are in Appendix 5.

4.7 ETHICAL CONSIDERATIONS

- The researcher himself is a part of the vaccine industry, and to overcome the competitive state of mind and give genuine responses to the telephonic discussions, followed by a questionnaire, the ethical considerations are strictly observed to develop confidence, and the objectives of the study are briefed. Hence, both primary and

secondary data are kept with the utmost care and with the promise of confidentiality. The following ethical considerations are observed during the study:

- Each person was briefed about the study and its objective by the researcher, and they are treated with the utmost respect and confidentiality.
- The briefing was done equally by the researcher and as per the standard set of information to draw a conversation, which was later built based on the level of information they were willing to share.
- The researcher only asked for information related to research and that it covered the major objectives of the research instead of dwelling on other confidential parts of the vaccine manufacturing process.
- All the data was collected and stored in one place—electronically.

Other major ethical considerations observed are:

- Names and designations (although asked by the researcher in the questionnaire) were kept confidential in the final research document.
- Although there were follow-ups to get the questionnaire filled out, the matter was left to the participant by the researcher.

This telephonic process is hugely confidential, and the researcher has used the structure of the discussion for the research outcome as a summary without naming the individuals.

4.8 OUTCOMES

The researcher hopes that the key findings of the research will be able to give direction to the vaccine industry on

- The risks and stakes involved before any new investments are made.
- Business processes are perceived before establishing a vaccine manufacturing unit and after operating.
- Customer choice compulsions are inherent characteristics of the vaccine industry.

This researcher attempts to bifurcate the business process in the vaccine and pharmaceutical industries. Risks and gains in the vaccine industry and the stakes involved This will provide the

Indian vaccine industry with a structured document for reference and help towards an informed decision-making process in the business. The overall results are summarized in Appendix 4.

4.9 SUMMARY

The research methodology aptly justified the aims and objectives within the limitations and is expected to drive outcomes to correlate the findings. Hence, in this exploratory study, qualitative data was examined along with hard secondary data from various vaccine manufacturers and tried to articulate the findings in a new manner that the researcher finds deemed fit.

CHAPTER 5 – RESULTS

5.1 INTRODUCTION

This chapter shares the findings of the research and presents trends and analysis based on the responses to the telephonic and informal interviews, questionnaires, and secondary research. The researcher collected the data between February 2023 and April 2023. Since the data and information are coming from top-level executives of the companies, it took a longer time span to spread the information, 3–4 months. Although the number of questionnaire respondents is 8 out of 7 manufacturing companies, the respondents for personal discussion through interviews, telephonic conversations, or interviews have been 4 respondents from top management (CEO, Dy Managing Director, or Vice President level) in the vaccine industry.

The response rate was 8 out of 23 companies chosen for responses, which is higher than 25% for the questionnaire and meets the desirable number. The response rate for both the questionnaire and the personal discussion is good, considering the fact that it spreads throughout the classes of the vaccine industry (human and animal health vaccines), domestic and multinational, private and public sectors within India, and represents all kinds of sectors, as mentioned in Appendix 7.

Besides, researchers also compiled the balance sheets and profit and loss statements of more than 40% of companies to assess the health of the industry for the sake of classification. There are already laid-down classifications for the pharmaceutical industry, which are also referred to in the literature review and introduction, and the researcher tried to define the vaccine manufacturers from different perspectives.

This chapter has two main sections, which will address "qualitative data, “quantitative data," and financials. This data will be analysed against the research questions to provide a meaningful reference. Both sections will introduce you to the respondent's profile and how that is representative of the total population. For each question in both the qualitative and quantitative sections, views, concepts, and perceptions of the respondents will be captured and analysed against the research questions.

5.2 QUANTITATIVE DATA ANALYSIS

This section involves the data generated from the questionnaire and the financial data collected for each manufacturer. There are 8 responses from the top leaders of the industry for a responsive 23 manufacturers (out of the total 32 units present). Financial data for 15 companies has been collected, which would fairly represent the entire number of manufacturing companies in India.

5.2.1 CUSTOMER SELECTION

The participants for the questionnaire and their profiles are mentioned in Appendix 7. Responses to the general understanding of the vaccine business and customer choices in the Indian industry were sought with a simple question. This gives a ringside view of the thought process involved in investing in the vaccine business and the customer choices. An open question was asked to all respondents: "What, according to you, is the correct description in the Indian context for high salience or dependence on a specific customer segment for the vaccine business?" A detailed response is in Appendix 4.

5.2.2 CLASSIFICATION OF CUSTOMERS

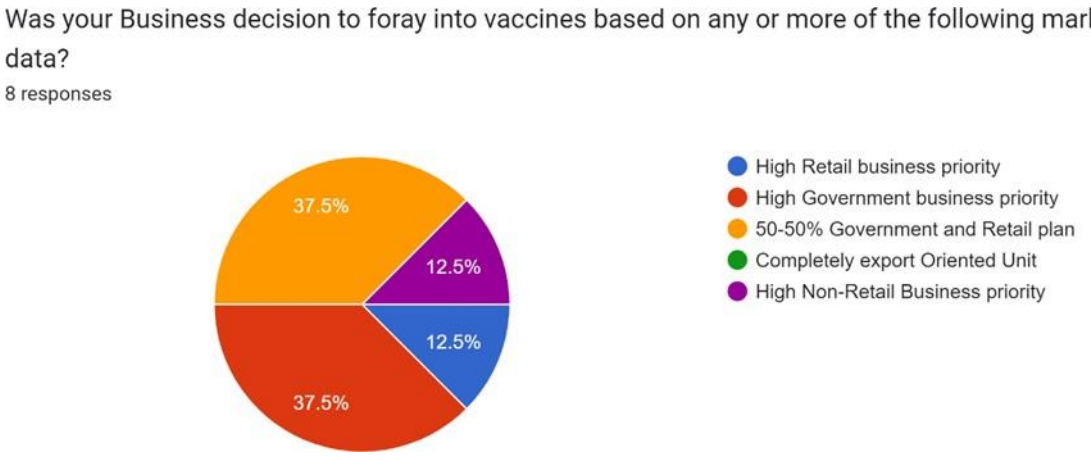
In the pharmaceutical industry, the domestic marketing strategy has always been to promote the products to doctors, generate prescriptions, and cater to their needs through retailers and distributors. However, in the vaccine industry, customer selection was analysed.

5.2.2.1 : CUSTOMER CHOICE PRIORITY

- Question: Was your business decision to foray into vaccines based on any or more of the following market data?

More than 50% agree that the priority was for government and non-retail business and another 37.5% have both retail and government supplies plan. Hence, more than 2/3rd of the responses agree that the government business is the dominant customer in India.

Fig-13: Summary of Questionnaire on Business decision to foray into vaccines.

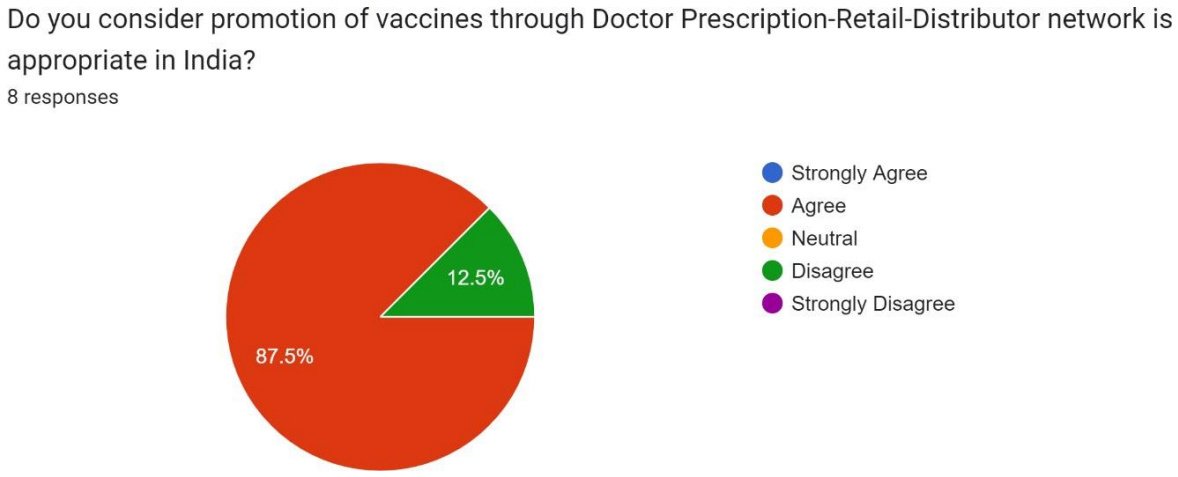


However, in the contrary, most companies agree that the retail and doctors' prescription is the right way to promote the product.

5.2.2.2 : RETAIL SEGMENT APPROPRIATENESS

- Question: Do you consider promotion of vaccines through Doctor Prescription-Retail-Distributor network is appropriate in India?

Fig-14: Retail Choice as perception

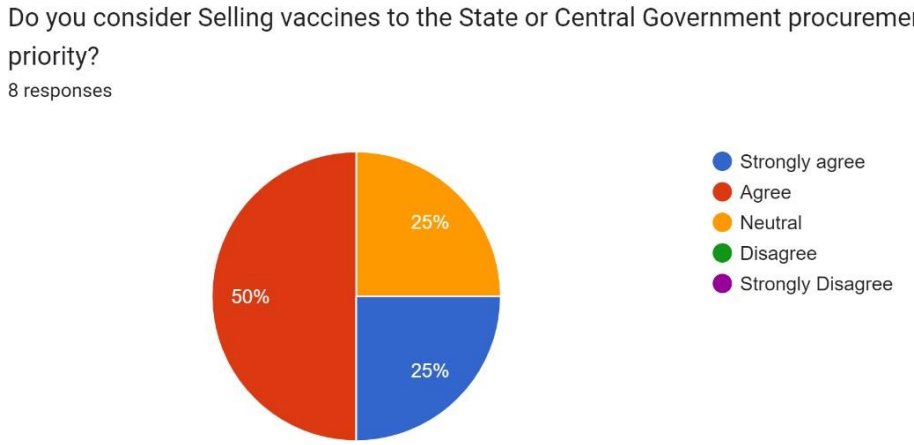


87.5% respondents agree that the retail business would be appropriate in India for sustainable business. This is the typical pharmaceutical product promotions method, which is the guiding principle for such understanding.

5.2.2.3 : MAJOR PROCUREMENT

- Question: Do you consider Selling vaccines to the State or Central Government procurement agencies as priority?

Fig-15: Distribution of Sales in Vaccine industry

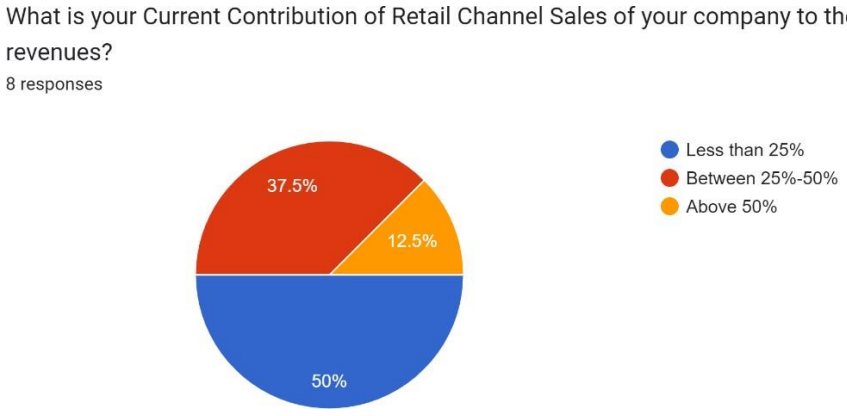


75% of the respondents agree or strongly agree that state or central government procurement agencies are the priority customers, while the rest do not even disagree. This gives a clear-cut idea about the customer choices across the vaccine manufacturing industry in India.

5.2.2.4 : CURRENT RETAIL CONTRIBUTION TO REVENUES

- Question: What is your Current Contribution of Retail Channel Sales of your company to the overall vaccine revenues?

Fig-16: Sales Revenues from Retail

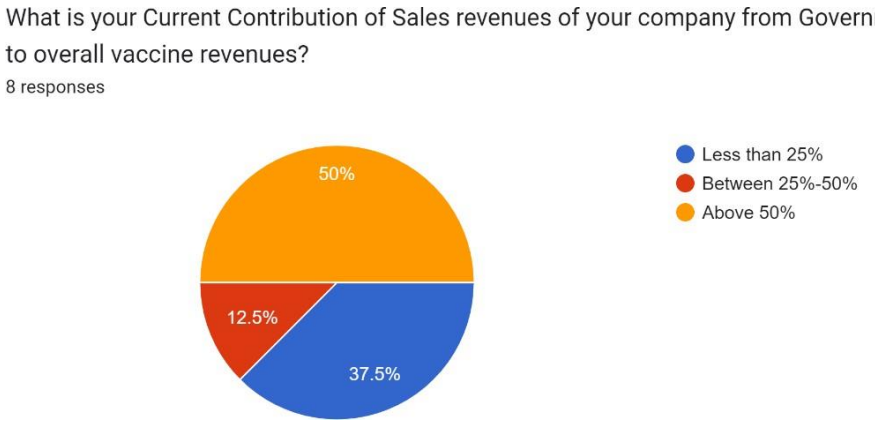


Contrary to widespread belief, it is again evident that the retail business is less than 25% for more than 50% of the companies as a contribution to their revenues, while it is between 25 and 50% for another 37.5% of the companies. Only 12.5% (or only one respondent) say that the retail contribution is higher than 50% of its annual revenues.

5.2.2.5 : CURRENT GOVERNMENT BUSINESS CONTRIBUTION

- Question: What is your Current Contribution of Sales revenues of your company from Government Customers to overall vaccine revenues?

Fig-17: Sales Revenues from Govt

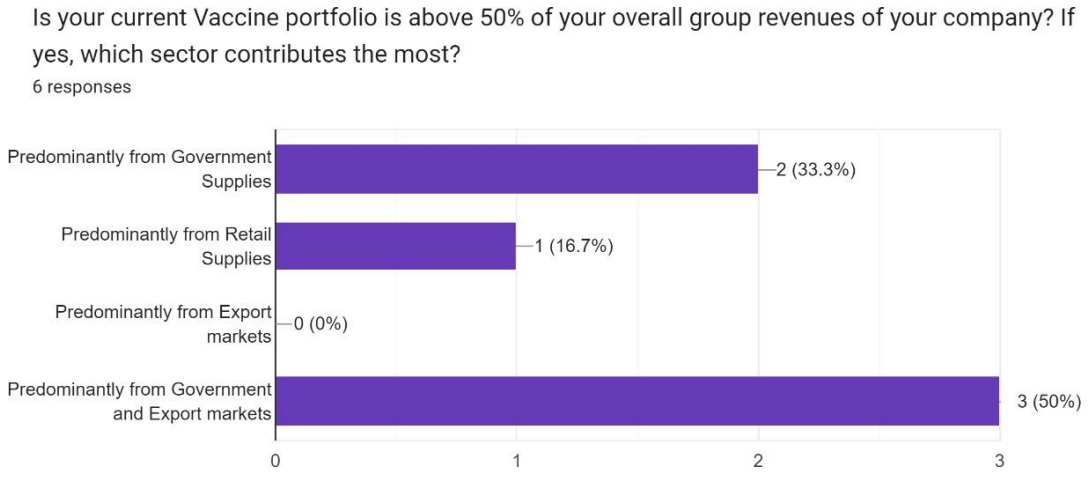


More than 50% of the companies have more than 50% of their sales revenues coming from government business.

5.2.2.6 : CURRENT VACCINE PORTFOLIO

- Question: Is your current Vaccine portfolio is above 50% of your overall group revenues of your company? If yes, which sector contributes the most?

Fig-18: Segment Contribution

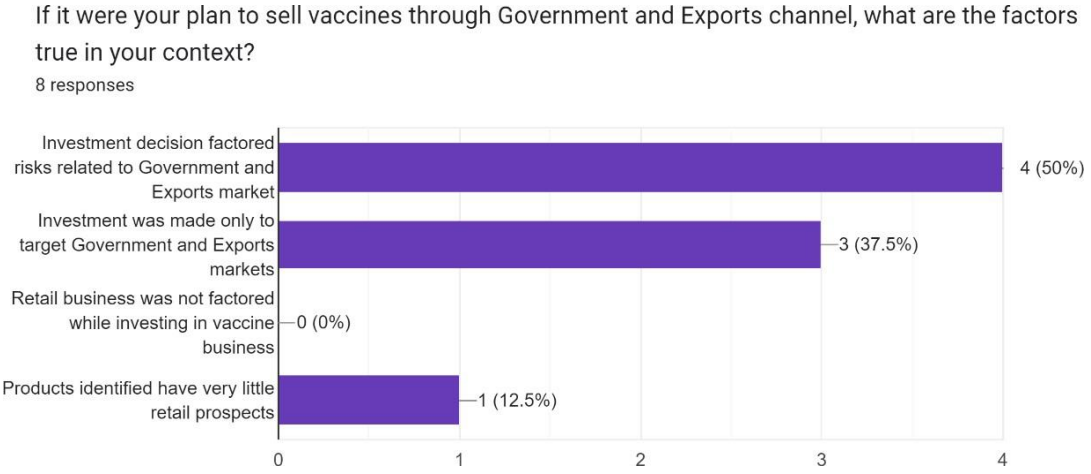


It is now evident that the conventional doctor's prescription and retail business in vaccines is limited to 16.7%, or one respondent. While 3 respondents agree that the portfolio is catering mostly to government and export customers, 2 respondents say that it is generating revenues from government business.

5.2.2.7 : INVESTMENT DECISIONS

- Question: If it were your plan to sell vaccines through Government and Exports channel, what are the factors true in your context?

Fig-19: Vaccine business in Government and exports



It is further clear that the entire investment decision was de-risked, anticipating supplies to Government and exports markets.

5.2.3 CUSTOMER SELECTION AND BUSINESS PROCESS

Direct or telephonic conversation with Industry leaders conducted on four vaccine manufacturers on the topics given in the table below and the responses of the key points listed in the Appendix-6.

Table-5: Broad Topics discussed in the questionnaire.

Topic	Sub-Topic
Business Models	• Business Process. • Difference of Business Process in Pharma and Vaccines • Vaccine Business Models and Contemporary experiences • Technological interventions
Customer Selection	• Customer selection in vaccines and pharma • Compulsions to choose customers
Classification	• How the vaccines / vaccine customers classified. • How vaccine companies classified. • Rating system for vaccines.
Marketing Challenges	• Ideal marketing approach for vaccines in India • Vaccine business – marketing challenges
Others	• Parameters to judge the health of vaccine business. • Questionnaire

The responders from the vaccine manufacturing industry given as under.

Table-6: Participant composition in Telephone Questionnaire

RESPONDER / Company	DESIGNATION	CATEGORY
1	Deputy Managing Director	Human and Animal Vaccines
2	Senior Vice President	Human Vaccines
3	Lead Regulatory Affairs	Human Vaccines

4	Vice President Marketing	Animal Vaccines

5.2.4 BUSINESS DECISIONS

The questionnaire also captured the decision on business investments in the vaccine industry, and prior to investments, the vaccine manufacturing companies with pharmaceutical-style operations had preconceived notions about the way vaccine businesses operated. Some of them have de-risked the business by factoring in the vulnerability of government businesses. However, the vaccine manufacturers in India have to depend on the government and export markets. Details of the response are in Appendix 8.

5.2.5 FINANCIAL STATEMENTS

Key figures from financial statements are summarized and furnished in Appendices 9, 10, 11, 12, and 13. These statements are-

- Comparative Profit and Loss Statements of 15 Vaccine Manufacturers from 2016–17 to 2020–21 (Appendix 9) from a set of 23 companies
- Vaccine manufacturer-wise key ratios (Profit Before Tax, Cost of Manufacturing, Employee Benefits, and Research) from 2016–17 to 2020–21 for 15 companies (Appendix 10).
- Pharmaceutical companies' key ratios (Profit Before Tax, Cost of Manufacturing, Employee Benefits, and Research) from 2016–17 to 2020–21 for 10 companies (Appendix 11) Year-wise ratios of pharmaceutical companies
- Vaccine manufacturers' summarized profit and loss statement from 2016–17 to 2020–21 in rupees (Appendix 12).

Vaccine manufacturers' summarized balance sheet key ratios from 2016–17 to 2020–21 in rupees (Appendix 13).

All financial statements are sourced from Ministry of Corporate Affairs, Government of India.

Table-7: Top Vaccine companies and their Profits Before Taxes and Cost of Materials

2020-21	Total Revenues (In Rs Crores)	Profit Before Taxes (PBT) In Rs Crores	%age PBT	Cost Of Materials (COM) In Rs Crores	% COM
SII	8335	3891	47%	919	11%
DANO	28.63	7.49	26%	6.01	21%
CHIRON	121.12	32.31	27%	31.7	26%
CADILA	2370.9	345	15%	675.7	28%
SANVITA	0.04	-6.18	-15450%	0.37	925%
INDOVAX	81.01	17.13	21%	20.35	25%
IIL	747.7	68.5	9%	193.99	26%
GREEN SIGNAL	28.51	6.38	22%	8.86	31%
GLOBION	96.55	10.59	11%	19.65	20%
BRILLIANT	75.83	0.68	1%	29.87	39%
BIOVET	129.54	73.89	57%	14.57	11%
BE	1418.07	245.05	17%	238.66	17%
BIOMED	48.1	27.6	57%	8.06	17%
BHARAT BIO	1439	536.5	37%	339.4	24%

Source: Ministry of Corporate Affairs, Government of India (https://www.mca.gov.in/content/mca/global/en/home.html)

- The linear regression analysis done to correlate between Cost of Materials and Profit Before Tax as mentioned in Appendix-15. The p value is <0.0001, hence highly significant.
- The correlation between Profit Before Tax and Current Assets is 0.99.
- This proves that the pattern between pharmaceutical companies and vaccines remain the same.

CHAPTER 6: DISCUSSION AND ANALYSIS

6.1 INTRODUCTION

India is a global manufacturing hub, supplying more than 60% of the world's vaccine requirement in volumes (Khan Sharun, 2021). It is clearly evident that the vaccine industry is not only meeting the domestic demand for such a highly populated country as India but also the global demand. This is driven by economies of scale and hence requires large vaccine manufacturing facilities, not only to drive down the cost but also to meet global demand. However, the Indian vaccine industry became a subset of either the pharmaceutical industry or the biotechnology industry. The business processes of the vaccine industry in India and all the classifications followed in India are becoming part of the larger industry and do not capture the challenges and processes that the vaccine industry faces. Although the vaccine industry may be smaller compared to the larger pharma industry (1.58 percent of the pharmaceutical industry), its processes and classifications need separate attention.

From the analysis of the literature review and the findings of the exploratory research (both primary and secondary research) conducted by the researcher on the vaccine business process, the important customers or customer choices before the vaccine manufacturer and the existing classification systems are significant departures from the pharmaceutical industry. According to (Jain N, 2021), questionnaires and direct interviews are examined, and direct interviews give better insights into research topics for exploratory research. A mixed method applied in this case will be helpful.

6.2 EVALUATING RESEARCH OBJECTIVES

This research is carried out with exploratory mechanisms and qualitative methods such as interviews and interactions with senior leaders in the vaccine industry, while simultaneously quantitative methods such as questionnaires were used to make assessments and validation. Research results coming out of qualitative data, quantitative data, and secondary research are mentioned in Chapter 5 of the thesis.

- Capturing the responses to the questionnaire and its analytics
- Capturing the interview and interaction data that is reflective of the vaccine industry.

- Financial data of the majority of the vaccine companies and its trends
- Financial data of the top pharmaceutical companies' companies and its trends

Vaccine companies' information as per literature review

6.3 RESEARCH OBJECTIVE: 1- TO UNDERSTAND THE CUSTOMER SELECTION MADE WHICH DRIVES THE BUSINESS PROCESS.

We defined the business process and the applicability of the process in the pharmaceutical' industry from a literature review.

A literature review categorizes the pharmaceutical industry into two main parts: the local domestic market and the export market. In the domestic market, products are manufactured and marketed through a doctors-distributors-retailers network to cater to patients. In India, for the domestic market of about Rs. 1,69,170 (USD 18.84 Bn), the government procurement of pharmaceutical products, including vaccines, is less than Rs. 22000 (or less than USD 3 Bn), which also includes the vaccine sector. The retail business is about Rs 2710 crore (USD 330 million). Government procurement (state and central) together makes up about two-thirds of the entire vaccine industry. Retail audit (IQVIA, 2018). Human vaccines are classified into childhood and paediatric vaccines; adult vaccines; and travellers' vaccines.

6.3.1 TRAVELLERS' VACCINE

- Travelers' vaccine is meant for people who are traveling to different countries with a prevalence of diseases that are not prevalent in India. For example, "Yellow Fever" disease is prevalent in Africa, and any person applying for a visa for African nations has to compulsorily get a vaccination with the yellow fever vaccine. The vaccine certificate must be displayed along with the visa application to qualify for the visa. Similarly, people from the EU also get vaccinated before traveling to Africa and other Asian countries for related diseases. This also means that in routine vaccinations, traveller's normally either do not get vaccinated against the disease or that disease is not prevalent in the country of origin.

- The National Health Service (NHS) in the UK recommends vaccination against several diseases, such as hepatitis-A, yellow fever, and many others, for traveller's, depending on the continent they intend to travel to.
- The number of international traveller's is not significant compared to the population of the country of origin, especially if it is India. Hence, traveller's vaccine does not form a significant market and is handled by the government for better biosecurity.

Since the country of origin does not have the disease, it is neither promoted nor hardly manufactured in the country of origin since the virus or bacteria is to be managed in the country of origin without having any disease. Hence, traveller's vaccines are imported by the state and administered to prospective traveller's seeking visas. The global travel vaccine market is estimated to be worth USD 3.7 billion, and considering the proportionate Indian size, it is estimated to be less than USD 10 billion, which is insignificant.

6.3.2 ADULT VACCINE

Whatever vaccine is neither "compulsory childhood immunization" nor meant for "traveller's" falls under the adult vaccine category.

- Vaccination is recommended throughout life to prevent vaccine-preventable diseases and their sequelae. The primary focus of vaccination programs has historically been on childhood immunizations. For adults, chronic diseases have been the primary focus of preventive and medical health care, though there has been increased emphasis on preventing infectious diseases. Adult vaccination coverage, however, remains low for most of the routinely recommended vaccines. Though adults are less susceptible to falling prey to traditional infectious agents, the probability of exposure to infectious agents has increased manifold owing to globalization and increasing travel opportunities both within and across countries. Thus, there is an urgent need to address the problem of adult immunization. The adult immunization enterprise is more complex, encompassing a wide variety of vaccines and a remarkably diverse target population. There is not as much coordinated public health infrastructure to support an adult immunization program as there is for children. Moreover, there is little

coordination among adult healthcare providers in terms of vaccine provision. Substantial improvement in adult vaccination is needed to reduce the health consequences of vaccine-preventable diseases among adults. Routine assessment of adult patient vaccination needs, recommendation, and offer of needed vaccines for adults should be incorporated into routine clinical care of adults (Mehta, B., Chawla, S., Kumar, V., Jindal, H., & Bhatt, B., 2014).

- Despite vast improvements in childhood vaccination coverage in India, adult vaccination coverage is negligible. Our aim was, therefore, to create awareness about the importance of adult immunization. Although the true burden of vaccine-preventable diseases (VPDs) among Indian adults is unknown, adults are particularly vulnerable during outbreaks due to a lack of immunization, waning immunity, age-related factors (e.g., chronic conditions), and epidemiological shifts. There are no national adult immunization guidelines in India, and although several medical societies have published adult immunization guidelines, these vary, making it unclear who should receive which vaccines (based on age, underlying conditions, etc.). Other barriers to immunization include vaccine hesitancy, missed opportunities, and cost. Steps to improve adult vaccination could include the adoption of national guidelines, education of healthcare providers and the public, and promotion of lifelong immunization. Improving adult vaccine coverage could help reduce the burden of VPDs, particularly among older adults (Dash, R., et al. 2020).
- As recommended by the Centres for Disease Control and Prevention (CDC), USA, the following adult vaccines are recommended for adulthood:
- All adults ages 19 to 26 should make sure they’re up to date on these vaccines: Chickenpox vaccine (varicella); COVID-19 vaccine; Flu vaccine (influenza); Hepatitis B vaccine; HPV vaccine (human papillomavirus); MMR vaccine (measles, mumps, and rubella); Tdap vaccine (Tetanus, diphtheria, and whooping cough); or Td (tetanus,

diphtheria). However, hepatitis B, MMR, TdaP, and Td are procured by the government under the Universal Immunization Programme (UIP).

- All adults ages 27 to 49 should make sure they are up to date on these vaccines: COVID-19 vaccine, Flu vaccine (influenza), Hepatitis B vaccine, MMR vaccine (measles, mumps, and rubella), Tdap vaccine (tetanus, diphtheria, and whooping cough), or Td (tetanus, diphtheria).
- All adults ages 50 to 64 should make sure they are up to date on these vaccines: COVID-19 vaccine, Flu vaccine (influenza), Shingles vaccine (zoster), Tdap (tetanus, diphtheria, and whooping cough), or Td (tetanus and diphtheria).
- As we get older, our immune systems tend to weaken over time, putting us at higher risk for certain diseases. All adults ages 65 and older should make sure they are up to date on these vaccines: COVID-19 vaccine, Flu vaccine (influenza), Pneumococcal vaccine, Shingles vaccine (zoster), Tdap (tetanus, diphtheria, and whooping cough), or Td (tetanus and diphtheria).
- The anti-Rabies vaccine is used for patients with animal bites, which falls under the category of post-bite vaccination or post-exposure vaccine.
- Except for the Varicella vaccine, Shingles vaccine, HPV, and Tdap rest, all vaccines are procured either by the UIP of the Central Government of India or by the state government or provinces.

On one hand, the adult vaccine market in India is in its infancy, and most vaccines except the four vaccines are procured and dispensed by governments. However, many of these adult vaccines are also marketed by vaccine manufacturers in the open retail market, with an extremely low market size as compared to the population in India.

6.3.3 CHILDHOOD IMMUNIZATION

Vaccines are among the greatest advances in global health and development. For over two centuries, vaccines have safely reduced the scourge of diseases like polio, measles, and smallpox, helping children grow up healthy and happy. Thanks to immunization efforts

worldwide, children are able to walk, play, dance, and learn. Vaccinated children do better at school, with economic benefits that ripple across their communities. Today, vaccines are estimated to be one of the most cost-effective means of advancing global welfare. They act as a protective shield, keeping families and communities safe. Despite these longstanding benefits, low immunization levels persist. (www.unicef.org).

- Childhood vaccines or immunizations can seem overwhelming when you are a new parent. Vaccine schedules recommended by agencies and organizations, such as the CDC, the American Academy of Paediatrics, and the American Academy of Family Physicians, cover about 14 different diseases. Vaccinations not only protect your child from deadly diseases, such as polio, tetanus, and diphtheria, but they also keep other children safe by eliminating or decreasing dangerous diseases that used to spread from child to child. A vaccine is a dead, weakened version, or part of the germ that causes the disease in question. When children are exposed to a disease in vaccine form, their immune system, which is the body's germ-fighting machine, is able to build up antibodies that protect them from contracting the disease if and when they are exposed to the actual disease. (Stanford Medicine, stanfordchildren.org)
- Under the Universal Immunization Programme (UIP), the Ministry of Health and Family Welfare, Government of India, is procuring several vaccines listed below:

National Coverage:

1. Diphtheria,
2. Pertussis,
3. Tetanus,
4. Polio,
5. Measles,
6. Rubella,
7. Severe form of childhood tuberculosis,
8. Rotavirus diarrhoea,
9. Hepatitis B,

10. Meningitis and pneumonia caused by Hemophilus influenza type B and
11. Pneumococcal Pneumonia

Sub-nationally against 1 disease:

12. Japanese Encephalitis (JE vaccine provided only in endemic districts)

Other adult vaccines procured by provincial states include:

13. Anti-Rabies vaccine
14. HPV Vaccine

Although the above list of vaccines is marketed in the open market and vaccine manufacturers engage in promotional efforts to generate higher value from the prescription market, the overwhelming presence of government and free vaccinations leaves less room for the open market. The concept of selecting customers is a “choice of compulsion” and not a “choice of availability." Childhood immunization is done mandatorily by the state, covering more than 89% of the Universal Immunization Program. India, 2023, while the private sector covers only 8.4% of the children.

6.3.4 ANIMAL VACCINES

States and UTs will be responsible for procurement and receipt of vaccines, procurement of accessories (syringes, needles, gloves, masks, etc. for use in vaccination), payment of remuneration to vaccinators, uploading data on INAPH, surveillance and monitoring as prescribed, strengthening of laboratories, awareness campaigns and training, etc. (Operational Guidelines Department of Animal Husbandry and Dairying Ministry of Fisheries, Animal Husbandry and Dairying Government of India, 2022). The government is solely responsible for the vaccination and disease control of livestock. This is important for the food security of the nation.

As per Invest India (National Investment Promotion and Facilitation Agency, India), The Indian Animal Vaccine Industry Is on an Upward Trajectory (Angad Singh Punia, July’ 2021), nearly till 2024, the National Animal Disease Control Programme intends to cover 30.33 crore animals, out of which more than 17 crore animals have been covered so far, and approximately

18 crore animals have been tagged. This clearly means the government is vaccinating every animal in the country.

According to the Annual Report 2023) published by the Department of Animal Husbandry and Dairying, disease control in canine or companion animals (canines, horses, mules, donkeys, and cats) is not in the scheme of things and left for the private market to cater. It is estimated that there are about 30 million dog population in the country, and the pet population is less than 20% of that, which makes 80% of stray dogs roam around the country. Although the companion animal population is growing in India, it is not significant enough to reach even closer to the livestock market. Hence, the entire market size for vaccines and disease prevention is skewed towards the livestock sector, which is in turn completely governed by the state.

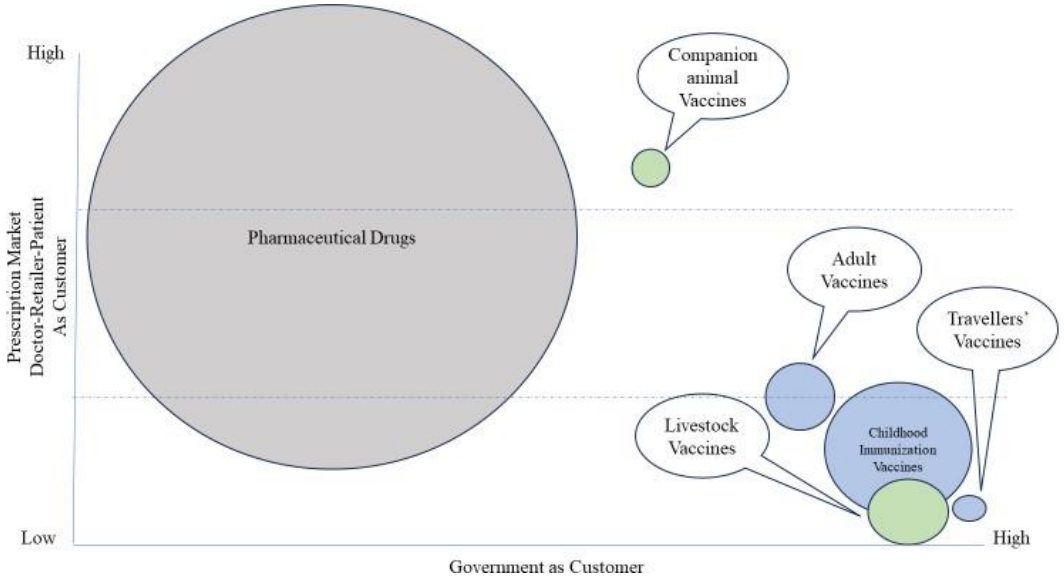
6.3.5 QUESTIONNAIRE AND INTERVIEW

Except for one respondent, all six other respondents in the questionnaire and all four respondents in the interview admitted that the vaccine business leads to the government and the major sole source of business is the government. Only multinational companies attempt to build brands through the doctor-prescription-retailer-patient route. It is evident that government procurement is a dominant factor in the vaccine business, and the researcher illustrated the vaccine business on a scale of government procurement and marketing promotion activity intensity for doctor's prescription, retailer dispensation, and patient consumption.

Studies indicate that the companies are heavily dependent on government business for vaccines in addition to export markets. In domestic consumption, a pattern has emerged: pharmaceutical products are driven by the doctor's prescription and hospital market, while vaccines are driven by government procurement.

Personal discussion or telephonic discussion revealed many aspects of operations, regulatory issues, process issues, and business issues, which are captured along with other outcomes.

Fig-20: Government Procurement for vaccines and pharmaceuticals



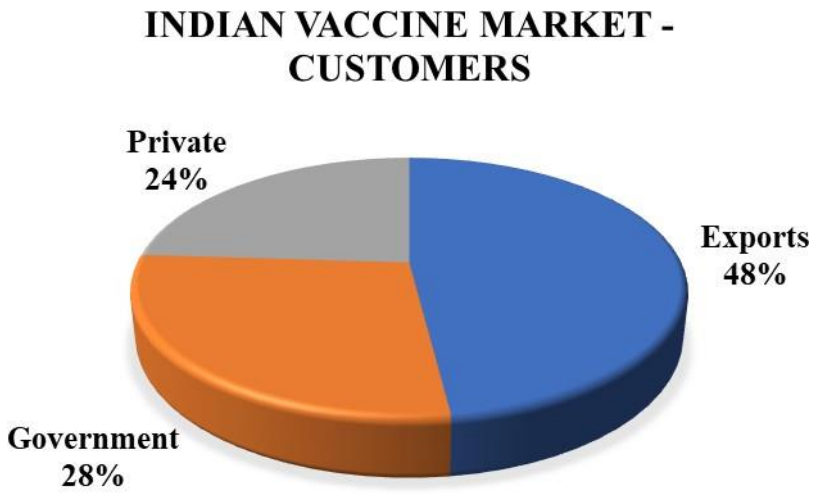
Source: Researcher

As demonstrated through research, procurement patterns, and program implementation, the customer choice is the government or state in India, and vaccine companies can otherwise opt for export markets, while the domestic prescription market is only for adult vaccines to a limited extent. Overall, the vaccine business skewed towards the government as a customer.

As per World Integrated Trade Solutions (WITS, World Bank) data, India exported vaccines worth USD 772.48 million. It is also evident that 79% of all the vaccine requirements were procured by the government within the region (Global Vaccine Market Report, 2022), published by the World Health Organization.

It was estimated that by the end of 2019, the UPI will procure 50 percent of the country's production in physical terms, representing only about 28 percent in value terms. The domestic sale of vaccines in the private market represents about 24 percent of turnover but about 21 percent of physical production quantities, while the exports account for about 48 percent of the total turnover of the vaccines industry. (Ghosh, P. K., 2019). Although many reports do not directly suggest the choice of customers for the vaccine industry in India, while corroborating the facts and several publications suggesting the state being the important consumer in both volume and value, along with export potential.

Fig-21: Government as customer for vaccines



Source: Researcher

This gives a ring-side view that is representative of the Indian vaccine industry and its customers, and it will help the manufacturers understand how to design their financial investments to de-risk the investments for safer returns. The domestic market is about 52%, and about 60% of the domestic market comes from the government segment in terms of value and much higher in terms of volume. Hence, marketing priorities revolve around the key customer, which is the state or government in India.

6.4 RESEARCH OBJECTIVE:2 – CLASSIFICATION OF VACCINE MANUFACTURERS WILL BRING OUT THE VULNERABILITY OF THE VACCINE INDUSTRY AND COULD PROVIDE GUIDELINES FOR THE MEDIUM TERM AND LONG-TERM CORRECTIONS.

Over and above all the classifications, it is the skilled workforce or the technical workforce that is highly essential for upkeep, manufacture, and handling of vaccines, requiring the highest scientific knowledge. Recommendations of the Task Force on the Development of Manufacturing Capabilities in Each Medical Vertical in Pharmaceutical Production

Hiring foreign experts to work in key facility positions is often necessary. Many may expect salaries on par with their current position or may have to be paid an additional premium depending on the desirability of the facility location. Local skilled workers will require

significant training, which may include being sent abroad for months at a time. Companies around the world tend to underestimate the time and cost of finding and training their local and expat workforce. Establishing Manufacturing Capabilities for Human Vaccines (UNIDO)

Based on the literature review and interviews, we summarize that there are broadly seven different approaches or methods existing to classify the vaccine industry in India.

1. Business model approach: We reviewed the platform, product, vertical, and hybrid models.
2. Regulatory Classification Approach: Here again, the vaccine industry is highly dependent upon WHO-PQ, WHO-GMP, and import permissions.
3. Product archetypes—segments of markets that the vaccine or pharma industry is choosing—are also a method to classify the product grouping.
4. Revenue Classification and Capital: This is about the efficiency of managing resources through better fiscal management, lower cost of materials, higher yields, and generating revenues and profits.
5. Technology and Research Classification: This kind of technology platform and research areas gives the vaccine manufacturer an edge to stay ahead of the race, and hence this form pillar or source of strength for the vaccine manufacturer.
6. Market Classification: retail-oriented market, government, or state as market, international or exports as market, UNICEF as market determines the feasibility of the business.
7. Capabilities and Scale: Large capacities with higher economies of scale will have significantly higher returns, subject to adherence to the other classifications listed.
8. Skilled workforce is the pillar of strength for any organization. Without hiring and retaining a skilled or talented workforce, overly sensitive manufacturing of vaccines will be impossible and would also pose biohazards and risks for the nations.

With primary and secondary research, it can be established that a combination of one or more on a scale of performance can determine the final magical classification style. As per the research literature and interviews, the vaccine industry in India can be classified as per the

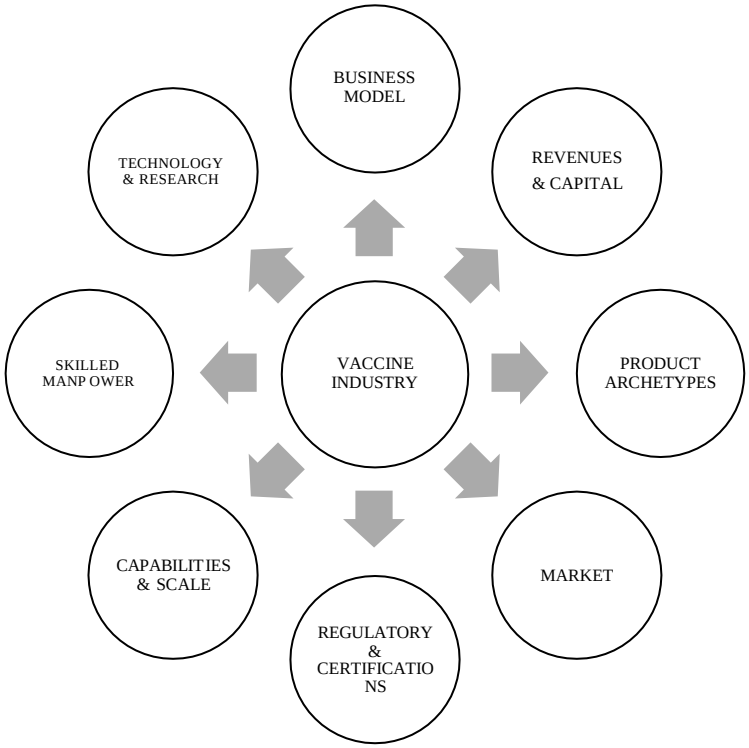
picture given below. As per the Economic Survey 2022–23, Page 92, the Government of India has always emphasized a special focus on skill development to enhance the generation of a technical workforce.

The researcher observes that the scope of each point mentioned above is not mutually exclusive but is interlinked with each other, and the degree of overlap is another scope for research. The above eight methods of classification are believed to have convergence in order to shape the health of the vaccine manufacturer. The compilation of all these classifications triggers interlink ability for the following reasons:

1. All such classifications, however independent, are linked to the vaccine industry.
2. Importance of each classification, impacting the vaccine industry.

The degree of importance expected to vary from each such classification trait.

Fig-22: Convergence of Classifications of vaccine industry



Source: Researcher

- The above structure, named “The Octagon,” and classification need the right mix and weight according to the attribute.

- It is also eminently evident that the right mix of all the components can give higher success rates to the companies. While no stand-alone attribute can result in better prospects, it is also not necessary that, to survive, all attributes have to be there.
- The weighted average method or any other algorithm can help develop the right mix for a vaccine manufacturer to be able to get into one side of the classification.

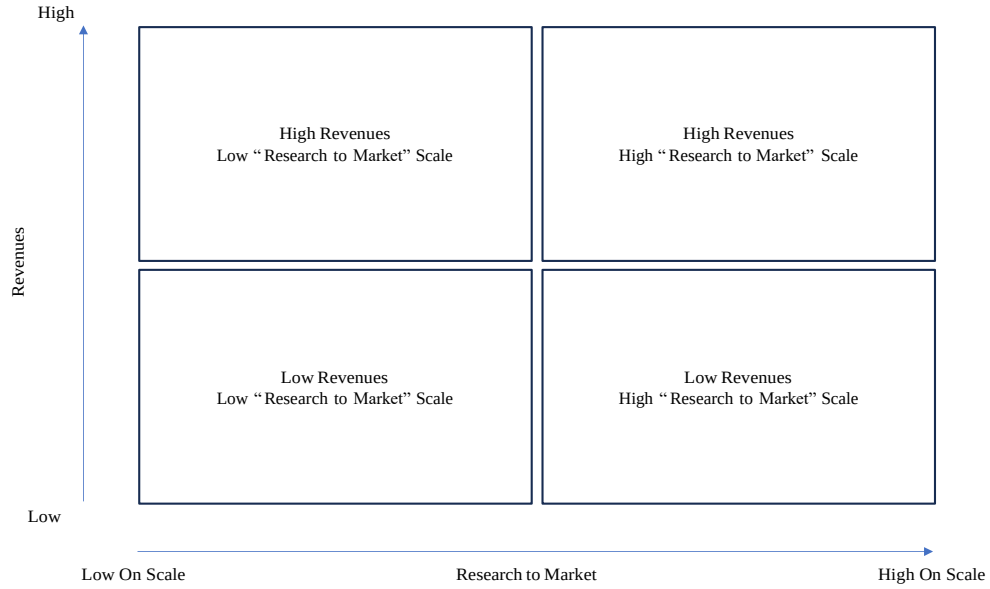
Every piece of literature attempts to classify the vaccine industry based on certain attributes. However, the optimum combination of all such attributes is going to be the new classification style, which should give way to robust organization building. The leaders in the vaccine industry responded to this question on classification, and their responses are factored into Appendix 6. Further, financial strength and profitability are also captured in Appendices 9, 10, and 11.

According to the interview with industry leaders, "research to market" is a significant attribute that covers most of the attributes mentioned above in The Octagon. While contract manufacturing companies, importing companies, antigen importing companies, and marketing products within India need not fulfil all the attributes of The Octagon, industry leaders prefer a "Research to Market" model, which has a competitive edge.

It also emerged from discussion with industry leaders that high research to market and revenues, low research to market and revenues, high research to market and low revenues, and low research to market and high revenues are distinctive characteristics that define outcomes as revenues in relation to the research to market classification. We noticed that the rating systems prevalent on the basis of revenues (www.biospectrumasia.com) and CRISIL provide rating systems on other aspects of financial health.

This will evolve the rating system or support the prevalent rating system and place companies according to the quadrants suggested below to rate them based on high research-to-market and high revenues at the top of the rating. each such classification trait

Fig-23: Metrics for "Research to Market" Classification



Source: Researcher

1. High Revenues and High "Research to Market" Scale: In this category, vaccine companies may be placed with all end-to-end resources to develop, manufacture, and market their vaccines, and the products are well marketed and positioned, earning higher revenues.
2. High Revenues and Low "Research to Market" Scale While the vaccine manufacturing company might be earning higher revenues, it is outsourcing certain processes, such as research, or engaging in the import of antigen.
3. Low on revenues and high on "research to market." Scale: Here the unit is engaged in active research, contract research, and supplying technology to other manufacturers.
4. Low on revenues and low on "research to market." Scale: The business unit is only engaged in temporary imports and markets the product to specific customers.

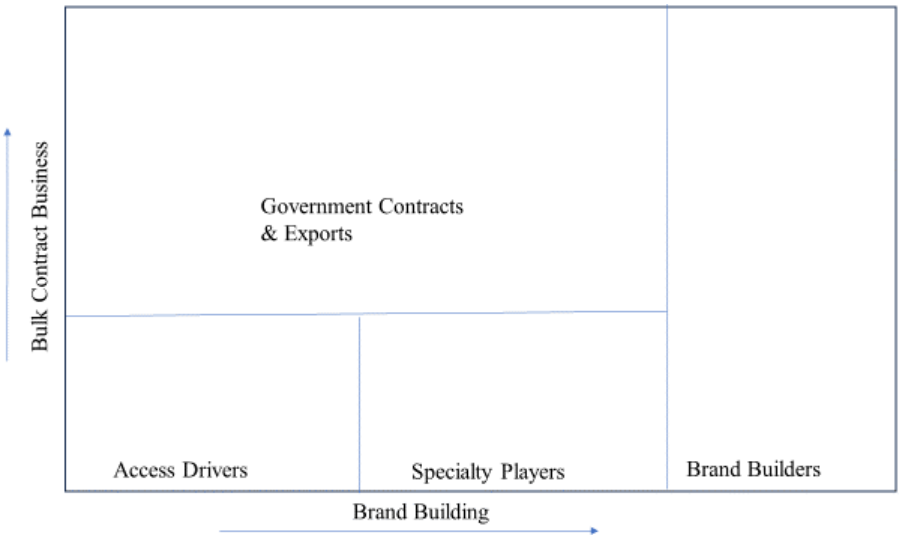
Vaccine manufacturing companies are to be placed in the above quadrants based on their research-to-market classification and revenues.

As referred to in the IQVIA (2018) document, pharmaceutical companies are classified as "access drivers," "therapy leaders," specialty players," and "brand builders." However, we

adequately established in our literature review that vaccines are not therapeutic products and are prophylactic in nature. Hence, the “Therapy Leaders” trait has been replaced by “Government Contracts” since the major source of customer classification of business for vaccines is from the government or the state.

As per the research, it is interpreted that most Indian vaccine manufacturers are supplying to the government or state, and the multinationals will feature in the brand-building quadrant. The quadrants are designed specifically for the Indian market. Hence, a suggestive interpretation for the vaccine industry is given as under for different archetypes, with government or state as a new archetype suggested. Quadrants are suggested below to be rated based on high research-to-market and high revenues at the top of the rating. each such classification trait

Fig-24: Archetypes suggested for vaccine business in India.



Source: Researcher

"Access Drivers” are those who manufacture limited vaccines or import vaccines and cater to the open market. These vaccines are either procured by the government or on the private market. The tetanus vaccine is one such example, procured by the government and also sold in the open market. Normally, for any injury or surgery or for pregnant women, the tetanus vaccine is used. This product is only made available in retail shops for better access, besides supplies to the government and exports. Companies such as Dano and BE are examples of manufacturers of such specific vaccines.

The “Specialty Players” are specifically for adult vaccines such as hexavalent vaccines, varicella vaccines, and hepatitis A vaccines, which are specific to niche markets. In this case, examples are GSK, Serum Institute, Sanofi, Gennova, etc.

The “brand builders” always try to be ahead of the race. They always bring novel vaccines and have the first-mover advantage. GSK’s Shingles vaccine is one such example, which is being promoted in the market besides the Human Papilloma Virus (HPV) promoted by the Serum Institute in India. These classifications have explored the methods to classify the marketing approach in India for vaccines as compared to pharma products. Vaccine manufacturers can now place their current position in the matrix, interpret the vulnerability in the vaccine industry, and provide guidelines for medium- and long-term corrections. Manufacturers are supplying to the government or state, and the multinationals will feature in the brand-building quadrant. The quadrants are designed specifically for the Indian market. Hence, a suggestive interpretation for the vaccine industry is given as under for different archetypes, with government or state as a new archetype suggested.

6.5 RESEARCH OBJECTIVE 3: STAND ALONE VACCINE MANUFACTURERS WILL BE GUIDED BY DIVERSIFICATION OR OTHER METHODS TO SUSTAIN IN THE INDUSTRY

- It is important to understand the dominant customers in India in the vaccine industry, as mentioned in Research Objective 1. It is clearly evident that the government is the major customer, and to build capacities and choose products for manufacture, government pricing and volumes have to be factored in.
- Manufacturers with only vaccine manufacturing units have to factor in the inherent risks of being in the vaccine industry and have little choice over the government as their customer. In June 2020, AstraZeneca and SII formed a partnership, with SII committing to participate in the COVAX program and promising to supply 400 million doses—of what it would call Covishield—by the end of the year in exchange for financial support from CEPI as well as Gavi. In an interview with the New York Times shortly thereafter, CEO Adar Poonawalla explained that SII was making at-risk vaccine

investments by relying on his family's own resources and not the Operation Warp Speed funding that manufacturers in the United States were receiving for scaling up their production at risk. (Bown, C. et al., 2021). How COVID-19 vaccine supply chains emerged in the midst of a pandemic India's number one vaccine manufacturer took the risk of personal finances as a backup for the possible untoward outcome of COVID-19 vaccine manufacturing. This risk-taking ability may not be there with other vaccine manufacturers in India.

- Referring to Appendices 9 and 10, it is evident from the financial performance of companies in India other than Serum Institute of India (SII) that it is impossible for others to take any risks on this.

Hence, the Octagon metrics are an indicator of diversification to minimize risks in the stand-alone vaccine business.

6.6 RESEARCH OBJECTIVE 4: IT SHOULD CREATE PARAMETERS FOR EACH COMPANY TO MOVE FORWARD AND DEVELOP THE INDUSTRY AS AN ATTRACTIVE INCUBATING HUB FOR INVESTIMENT FOR ASPIRING ENTREPRENEURS.

The first main component of the model is a cost-benefit analysis focused on a single vaccine development and delivery scenario. We focus on a single vaccine buyer and a single vaccine seller, each of whom faces independent but interrelated cost-benefit decisions about whether to move forward with a particular vaccine investment or purchase.

- **Vaccine buyers** typically consist of donor agencies and/or country governments, which are responsible for funding vaccine development efforts as well as purchasing and delivering finished vaccine doses. Because these parties have a common objective of maximizing societal benefit through increased vaccination coverage rates, we can treat them as a single entity.
- **Vaccine sellers** typically consist of manufacturers who develop, commercialize, and produce a vaccine presentation to sell to vaccine buyers. Sellers typically do not share a common objective. Each seller seeks to maximize its own benefit rather than societal

benefit. In the case where multiple manufacturers operate in parallel, we must focus on one seller at a time.

At least one willing buyer and seller are needed for a particular vaccine technology to be successfully developed and deployed. By capturing both buyer and seller cost-benefit decisions in the same overarching model, the Cost Benefit Analysis (CBA) framework helps clarify the conditions (e.g., development cost, unit price, demand volume) in which both parties would be willing to invest in a given vaccine technology. Net present values (NPVs) are calculated independently for buyers and sellers. An NPV greater than zero implies that the present value of the benefits exceeds the present value of the costs, making the vaccine technology a worthwhile investment for the buyer or seller conducting the analysis. An NPV less than zero, on the other hand, implies that the vaccine technology is not a worthwhile investment for the buyer or seller. A change to one or more of the cost or benefit inputs (e.g., a change in unit price, expected demand, or other estimates and assumptions) would be needed to change the NPV. (Krautmann, M., Davis, B., & Leroueil, P. R., 2023). A model for estimating the costs and benefits of new vaccine technologies from the perspective of both buyers and sellers.

The Bill and Melinda Gates Foundation (www.gatesfoundation.org) invests in expertise and platform technologies that help us make vaccines faster, better, and cheaper. They also invest in education and training to ensure that knowledge around vaccine development and manufacturing is created, shared, and retained. Examples of this include:

- Adaptive clinical trial design
- Streamlining the schedule and dosing of vaccines
- Novel delivery formats for vaccines
- Developing modular, automated manufacturing platforms that enable small-batch vaccine production.

Hence, for a new manufacturer, there are many resources that can help them create a robust manufacturing unit.

- Innovative or own source of technology; technology through collaboration from private or international sources; government sources for technology

- Agencies such as the Bill and Melinda Gates Foundation for the investments
- Financial assistance can be obtained from Bio-NEST, launched by the Biotechnology Industrial Research Assistance Council (BIRAC) of the Government of India with a vision focused on fostering the biotech innovation ecosystem in the country. Unlike startups in the IT sector, enterprising ideas in the biotech sector need incubation support of a different kind, where they need a landing space to test their ideas, run their operations, have access to high-end instruments, and locate in a place where they can connect with other startups and mentors.
- Department of Biotechnology (DBT), Government of India, engaged in realizing the full potential of biotechnology; A well-directed effort and significant investment in the generation of products, processes, and technologies Enhance efficiency, productivity, and cost-effectiveness in agriculture, nutritional security, molecular medicine, environmentally sustainable technologies, scientific and technological empowerment of human resources, a strong infrastructure for research and commercialization, enhancing the knowledge base, nurturing the leads of potential utility, and bringing the bioproducts to the market; Socio-economic development and applicants of biotech for the upliftment of women, rural, Scheduled Caste, and Scheduled Tribe (SC and ST) populations and to promote the biotech industry (dbtindia.gov.in)
- Venture capital firms invest depending on the promising technologies used.
- Bank loans, equity, and other known sources of capital

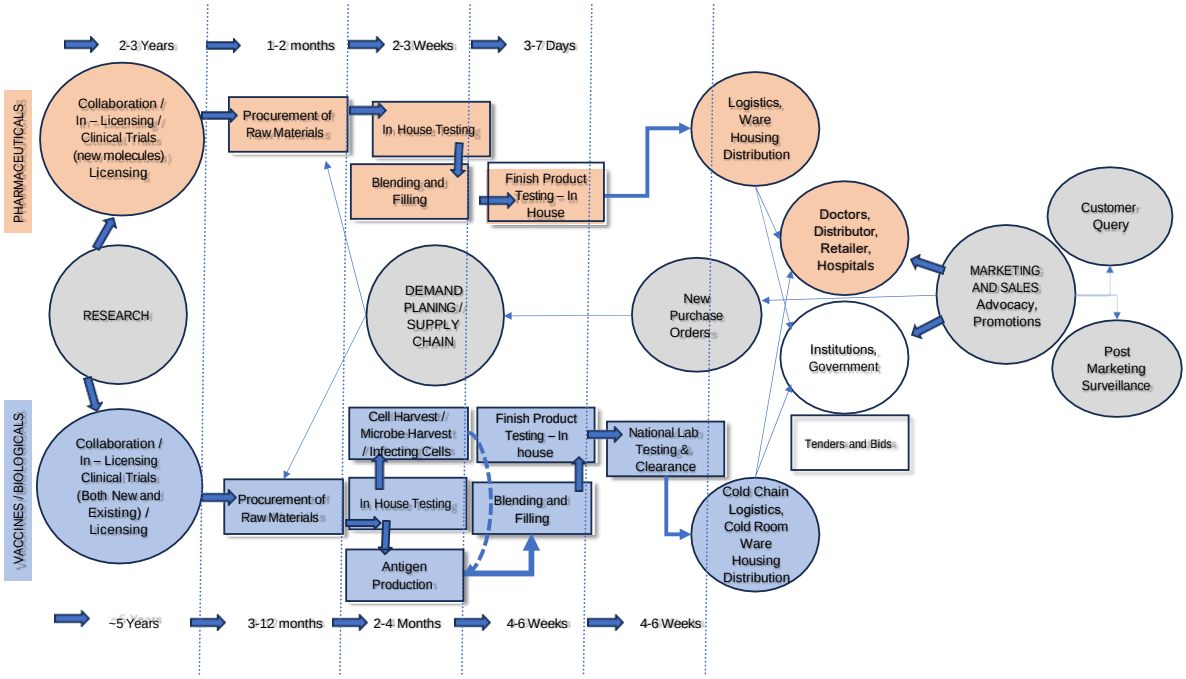
Parameters for companies are summarized below.

1. Technology parameters and their sources
2. Research parameters and their uniqueness
3. Revenue and capital generation ability
4. Selection of vaccines
5. Selection of customers and markets
6. Regulatory certifications
7. Capabilities and scaling-up mechanisms.

8. Business model adopted.
9. Skilled Manpower
10. Diversification for better investment spread.

The ability of any new manufacturing unit in India to figure out the factors listed above while investing in vaccine production will give it a straight edge. The single most crucial factor that has been factored in is that the business processes for pharmaceuticals and vaccines are different, and this needs to be carefully understood. Business process models, customers, and timeline studies as per Appendix-6 trigger the below diagram.

Fig-25: Process difference of Pharmaceuticals and vaccines



Source: Researcher

Key takeaways from Figure 25 on process differences between pharmaceuticals and vaccines

- Research timelines are higher for vaccines, ranging from a minimum of 5-7 years as compared to 2-3 years for pharmaceutical products (especially known products).
- Procurement of raw materials may take even 1 year and above for vaccines, while it may take as little as 2–3 months for pharmaceutical products, depending on the available raw materials.

- Production and quality clearances may take up to 4–7 months for vaccines, while for pharmaceutical products, it may take a maximum of 1 month.
- The government is the biggest customer.
- Vaccines attract higher regulatory clearances, while in the pharmaceutical industry, they are comparatively lower.

Such critical differences have to be factored in while evaluating entry into the vaccine business for any young, aspiring entrepreneur.

6.7 SUMMARY OF DATA AND ANALYSIS

6.7.1 DATA FROM QUESTIONNAIRES

Questionnaire data obtained from samples or cohorts identified from the available amount of information gives us clarity on the customer selection process and the classification of the industry. It gives a ringside view of the business process and the things that are implied. Hence, it becomes incumbent upon us to interpret the data that has come out of the questionnaire. It is evident from the data that.

- The vaccine industry, prior to investments in the vaccine business, has given in to the thought process, inspired by some multinationals, that there is a market in the doctor prescription-retailer segment. Later, they realized that the government procurement system is more than 50%
- The government procurement and export business make up more than 87% of the entire vaccine industry.

6.7.2 DATA FROM TELEPHONIC / INTERVIEWS

There are revelations in the interviews that give a fair idea of the challenges in the vaccine industry, classification, comparative aspects of the vaccine industry with the pharmaceutical industry, business processes in the vaccine industry, marketing compulsions, and challenges in India.

- It establishes a clear-cut comparison between the pharmaceutical and vaccine industries and the lead times and process delays due to biological and regulatory processes.
- Vaccine business is a highly capital-intensive and time-consuming process, besides stringent regulatory controls.
- Four out of eight factors contribute to the classification of the vaccine industry.

Parameters to judge the vaccine companies and their performances are listed in the form of a matrix in Figure 23.

6.7.3 LITERATURE REVIEWS

From the available literature, there is information on the vaccine industry on aspects staggered through various publications, but it is not representative of the entire Indian vaccine industry, which could be completed with primary research through questionnaires and interviews.

- Another four attributes of classification are available in a literature review other than what was discovered with interviews.
- The business process is part of the vaccine business.
- The Indian vaccine industry spends a little less for research and development compared to its pharmaceutical counterpart, which is significantly lower (Appendix 16).

Profit before taxes and cost of materials are key criteria to evaluate the performance of the vaccine industry. Profit and loss statements and balance sheets of more than fifteen vaccine companies were examined for a 5-year period prior to the COVID-19 pandemic. Since the vaccine business is getting skewed, a steep fall cannot be evaluated for consistency purposes.

6.8 FUTURE RESEARCH DIRECTIONS

- The classification of the vaccine industry was collated with primary and secondary research, and the eight attributes (octagon) were discovered. However, the relationship between each such attribute and its weighted content to develop a classification matrix could be the scope for future research. An online evaluation system integrated with

rating systems could become a new way of dealing with idiosyncrasies within the vaccine industry.

- The impact of regulatory compliances and certifications on the vaccine industry vis-à-vis the pharmaceutical industry is another scope that can shed light on various aspects of inherent complications in the vaccine industry.

How can robust research and development and an efficient supply chain improve the performance of the vaccine business?

CHAPTER 7: CONCLUSION

7.1 CONCLUSION

This section of the study will summarize the research and give a synopsis of all the findings achieved through qualitative methods and secondary data. These findings thereby meet the aims and objectives of the study. This chapter will be followed by a last chapter offering recommendations that would be useful for vaccine manufacturers, venture capital firms, and new investors in the Indian vaccine industry.

The researcher found that there is negligible enumeration done on the procurement of vaccines by the government, and the government's emergence as the largest consumer of vaccines in India is unlike the pharmaceutical business, and the enumeration done by researchers for the pharmaceutical business is not representative of the vaccine industry.

Although financial outcomes have a correlation between the vaccine and pharmaceutical industries, the manufacturing process, research, regulatory framework, stringent certification and control mechanisms, and customers vary significantly.

The main aim of this study was to explore the following research objectives:

- Understand the customer selection process that drives the business process.
- The classification of vaccine manufacturers will bring out the vulnerability of the vaccine industry and could provide guidelines for medium- and long-term corrections.
- Stand-alone vaccine manufacturers will be guided by diversification or other methods to sustain the industry.
- It should create parameters for each company to move forward and develop the industry as an attractive incubating hub for investment for aspiring entrepreneurs.

In the introduction section, the aim and objectives of the study are defined after a brief narration of the background of the vaccine industry. India is on the threshold of exciting times, and the vaccine industry is no different. Already, India has achieved the status of providing more than 60% of the global vaccine requirement through UNICEF and other international agencies.

Literature review is another challenging area, with very few enumerations done on the Indian vaccine industry and its classification methods, which remains the cornerstone of this research initiative.

Research methodology was followed based on the high-level information, and this cannot be dealt with public opinion since technology, business models, regulatory challenges, manufacturing challenges, and customer choice challenges are niche areas and only highly placed individuals in the industry can respond and share opinions.

The results section explained the various aspects of the questionnaire, telephonic and personal conversations, balance sheets, profit and loss statements, and literature materials and books available to indicate the outcomes.

With **Objective -1**, it is demonstrated through research, procurement patterns, and program implementation that the customer choice is the government or state in India, and vaccine companies otherwise can opt for export markets, while the domestic prescription market is only for adult vaccines to a limited extent. Overall, the vaccine business skewed towards the government as a customer.

Although reports do not directly suggest the choice of customers for the vaccine industry in India, while corroborating the facts and publications, they hint or suggest that the state is the important consumer in both volume and value, along with export potential. This was corroborated by the industry leaders during personal interviews and through questionnaires.

This gives a ring-side view that is representative of the Indian vaccine industry and its customers, and it will help the manufacturers understand how to design their financial investments to de-risk the investments for safer returns. The domestic market is about 52%, and about 60% of the domestic market comes from the government segment in terms of value and much higher in terms of volume. Hence, marketing priorities revolve around the key customer, which is the state or government in India.

With **Objective-2,** "the Octagon" structure emerged for holistic classification and needed the right mix and weight according to the attribute.

It is also eminently evident that the right mix of all the components can give higher success rates to the companies. While no stand-alone attribute can result in better prospects, it is also not necessary that, to survive, all attributes have to be there. The weighted average method or any other algorithm can help develop the right mix for a vaccine manufacturer to be able to get into one side of the classification.

However, we adequately established in our literature review that vaccines are not therapeutic products and are prophylactic in nature. Hence, the "Therapy Leaders" trait has been replaced by "Government Contracts" since the major source of customer classification of business for vaccines is from the government or the state.

As per the research, it is interpreted that most Indian vaccine manufacturers are supplying to the government or state, and the multinationals will feature in the brand-building quadrant. The quadrants are designed specifically for the Indian market. Hence, a suggestive interpretation for the vaccine industry is given as under for different archetypes, with government or state as a new archetype suggested. These classifications have explored the methods to classify the marketing approach in India for vaccines as compared to pharma products. Vaccine manufacturers can now place their current position in the matrix, interpret the vulnerability in the vaccine industry, and provide guidelines for medium- and long-term corrections.

With **Objective 3**, it is pertinent to understand the dominant customers in India for the vaccine industry, and this was explained by the researcher while addressing Research Objective 1. It is clearly evident that the government is the major customer, and to build capacities and choose products for manufacture, government pricing and volumes have to be factored in.

Manufacturers with only vaccine manufacturing units have to factor in the inherent risks of being in the vaccine industry and have little choice over the government as its customer. This risk-taking ability may not be there with vaccine manufacturers in India due to the prominent level of capital requirements. Only a few vaccine manufacturers can take the risk, and as per Appendices 9 and 10, it is evident from the financial performance of companies in India other than Serum Institute of India (SII) that it is impossible for others to take any risks on this.

Hence, the Octagon metrics are an indicator of diversification to minimize risks in the stand-alone vaccine business.

With **Objective-4,** the ability of any new manufacturing unit in India to figure out the factors listed above while investing in vaccine production will give it a straight edge for its purpose. The single most key factor in the business process is that pharmaceuticals and vaccines are different, and this needs to be carefully understood. Business process models, customers, and timeline studies as per Appendix 6Such critical differences have to be factored in while evaluating entry into the vaccine business for any young, aspiring entrepreneur.

7.2 KEY RESEARCH FINDINGS

- In the Indian vaccine business, the state or government is the key customer. Because the majority of the vaccines used on children for childhood immunization and adult vaccine use in India through promotional channels are significantly less However, pharmaceutical drugs, which are inherently therapeutic in nature, always walk through the prescription market.
- Different research papers attempted to classify the vaccine industry based on the research topic. After personal interviews and financial evaluation, new classification methods were factored in, which finally took the shape of an octagon. It is believed that these eight factors have interconnection, and their weights need to be determined for better understanding.
- A clear-cut approach to business processes for the vaccine industry in comparison to the pharmaceutical industry is established, which gives the idea that not only are there many new steps involved in the manufacturing process but also additional steps in quality clearance and marketing involved. A business purposes flow chart was developed for that purpose by the researcher.

CHAPTER 8: RECOMMENDATIONS

8.1 RECOMMENDATIONS

Keeping in view of the scope of research, which attempts to classify the vaccine industry or factors influencing the vaccine industry and the customers that the Indian vaccine industry selects to be in business, The business process that the vaccine industry is following is distinctively different and time-consuming compared to the pharmaceutical industry. Considering the findings from the research, the researcher proposes the following recommendations:

- **Vaccines are different from pharmaceutical products;** the vaccine industry, although a part of the pharmaceutical industry, cannot be measured by the same yardstick as that used for the pharmaceutical industry. The research process, manufacturing complexities, stringent regulatory guidelines, and the fact that vaccines are marketed only after each lot or batch of every vaccine produced is cleared by the Central Drug Laboratory, Government of India, unlike pharmaceutical products, which can be internally cleared, lengthy process timelines, capital intensiveness, different business processes, and dominant customer types
- Stand-alone vaccine businesses need careful evaluation of technology and should be guided by incubation hubs or biotechnology hubs set up by the Government of India and some states, such as Telangana State in India. It is recommended that any existing player in the life sciences sector or pharmaceutical sector consider diversifying into the vaccine business, which can withstand the complexity of the business. Funding agencies and the government, technology providers, bio-security level (BSL), and cGMP facility developers roped in for a better introduction into the vaccine sector.

- **Classifications that influence the vaccine business:** The factors that influence the vaccine business with several methods of classification give insight that the business model approach, regulatory classification approach, product archetypes, segments of markets, revenue classification and capital, technology and research classification,

market classification, capabilities and scale, and skilled workforce are the keys. All eight parameters are interconnected to a varied degree, and all the above factors contribute to the appropriate shape and health of the vaccine industry.

- In each classification method discussed, the manufacturer gets an opportunity to place itself in one such class and determine its own competence and marketability. It will also give direction for planners and project managers to draw future projections based on the type of manufacturing facility, extent of research, and product segment (childhood vaccines, adult vaccines, livestock vaccines, companion animal vaccines, etc.) to position their company.

- **The business process for vaccines is different** and has different timelines. Hence, while committing any customer to delivering vaccines, numerous factors have to be considered, and long lead times are required to process business.
- Long lead times and regulatory clearances for each manufactured batch are definitely a serious bottleneck to honouring any commitments of the customers. This exercise for each vaccine manufacturing to marketing lead time can be worked out for each vaccine, which can help in planning and efficient maintenance of raw materials and packing materials by the supply chain.

Only the vaccine business gives higher than 30% gross margins as compared to the top 10 pharma companies, which are performing with less than 30% margins. Serum Institute of India achieved gross margins of 54%, which is phenomenal. While the risk factor in the vaccine business is high as many vaccine companies are in red, pharma companies have lower margins among the top 10 (Appendix 17).

5 out of 15 vaccine companies in India have a poor asset turnover ratio, signifying their health and the vulnerability or risks associated with the vaccine industry. More than 33% of the sampled companies do not have adequate turnover or assets exposed. This risk mitigation strategy and proper planning are required for better operational success. (Appendix-18)

8.2 SUMMARY

This research aimed primarily to distinctively place the vaccine industry, currently classified as a part of the pharmaceuticals industry. The research objective is to identify the kind of customer choice driving the vaccine industry, similarities and differences between the vaccine industry and pharmaceuticals, thereby classifying the attributes, and identifying the business process of the vaccine industry. To study this, researchers chose to study the vaccine manufacturers and the ecosystem that drives the vaccine industry. There are about 32 vaccine manufacturers (other than defunct), including government-operated vaccine units. The researcher chose to select 25% of the samples from the commercially operated vaccine manufacturing units, estimated to be 23 (25% sample makes 6), and therefore seven companies were chosen for the study. Apart from studying the companies through questionnaires and interviews, the regulatory system, financial health of the vaccine companies, literature reviews, magazines, websites, and government agencies were also examined.

The results of this study confirmed that the vaccine industry is distinctively different in all aspects while being a subset of the pharmaceuticals, biotechnology, and biopharmaceuticals industries. The Indian vaccine industry incurs lower research and development costs and invariably does not have any disruptive or path-breaking research, which results in marketing existing products by manufacturing with the concept of economies of scale. This low-cost, high-volume manufacturing finds place in government procurement and UNICEF supplies (with WHO-PQ facilities). The psyche of the Indian market has not upgraded to voluntary vaccination of adult vaccines, and hence, the bigger markets such as childhood immunization, adult vaccines, and livestock vaccines find place in government procurement policies, while some parts of adult vaccines and companion animal vaccines are marketed through the prescription market. It is also found that the vaccine business process is different from that of the pharmaceutical industry, and the vaccine industry has various processes and regulatory factors and longer timelines to roll out the product in the market. There are many research articles, websites, and magazine articles making classifications of the vaccine industry based on different attributes. In this study, we collated all such classifications observed and found that

these factors are interrelated. Hence, the vaccine industry in India should be separately enumerated on all counts and cannot be hidden within the pharmaceuticals or biotechnology industries.

8.3 RESEARCH CONTRIBUTION

The data analysis, study materials on vaccines, and surveys on vaccine companies were done to find out the inherent truth about the processes of the vaccine industry. It also gives a clear understanding that the "Indian vaccine industry," which is also part of the growth story of the Indian economy, needs separate attention on processes, classification, and regulatory compliance. This study will be useful for the pharmaceutical, biotechnology, biopharmaceuticals, and biologics industries to better understand the vaccine industry for future investments. This study provides a better understanding of the business processes, classifications, financials, and customer segmentation of the vaccine industry.

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APPENDIX-1: SURVEY QUESTIONNAIRE

Table-8: Survey Questionnaire

Section	Heading	Details / Questionnaire
Vaccine Industry		Vaccine-making is a long-drawn process, right from project stage to vaccine roll out, and requires huge capital. Long lead times in rolling out vaccines is also due to stringent regulatory processes. Finding the right customer segment and utilizing capacities is also a big challenge. This survey is part of the research aimed at understanding the decision process for investing in vaccine manufacturing. Questions are very generic and will help us understand the industry. I request you to kindly respond to this brief questionnaire and help me in the research. Regards,
1	Introduction	• Name of the Company • Number of Vaccine man8ufacturing plants in India • Year of establishment • Name and Designation of the person responding to the questionnaire
2	Investment Decision	• What other related industry / field that your firm was operating prior to taking decision on investing in vaccine manufacturing? • What kind of initial input or resource was accessible to your firm before making diligence on investment in vaccine manufacturing? (Tick Boxes wherever applicable).

		• What is the source of funding? (Tick Boxes wherever applicable) • Was your business decision to foray into vaccines based on any or more of the following market data?
3	Market for Vaccines in India	• Do you consider promotion of vaccines through Doctor Prescription-Retail-Distributor network is appropriate in India? • Do you consider Selling vaccines to the State or Central Government procurement agencies as priority? • What is your Current Contribution of Retail Channel Sales of your company to the overall vaccine revenues? • What is your Current Contribution of Sales revenues of your company from Government Customers to overall vaccine revenues? • Is your current Vaccine portfolio being above 50% of your overall group revenues of your company? If yes, which sector contributes the most?
4	Customer Selection	• If it were your plan to sell vaccines through Government and Exports channel, what are the factors true in your context? • If your portfolio is meant for Govt/State as customer, then what are the factors true in your context? • According to you as a manufacturer, what is the appropriate scenario for Indian vaccine market?
	Open Question	• What according to you is correct description in Indian context for high salience or dependence on specific customer segment for vaccine business

APPENDIX-2: TELEPHONIC DISCUSSION STRUCTURE

Table-9: Broad Structure for Telephonic / Personal discussion

Topic	Sub-Topic
Business Models	• Business Process. • Difference of Business Process in Pharma and Vaccines • Vaccine Business Models and Contemporary experiences • Technological interventions
Customer Selection	• Customer selection in vaccines and pharma • Compulsions to choose customers
Classification	• How the vaccines / vaccine customers classified. • How vaccine companies classified. • Rating system for vaccines.
Marketing Challenges	• Ideal marketing approach for vaccines in India • Vaccine business – marketing challenges
Others	• Parameters to judge the health of vaccine business. • Questionnaire

PURPOSE

The research focuses on vaccine business process, classifications based on data collected with an aim to understand the customer compulsion process.

ROLE OF PARTICIPANTS

The participants briefed about the research by the researcher and expected to have conversation on key topics outlined above (Appendix-2) and formally fill the questionnaire. The entire information is confidential and structured.

COLLECTION OF INFORMATION

The information collected shall be used by the researcher to draft the thesis. Anonymity and Confidentiality assured in terms of participation and the organizations they work for. The researcher will keep the data with strict confidentiality.

APPENDIX-3: VACCINE MANUFACTURERS LIST AND SAMPLE CHOSEN AND PARTICIPANTS

Table-10: List of vaccine companies and Status

SL	Name of Vaccine Manufacturer	Category	Origin	Status	Operations	Financials
1	Bharat Biotech	Human Vaccines	Indian	Private	Yes	Yes
2	Biological E Limited	Human Vaccines	Indian	Private	Yes	Yes
3	Cadila Healthcare	Human Vaccines	Indian	Private	Yes	Yes
4	Cadila Pharmaceuticals	Human Vaccines	Indian	Private	Yes	Yes
5	Chiron Behering	Human vaccines	Indian	Private	Yes	Yes
6	Dano	Human Vaccines	Indian	Private	Yes	Yes
7	Green Signal	Human Vaccines	Indian	Private	NA	Yes
8	Panacea Biotech	Human Vaccines	Indian	Private	Yes	Yes
9	Ranbaxy	Human Vaccines	Indian	Private	Yes	Yes
10	Serum Institute of India	Human Vaccines	Indian	Private	Yes	Yes
11	Shanta Biotech	Human Vaccines	Indian	Private	NA	NA

12	GSK Asia	Human Vaccines	MNC	Private	Yes	Yes
13	Sanofi Pasteur	Human Vaccines	MNC	Private	Yes	Yes
14	Gennova biopharmaceuticals	Human Vaccines	Indian	Private	Yes	Yes
15	Biomed	Human and Animal Vaccines	Indian	Private	NA	Yes
16	Reliance Life Sciences	Human and Animal Vaccines	Indian	Private	New	Yes
17	Indian Immunologicals Limited	Human and Animal Vaccines	Indian	PSU	Yes	Yes
18	BiBCol	Human Vaccines	Indian	PSU	Yes	Yes
19	Haffkiene	Human Vaccines	Indian	PSU	Yes	Yes
20	HLL Biotech	Human Vaccines	Indian	PSU	NA	NA
21	BCG Institute	Human Vaccines	Indian	State	NA	NA
22	Conoor Institute	Human Vaccines	Indian	State	NA	NA
23	CRI Kasauli	Human Vaccines	Indian	State	NA	NA

24	Sanvita	Animal Vaccines	Indian	Private	Yes	Yes
25	Brilliant Biopharma	Animal Vaccines	Indian	Private	Yes	Yes
26	Biovet	Animal Vaccines	Indian	Private	Yes	NA
27	Hester	Animal Vaccines	Indian	Private	Yes	Yes
28	Indovax	Animal Vaccines	Indian	Private	Yes	Yes
29	Venky Biologicals	Animal vaccines	Indian	Private	Yes	Yes
30	Globion	Animal Vaccines	Indian	Private	Yes	Yes
31	IAHVB	Animal vaccines	Indian	State	Yes	NA
32	VBRI (States)	Animal Vaccines	Indian	State	NA	NA

Table-11: Companies selected for Questionnaires.

SL	Name of Vaccine Manufacturer	Category	Origin	Status	Operations	Financials
1	Biological E Limited	Human Vaccines	Indian	Private	Yes	Yes
2	Sanofi Pasteur	Human Vaccines	MNC	Private	Yes	Yes

3	Gennova biopharmaceuticals	Human Vaccines	Indian	Private	Yes	Yes
4	Indian Immunologicals Limited	Human and Animal Vaccines	Indian	PSU	Yes	Yes
5	Sanvita	Animal Vaccines	Indian	Private	Yes	Yes
6	Brilliant Biopharma	Animal Vaccines	Indian	Private	Yes	Yes
7	Hester	Animal Vaccines	Indian	Private	Yes	Yes

Private Vaccine Manufacturers -6 (5 Indian and 1 MNCs) and PSU-1

Human Vaccine -3; Animal Vaccine-3 and Animal and Human Vaccines-1

APPENDIX-4: QUESTIONNAIRE SURVEY PARTICIPANT INFORMATION SHEET

Vaccine-making is a long-drawn process, right from project stage to vaccine roll out, and requires huge capital. Long lead times in rolling out vaccines is also due to stringent regulatory processes. Finding the right customer segment and utilizing capacities is also a big challenge. This survey is part of the research aimed at understanding the decision process for investing in vaccine manufacturing. Questions are very generic and will help us understand the industry. I request you to kindly respond to this brief questionnaire and help me in the research.

RESPONSE TO OPEN QUESTION IN QUESTIONNAIRE

What according to you is correct description in Indian context for high salience or dependence on specific customer segment for vaccine business.

Table-12: Open Question Response in Questionnaire

PARTICIPANT	RESPONSE
1	With the implementation of mass vaccination programs in India there is very less scope in retail business
2	Immunize and protect from the preventable diseases with high safety, efficacious and quality of vaccines to the population globally.
3	Tender business
4	customer need based with safe and efficacious vaccine
5	advance tech driven safe and effective vaccine
6	Low public knowledge and awareness, Vaccines not covered under insurance, Price sensitive end user, low respect, and appreciation for product innovation
7	Prophylaxis vaccination programs run and funded by Govt. Even-though the importance of vaccination realized to certain extent due to COVID19, it has made minor impact in animal health. As such Govt continues to fund various programs for preventive vaccination and hence manufacturer depends on this for their capacity utilization.

APPENDIX-5: QUESTIONNAIRE GROUPING

Table-13: Questionnaire grouping

Group / Section	Questions	Statements
1	1-4	Vaccine Industry and Introduction of the participants
2	5-8	Investment decisions – Prelude to investment decisions on vaccines
3	9-13	Market for Vaccines in India – Some of the key considerations of your company before making investment in vaccine business.
4	14-17	Customer Selection – Customer selection process before arriving at market driven decisions on investments

APPENDIX-6: TELEPHONIC RESPONSES

Table-14: Telephonic / Personal Discussion responses

Topic	Key Points	Respondent	Response
Business Models	Business Process.	1	Business Process cycle for vaccines is longer in duration as compared to pharma. Vaccine business has higher dependence on tenders and exports.
		2	Vaccines are normally sold through tender business and the Doctor-Retail prescription activity is less than 10%. Vaccine manufacturing cycle is 6-8 months and risks due to inconsistencies are higher.
		3	A little share of adult vaccines and paediatric vaccines, sold through retail route. Rest is meant for Government, UNICEF supplies.
		4	To achieve economies of scale in vaccine business, it requires consistency in production and generate volumes, which comes from Government supplies. Retail demand is insufficient to have higher volumes to achieve economies of scale.
	Difference of Business Process in Pharma and Vaccines	1	It takes at least 5 years for vaccines for product development, clinical trials, and licensing, while in the case of pharmaceutical drugs, it takes a minimum of 2–3 years (assuming the product and technology are already in place). If another

			firm is already marketing the same product in India, then it would take less time. For vaccine companies, from procurement of raw materials to delivery, it takes 7–12 months, as compared to 1-2 months for pharmaceutical products. Procurement of some critical raw materials may take even 1 year and above for vaccines, while it may take as little as 2–3 months for pharmaceutical products, depending on the available raw materials. Production and quality clearances may take up to 4–7 months for vaccines (in-house testing; third-party testing is mandatory for vaccines), while for pharmaceutical products, it may take a maximum of 1 month (with only in-house testing).
		2	Pharma testing time is as low as 2 days and do not require high disease security labs.
		3	Most MNCs are dependent on small manufacturers for outsourcing. Vaccine outsourcing can be done if there is a significant retail business or in-licensing from other countries for antigens.
		4	Companion animal vaccines are promoted in the retail market and to the dispensing clinical veterinarians, although a large part

			of companion animal vaccines is procured by the state.
	Vaccine Business Models and Contemporary experiences	1	Vaccine manufacturers in India should have complete end-to-end capabilities viz., "Research to Marketing" to be able to leverage technology and market, although expensive. (Research & Development-Regulatory compliant Manufacturing-Marketing & Distribution)
		2	A hybrid structure of for vaccine companies -research to manufacturing will be ideal. Companies may be classified on the basis of high Research to market & High Revenues, Low Research to market and low revenues.
		3	It is important for vaccine companies to first get platform technologies, build on multiple development models and clinical research, and bag the contract research work. Then expand into clinical trials, manufacturing, and marketing areas. This systematic expansion will de-risk huge capital investments. Post-Marketing Surveillance (PMS) is also part of the regulatory framework.
		4	Scout for technology, which can emerge as a game changer in the next decade and invest in a world-class international regulatory-

			compliant unit. Then position the products for both prescription and institutional/export markets. Diversify into the human vaccine business alongside the animal vaccine business to de-risk and build better economies of scale.
	Technological interventions	1	Any product with advanced technology, high yield, consistent output, and a low-cost mechanism will be worth investing in. Get an advantage with technology from local government, Indian, or international universities. It is important to build capabilities right from platform technologies and the required machines to manufacture the vaccine once developed with better economies of scale.
		2	Vaccine development takes many years and even decades. Study various technological platforms for each vaccine. Classify the vaccine and work on the need for the facility to develop a vaccine. Get the technology transferred or developed in-house to be ready in a short time.
		3	“Inactivated,” “live attenuated, lyophilized”, "recombinant," and "mRNA" are examples of different segments, and any one segment can be established with a range of vaccines

			for that segment. For multinational companies (MNCs) in advanced countries such as the USA and EU, the platform technology for vaccines is a matter of competitive edge. Due to the low population and lower epidemiology, the MNCs have no other option but to charge a higher price and salvage research value before disruptive technology comes. Hence, they let developing economies such as India build capabilities by transferring technology for a royalty.
		4	Modern technology requires a completely new setup, and regulatory mechanisms start from scratch. Hence, consolidate on your strengths unless we have a very promising technology and a committed development partner.
Customer Selection	Customer selection in vaccines and pharma	1	In India, vaccines are generally procured by the government for childhood immunization, adult vaccines, and traveller's vaccines. More than 70% of the total volume and value come from the government. Since the Indian consumer mindset or decision is always to get vaccination based on government recommendation and free vaccination,

			specialty vaccines are used only in niche segments and in higher-income groups.
		2	To drive down costs, at least 80% capacity utilization in manufacturing is considered a good unit. To achieve that, either bulk businesses, such as government or exports, will be tapped.
		3	Multinationals always want to build brands and generate higher value. Hence, they seldom participate in tenders and make supplies to governments. MNCs do not want to contradict pricing in their country of origin by desperately choosing states as their customers and offering lower prices. Tetanus vaccine, Td vaccine, and other traveller's or adult vaccines can be promoted through retail or doctors.
		4	But to achieve cost leadership, it is important to bag Government or exports business for economies of scale.
	Compulsions to choose customers	1	Low retail volumes do not achieve economies of scale. Consistently operating vaccine facilities with me-too vaccines operate with much-needed volumes, which can come only from states or exports.
		2	In a vaccine facility it is not possible to shut down power or water during non-production

			days (as is done in pharma) since virus banks and cell banks have to be maintained. For such continuous maintenance activity to meet national regulations, huge capital is required. Hence, a facility with consistent production and cash flow is required. This can come through government or export business.
		3	The Central Government runs all childhood immunization vaccinations, and states and provinces are buying most adult vaccines. Hence, it is imperative to choose government business. But newer vaccines are promoted through the prescription market.
		4	New vaccines were initially chosen to be marketed through the prescription market and later adopted by governments.
Classification	How the vaccines / vaccine customers classified	1	Doctors, hospitals (through prescriptions); NGOs and communities (through campaigns); the government through hospitals and clinics; and exports Vaccines are always prophylactic and not therapeutic; hence, the target customer is always a healthy individual.
		2	The doctors' prescriptions segment is a smaller market, especially for adult vaccines; NGOs or community campaigns

			for recurring diseases such as hepatitis, COVID, etc. For the larger market segment, government procurement for childhood vaccines and traveller's vaccines; and for international business or exports.
		3	Doctor's prescriptions—retailer dispensing; NGOs and communities through campaigns; exports for international markets.
		4	Veterinary doctor prescriptions or dispensing; government-run disease control programs; exports
	How vaccine companies classified	1	Research to market companies with a focus on government or government and exports MNCs research to market is always retail focused. Manufacturing / Marketing Organization - Retail / Government / Exports.
		2	Exports. Exports and government supplies Exports, Retail, and Government Supplies Retail and government supplies Retail only.
		3	High Research to Market and Revenues Low Research to Market and Revenues High Research to Market and Low Revenues Low research to Market and High Revenues

		4	Exclusive Vaccine companies (Either Animal / Human vaccines or both.) Vaccines with pharma and other diversified areas
	Rating system for vaccines.	1	CRISIL rating is already available
		2	Rating done as per revenues and Profitability.
		3	Rating as per PE ratio and Research to Market efficiency.
		4	Dimensions may be used, such as market capitalization, research pipeline, revenues, profitability, assets, and liabilities.
Marketing Challenges	Ideal marketing approach for vaccines in India	1	Contract manufacturing, Government and Exports business
		2	Retail, Government and Exports business
		3	Retail, Government and Exports business
		4	Government and Exports business
	Vaccine business – marketing challenges	1	In India, the biggest challenge is updating or discovering disruptive technologies, which are already in vogue in advanced countries. Advocating quick changes in government and local markets. For this change to be adopted in the Indian market, it would take 5–10 years, and existing manufacturing systems and regulatory mechanisms may or may not support the changes.

		2	Raw material availability on time and regulatory hurdles, besides consistent manufacturing to keep the cash flows right. Although the Government of India buys vaccines based on local content (above 80% local content to be an A-class manufacturer for government supplies and above 50% local content to be a B-class Class). Getting local content above 80% is a big challenge, considering many critical consumables are imported.
		3	Marketing vaccines in retail is tough due to consumer attitudes towards preventive vaccination and the mindset to avail of government supplies, which come at no cost.
		4	Meet timelines for supplies to large Government and exports orders.
Others	Parameters to judge the health of vaccine business	1	1. No of new research / innovation-based products introduced every year and research pipeline. 2. Revenues and Cash flow 3. High economies of scale due to higher production capacities 4. High regulatory compliances
		2	1. 80% utilization of capacities 2. Better PE ratio and Cash flow 3. PBT and assets are in healthy ratio

		3	1. Higher value of the brands 2. No critical deviations in vaccine regulatory compliances and research timelines. 3. First mover advantage with innovative research
		4	1. To achieve zero issues or constraints on manufacturing and Quality depts.
	Questionnaire		Separate questionnaire responses

- Above inputs are compiled for the determination of business process and a comparison of the process flow between vaccine and pharmaceuticals.
- This also validates the customer selection process since the Indian vaccine industry is more dependent on “made to order” instead of “Creating a niche” market.
- It also suggests rating system based on “Research to market” along with “Revenues” instead of mere revenue stratification.
- This discussion also gives a ringside view of the regulatory classifications and other views.
- Views and opinions on the process are valuable and helped in making these inferences after validating with other methods of research.

APPENDIX -7: QUESTIONNNAIRE RESPONSES

Table-15: RESPONDERS

RESPONDER / Company	DESIGNATION	CATEGORY
1	Deputy Managing Director	Human and Animal Vaccines
2	Senior Vice President	Human Vaccines
3	Vice President Marketing	Animal Vaccines
4	Chief Executive Officer	Animal Vaccines
5	Lead Regulatory Affairs	Human Vaccines
6	Associate Director	Animal Vaccines
7	Chief Executive Officer	Human Vaccines

It is a perfect mix of responders, with three from human health, three from animal health, and one from human and animal health. Six samples out of 23 PSU were selected for analysis. This is in line with 25% sampling other than state units.

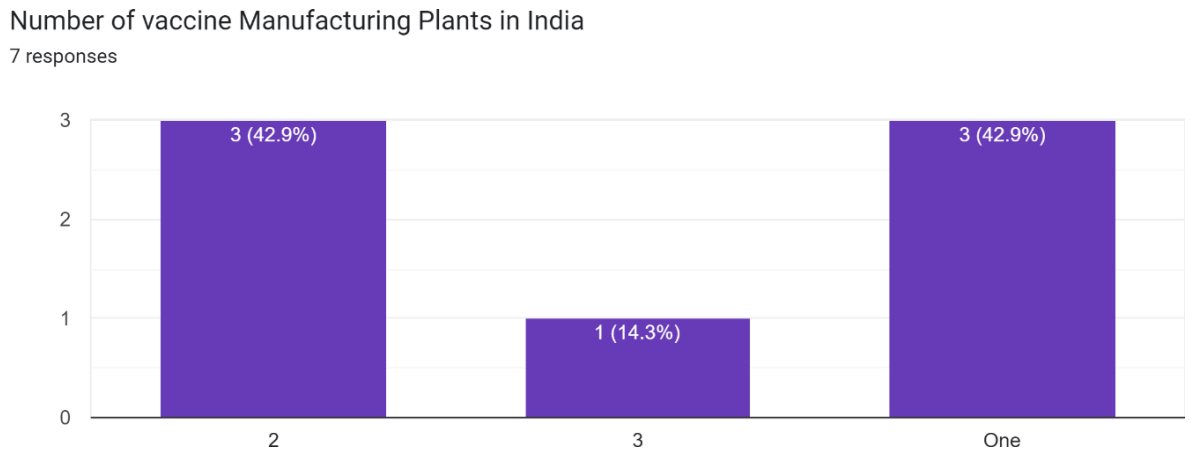
Table-16: Percentage Responders

	Total	CEO	Director	SVP	VP/Lead
No of Responders	7	2	2	1	2
%age	100%	29%	29%	14%	29%

APPENDIX-8: QUESTIONNAIRE RESPONSE

Question: Number of Vaccine manufacturing companies in India.

Fig-26: Vaccine manufacturing plants operated by responders.



A decent mix of one or more vaccine manufacturing units managed by the responders. 3 responders managing 1 unit; 1 responder having 3 units; and 3 responders having 2 each.

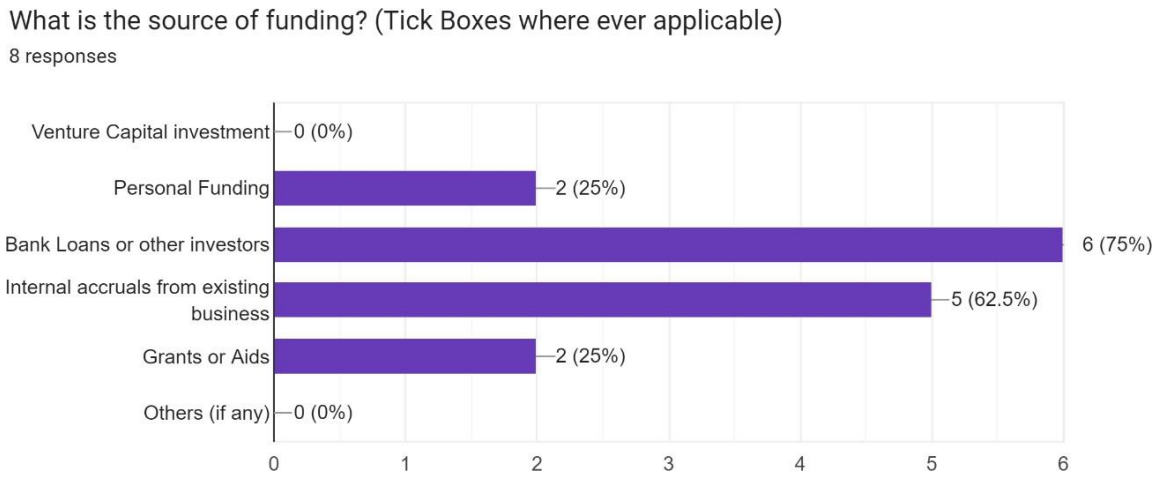
Question: What kind of initial input or resource was accessible to your firm before making diligence on investment in vaccine manufacturing? (Tick boxes wherever applicable.)

Fig-27: Investment decision by responders

Fig-28: Funding source of responders

62.5% Identified customers, technology, and products prior to investment decision.

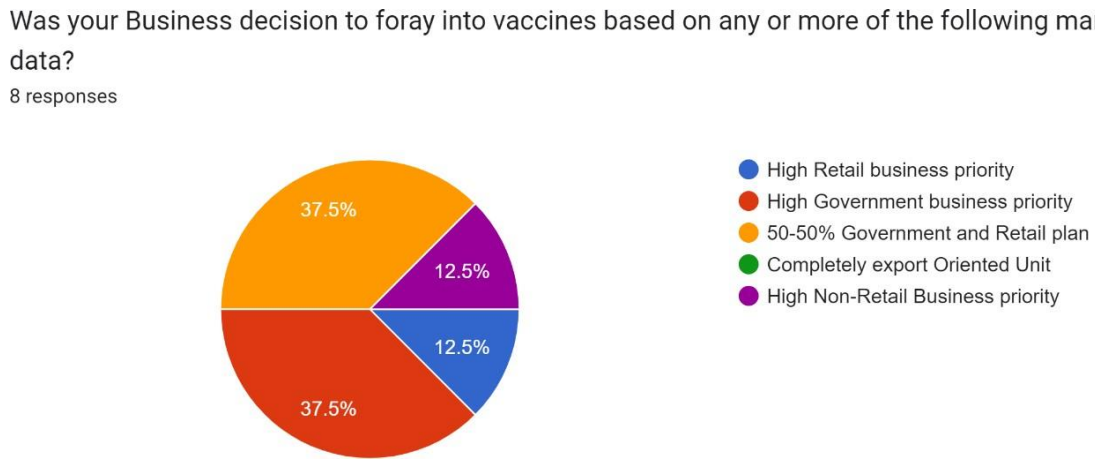
Question: What is the source of funding?



Bank loans and internal accruals from existing business has been the source of funding for 75% of the responders.

Question: Was your business decision to foray into vaccines based on any or more of the following market data?

Fig-29: Business decision to foray into vaccine by responders.



More than 50% agree that the priority was for Government and Non-retail business and another 37.5% have both retail and Government supplies plan.

APPENDIX-9: FINANCIAL DATA

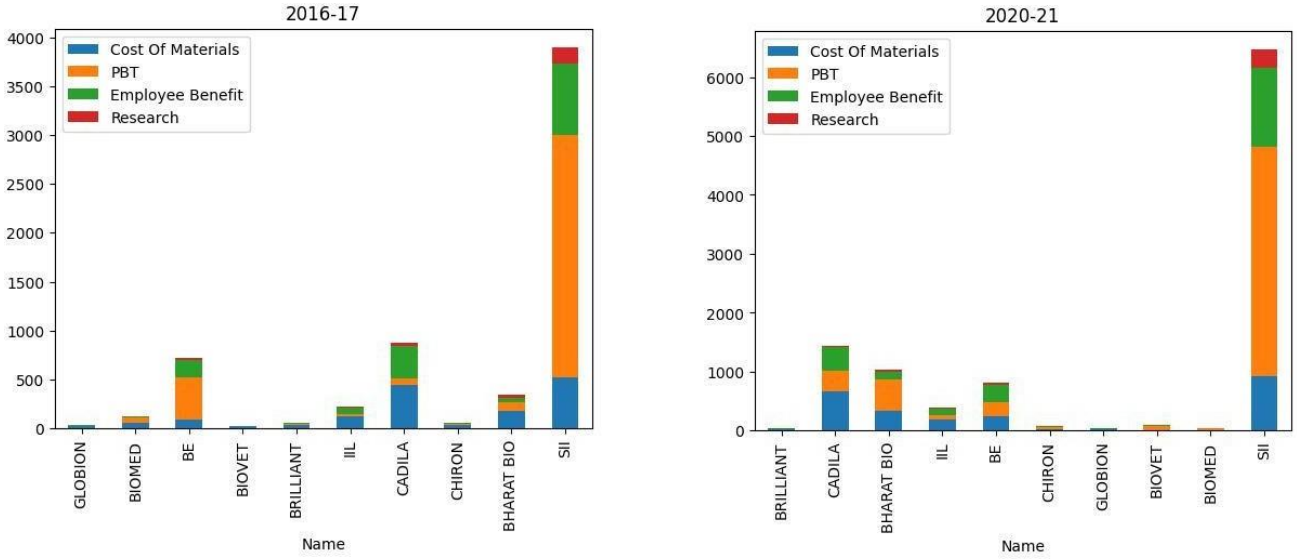
The Proft and Loss Statement and Balance Sheets are sourced from Ministry of Corporate Affairs, Government of India.

PROFIT AND LOSS STATEMENTS

A comparison of the P&L statement comprising of Cost of Materials, Profit Before Taxes, Revenues, Employee Benefits and Research Expenditure is made for the industry for the year 2016-17 and 2020-21.

Name of the company in X Axis and Rs in Crores in Y Axis.

Fig-30: Comparison of Cost of Materials, Employee Benefits, Profit Before taxes and R&D expenditure from Year-1 (2016-17) to Year-5 (2020-21) for vaccine manufacturers



Comparison of Sales Turnover with other key parameters from 2016-17 to 2020-21. There is no change bin the leadership in the industry, but there are changes in the “Cost of materials” and “Cost of Employee Benefits.” This also has resulted in the change in “Profit Before Taxes.”

Serum Institute India has the highest operating revenues and Profit Before taxes considering that this manufacturer is a vaccine manufacturer, Sanvita has the lowest Profit Before Taxes.

Table-17: Vaccine companies revenue details for 2020-21

2020-21 (In Rupees Crores)	Total Revenues	PBT	Cost Of Materials	Employee Benefit	Research
SII	8335	3891	919	1350	303
DANO	28.63	7.49	6.01	6.57	0
CHIRON	121.12	32.31	31.7	18.2	0
CADILA	2370.9	345	675.7	396.6	23.42
SANVITA	0.04	-6.18	0.37	1.29	
INDOVAX	81.01	17.13	20.35	21.88	2.21
IIL	747.7	68.5	193.99	108.2	12.5
GREEN SIGNAL	28.51	6.38	8.86	5.03	0
GLOBION	96.55	10.59	19.65	11.58	1.77
BRILLIANT	75.83	0.68	29.87	10.1	0.92
BIOVET	129.54	73.89	14.57	10.88	0.84
BE	1418.07	245.05	238.66	297.65	32.42
BIOMED	48.1	27.6	8.06	6.63	0
BHARAT BIO	1439	536.5	339.4	115.1	35.3

APPENDIX-10: VACCINE COMPANY WISE PERFORMANCE FROM 2016-17 TO 2020-21

Company wise Performance from 2016-17 to 2020-21 in terms of critical ratios such as Cost of Materials (COM); Profit Before Taxes (PBT); Employee Benefit (EB); Research Expenses which drives the profits consistently is given as under.

Fig-31: SERUM INSTITUTE OF INDIA

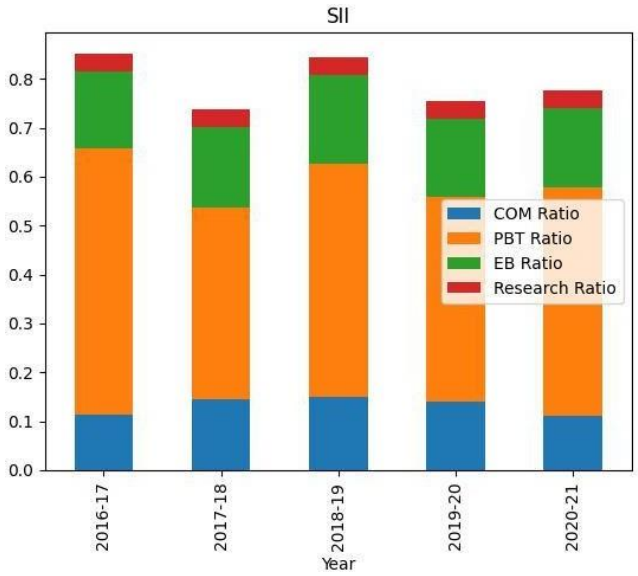


Fig-32: BIOLOGICAL EVANS LIMITED

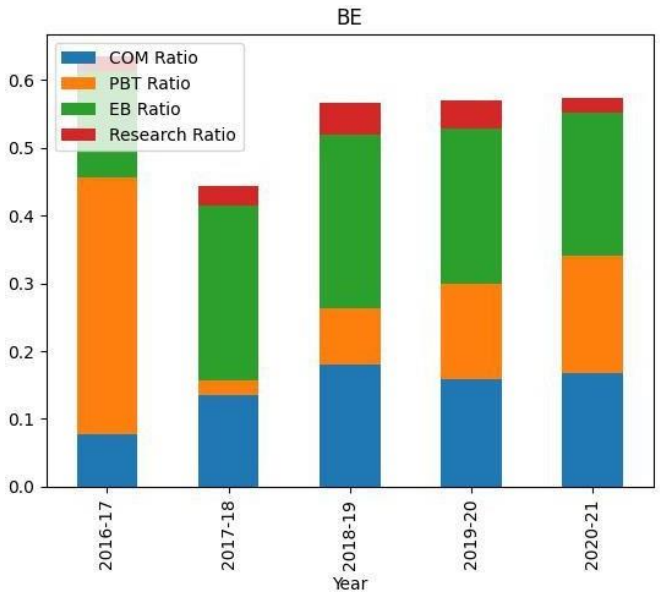


Fig-33: BHARAT BIOTECH PRIVATE LIMITED

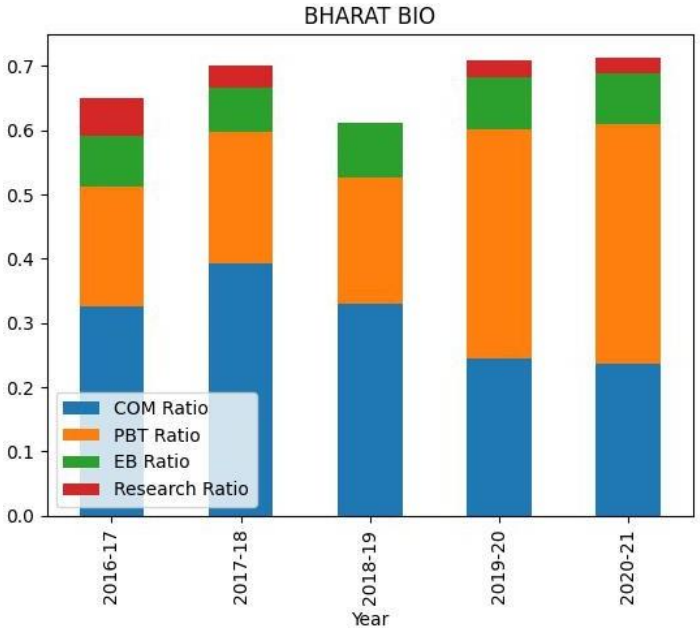


Fig-34: BIOMED LIMITED

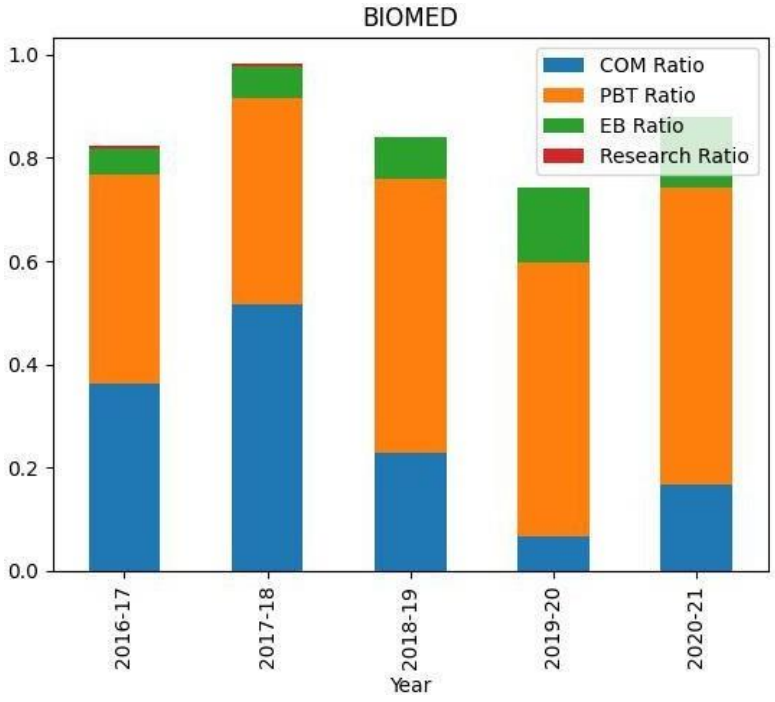


Fig-35: BIOVET PRIVATE LIMITED

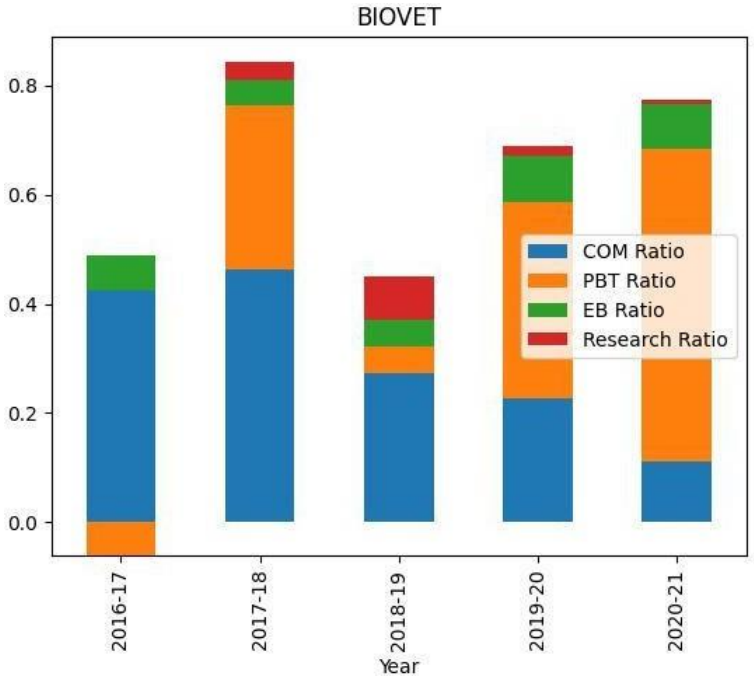


Fig-36: BRILLIANT BIO PHARMA PRIVATE LIMITED

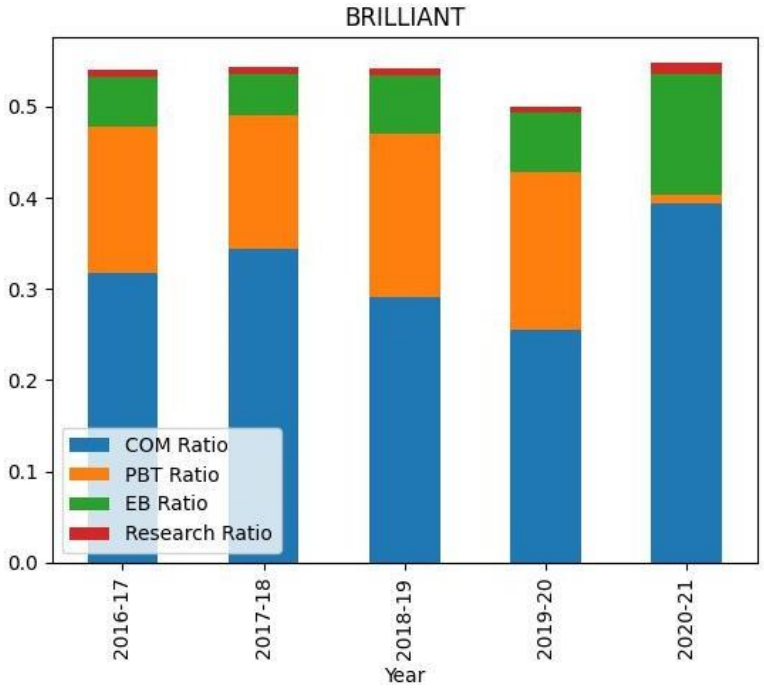


Fig-37: CADILA PHARMACEUTICALS

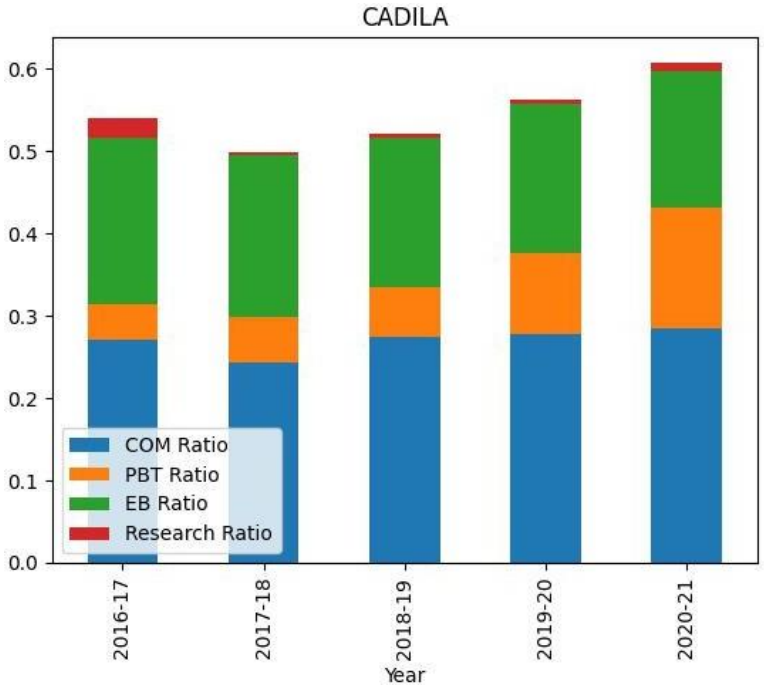


Fig-38: CHIRON BEHRING

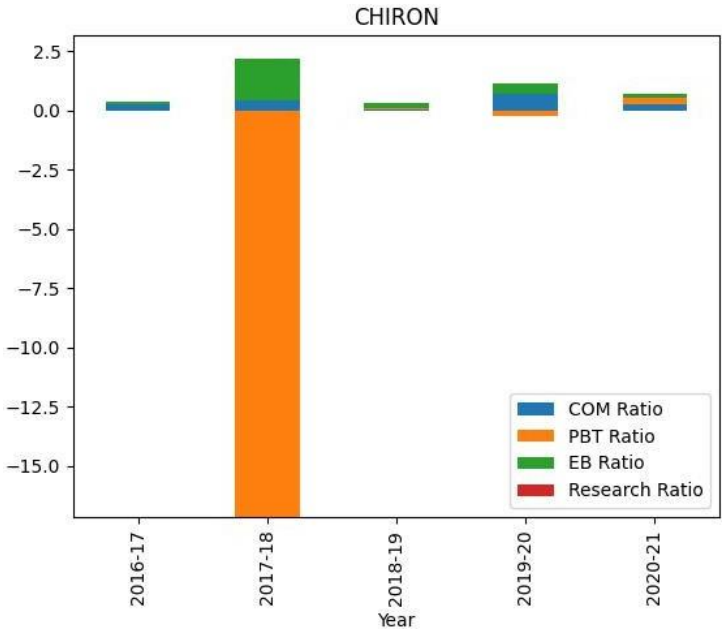


Fig-39 DANO

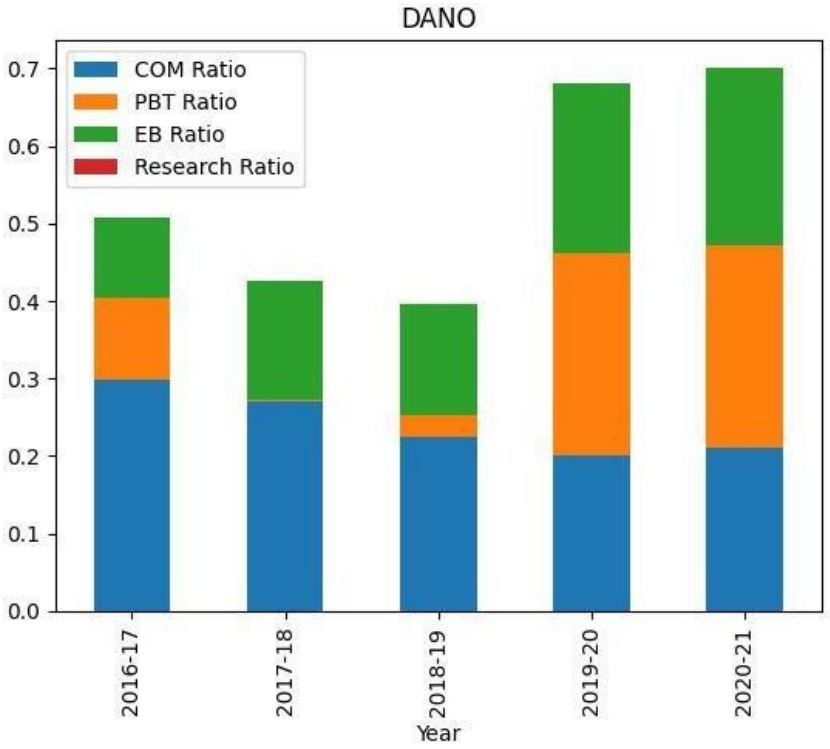


Fig-40: GLOBION

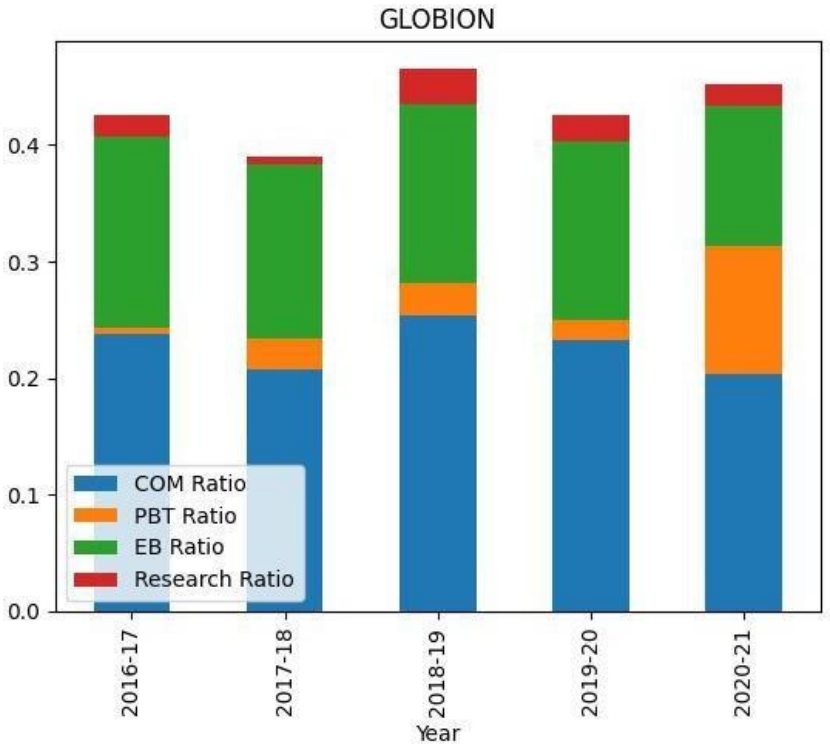


Fig-41: GREEN SIGNAL

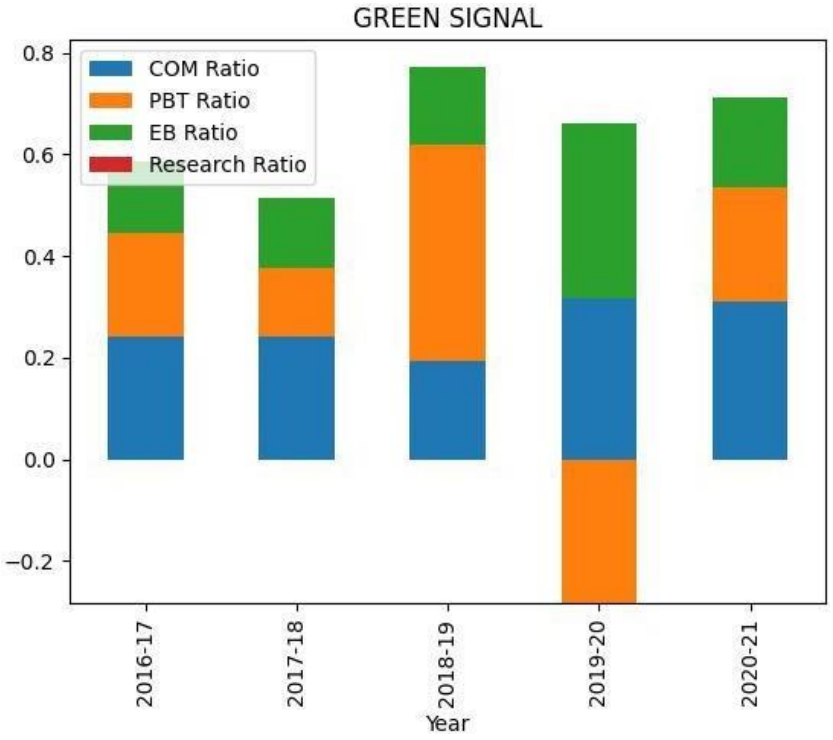


Fig-42: HLL BIOTECH

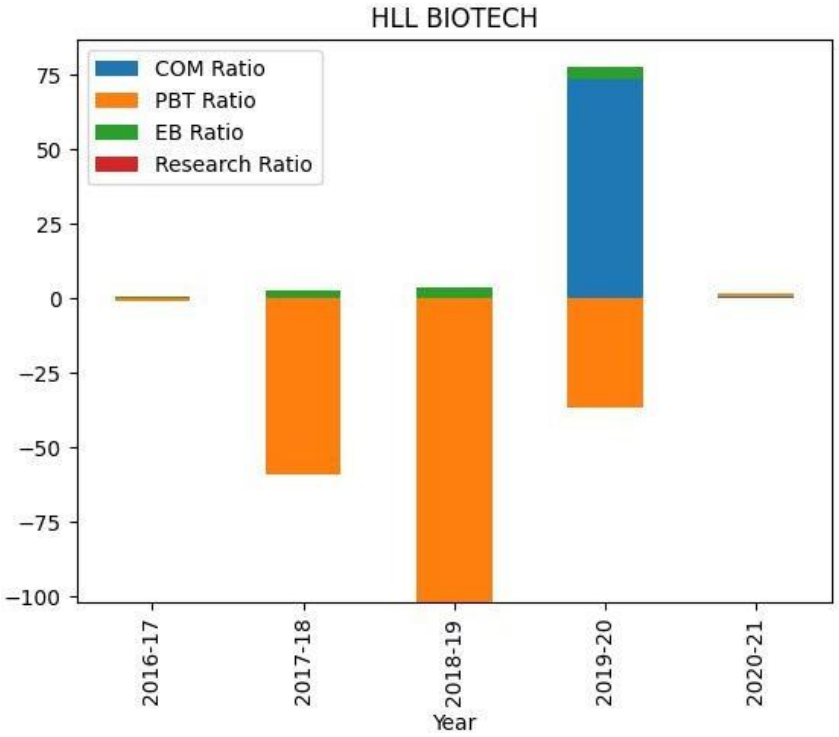


Fig-43: INDIAN IMMUNOLOGICALS LIMITED

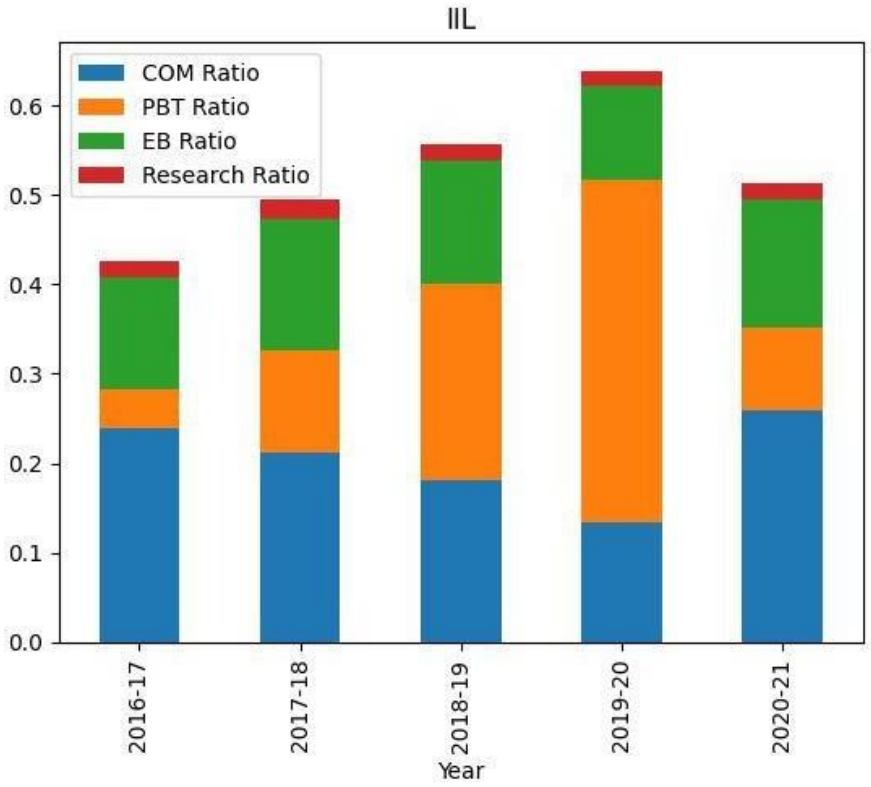


Fig-44: INDOVAX PRIVATE LIMITED

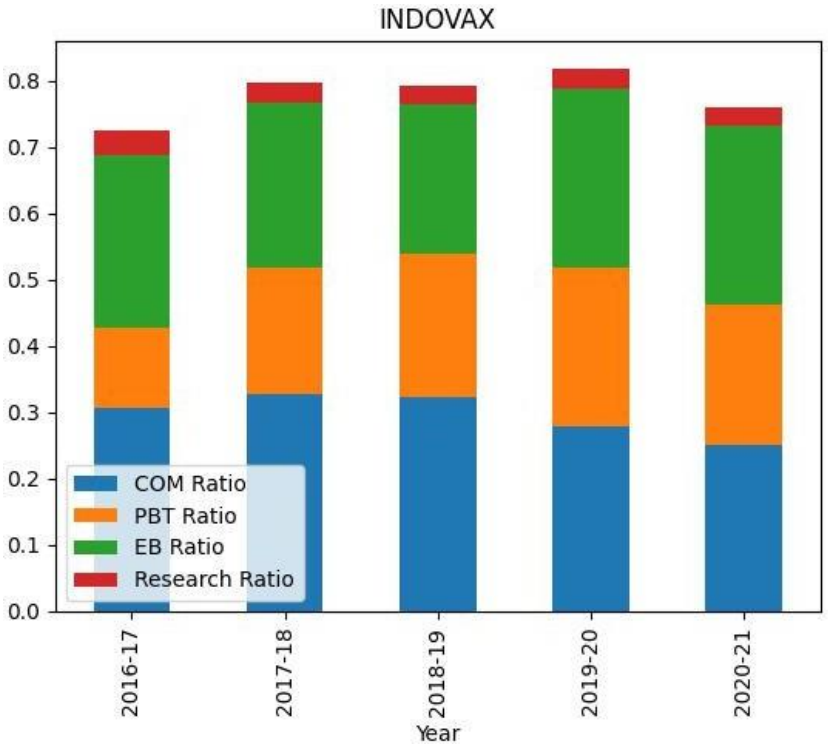


Fig-45: SANVITA BIOTECHNOLOGIES

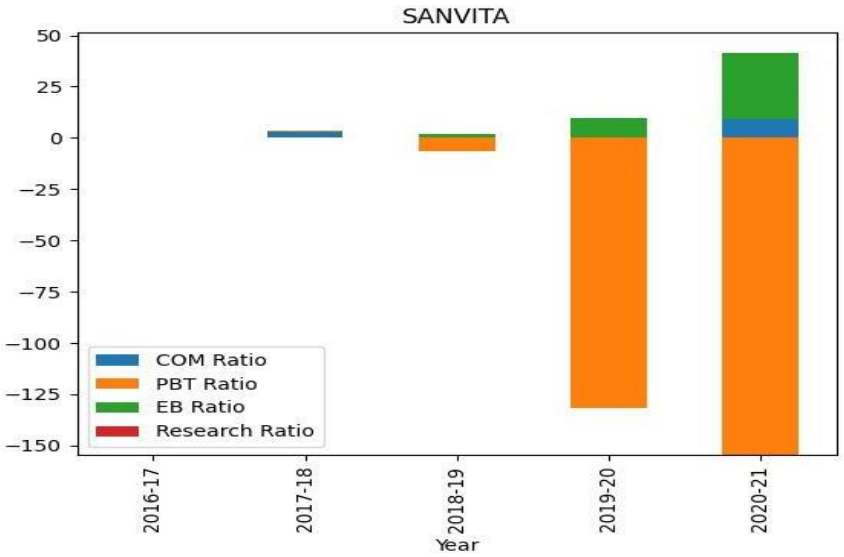


Table-18: SUMMARY OF PBT (%AGE) FOR VACCINE COMPANIES

2020-21	Total Revenues (In Rs Crores)	PBT	%age
SII	8335	3891	47%
DANO	28.63	7.49	26%
CHIRON	121.12	32.31	27%
CADILA	2370.9	345	15%
SANVITA	0.04	-6.18	-15450%
INDOVAX	81.01	17.13	21%
IIL	747.7	68.5	9%
GREEN SIGNAL	28.51	6.38	22%
GLOBION	96.55	10.59	11%
BRILLIANT	75.83	0.68	1%
BIOVET	129.54	73.89	57%
BE	1418.07	245.05	17%
BIOMED	48.1	27.6	57%
BHARAT BIO	1439	536.5	37%

APPENDIX 11: PHARMECEUTICAL COMPANIES FINANCIALS

Table-19: Critical Financials of Pharmaceutical companies in India in Rs Crores

	Company	Particulars	2016-17	2017-18	2018-19	2019-20	2020-21
1	SUN Pharma	Revenue from operations	31,578.44	26,489.46	29,065.91	32,837.50	33,498.14
	SUN Pharma	Revenue from other income	623.15	838.76	1,025.49	635.98	835.52
	SUN Pharma	Material Cost	8,130.74	7,424.68	7,868.97	9,230.45	8,690.08
	SUN Pharma	PBT	9,047.87	3,478.98	3,810.20	5,009.59	2,799.37
	SUN Pharma	Employee Cost	4,902.30	5,367.05	5,967.09	6,362.35	6,862.23
	SUN Pharma	R&D Cost	2,102.43	2,052.09	1,905.71	1,920.62	2,097.21
2	Divis	Revenue from operations	4,106.26	3,912.78	4,946.26	5,394.42	6,969.40
	Divis	Revenue from other income	74.89	113.44	155.63	189.63	62.53
	Divis	Material Cost	1,534.00	1,534.06	1,825.22	2,108.54	2,324.08
	Divis	PBT	1,395.34	1,231.33	1,855.07	1,819.46	2,666.04
	Divis	Employee Cost	468.74	456.06	542.27	621.05	825.76
	Divis	R&D Cost	43.12	31.77	34.89	38.23	51.01
3	Dr Reddy's	Revenue from operations	14,196.10	14,281.00	15,448.20	17,517.00	19,047.50
	Dr Reddy's	Revenue from other income	171.50	155.20	337.50	620.60	291.40
	Dr Reddy's	Material Cost	3,444.90	4,039.50	4,494.80	5,554.40	6,078.90
	Dr Reddy's	PBT	1,553.70	1,350.40	2,292.00	1,885.70	2,883.50
	Dr Reddy's	Employee Cost	3,107	3,215	3,356	3,380	3,630
	Dr Reddy's	R&D Cost	1,865.80	1,739.20	1,438.90	1,469.60	1,546.80
4	Cipla	Revenue from operations	14,630.24	15,219.25	16,362.41	17,131.99	19,159.59
	Cipla	Revenue from other income	228.69	357.65	476.57	344.2	265.99
	Cipla	Material Cost	5,317.12	5,438.42	5,784.49	5,991.42	7,351.89
	Cipla	PBT	1222.17	1,669.46	2,079.14	2,178.18	3,290.06
	Cipla	Employee Cost	2,633.82	2,690.10	2,856.53	3,027.01	3,251.83
	Cipla	R&D Cost	1,030.57	980.24	1,047.55	1,021.33	791.05

5	Torrent	Revenue from operations	5,856.92	6,002.07	7,672.80	7,939.31	8,004.83
	Torrent	Revenue from other income	223.3	298.84	57.05	121.3	56.65
	Torrent	Material Cost	1,791.66	1,673.47	2,219.69	2,166.92	2,146.42
	Torrent	PBT	1,088.09	931.01	561.66	1,186.57	1,526.26
	Torrent	Employee Cost	993.41	1,135.25	1,403.79	1,429.04	1,439.62
	Torrent	R&D Cost	432.00	460.00	538.00	494.00	487.00
6	Zydus	Revenue from operations	9,625.30	11,936.40	13,165.60	14,253.10	15,102.20
	Zydus	Revenue from other income	128.60	113.20	201.10	113.90	37.20
	Zydus	Material Cost	3,445.10	4,122.00	4,716.40	4,920.00	5,210.10
	Zydus	PBT	1,611.90	2,330.80	2,382.10	1,495.40	2,284.80
	Zydus	Employee Cost	1,500.20	1,854.50	2,124.10	2,414.50	2,490.20
	Zydus	R&D Cost	665.30	690.00	748.20	850.10	918.40
7	Abbott	Revenue from operations	2,938.69	3,307.12	3,678.60	4,093.14	4,310.02
	Abbott	Revenue from other income	57.64	116.99	113.29	114.39	80.90
	Abbott	Material Cost	1,712.07	1,904.74	2,088.00	2,314.00	2,391.00
	Abbott	PBT	436.49	621.48	698.85	802.69	925.95
	Abbott	Employee Cost	345.27	393.69	435.58	476.11	492.65
	Abbott	R&D Cost	0.80	0.70	0.68	0.81	1.08
8	Aurobindo	Revenue from operations	15,089.86	16,499.83	19,563.55	23,098.51	24,774.62
	Aurobindo	Revenue from other income	115.89	101.98	155.32	191.87	380.85
	Aurobindo	Material Cost	6,434.26	6,752.74	8,712.64	9,735.23	9,902.47
	Aurobindo	PBT	3,060.84	3,241.18	3,091.35	3,743.04	7,343.59
	Aurobindo	Employee Cost	1,767.76	2,130.84	2,584.87	3,219.18	3,535.02
	Aurobindo	R&D Cost	590.40	649.15	753.70	761.60	840.40
9	Alkem	Revenue from operations	5,852.50	6,431.18	7,357.19	8,344.36	8,865.01
	Alkem	Revenue from other income	112.01	95.95	87.70	104.22	233.21
	Alkem	Material Cost	2,221.53	2,512.90	2,944.97	3,344.94	3,498.46

	Alkem	PBT	964.63	925.98	954.66	1,259.79	1,842.10
	Alkem	Employee Cost	1,003.85	1,191.64	1,362.46	1,505.49	1,621.03
	Alkem	R&D Cost	320.37	364.62	462.15	472.57	532.21
10	Lupin	Revenue from operations	17,494.33	15,804.15	16,718.18	15,374.76	15,162.96
	Lupin	Revenue from other income	106.51	150.35	364.02	483.76	136.29
	Lupin	Material Cost	5,001.43	5,274.40	5,845.79	5,430.60	5,362.24
	Lupin	PBT	3,543.14	546.81	1,517.17	757.23	1,676.45
	Lupin	Employee Cost	2,849.52	2,864.71	3,151.29	2,986.84	2,825.90
	Lupin	R&D Cost	2,794.57	1,843.07	1,582.84	1,507.16	1,432.42

Fig-46: ABBOTT LIMITED

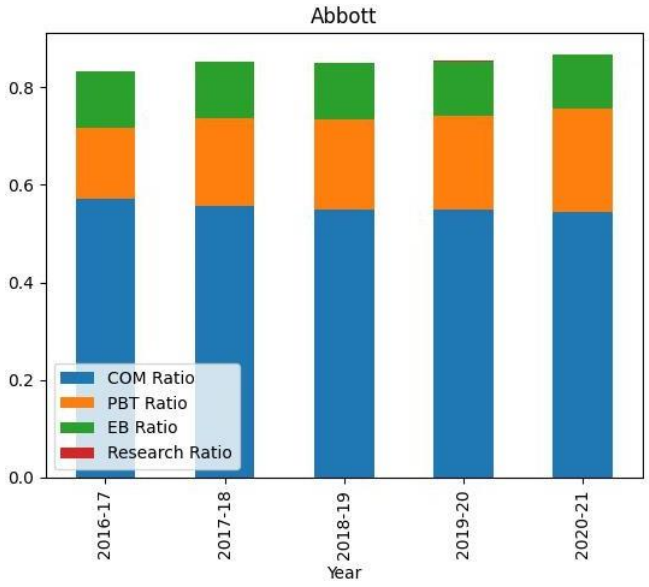


Fig-47: SUN PHARMA

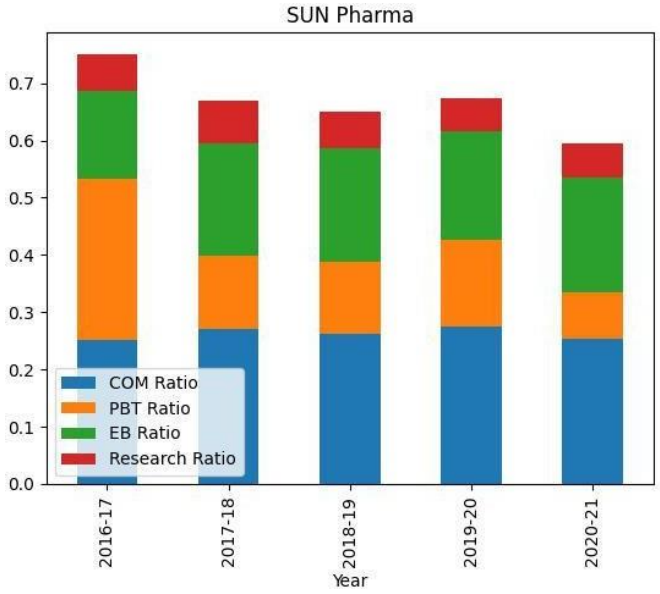


Fig-48: ALKEM LABORATORIES

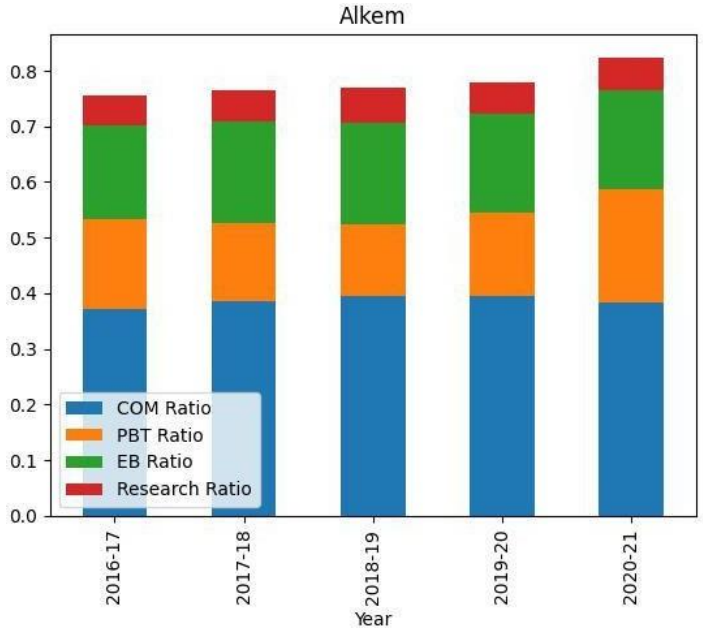


Fig-49: AUROBINDO PHARMA

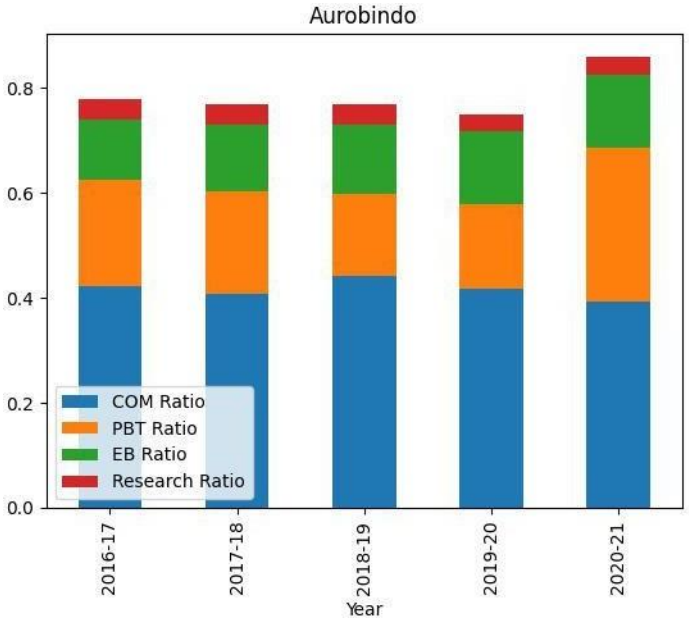


Fig-50: CIPLA LIMITED

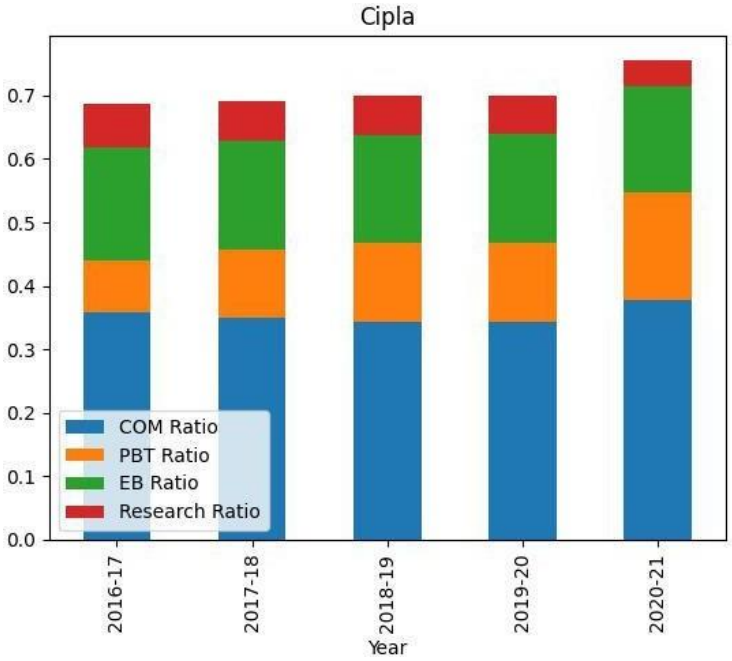


Fig-51: DIVIS LABORATORIES

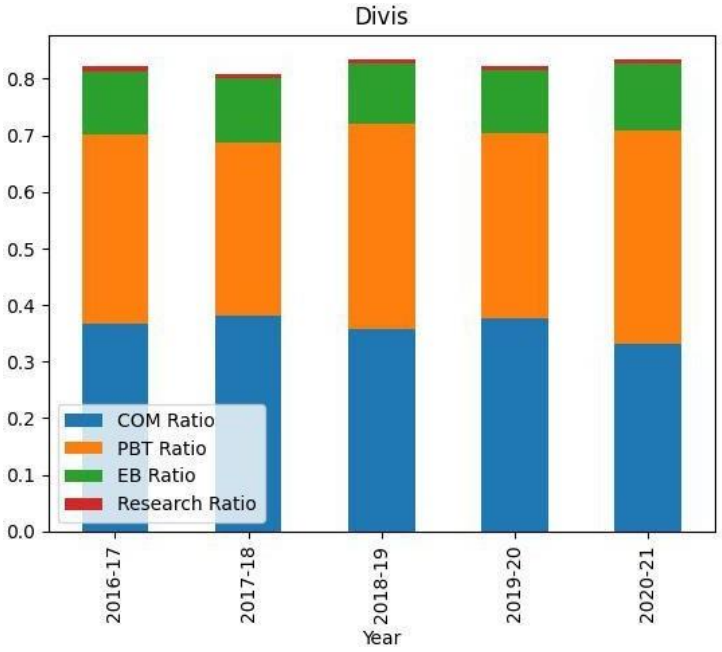


Fig-52: Dr REDDY'S LABORATORIES

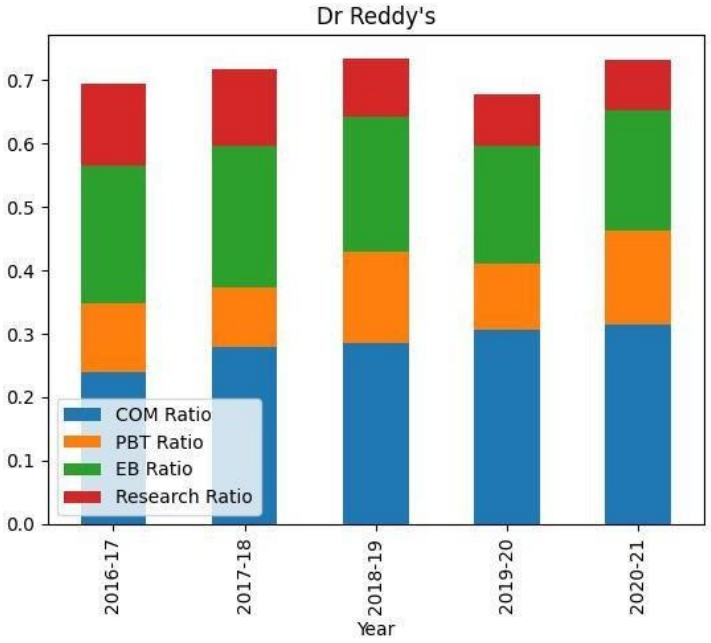


Fig-53: LUPIN LABORATORIES LIMITED

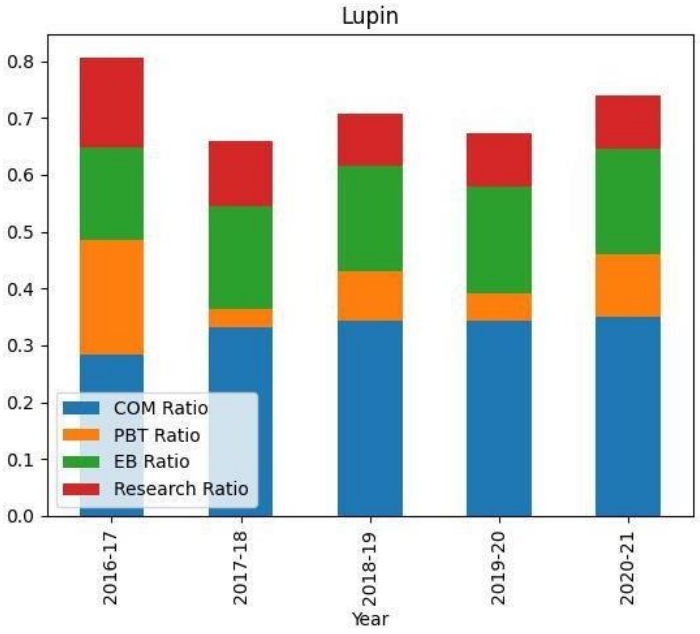


Fig-54: TORRENT PHARMA

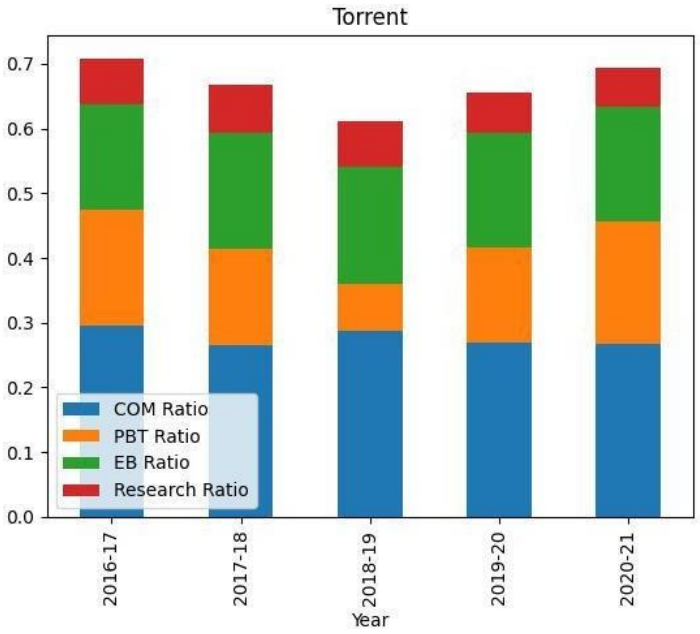
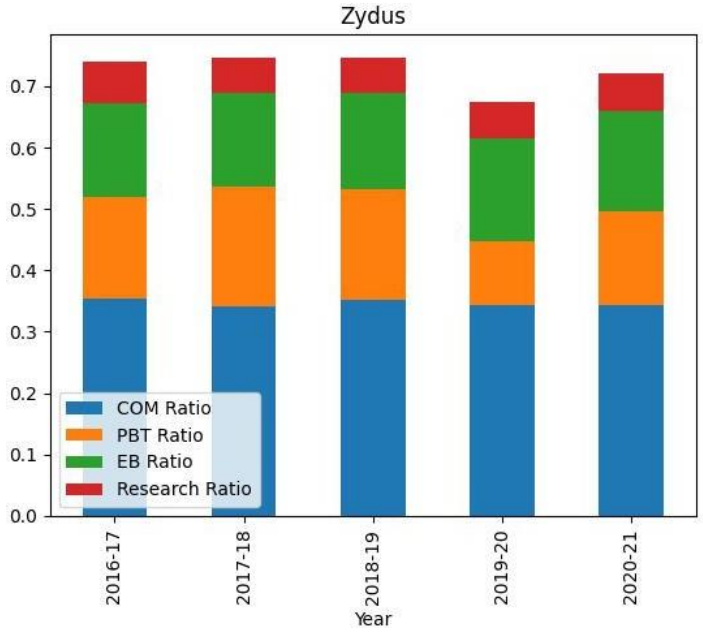


Fig-55: ZYDUS



YEAR WISE COMPARISION OF PHARMA COMPANIES

Comparison of Pharma companies on turnover / revenues in Rs Crores and ratios for the year 2016-17 with 2020-21

Fig-56: Top 10 Pharma companies in 2016-17

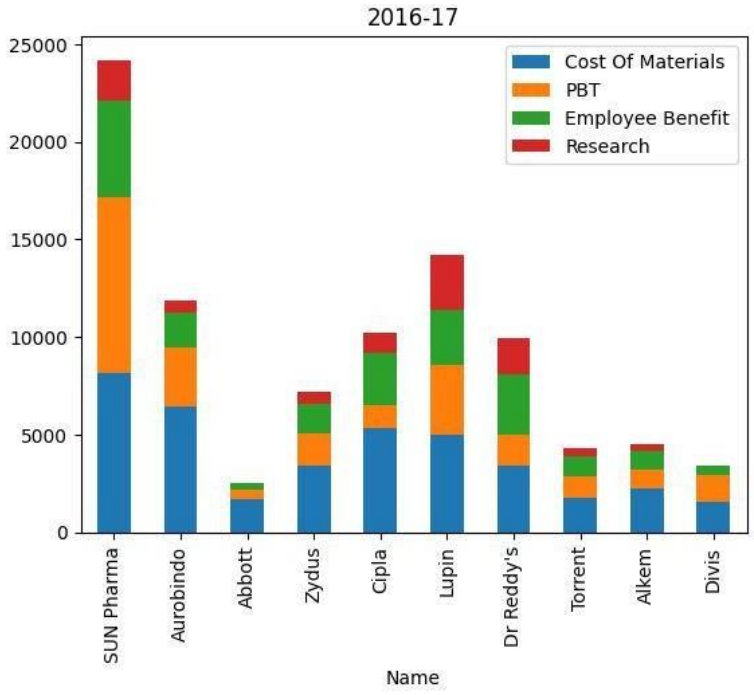


Fig-57: Top 10 Pharma companies in 2016-17 ratios

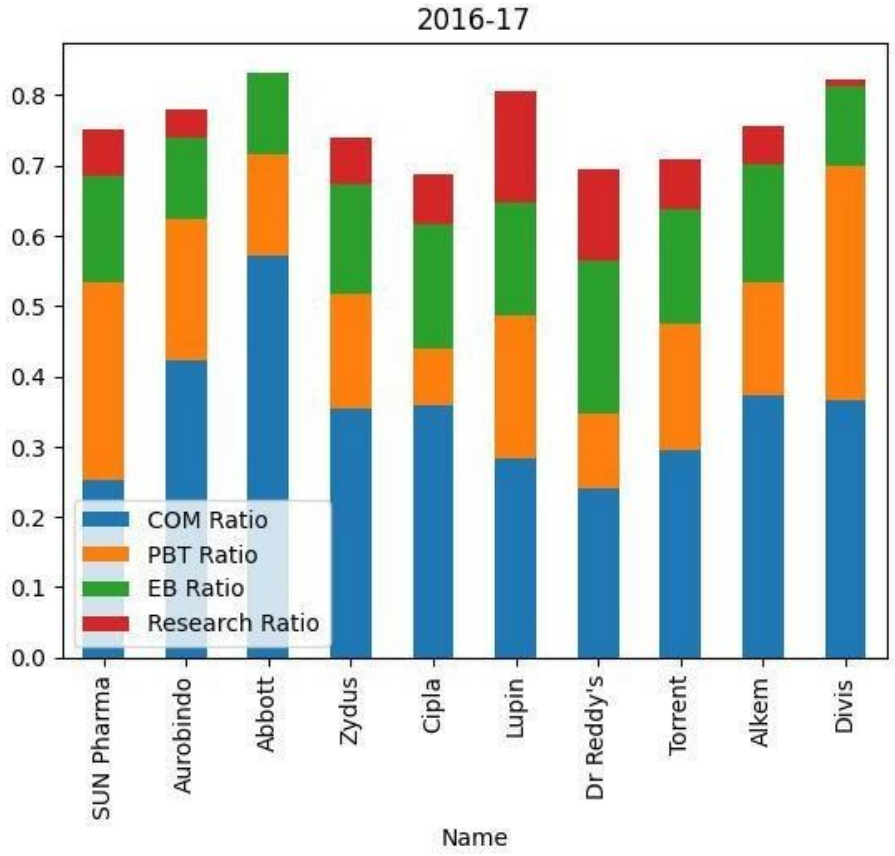


Fig-58: Top 10 Pharma companies in 2020-21

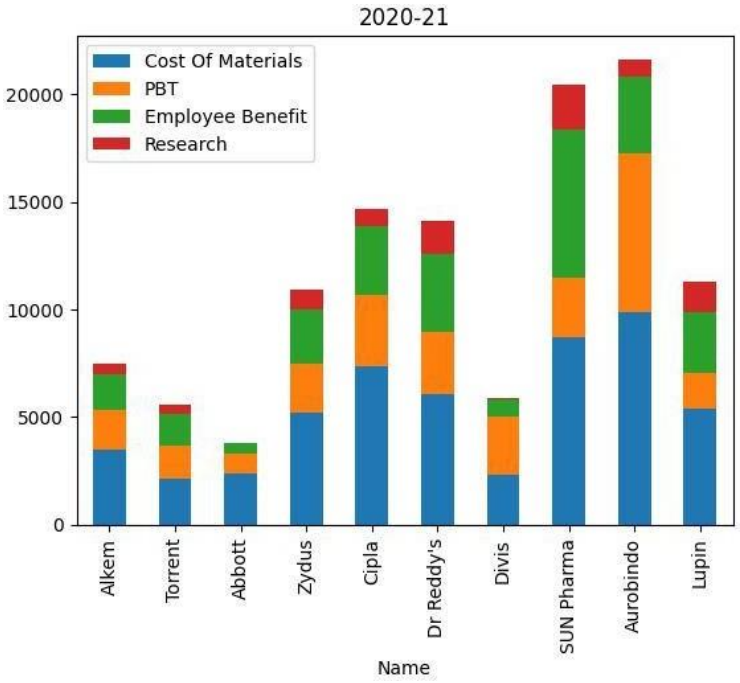
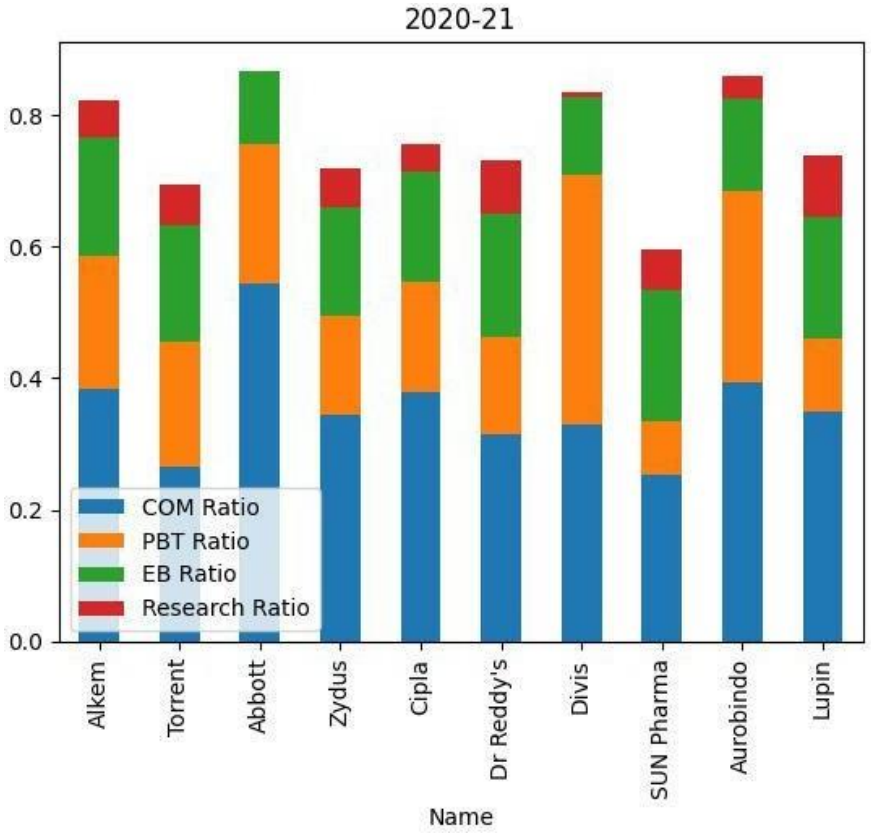


Fig-59: Top 10 Pharma companies in 2020-21 ratios


2020-21
0.0
0.2
0.4
0.6
0.8
COM Ratio
PBT Ratio
EB Ratio
Research Ratio
Alkem
Torrent
Abbott
Zydus
Cipla
Dr Reddy's
Divis
SUN Pharma
Aurobindo
Lupin
Name

APPENDIX-12: VACCINE MANUFACTURERS – PROFIT AND LOSS STATEMENTS (IN RS CRORES)

Table-20: Vaccine companies revenue status

		2020-21	2019-20	2018-19	2017-18	2016-17
SII	Total Revenues	8335	5372	5165	4839	4571
	PBT	3891	2252	2463	1908	2486
	Cost Of Materials	919	750	768	695	516
	Employee Benefit	1350	853	942	787	725
	Research	303	195	188	176	166
		2020-21	2019-20	2018-19	2017-18	2016-17
HLL BIOTECH	Total Revenues	43.99	0.27	0.41	0.56	4.54
	PBT	25.52	-9.86	-41.82	-33.22	-4.71
	Cost Of Materials	36.65	19.83	0.00	0.00	0.00
	Employee Benefit	8.33	1.19	1.51	1.39	2.28
	Research	0.00	0.00	0.00	0.00	0.00
		2020-21	2019-20	2018-19	2017-18	2016-17
DANO	Total Revenues	28.63	23.05	13.49	9.99	12.94
	PBT	7.49	6.00	0.38	0.02	1.39
	Cost Of Materials	6.01	4.64	3.02	2.71	3.85
	Employee Benefit	6.57	5.03	1.95	1.53	1.32
	Research	0.00	0.00	0.00	0.00	0.00
		2020-21	2019-20	2018-19	2017-18	2016-17
CHIRON	Total Revenues	121.12	38.56	84.19	10.63	146.90
	PBT	32.31	-8.14	5.27	-182.22	4.78
	Cost Of Materials	31.70	27.26	2.30	4.62	36.36
	Employee Benefit	18.20	17.30	19.03	18.65	14.97
	Research	0.00	0.00	0.00	0.00	0.00

		2020-21	2019-20	2018-19	2017-18	2016-17
CADILA	Total Revenues	2370.90	2107.40	1862.60	1699.00	1624.85
	PBT	345.00	206.90	112.90	94.50	67.91
	Cost Of Materials	675.70	583.90	510.00	411.70	441.35
	Employee Benefit	396.60	382.80	338.20	333.80	330.07
	Research	23.42	10.86	8.40	6.80	37.71
		2020-21	2019-20	2018-19	2017-18	2016-17
SANVITA	Total Revenues	0.04	0.13	0.12	0.11	0.45
	PBT	-6.18	-17.12	-0.76	0.005	0.027
	Cost Of Materials	0.37			0.36	
	Employee Benefit	1.29	1.28	0.2	0.03	0.11
	Research					
		2020-21	2019-20	2018-19	2017-18	2016-17
INDOVAX	Total Revenues	81.01	76.01	77.47	64.78	55.71
	PBT	17.13	18.18	16.83	12.29	6.74
	Cost Of Materials	20.35	21.20	24.96	21.29	17.07
	Employee Benefit	21.88	20.53	17.41	16.14	14.48
	Research	2.21	2.32	2.15	1.92	2.07
		2020-21	2019-20	2018-19	2017-18	2016-17
IIL	Total Revenues	747.70	906.60	613.10	503.90	510.50
	PBT	68.50	346.90	133.60	57.50	22.20
	Cost Of Materials	193.99	122.20	111.50	107.00	122.00
	Employee Benefit	108.20	94.90	84.90	74.30	63.70
	Research	12.50	14.80	10.80	10.70	9.90
		2020-21	2019-20	2018-19	2017-18	2016-17
GREEN SIGNAL	Total Revenues	28.51	15.01	30.88	30.69	27.80
	PBT	6.38	-4.24	13.12	4.10	5.62

	Cost Of Materials	8.86	4.75	5.99	7.45	6.74
	Employee Benefit	5.03	5.18	4.74	4.27	3.97
	Research	0.00	0.00	0.00	0.00	0.00
		2020-21	2019-20	2018-19	2017-18	2016-17
GLOBION	Total Revenues	96.55	113.55	103.22	98.44	79.90
	PBT	10.59	2.05	2.84	2.62	0.43
	Cost Of Materials	19.65	26.36	26.21	20.37	19.00
	Employee Benefit	11.58	17.30	15.83	14.76	13.10
	Research	1.77	2.64	3.17	0.59	1.45
		2020-21	2019-20	2018-19	2017-18	2016-17
BRILLIANT	Total Revenues	75.83	168.88	150.98	151.00	106.20
	PBT	0.68	29.13	27.00	22.08	17.07
	Cost Of Materials	29.87	43.12	43.91	51.86	33.71
	Employee Benefit	10.10	11.10	9.70	6.86	5.77
	Research	0.92	0.99	1.21	1.22	0.79
		2020-21	2019-20	2018-19	2017-18	2016-17
BIOVET	Total Revenues	129.54	112.13	83.46	67.98	43.22
	PBT	73.89	40.37	4.26	20.27	-2.61
	Cost Of Materials	14.57	25.37	22.70	31.57	18.39
	Employee Benefit	10.88	9.64	3.98	3.26	2.78
	Research	0.84	1.99	6.61	2.26	0.00
		2020-21	2019-20	2018-19	2017-18	2016-17
BE	Total Revenues	1418.07	1076.36	952.63	810.14	1137.53
	PBT	245.05	151.25	79.23	17.38	431.74
	Cost Of Materials	238.66	171.11	171.39	108.91	88.21
	Employee Benefit	297.65	245.73	244.29	209.39	178.67
	Research	32.42	45.44	43.82	23.99	23.92

		2020-21	2019-20	2018-19	2017-18	2016-17
BIOMED	Total Revenues	48.10	44.27	100.61	144.61	143.92
	PBT	27.60	23.53	53.30	57.84	57.99
	Cost Of Materials	8.06	2.93	22.96	74.68	52.24
	Employee Benefit	6.63	6.43	8.16	8.74	7.58
	Research	0.00	0.00	0.00	0.84	0.70
		2020-21	2019-20	2018-19	2017-18	2016-17
BHARAT BIO	Total Revenues	1439.00	1097.70	866.40	710.30	529.50
	PBT	536.50	392.30	169.90	146.50	98.00
	Cost Of Materials	339.40	268.70	285.40	278.30	172.80
	Employee Benefit	115.10	89.10	73.90	48.30	41.90
	Research	35.30	29.07	0.24	25.30	31.00

APPENDIX-13: VACCINE MANUFACTURERS BALANCE SHEET KEY INFORMATION (IN RS CRORES)

Table-21: Vaccine companies Balance sheet details

		2020-21	2019-20	2018-19	2017-18	2016-17
SII	Total Current Assets	7863	4164	3824	4585	3691
	Total Current Liabilities	4607	944	936	675	584
	Net Working Capital	3256	3220	2888	3910	3107
	Quick Ratio	170.68%	441.10%	408.55%	679.26%	632.02%
	Debt Asset Ratio	58.59%	22.67%	24.48%	14.72%	15.82%
		2020-21	2019-20	2018-19	2017-18	2016-17
HLL BIOTECH	Total Current Assets	10.89	4	5.45	10.63	0
	Total Current Liabilities	414.25	405.63	368.36	322.69	195.77
	Net Working Capital	-403.36	-401.63	-362.91	-312.06	-195.77
	Quick Ratio	2.63%	0.99%	1.48%	3.29%	0.00%
	Debt Asset Ratio	3803.95%	10140.75%	6758.90%	3035.65%	
		2020-21	2019-20	2018-19	2017-18	2016-17
DANO	Total Current Assets	17.78	12.42	9.41	10.23	10.17
	Total Current Liabilities	5.98	2.85	2.73	5.68	5.39
	Net Working Capital	11.8	9.57	6.68	4.55	4.78
	Quick Ratio	297.32%	435.79%	344.69%	180.11%	188.68%
	Debt Asset Ratio	33.63%	22.95%	29.01%	55.52%	53.00%
		2020-21	2019-20	2018-19	2017-18	2016-17
CHIRON	Total Current Assets	150	89.13	39.97	39.33	172.78
	Total Current Liabilities	192.8	149.46	61.74	74.49	32.22
	Net Working Capital	-42.8	-60.33	-21.77	-35.16	140.56
	Quick Ratio	77.80%	59.63%	64.74%	52.80%	536.25%
	Debt Asset Ratio	128.53%	167.69%	154.47%	189.40%	18.65%

		2020-21	2019-20	2018-19	2017-18	2016-17
CADILA	Total Current Assets	872.5	844.2	755.2	649.3	701.76
	Total Current Liabilities	1195.7	1365.4	1313.5	1164.6	723.22
	Net Working Capital	-323.2	-521.2	-558.3	-515.3	-21.46
	Quick Ratio	72.97%	61.83%	57.50%	55.75%	97.03%
	Debt Asset Ratio	137.04%	161.74%	173.93%	179.36%	103.06%
		2020-21	2019-20	2018-19	2017-18	2016-17
SANVITA	Total Current Assets	22.26	13.88	16	14.2	11.46
	Total Current Liabilities	6.08	5.92	16	14	11.4
	Net Working Capital	16.18	7.96	0	0.2	0.06
	Quick Ratio	366.12%	234.46%	100.00%	101.43%	100.53%
	Debt Asset Ratio	27.31%	42.65%	100.00%	98.59%	99.48%
		2020-21	2019-20	2018-19	2017-18	2016-17
INDOVAX	Total Current Assets	51.54	50.25	42.87	34.47	29.19
	Total Current Liabilities	18.21	12.55	11.06	7.44	6.4
	Net Working Capital	33.33	37.7	31.81	27.03	22.79
	Quick Ratio	283.03%	400.40%	387.61%	463.31%	456.09%
	Debt Asset Ratio	35.33%	24.98%	25.80%	21.58%	21.93%
		2020-21	2019-20	2018-19	2017-18	2016-17
IIL	Total Current Assets	722.9	641.5	408.3	300.9	289.8
	Total Current Liabilities	46.79	29.1	30.1	24.85	28.85
	Net Working Capital	25.5	35.05	10.73	5.24	0.13
	Quick Ratio	154.50%	220.45%	135.65%	121.09%	100.45%
	Debt Asset Ratio	64.73%	45.36%	73.72%	82.59%	99.55%
		2020-21	2019-20	2018-19	2017-18	2016-17
GREEN SIGNAL	Total Current Assets	50.89	32.43	29.26	18.48	18.93
	Total Current Liabilities	8.64	1.64	1.78	2.65	4.82

	Net Working Capital	42.25	30.79	27.48	15.83	14.11
	Quick Ratio	589.00%	1977.44%	1643.82%	697.36%	392.74%
	Debt Asset Ratio	16.98%	5.06%	6.08%	14.34%	25.46%
		2020-21	2019-20	2018-19	2017-18	2016-17
GLOBION	Total Current Assets	60.08	77.35	71.29	61.76	44.1
	Total Current Liabilities	65.23	71.54	69.83	48.8	32.7
	Net Working Capital	-5.15	5.81	1.46	12.96	11.4
	Quick Ratio	92.10%	108.12%	102.09%	126.56%	134.86%
	Debt Asset Ratio	108.57%	92.49%	97.95%	79.02%	74.15%
		2020-21	2019-20	2018-19	2017-18	2016-17
BRILLIANT	Total Current Assets	111.29	119.24	114.42	79.1	52.77
	Total Current Liabilities	68.11	81.43	84.53	69.82	48.65
	Net Working Capital	43.18	37.81	29.89	9.28	4.12
	Quick Ratio	163.40%	146.43%	135.36%	113.29%	108.47%
	Debt Asset Ratio	61.20%	68.29%	73.88%	88.27%	92.19%
		2020-21	2019-20	2018-19	2017-18	2016-17
BIOVET	Total Current Assets	59.5	79.69	41.83	48.05	25.96
	Total Current Liabilities	73.19	57.95	23.52	29.79	17.66
	Net Working Capital	-13.69	21.74	18.31	18.26	8.3
	Quick Ratio	81.30%	137.52%	177.85%	161.30%	147.00%
	Debt Asset Ratio	123.01%	72.72%	56.23%	62.00%	68.03%
		2020-21	2019-20	2018-19	2017-18	2016-17
BE	Total Current Assets	1324.5	1196.47	1067.76	729.63	638.76
	Total Current Liabilities	1750.45	1285.69	1002.13	598.88	307.62
	Net Working Capital	-425.95	-89.22	65.63	130.75	331.14
	Quick Ratio	75.67%	93.06%	106.55%	121.83%	207.65%
	Debt Asset Ratio	132.16%	107.46%	93.85%	82.08%	48.16%

		2020-21	2019-20	2018-19	2017-18	2016-17
BIOMED	Total Current Assets	328.98	304.33	192.01	64.66	189.71
	Total Current Liabilities	160.96	15.22	24.23	17.89	7.78
	Net Working Capital	168.02	289.11	167.78	46.77	181.93
	Quick Ratio	204.39%	1999.54%	792.45%	361.43%	2438.43%
	Debt Asset Ratio	48.93%	5.00%	12.62%	27.67%	4.10%
		2020-21	2019-20	2018-19	2017-18	2016-17
BHARAT BIO	Total Current Assets	1100	737.2	487.8	532	525.2
	Total Current Liabilities	1219	602.7	418.7	326.1	469.8
	Net Working Capital	-119	134.5	69.1	205.9	55.4
	Quick Ratio	90.24%	122.32%	116.50%	163.14%	111.79%
	Debt Asset Ratio	110.82%	81.76%	85.83%	61.30%	89.45%

APPENDIX-14: CORRELATION BETWEEN PHARMA AND VACCINE COMPANIES (IN RUPEES CRORES)

The correlation of Revenues is 0.917684 between top 10 Pharmaceutical companies and vaccine companies.

Fig-60: Top vaccine and pharma companies' performance correlation from 2016-17 to 2020-21

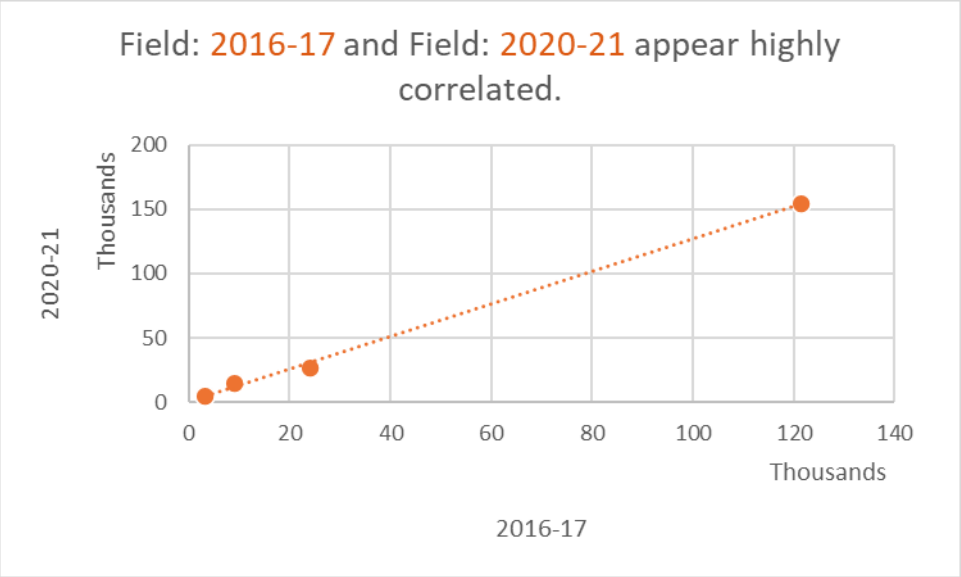
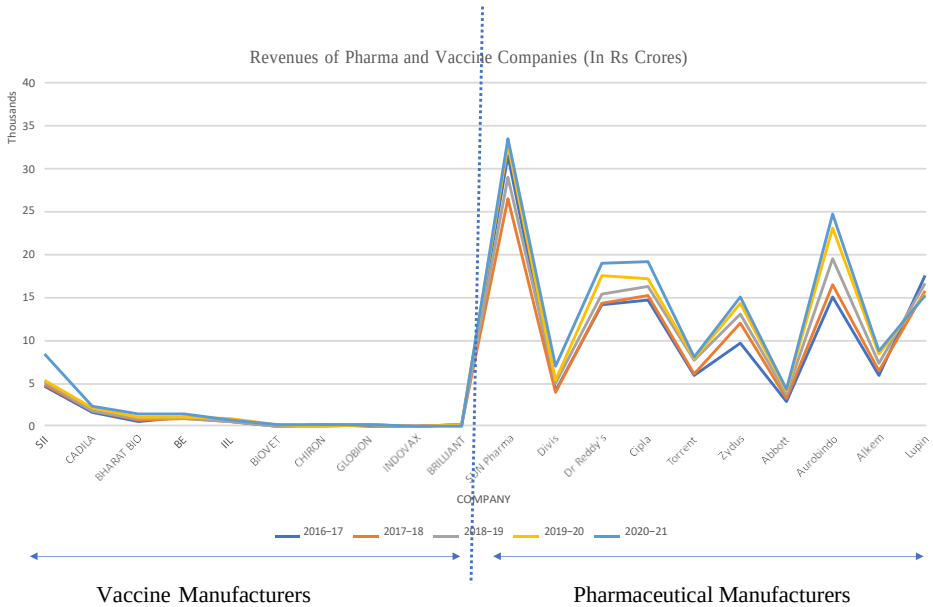
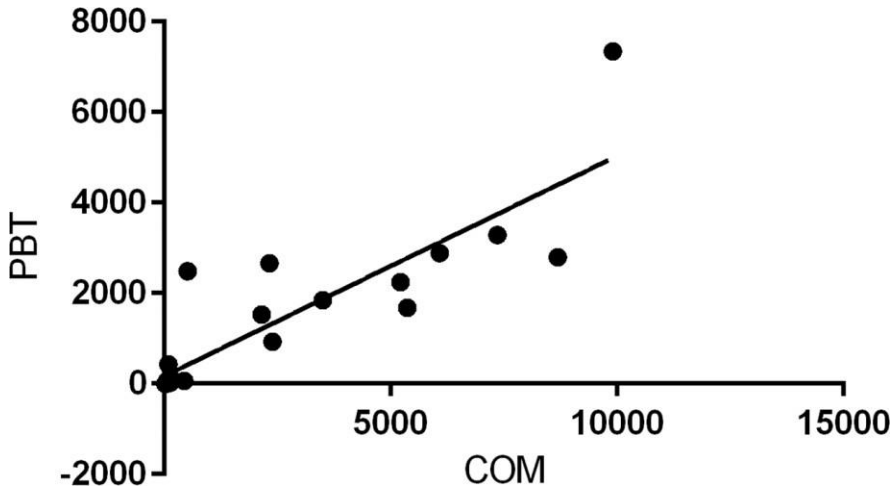


Fig-61: Top 10 Pharma and Vaccine companies' performance in Rs Crores



APPENDIX-15: CORRELATIONS OF COM & PBT

Fig-62: Material cost and PBT comparison of Top 10 Vaccine and Pharma companies



Material Cost and Profit Before tax is also highly correlated as per linear regression curve and for both top 10 pharmaceuticals companies and vaccine companies with P Value <0.0001, hence highly significant.

Fig-63: Top Pharma and Vaccine companies' performance in Rs Crores with respect to Employee benefit, Material Cost, PBT, Research and Total revenues

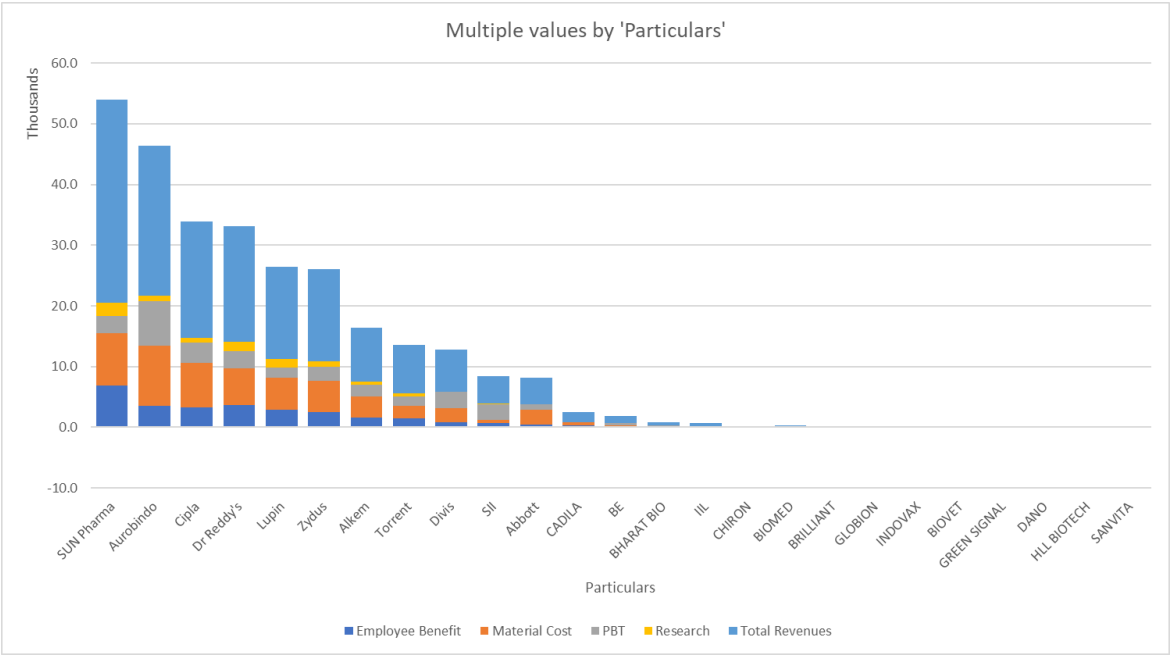
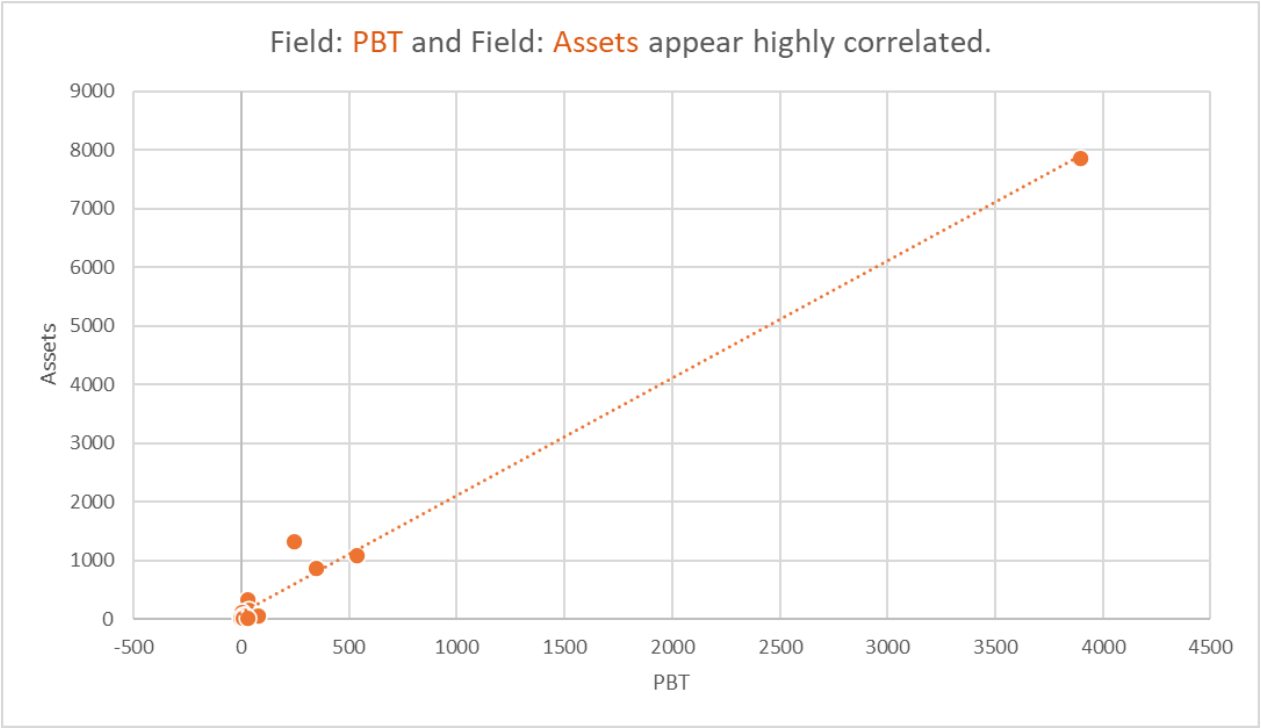


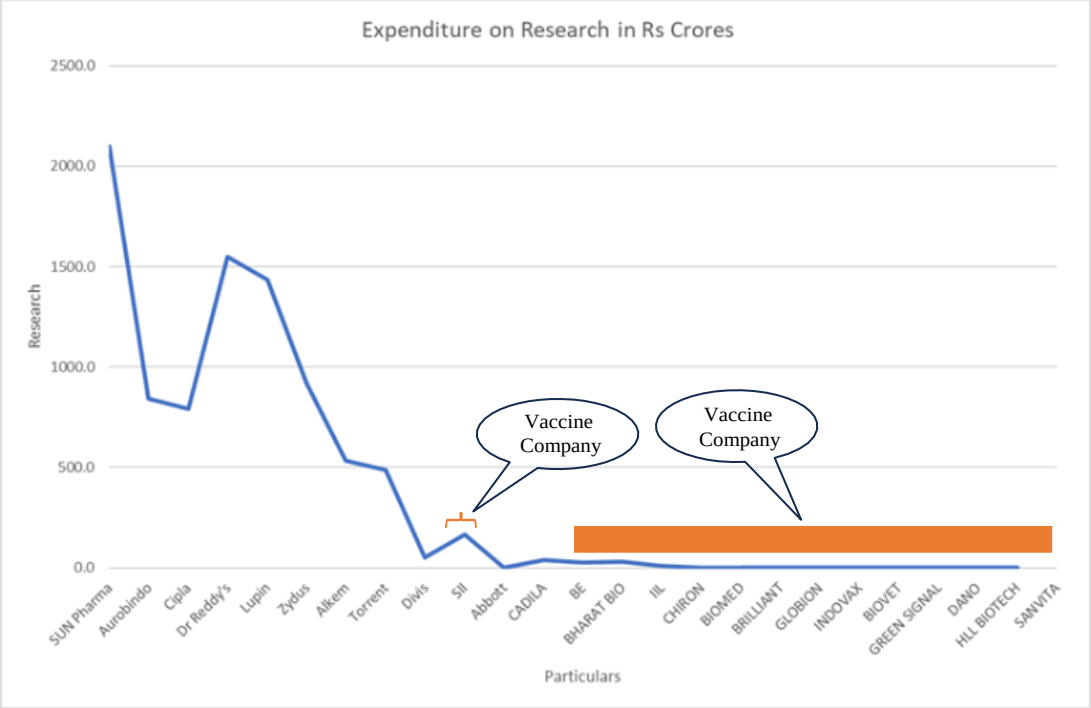
Fig-64: Correlation between PBT and assets of Pharma and vaccine companies



The correlation between Profit Before Taxes and Current Assets is 0.993794 which is highly correlated.

APPENDIX-16: RESEARCH SPEND

Fig-65: Expenditure on Research in Rs Crores



Research spends by vaccine companies significantly less compared to pharmaceuticals companies in India. This goes on to prove that the Indian vaccine industry outsources or buys technology for immediate vaccine manufacturing and new vaccine models emergence will take a long time. With lower research spend, novel vaccine launches from India is unlikely and hence, in-licensing vaccines from other countries and creating a manufacturing hub makes India a very vulnerable place for low-cost vaccines and higher dependence on exports and Government business.

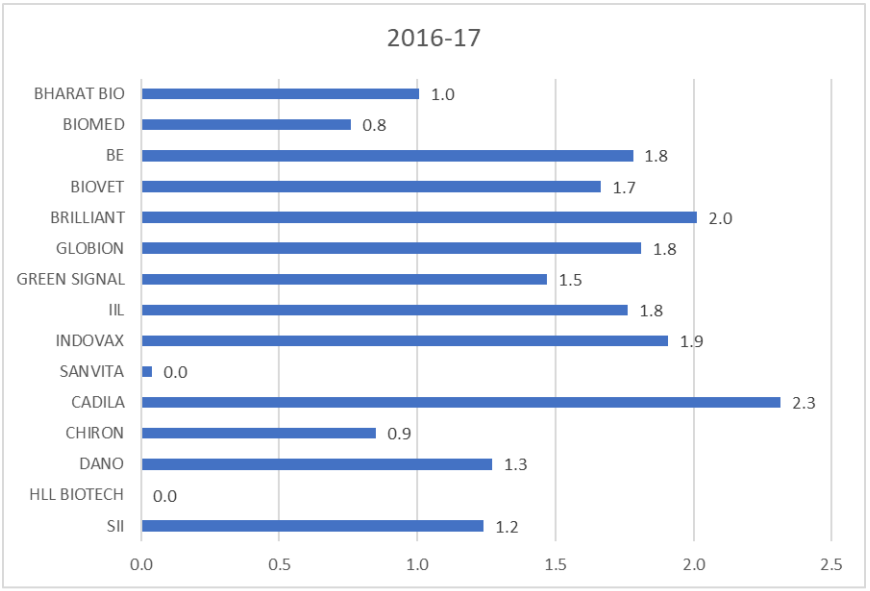
APPENDIX-17: GROSS PROFIT MARGINS

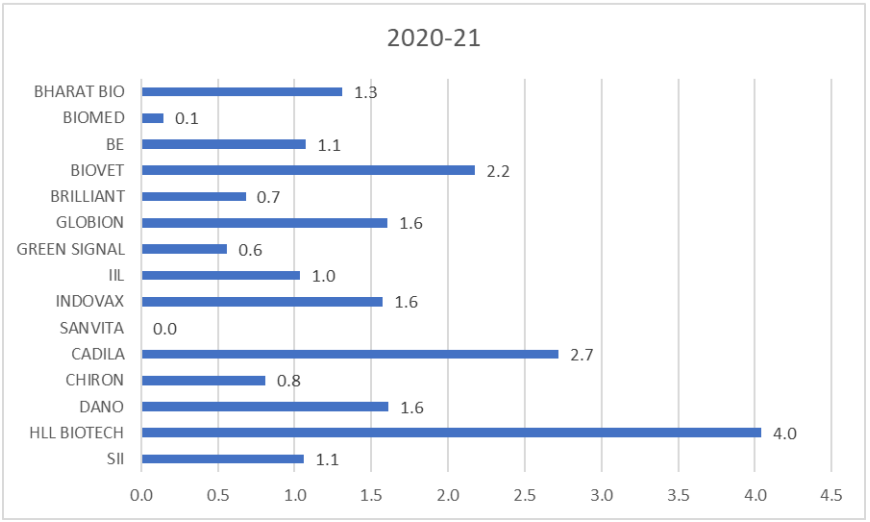
Fig-66: Gross Profit Margins in percentage

The biggest motivation for investments in vaccine business is the higher gross margins compared to pharma companies. Only vaccine business gives higher than 30% Gross margins as compared to top 10 pharma companies which are performing with less than 20% margins. Serum Institute of India achieved gross margins of 54% which is phenomenal. While the risk factor in Vaccine business is high as many vaccine companies are in RED while pharma companies are having lower margins among the top 10.

APPENDIX-18: ASSET TUROVER RATIO

Fig 67: Asset Turnover ratio = Cost of Goods Sold / Assets





Considering Asset Turnover ratio of vaccine companies, it is observed that the 5 out of 15 companies considered for evaluation among the total 23 companies, are having below 1 which is not healthy. Out of the sampled 15 companies for financials, 33% of the companies do not have desired asset turnover ratio. Therefore, the risk element in vaccine business is extremely high. While one HLL Biotech is an outlier as this company is already not performing since past three years and the data posted by HLL remains a subject of verification.