MARKET RESEARCH STUDY OF MONOCLONAL ANTIBODIES (MABS) IN CANCER THERAPY RECOGNIZING THE POTENTIAL OF DIFFERENT MOLECULES IN URBAN CITY IN INDIA.

Dissertation Submitted to

The IIHMR University, Jaipur

for the partial fulfilment for the award of the degree of

Master of Business Administration (MBA)
in
Pharmaceutical Management

By

Niraliben Satishbhai Patel

Under the Supervision and Guidance of

Dr Saurabh Kumar Banerjee

2023

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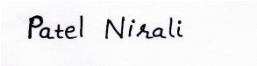
DECLARATION STUDENT

I hereby declare that the dissertation with the aforementioned title is an accurate account of my original research. I certify that it has not been applied for a degree or certificate from any other university or institution. Information that was taken from other people's published or unpublished work has been properly acknowledged in the text.



(Signature)
Niraliben Satishbhai Patel
Name of Student

Date

CERTIFICATE

This is to certify that dissertation titled Market Research Study of Monoclonal Antibodies (MABs) In Cancer Therapy Recognizing The Potential Of Different Molecules In India a record of the research work undertaken by Niraliben Satishbhai Patel in partial fulfillment of the requirements for the awardof the degree of MBA (PharmaceuticalManagement) from the IIHMR University, Jaipur under my guidance and supervision and his/her approach to the research study has been sincere, scientific, and analytical.

Faculty Guide Dr. Saurabh Kumar

IIHMR University, Jaipur

Date

School Dean Dr. Saurabh Kumar

IIHMR University, Jaipur

Date

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Abstract

Monoclonal Antibodies (MABs) are one of the most often given medications in Cancer Treatment. There has been a change in the selection of prescription medications from a variety of distinct therapeutic drug classes. Monoclonal Antibodies (MABs). The goal of the study was to ascertain the market environment for Monoclonal Antibodies (MABs) in an urban city of India with the express goal of assessing market volume and value of Monoclonal Antibodies (MABs), examining the competitive environment for monoclonal antibodies (MABs), assessing the market for medicinal goods and brands, and identifying market drivers and barriers. It was descriptive research. Information on monoclonal antibodies (MABs) available on the market was gathered through both primary and secondary research. The study was carried out in a significant Indian metropolis with a population of around 1,70,75,000 using a questionnaire that was given out by the researcher. Hospital chemists at the city's cancer hospital made up the target demographic. The participant was chosen using a non-probability convenience sampling technique. The sample size was determined to be 151 with an 8% margin of error and a 95% confidence interval. Software from Microsoft Excel 2023 and SPSS 20 was used to analyze the data that was gathered. The market share % comprises pembrolizumab 21%, rituximab 18%, Trastuzumab 6%, Adalimumab 4%, Cetuximab 12%, Bevacizumab 10%, Nivolumab 9%, Avelumab 7%, Atezolizumab 12%. The increase in market share is significantly facilitated by the sales force. Despite being lucrative, the MAB business is very cutthroat, and several factors affect how appealing the market is.

Keywords: Monoclonal Antibodies (MABs) market size, market share, potential, and analysis of competitors

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I am immensely appreciative to everyone who has contributed to the difficult yet gratifying process of writing my dissertation. Their efforts—large and small—have had a tremendous influence on the success of this project.

CHAPTER 1:- INTRODUCTION

1.1 INTRODUCTION

One in six fatalities will be caused by cancer in 2020, making it the top cause of mortality globally[1]. The breast, lung, colon, rectum are the four cancer types that are most common. Breast, lung, colon, and rectum cancers are the most prevalent types of cancer, and prostate cancer is one of the main chronic diseases that still has a high death and morbidity rate. Disease burden has increased because of socioeconomic status, behaviour, food, and public health issues. There are various new cancer treatments on the market.

The therapeutic modalities, cancer types, and geographic regions are used to segment the market for cancer medications. Market based on therapeutic approaches Chemotherapy, Targeted Therapy, Hormonal Therapy, Monoclonal and Polyclonal Antibodies, Stem Cell Transplantation, and Surgery are examples of medical treatments. Alkylating agents, Antimetabolites, Anthracyclines, Topoisomerase Inhibitors, Mitotic Inhibitors, Hormonal Agents, Immunomodulatory Drugs, and Monoclonal Antibodies (MABs) are a few of the different kinds[2].

The use of mAbs increasingly frequently used in conjunction with chemotherapy, radiotherapy, molecularly focused drugs like tyrosine kinase inhibitors, additional antibodies against the same target, immune checkpoint inhibitors, vaccines, and/or cellular treatments, even though some patients have success with them as monotherapies. Preclinical research and clinical trials for these numerous combination techniques are now being conducted, and this enormous subject is more thoroughly addressed elsewhere[3].

A potential class of targeted anticancer drugs called monoclonal antibodies boosts the capabilities of the immune system to inhibit the growth of cancer cells and eradicate them. 14,61,427 incident cases of cancer were recorded to be the projected number in India for 2022 (the crude rate was 100.4 per 100,000One in nine Indians have a lifetime chance of contracting cancer. Lung and breast cancers were the most prevalent types of cancer in both men and women, respectively.. Lymphoma was the most common site among children (0-14 years) with cancer (boys: 29.2%; girls: 24.2%). According to estimates, there will be 12.8% more cancer cases in 2025 than there were in 2020[4].

To evaluate the possibility for the medicine to achieve a competitive advantage utilising the findings of the market assessment, this thesis will undertake a market research analysis of MABs. The main drivers of the market growth are the increased incidence of cancer, the rise

in medication approvals, and a healthy pipeline. Additionally, mAbs have fewer adverse effects on the body of the patient than chemotherapy does.

Incidence and mortality rates have been continuously growing in India over the last few decades. As a result, there is a rising need for efficient and cutting-edge treatment alternatives to stop this terrible illness. As a potential class of therapeutic agents for cancer treatment, monoclonal antibodies (mAbs) provide targeted and individualised strategies to treat cancer types. Given that mAbs have the potential to improve patient outcomes, it is essential to perform a thorough market research study to learn more about their present usage, market dynamics, and potential in Indian urban centres.

Urban areas of India serve as important centres for the treatment of cancer, housing important medical facilities, research organisations, and a sizeable patient base. These cities serve as hubs for clinical trials and advancements in cancer therapies, in addition to providing access to cutting-edge medical infrastructure. Healthcare professionals, pharmaceutical companies, politicians, and other stakeholders involved in cancer care delivery and development must fully comprehend the market environment and mAbs usage trends in these urban centres.

This market research study aims to provide a detailed analysis of the monoclonal antibody market's current situation for the treatment of cancer in Indian cities. By understanding the promise and limitations associated with their use, we can provide evidence-based recommendations to raise access, cost, and awareness of these cutting-edge medicines. The goal of this research is to help create effective strategies for using mAbs' full potential in the battle against cancer, improving patient outcomes and reducing the burden of this disease in India's urban areas.

1.2 BACKGROUND AND RATIONALE

Investigations are urgently needed to have a better knowledge and estimate of the market for mAbs in the cancer industry because to the intense competition and market fragmentation that this segment faces. The way that cancer is treated is continually changing in reaction to newly published research, and an excessive number of new medications are being added at a quick rate. Newer, more effective medicines with fewer adverse effects are replacing older ones. As a result, this report concentrates on the market's assessment and growth of ACE Inhibitors as well as an analysis of recent market entrants in the same industry.

CHAPTER 2:- LITERATURE REVIEW

The market for monoclonal antibodies was estimated to be USD 210.06 billion in 2022, and from 2023 to 2030, it is anticipated to increase at a compound annual growth rate (CAGR) of 11.04%. Increased use of mAbs treatments for targeted therapies, rising awareness of such medicines among patients and clinicians, and rising prevalence of chronic diseases like cancer are anticipated to considerably contribute to the market's growth.[5]Monoclonal antibodies are called antibodies are synthetic versions of immune system proteins that are injected into the body to assault specific targets on cancer cells. They have a higher percentage of human than murine components. Their attack strategies involve engaging the target cell's immune system to attack it, attaching to ligands or receptors to stop vital cancer cell processes[6].

Indian Monoclonal Antibody Market Dynamics is studies for the Indian market for monoclonal antibodies has grown significantly in recent years. According to a report by Allied Market Research, the Indian mAbs market has a predicted compound annual growth rate (CAGR) of 7% from 2017 to 2025, reaching a value of USD 55.4 billion in 2023. This development can be ascribed to a few variables, including rising cancer incidence rates, the accessibility of cutting-edge healthcare infrastructure in urban areas, and growing public and professional awareness of the advantages of mAbs in cancer treatment.[7].

Numerous studies have looked at how monoclonal antibodies are used in Indian cities, revealing information about the sorts of tumours that are targeted, prescribing habits, and patient demographics. In a study that examined the use of mAbs in a tertiary cancer centre in Mumbai, it was discovered that Trastuzumab for HER2-positive breast cancer and Rituximab for B-cell lymphomas were the two most often given mAbs. The study also emphasised the difficulties that patients from low socioeconomic backgrounds experience when trying to acquire and afford these medications. When treating cancer, medications like monoclonal antibodies are frequently utilised differently depending on the patient, the treating physician, the severity and kind of the disease, and the recommended daily dose[8].

Despite the great potential of mAbs in the treatment of cancer, there are several obstacles and difficulties in product positioning as well as occupying highest share of the category. This study focusses on majorly estimation of the of mAbs market and potential of individual molecule in category for better forecasting.

CHAPTER 3 METHODOLOGY

3.1 Research Design

Descriptive research design

Primary and secondary sources of data

Technique for gathering data: survey, interviews.

Semi-structured questionnaire, records, and documents are the data collecting tools.

The market research analysis will make use of both primary and secondary data. Primary data will be gathered through surveys and interviews with patients, chemists, and healthcare professionals. Secondary data will be acquired by looking through sales data, reports from pharmaceutical companies, and published research articles.

3.2. Sample Design

Target audience: Pharmacy in hospitals

Non-probability convenience sampling is the sampling technique.

Sample size: 151 Hospital Pharmacy prescription (with an 8% margin of error and a 95% confidence interval)

Study Location: Urban city of India

The intended audience consisted of hospital pharmacy. The participant was chosen using a nonprobability convenience sampling technique. The sample size was determined to be 151 with an 8% margin of error and a 95% confidence interval. A significant cancer hospital in the city performed the study among 151 hospital pharmacy patients. Utilising SPSS 20 and MS Excel 2023, the data was examined. The investigation was carried out between February and May 2023.

3.3 RESEARCH OBJECTIVE:

Primary Objective:

Market assessment study for the monoclonal antibodies' molecule for competitor analysis.

Secondary Research:

- To Study the Monoclonal antibodies Market, Practice patterns in India.

- To Find Out the top brands of Monoclonal antibodies in Oncology group and its analysis of the Market Share of other brands.

Scope of article:

The primary goal of this study is to understand the market share of monoclonal antibodies in the oncology segment and understand doctors' preferences for the same.

3.4 RESEARCH PROBLEM

Over the course of the projected period, the Asia-Pacific cancer therapy market is anticipated to grow at a CAGR of 10.2%. The market for monoclonal antibodies worldwide, which was It is anticipated to grow at a CAGR of 12.0% from 2022 to 2030, with a market value of USD 187.0 billion in 2022.By 2030, it is anticipated that the market for monoclonal antibodies would be worth USD 463.0 billion. The region with the fastest growth is predicted to be Asia Pacific. This calls for an analysis of an extremely fragmented market and competitive environment to encourage new competitors to make smart decisions and gain an advantage. The study's main goal was to determine the city's potential market size for monoclonal antibodies (MABs). The objectives were:

- To calculate the monoclonal antibody market's volume and value.
- Identification of the monoclonal antibody industry's driving forces and market obstacles.
- To research monoclonal antibodies' market competition.
- What is the Major Drug Use in Oncology Market.

Data Analysis Plan:

- Use of MS Excel for analysis of surveys and reports.

3.4 ETHICAL CONSIDERATION

The research was carried out according to the necessary research standards. The study's respondents were given enough time to express their real opinions on the research issues. The respondents' consent was obtained, and proper authorization was also made sure for the use of the information they provided. If the responder did not want to have them identify revealed, it was not shown. The publication of the respondent's identity was based on their consent. The required citations were used to acknowledge the use of secondary data from sources.

CHAPTER 4:- RESULTS, ANALYSIS, AND DISCUSSION

Market size of Monoclonal Antibodies MABs for cancer treatment by market volume and market value

The market size and value were determined through secondary research, utilizing models based on epidemiology and hospital pharmacies.

Method I: Epidemiology model: -

Literature research was conducted to investigate the city's population. According to a meta-analysis, India's urban cities have a crude cancer prevalence incidence of 100.4 per 100,000 people. Using primary research, the market share of monoclonal antibodies (MABs) was discovered and added to the model. The average dose frequency of the various MAB monoclonal antibody molecules was discovered to vary depending on the patient's body mass, age, and injectable therapy regimen.

As a result, it has been defined in accordance with the dose recommendation, however it may change. The Total Market Volume of Monoclonal Antibodies for Cancer Treatment was calculated using these data. Figure No. 1 presents the findings.

Population		1,70,75,000
Prevalence cases		17143.3
Average dose per month		1
crude rate		100.4
current cases in state		73,382
Total Market Value		**1,40,42,772**
Pembrolizumab		
Market Volume	5.40%	14
ASP(INR)		2,12,900
Market Value(INR)		29,80,600
Rituximab		
Market Volume	28.40%	74
ASP(INR)		34,500
Market Value(INR)		25,53,000
Trastuzumab		
Market Volume	16.90%	44
ASP(INR)		20,651

Market Value(INR)		**9,08,644**
Adalimumab		
Market Volume	8%	21
ASP(INR)		25,000
Market Value(INR)		5,25,000
Cetuximab		
Market Volume	7.70%	20
ASP(INR)		86,981
Market Value(INR)		17,39,620
Bevacizumab		
Market Volume	13.00%	40
ASP(INR)		35,275
Market Value(INR)		14,11,000
Nivolumab		
Market Volume	13.00%	34
ASP(INR)		36616
Market Value(INR)		12,44,944
Avelumab		
Market Volume	2.70%	7
ASP(INR)		1,46,800
Market Value(INR)		10,27,600
Atezolizumab		
Market Volume	2.70%	7
ASP(INR)		2,36,052
Market Value(INR)		1652364
Total MABs Market		**1,40,42,772**

Figure 1. shows the % market share of each monoclonal antibody molecule as determined from primary research and the corresponding market.

Method II: Hospital Pharmacy Approach/ Model

According to the literature, the city has around 30 of the finest cancer hospitals, thus an average number of pharmacies was determined to be 30 and utilised in the calculations. The average selling prices and average number of vials monthly were reported by the main research. The market volume and market value of each individual molecule that is currently on the market were calculated using the combined research data. The outcomes are shown in figure no. 2

Molecule	No. of hospitals	Dose/month (Vials)	Average Patient counts	ASP(INR)	market volume	market value	%share	Market volume
Pembrolizumab	30	1	14	2,12,900	14	2980600	21%	5.4%
Rituximab	30	2	37	34,500	74	2553000	18%	28.4%
Trastuzumab	30	2	22	20,651	44	908644	6%	16.9%
Adalimumab	30	3	7	25,000	21	525000	4%	8.0%
Cetuximab	30	1	20	86,981	20	1739620	12%	7.7%
Bevacizumab	30	2	20	35,275	40	1411000	10%	13.0%
Nivolumab	30	2	17	36616	34	1244944	9%	13.0%
Avelumab	30	1	7	1,46,800	7	1027600	7%	2.7%
Atezolizumab	30	1	7	2,36,052	7	1652364	12%	2.7%
Total			151		261	14042772	100%	97.7%

Figure 2. Both methodologies produced results that appeared to differ by 11% in terms of Market volume and Market value.

Market Volume trends of different Molecules

Figure 3. Market volume trends for different Molecules

The primary data through primary research identified the most often prescribed compounds. Those are Rituximab which has highest market volume prescribed by trastuzumab, bevacizumab, nivolumab, cetuximab, pembrolizumab, atezolizumab, avelumab.

Trends of Market Value of different Molecules

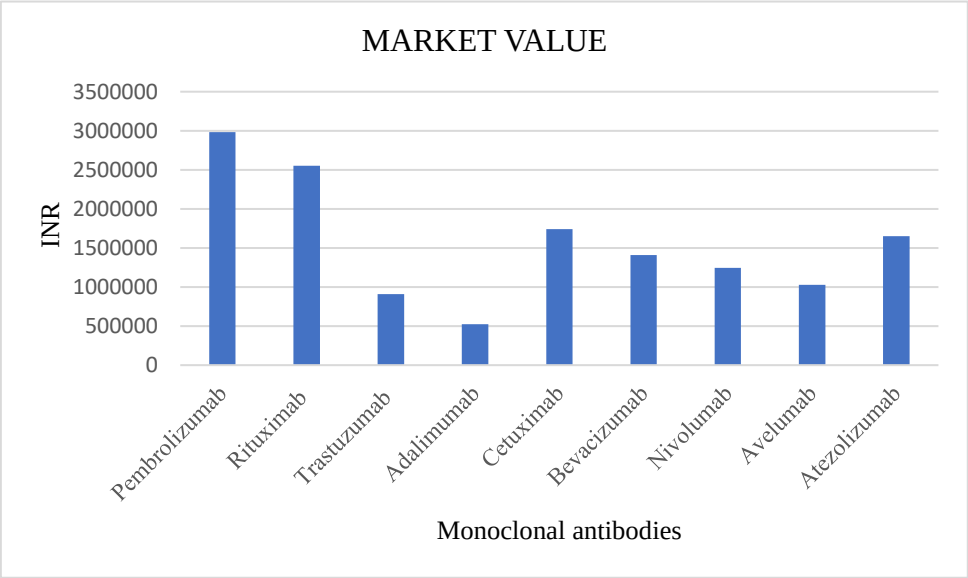

Figure 4. Market Value Comparison of different Molecules

Pembrolizumab occupies the highest share followed by the rituximab, cetuximab, trastuzumab, atezolizumab and bevacizumab while nivolumab and adalimumab has lower share value.

Comparison of number of brands of different Molecules

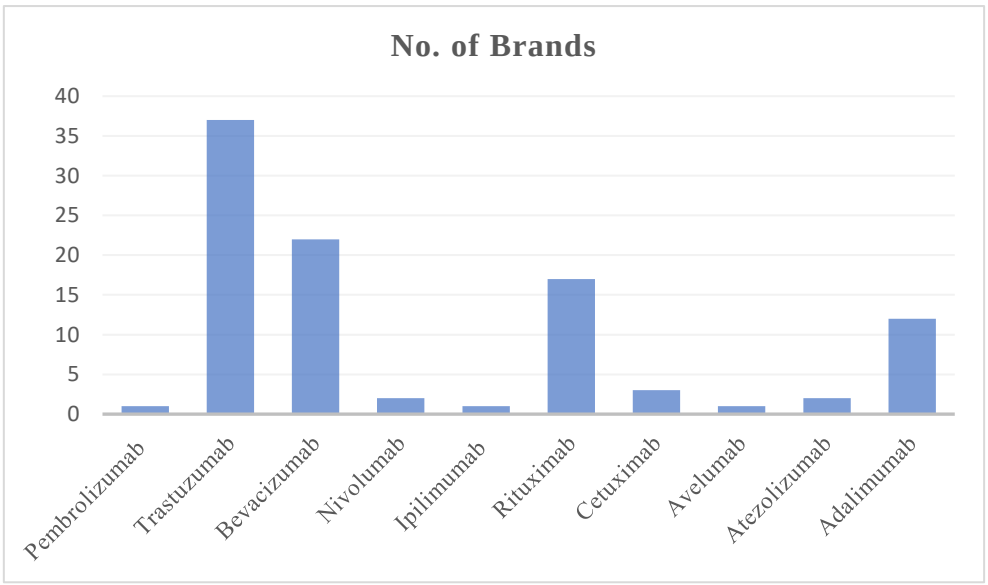

Figure 5. Comparison of the several Molecules' brands

It was discovered that the number of brands in the market is directly correlated with the market volume that the molecules occupy.

Market overview with Top Selling Brands

Factors for availability of Brands present in the Market.

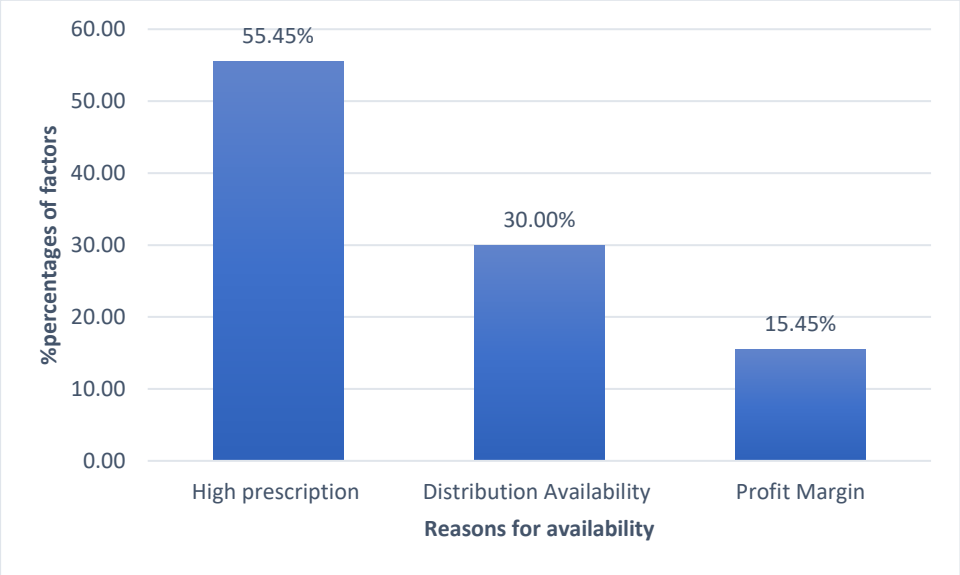

Figure 6: Market Brands' reasons for being available.

The availability of the big brands was cited by 55.45% of respondents as the primary factor was high prescription while roughly 30.0% of respondents cited the distributor availability. Only 15.45% of participants said they kept these brands in their stores because of the significant profit margins they offered, whereas distributors were the reason they made them available at their stores.

Patterns observed in the prescription frequency and trends of average Selling Prices

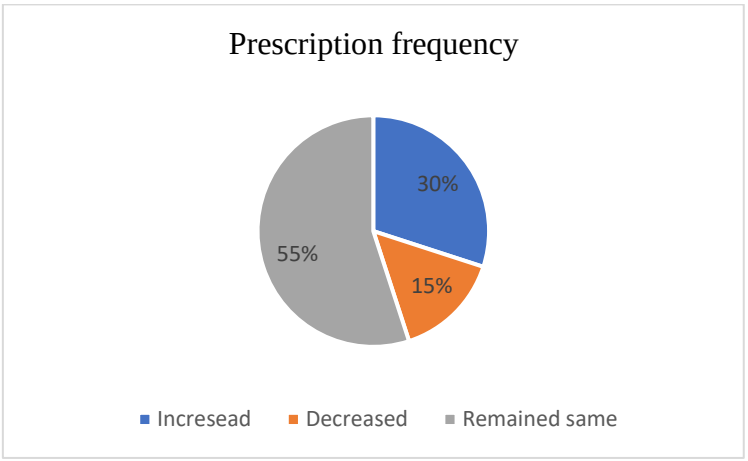

Figure 7. Trends observed in the prescription habits.

About 55% of those surveyed claimed that they had not noticed any modifications to the regularity of MABs patients' prescription refills at their locations.

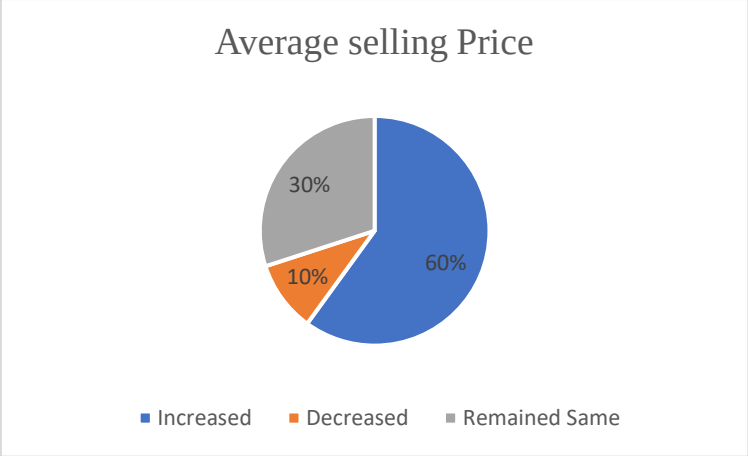

Figure 8. Trends in selling Prices.

A little over 30% of those surveyed claimed to have seen a reduction in selling prices.

Anti-Cancer Market uses as per indication wise segmentation.

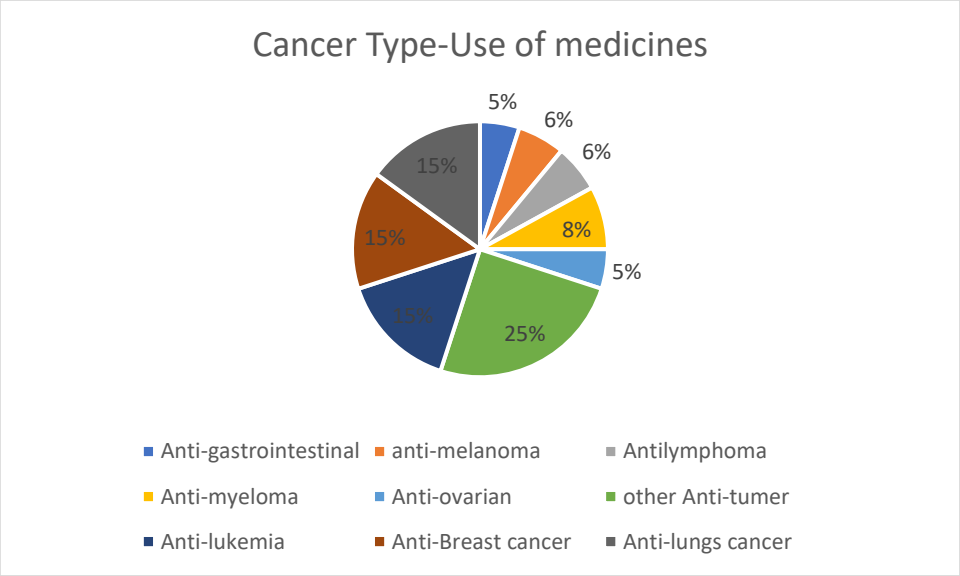

Figure 9. Medicine consumption as per type of cancer

MABs Market Landscape Brand-wise

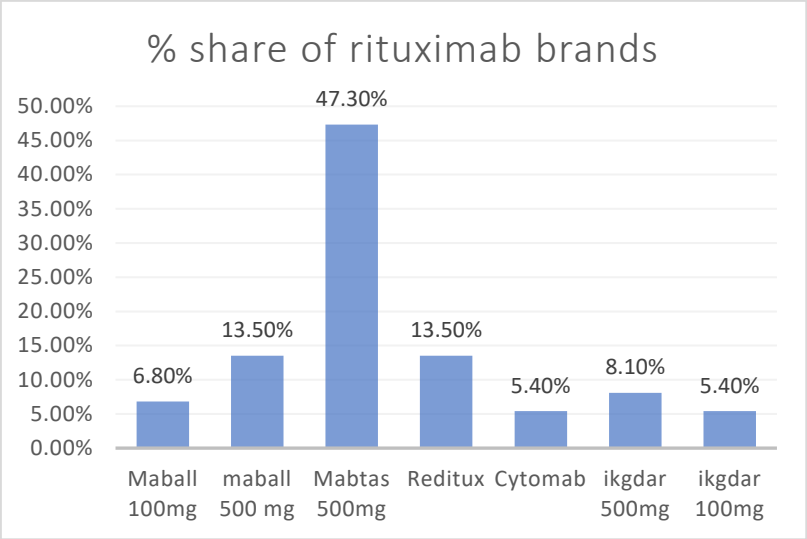

Figure 10.1 Rituximab brand trends

It was observed that the highest selling brand was Mabtas with 47.30%, followed by Reditux 13.5%, Maball 500mg with 13.5% are the Macro brands in rituximab molecule category. Microbrands are Cytomab with 5.4% ikgdar 100mg and Maball 100mg with 6.8%.

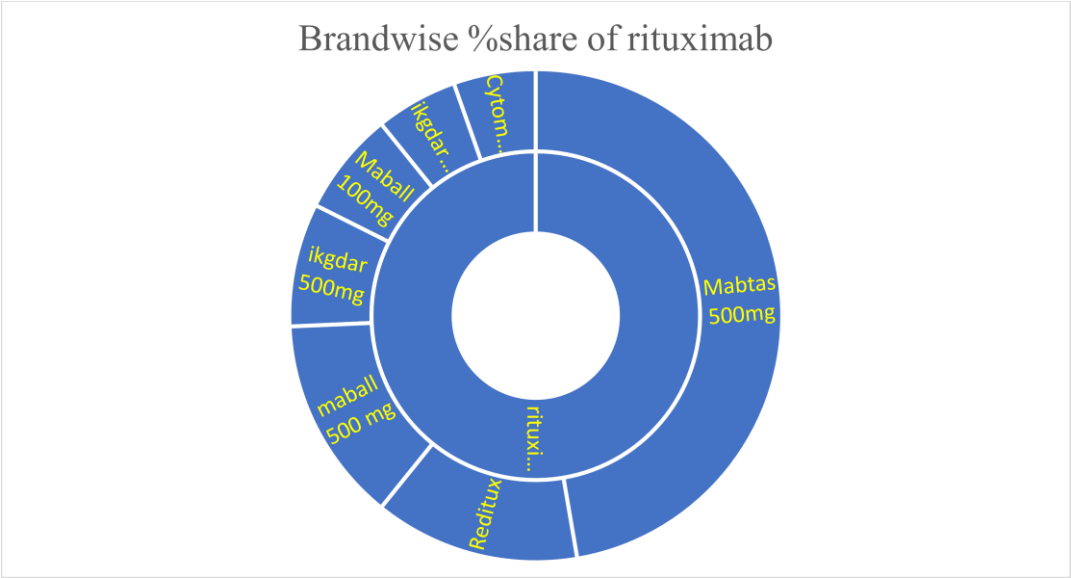

Figure 10.2 Rituximab market overview brand wise

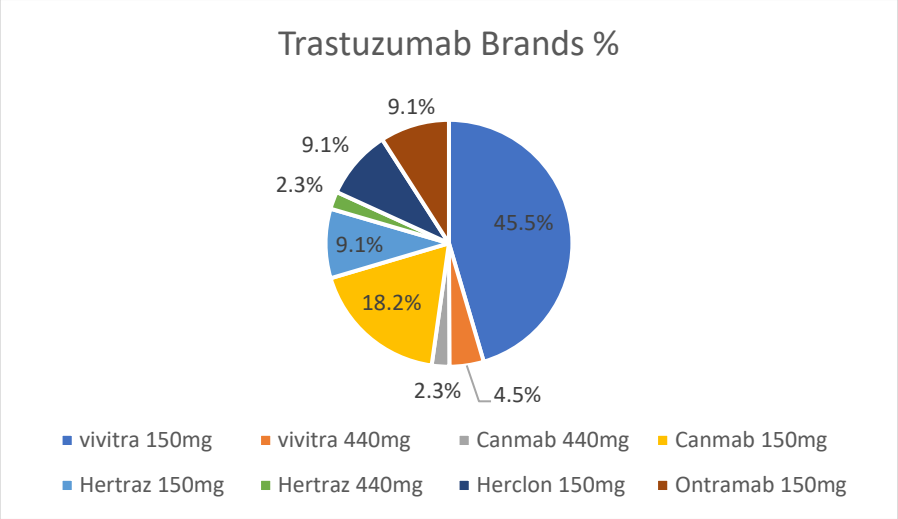

Figure 11 Trastuzumab brand trends

Macro brands are Hertraz 150mg, Canmab 150mg. While Micro brands are Canmab 440mg, Hertraz 440mg.

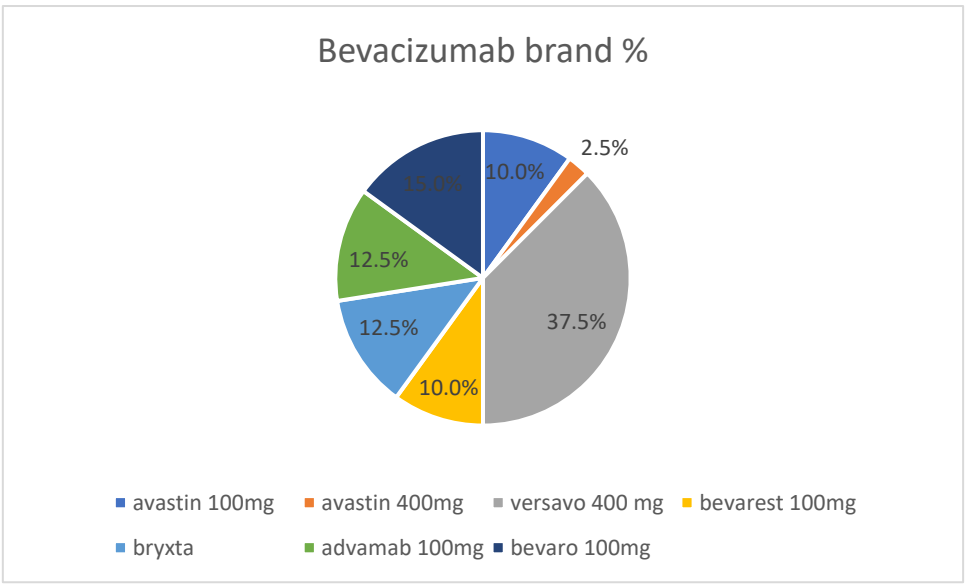

Figure 12 Bevacizumab Brand Trends%

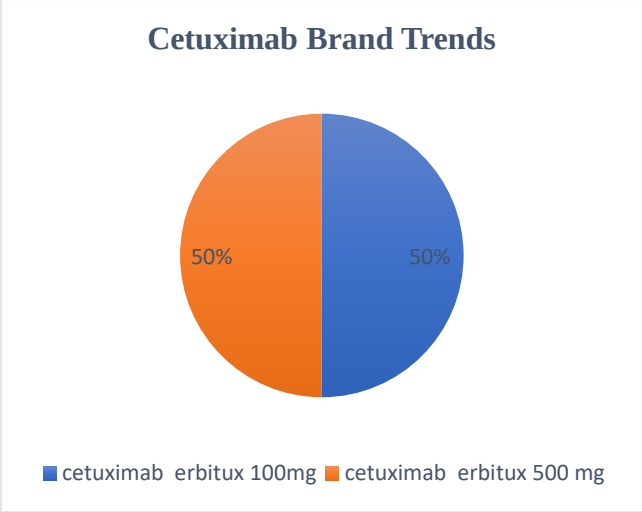

Figure 13 Cetuximab Brand Trends

Equal market share of 50% was recorded for Erbitux 100mg and Erbitux 500mg.

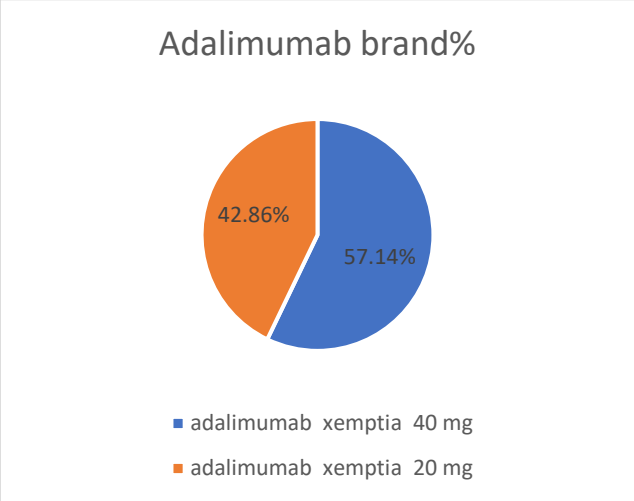

Figure 14. Adalimumab brand trends

Equal Brand share was occupied by xemptia 40 mg & xemptia 20 mg.

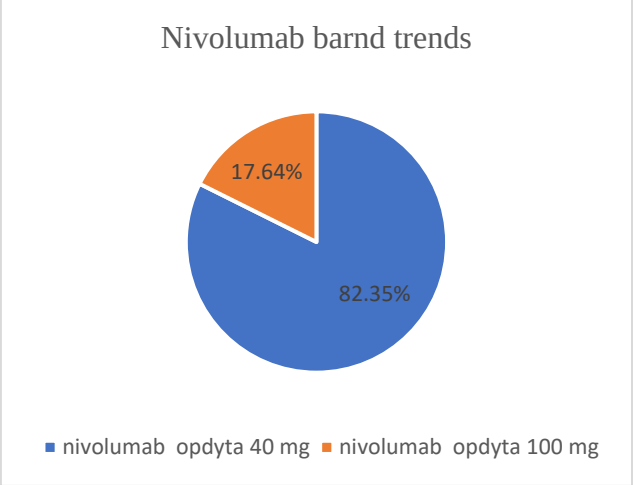

Figure -15 Nivolumab brand trends

CHAPTER 5:- DISCUSSION

The city's monoclonal antibody market was projected to be around Rs.1,40,42,772 at market volume of 261. The anti-cancer market was found to comprise of Alkylating agents, Antimetabolites, Anthracyclines, Topoisomerase Inhibitors, Immunomodulatory Drugs, Mitotic Inhibitors, Hormonal Agents, and Monoclonal Antibodies (MABs). Market share % are comprising of pembrolizumab 21%, rituximab 18%, Trastuzumab 6%, Adalimumab 4%, Cetuximab 12%, Bevacizumab 10%, Nivolumab 9%, Avelumab 7%, Atezolizumab 12%. Market volumes are as following it suggest the unit's vials percentages Pembrolizumab 5.4%, Rituximab 28.45, Trastuzumab 16.9%, Adalimumab 8.0%, Cetuximab 7.7%, Bevacizumab 13.0%, Nivolumab 13.0%, Avelumab 2.7%, Atezolizumab 2.7%.

151 Sample size was analysed for the above calculation and the highly prescribed brands are Market The key participants reported that while the average selling price has reduced over time, the rate of prescription has remained constant. This can be a result of fierce product rivalry.

CHAPTER 6:- CONCLUSION

About 40% of the city's anti-cancer market is made up of monoclonal antibodies, however this industry has been significantly impacted by the constantly growing market for targeted medications like tyrosine kinase inhibitors. Although rituximab is often prescribed, its market is severely fragmented because of the numerous rivals. Due of established client devotion by Older businesses, the industry seems to be extremely difficult for New entrants. To increase market share, the market penetration tactics might be used. In such cutthroat sectors, the sales force is crucial to generating prescriptions.

LIMITATIONS

There was a small sample size due to the type of city. Study was conducted in one city therefore the factors like demographics, cultural, psychological factors also affect the approach to the consumer behaviours that can lead to the wrong estimation and under Performance of brands. The study only shows current data; forecasting is not provided, which is a constraint for inventory planning and market share growth.

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