

MARKET ASSESSMENT OF MEDICAL DEVICES USED FOR COVID TREATMENT IN INDIA

Dissertation Submitted to



for the partial fulfillment for the award of the degree of

Master of Business Administration (MBA)

in

Pharmaceutical Management

by

Mr. Suryakant Patel

Under the Supervision and Guidance of

Dr. Surya Prakash

Associate professor, School of Pharmaceutical management

IIHMR university, Jaipur-302029

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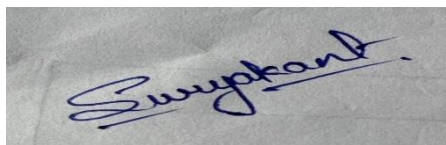
Associate professor, School of Pharmaceutical management

IIHMR university, Jaipur-302029

2022

DECLARATION BY STUDENT

I hereby declare that this dissertation titled **Market assessment of medical devices used for covid treatment in India** is the bonafide record of my original research work. I declare that it has not been submitted to any other university or institution for the award of any degree or diploma. Information derived from the published or unpublished work of others has been duly acknowledged in the text.



(Signature)

Name of the student- Mr. Suryakant Patel

Date- 04/07/2022

CERTIFICATE

This is to certify that Suryakant Patel in partial fulfillment of the requirements for the award of the degree of MBA (Pharmaceutical Management) from the IIHMR University, Jaipur has successfully completed her/his internship at IIHMR University during March 22, 2022, to June 19, 2022.

Place: Jaipur
Date:04/07/2022

Preceptor/Head of the Organization
IIHMR University

CERTIFICATE

This is to certify that dissertation titled **Market assessment of medical devices used for covid treatment in India is** a record of the research work undertaken by **Mr. Suryakant Patel** in partial fulfillment of the requirements for the award of the degree of MBA in Pharmaceutical Management from the IIHMR University, Jaipur under my guidance and supervision and his/her approach to the research study has been sincere, scientific, and analytical.

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ABSTRACT

We suggest the following definition of a medical device: "A device designed and produced for use in healthcare, other than for medicinal or dietary purposes." Medical device classifications under current regulations are complicated and mostly intended for regulators. We suggest a more straightforward classification based on the device's location, duration of usage, and availability of an external power supply. Compared to the control of pharmaceuticals, which it could adhere to more closely, the regulation of medical devices is less developed. Particularly, it should be necessary for gadgets that contain medications to adhere to the same regulatory criteria as pharmaceuticals. By doing so, the anomaly that some systems for delivering medications are categorized as devices while other, comparable methods for delivering the same medications are categorized as medicinal items would be eliminated. More people using registries, like those used for prosthetic joint replacements, may also lead to some improvements. Registries would enable both prospective and retroactive investigation when signals from other information sources suggest issues with high-risk devices. Before receiving a license, those who request a marketing permission for a novel gadget should be required to reassure regulators of its high manufacturing standards, safety, and efficacy. It should be demonstrated that even the simplest equipment can be put to practical use. For most devices, it should be possible to conduct patient trials or at the very least simulate real-world usage.

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**MARKET ASSESSMENT OF MEDICAL DEVICES USED FOR COVID
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CHAPTER- 1: INTRODUCTION

An Overview of Medical Devices

An essential element of patient care is the use of medical gadgets. Because of their complexity and the fact that most medical devices have power factors, there are now higher criteria and procedures for safety. Our series on developments in medical isolation transformer design begins with this article, An Introduction to Medical Devices.

A medical device is what?

Any appliance, instrument, material, apparatus, or other item that is either used alone or in conjunction with other tools or devices, including the software necessary for its intended usage by the manufacturer, and that is intended to be used for people for the purposes of:

- diagnosis, prevention, monitoring, treatment, or alleviation of disease
- disease diagnosis, prevention, monitoring, treatment, or symptom relief
- diagnosis, surveillance, therapy, pain relief, or disability compensation
- examination, substitution, or alteration of the physiology or of the anatomy
- control of conception and that, while it may be aided in function by pharmacological, immunological, or metabolic mechanisms, does not achieve its primary intended action in or on the human body.

An essential element of patient care is the use of medical gadgets. The term "medical devices" refers to a very broad and sophisticated range of technology, ranging from tongue depressors to dialysis equipment. The majority of medical equipment have power factors, which adds to the complexity. As a result, in addition to the device's functionality, the vital aspects of patient and healthcare provider safety are also taken into account. Sets of global standards and norms have been established in order to satisfy all safety requirements, and adherence to them guarantees the proper supply of technology. Testing is a way to make sure the gadgets comply with the desired standards. As a result, product testing creates the initial degree of evaluation of a device's appropriateness and safety.

People are becoming more concerned about their health as a result of emerging economies and rising awareness. People are willing to choose cutting-edge technologies and solutions to better their health, regardless of the expense. As a result, the market for medical devices in the healthcare sector has seen tremendous expansion. The medical device sector also includes subsectors such those in diagnostics, imaging, cardiology, surgical, and orthopaedic equipment.

Medical Device Types

Active medical device — Any medical gadget that depends on electricity or any form of energy other than that produced directly by the human body or gravity is referred to as an active medical device.

Active implantable medical device — any active medical device that is designed to be surgically or medically inserted entirely or partially into the human body or through a natural orifice and to remain there after the procedure.

In vitro diagnostic medical device — any medical device that is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment, or system, whether used alone or in combination, and intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body, with the sole or primary goal of providing information:

- Referring to a diseased or physiological condition,
- Relating to a congenital anomaly,
- To assess the compatibility and safety of possible receivers,
- To keep track of treatment plans.

Medical Device Classification

Class	Characterization / Device type	Example
Class I	Low risk level	Thermometers, Tongue depressors
Class IIA	Low to Moderate risk level	Hypodermic needles
Class IIB	Moderate to High risk level	Lung ventilators and bone fixation plates
Class III	High risk level	Heart valves and implantable defibrillators

CHAPTER - 2: LITERATURE REVIEW

SARS-CoV-2, or the severe acute respiratory syndrome coronavirus, can cause the 2019 coronavirus disease (COVID-19), a pandemic that resulted in numerous and long-lasting interruptions in the global supply of many different commodities and services. Hospitals discovered that inventory management strategies used to maximise efficiency were unable to keep up with rapidly growing demand, especially for COVID-19 pertinent medical items, such as ventilators, testing supplies, and personal protective equipment (PPE). These gadgets have a complicated supply chain that uses a wide range of raw materials and a number of organisations. A better understanding of these supplies' supply chains COVID-19 applicable Medical equipment might offer context and insight for ongoing supply issues, while long-term support for system resilience.

The goal of this paper is to give an overview of the COVID-19 relevant medical device supply chain and the associated difficulties encountered when ramping up manufacture of these devices during the COVID-19 pandemic. The Payment, Cost, and Coverage Program in RAND Health Care conducted this study, which was supported by the U.S. Department of Health and Human Services Office of the Assistant Secretary for Planning and Evaluation under Contract Number HHSP233201500038I. (Chen, 2021) (1)

Beginning in 2011, the WHO Priority Medical Devices project established the process for choosing medical devices needed for diagnostic, therapeutic, or rehabilitative purposes due to disease or clinical intervention. More illnesses and medical disorders have been added to the list over time. The priority medical equipment lists' ultimate goal is for Member States to use them as a guide for creating or updating their national lists in order to ensure patient access, procurement, availability in healthcare facilities, and appropriate use. These lists should be modified by nations and environments based on the infrastructure, health workforce, financial resources, and local priorities that are available. Priority medical devices for the present pandemic are included in this book, which WHO developed in the last five years. These lists include those needed for reproductive, maternal, neonatal, and child health, as well as specific diseases like cancer and Ebola. (WHO, 2020) (2)

The healthcare sector in India has experienced substantial expansion during the past ten years. However, access to high-quality, reasonably priced healthcare is still difficult in many areas of the country, and healthcare provision is still uneven.

The market for medical devices has expanded significantly over this time and is essential to every stage of the healthcare continuum. Although it has helped make healthcare services more accessible and affordable, a variety of ecosystem constraints have made it difficult to meet domestic demand domestically, which has resulted in a heavy dependence on imports.

The current dynamics of supply and demand offer a considerable opportunity and justification for medical device production in India. The "Make in India" project of the Indian government offers a platform for the industry to review its operating principles, pinpoint important growth drivers, and investigate potential avenues for bringing about a step change in the medical devices market.

In order to analyse the existing landscape and role of the medical devices industry and identify the significant roadblocks and imperatives to take advantage of the "Make in India" opportunity, NATHEALTH and Deloitte teamed up.

This paper is the result of in-depth investigation and numerous discussions with stakeholders from the public and private healthcare sectors. (Deloitte, 2016)(3)

Governments across the world have established travel restrictions because of the COVID-19 epidemic, which has influenced the trafficking of subpar and fake medical supplies. Interpol and the World Customs Organization (WCO) announced that in March 2020, there was an increase in the number of substandard and counterfeit medical products seized, including personal protective equipment (PPE). The COVID-19 epidemic, which has caused enormous demand for medical supplies like PPE over a relatively short period of time, is directly responsible for the emergence of PPE trafficking, which marks a substantial change in organised criminal group behaviour. It is expected that criminal activity will switch from trafficking in PPE to the creation and distribution of a COVID-19 vaccine as a result of the evolution of COVID-19, improvements in medical therapies, and/or the repurposing of existing pharmaceuticals. Furthermore, it is probable that online frauds targeting health procurement authorities would continue to target crucial infra structure engaged in combating the epidemic.

Before COVID-19, there were problems with pandemic preparedness that ranged from inadequate regulatory and legal frameworks to the prevention of the production and trafficking of substandard and counterfeit products to weaknesses in cyber security. However, the pandemic has made these problems worse, and it will be challenging to make significant improvements in the near future. The analysis finds that when the pandemic moves from its containment phase to its treatment and preventive stages, crime targeting COVID-19 medical supplies will become more concentrated and pose much bigger hazards to the public's health. (UNODC, 2022) (4)

In terms of income and employment, the healthcare sector has grown to be one of the biggest in India. Since 2016, it has expanded at a CAGR of 22%, directly employing 4.7 million people. Between 2017 and 22 the sector has the potential to add 2.7 million new employment in India, or over 500,000 new jobs annually.

An ageing population, a rising middle class, the prevalence of lifestyle diseases, a focus on public-private partnerships, the rapid adoption of digital technologies, including telemedicine, as well as increased investor interest and increased FDI inflows over the past two decades are some of the factors driving the growth of the Indian healthcare sector. (NitiAyog, 2016) (5)

A point-of-care (POC) diagnostic gadget is a tool used to gather specific clinical data about patients in clinical and resource-constrained situations. The traditional clinical diagnostic process is time-consuming and expensive because it calls for expensive, high-end equipment, a skilled technician to operate it and interpret the results, among other factors. The adoption of POC diagnostic tools is still in its early stages, despite the fact that the medical facilities in the Indian healthcare system have undergone significant advancements. This review describes the limitations to the use of POC diagnostic tools currently employed in clinical settings. Emphasis is placed on the devices and technologies that are now undergoing research and development

across the nation and have the potential to significantly improve clinical diagnostics and the identification of the continuing COVID-19 epidemic. This article also discusses the effects of deploying POC diagnostic equipment and the long-term goals for technological development that could eventually improve the status of India's healthcare system and related industries. (Aditya Narayan Konwar, 2020) (6)

In the twenty-first century, India's healthcare system has made major improvements. India has shown consistent 10 percent growth in this industry, and by 2025, it is anticipated to reach \$280 billion. In 2016, India spent only \$75 per person on healthcare, a pittance compared to the US, EU, China, and global average (\$9403, \$3613, \$420, and \$1061, respectively), which spent \$9403, \$3613, \$420, and \$1061, respectively. The current \$128 billion Indian healthcare sector is projected to increase at a 12 percent annual rate over the next four years.

Medical devices have become a crucial component of any developing, healthcare-sensitive nation's healthcare system. These are employed in the healthcare industry for a number of purposes, including but not limited to screening and diagnosis, treatment and care, restoration, and monitoring. One of the top 20 medical device markets in the world is the one in India. [4] It is expanding quickly—at a rate of 15% annually—and is predicted to reach \$50 billion by 2025. In India, the market shares of the gadgets delivered in distinct segments vary. The largest sector is made up of medical devices and equipment (34%) and is followed by diagnostic imaging equipment (31%) and patient assistance and miscellaneous items (19%). (16 percent). (Manas Manu, 2021) (7)

Vital sign monitoring is provided by a medical wearable device. In order to monitor fitness and perform medical diagnostics, it involves monitoring one or more of the physiological vitals listed below as well as any others, including blood glucose level, blood pressure, pulse rate, electrocardiogram (ECG) patterns, respiration rate, and respiration effectiveness (e.g., blood oxygen saturation). Therefore, medical wearable devices are incredibly helpful preventative technology. There are numerous similar devices on the market now. Although they are useful, they are not very well known in India. Low awareness may be to blame for this. Since metropolitan areas are the main markets for such devices. (Nanda, 2018)(8)

Global concerns have been raised about shortages of vital materials used to prevent, identify, and treat COVID-19, and price speculation and increases may have had a negative impact on availability. In Ecuador during the initial pandemic response, when the highest mortality rates were recorded in a single day, this analysis identifies variation in costs of goods obtained through government-driven contracts. Between March 1 and July 31, 2020, data were retrieved from the National Public Procurement Service (SERCOP) database. In order to derive pertinent metrics for frequently purchased commodities, medical equipment, prescription medications, and other products, a statistical descriptive analysis was carried out. The most money was spent on face masks (\$4.5 million), acetaminophen (\$2.2 million), and reverse transcriptase quantitative polymerase chain reaction assay kits among the most popular goods. (Ortiz-Prado, 2021) (9)

An outstanding accomplishment is the quick creation of the medicinal device against COVID-19. The global population is effectively up against a number of barriers, from production to

distribution, deployment, and acceptance. Due to the growing awareness of and need for home medical equipment, numerous manufacturers have joined the market. For international manufacturers of medical devices, India offers a large market opportunity. The existing low per-person expenditure rate on medical equipment is anticipated to fuel significant growth for the Indian medical device market. Maintaining public confidence in home-use medical devices during COVID-19 would be crucial since the expansion of the medical device business in India poses difficulties with competition law (antitrust). The review article's objectives are to increase public awareness of frequently used medical devices during the COVID-19 epidemic and to gauge Indians' faith in home-useable medical equipment. Medical gadget makers would struggle to meet the needs of the health centre in the event of a global pandemic due to inadequate storage. (Saini, 2021) (10)

CHAPTER 3: RESEARCH OBJECTIVE

The objective of this study is to identify the current and future market potential of medical devices in India.

- To Access the current market for Medical Devices in India.

To access the current market, we need to study the market requirements, market gaps, market insights & market availability using a questionnaire.

- To Study the Supply gaps during covid pandemic.

The supply gap in Pharmaceutical market could happen due to lesser manufacturing of products, that's why along with current market, a forecast is needed to be done by taking the data of supply gaps during covid pandemic.

- To Study the Sales increment during covid pandemic.

As increasing demand & needs of products may result into getting the higher sales and reaching the targeted point in a minimal time.

- To Study the Majorly used covid rapid test kit.

Getting the higher no. of cases was not able to be identified by pathology labs, so the higher use of covid rapid test kit took place at domestic level. So by doing this study a future need & forecasting could be determined.

CHAPTER- 4: RESEARCH METHODOLOGY

4.1 Research Design:

- Type of Research: Descriptive study
- Source of Data: Primary research
- Data collection technique: Physical presence at pharmacy store
- Data collection: Questionnaire

4.2 Study Period

The study covers the duration of March 21, 2022, to June 15, 2022.

4.3 Research Question

- What is the future market of medical devices in India?
- Which are more preferred devices used in emergency in Jaipur using questionnaire?

4.4 Sample Design and Methodology

A descriptive cross-sectional, convenience sampling technique is used for the assessment. The study is conducted in Jaipur for 3 months. For sampling, non-probability sampling was used. A structured questionnaire was circulated, and responses were collected. A total of 30 responses were collected.

4.5 Data Analysis

The collected data has been analyzed using Microsoft Excel. Tables, Bar charts, graphs, averages, percentages, etc. were used to depict the analyzed data.

4.6 Limitation of Study

One of the study's limitations is the limited sample size, but some important findings can be used for further investigation.

CHAPTER - 5: RESULTS AND DISCUSSIONS

The study includes 30 respondents (pharmacies and retailers) from different locations of Jaipur. The data taken from retail pharmacies of Jaipur region states about the market requirements, market gap, market trends of pharmaceutical market

We analysed the data in different graphical representations such as pie charts, bar graphs as followed:

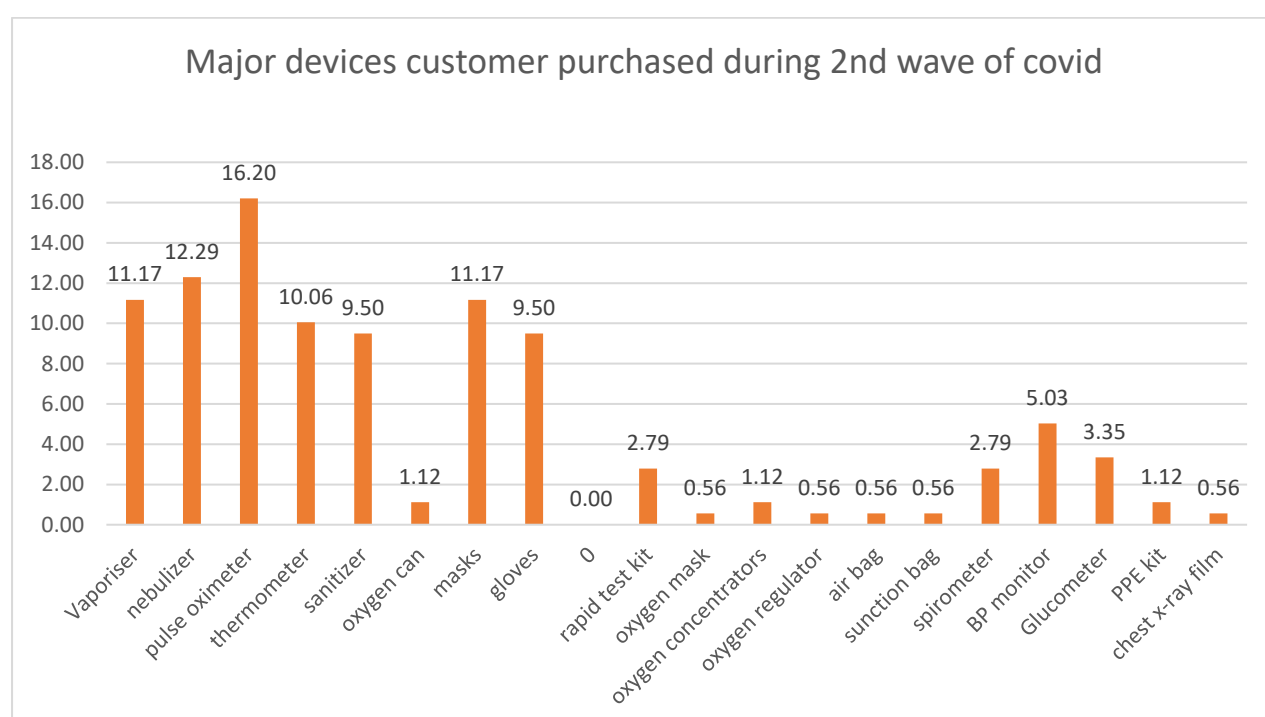


Figure no. 5.1: Medical devices purchased during covid pandemic (2nd wave)

- This above graph chart shows the % of the devices sold during covid pandemic.
- The higher market share was covered by the pulse oximeter and that too resulted in shortage in supplies as it was in high demand.
- Followed market share was covered by other devices was able to fulfil the supplies.

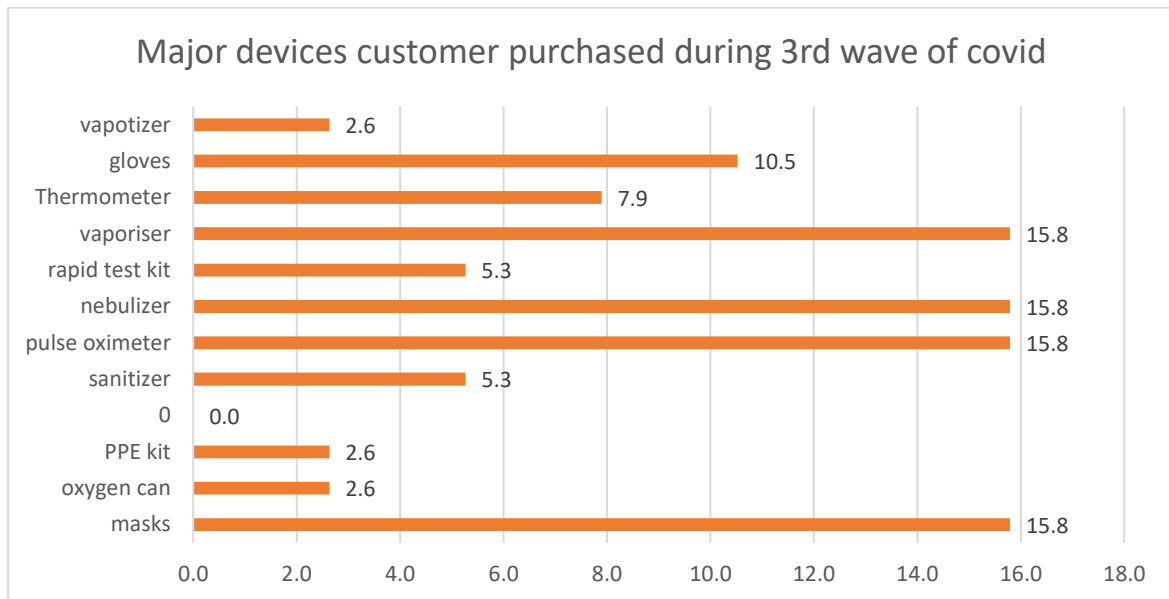


Figure no. 5.2: Medical devices purchased during covid pandemic (3rd wave)

- This above graph shows that the majorly selling devices were Thermometer, Nebulizer, Pulse oximeter & masks i.e., 15.8% of market in Jaipur respectively, then followed by other devices.

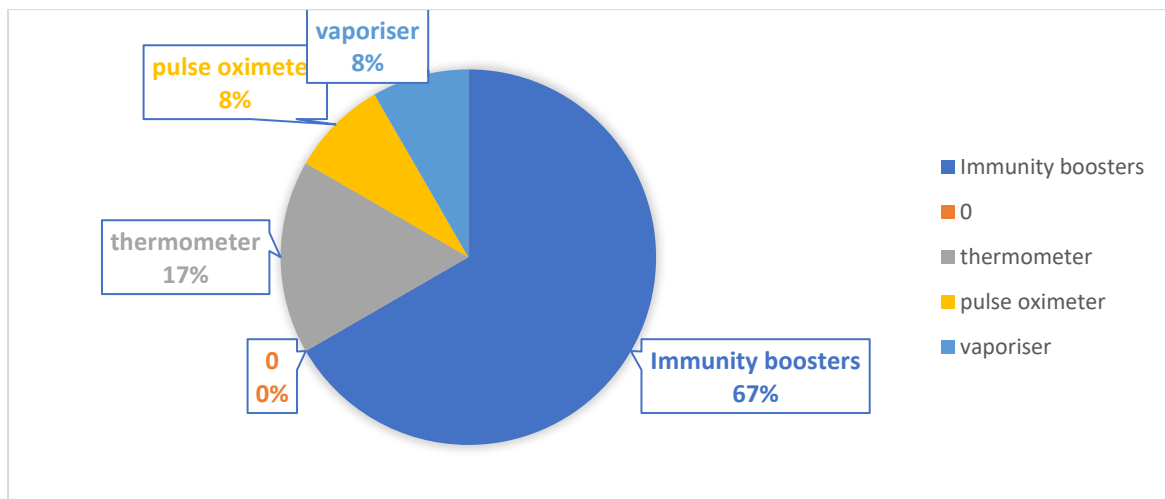


Figure no. 5.3: Buying behaviour towards preparing for covid pandemic

- As data taken by retail pharmacies shows that 67% customer purchased Immunity boosters for their better health during 3rd wave covid pandemic followed by 17% Thermometer & 8 % by Pulse oximeter & Vaporiser respectively.

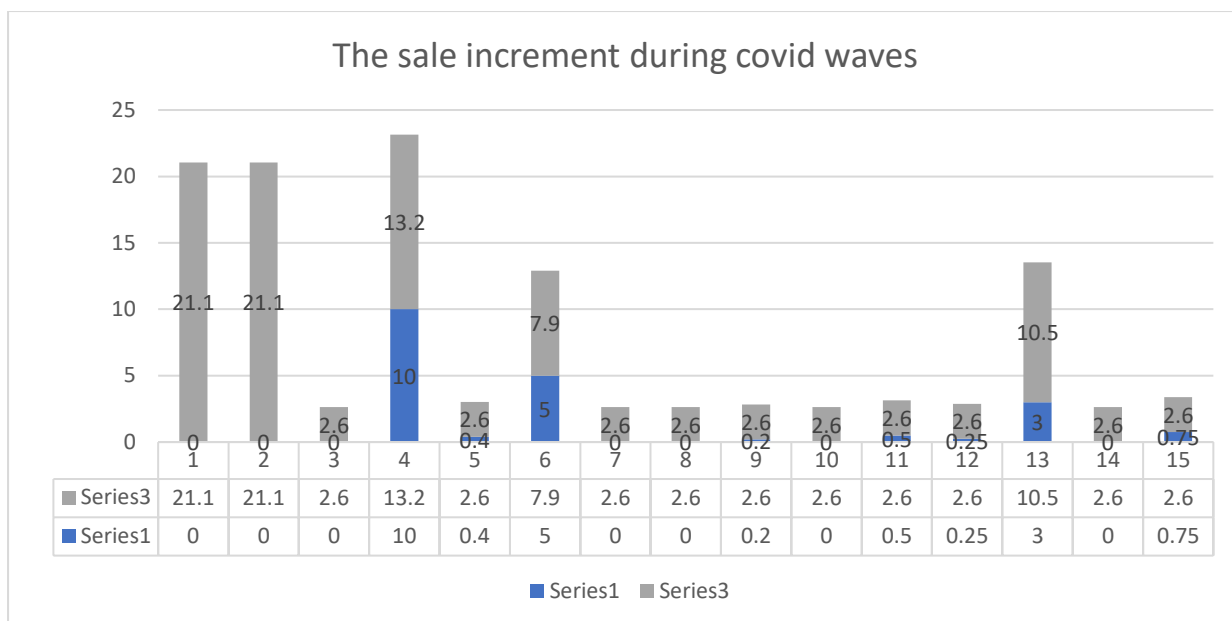


Figure no. 5.4: The sale increment of retail pharmacies during covid pandemic

- The sale increment was highest of 10 times at 13.2%.

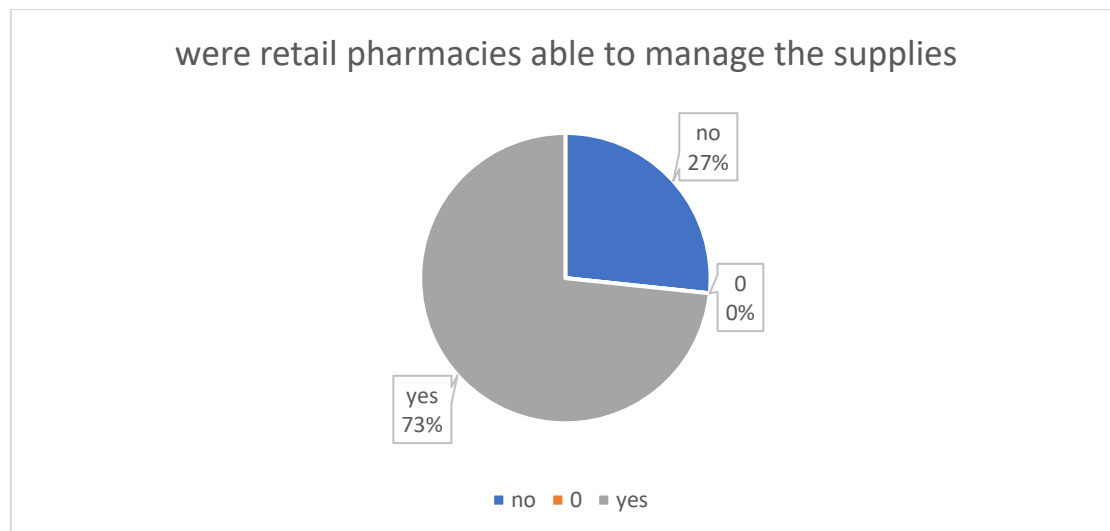


Figure no. 5.5: supply managed by retail pharmacies

- This above pie graph shows the supplies managed by retail pharmacies.
- Out of 30 retail pharmacies, 73% pharmacies were able to manage the supply gaps during covid pandemic, & 27% pharmacies were not able to supply gaps.
- Out of these 73% pharmacies who were able to manage the supplies, 3 pharmacies were the Apollo pharmacy sampled randomly had supply managed by the company itself.
- Other retail pharmacies clarified that during covid pandemic they were bringing the supplies on cash wherever it was available by themselves.

Medical device	Average price/unit (Rs)
Thermometer	170.86
vaporiser	314.83
Pulse oximeter	1270.83
glucometer	897.83
gloves	19.17
masks	9.40
sanitizer	159.62
covid rapid test kit	229.33
small oxygen concentrators	51666.67
oxygen can	525.00
BP monitor	1343.75
Spirometer	339.29
Total	100.00%

Table no.5.1 Average price of devices sold in Jaipur

- This above table data shows that the average selling price of devices sold in Jaipur during covid pandemic.
- The highest market share was covered by oxygen concentrators i.e., about 90%, followed by other devices & lastly by masks.
- Some of the devices were sold on MRP, followed by 10-15 % discount while some of them were sold at higher costs.

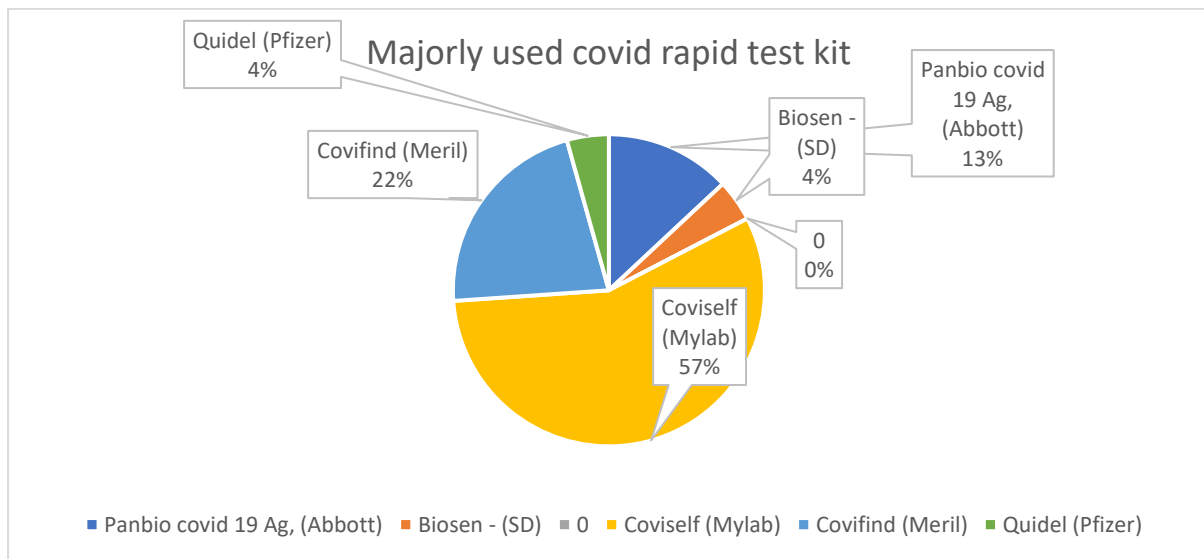


Figure no. 5.6: Majorly used covid rapid test kit

- This above graph show that the highest selling rapid test kit was coviself (Mylab) which covered around 57% of surveyed market of Jaipur region.
- And Quidel (Pfizer) was minimal selling rapid test kit.

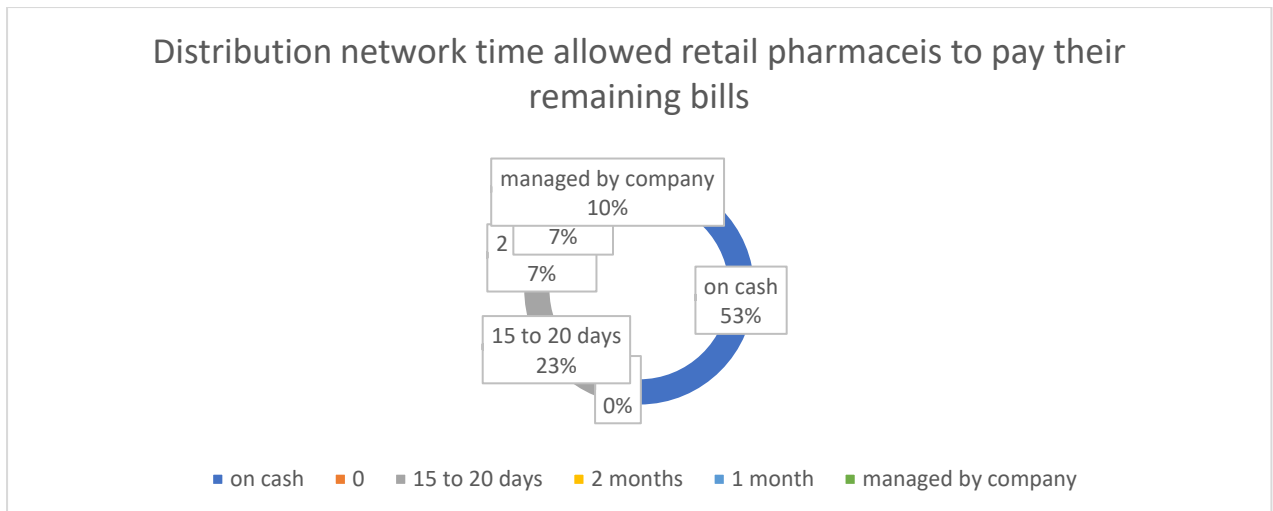


Figure no. 5.7: Distribution network time allowed retail pharmacies to pay their remaining bills

- This above graph shows that 53% of distribution was done on cash during the covid pandemic.
- 23% distribution network allowed a time of 15 to 20 days to pay their due bills.
- 14% distribution network allowed a time of 1 month & 2 month respectively days to pay their due bills.
- Remaining 10% were the Apollo pharmacies who were getting their supplies managed by the company.

CHAPTER- 6: CONCLUSIONS

- This study performed at 30 retail pharmacies of Jaipur states about the need, increments, supply gaps, and demand of medical devices which got results about the majorly sold devices in second wave of covid, majorly sold devices in third wave of covid, sales increments, supply gaps, specially about rapid test kit, & distribution network.
- In second wave of covid Vaporiser is found to be highly sold at 16.20%.
- In third wave of covid, Vaporizer, Pulse oximeter, & Nebulizer are found to be highly sold at 15.8% respectively.
- During third wave of covid, 67% customer purchased Immunity Boosters.
- Maximum of 1000% sales increment was found there at retail pharmacies for 21%.
- 73% of retail pharmacies were able to manage the supply gaps, & 27% pharmacies were not able to manage the supply gaps & took average of 2 months to fulfill their supply gaps.
- The highest selling price hold by Oxygen Concentrator having average of Rs. 51,666.
- In the Jaipur region, Coviself (Mylab) was the highest selling Covid rapid test kit had the market share of 57%.
- 53% of distribution was on cash, followed by 23% for 15 to 20 days, 7-7% for 1 and 2 months respectively & 10% managed by the company for the Apollo Pharmacies.

CHAPTER- 7: REFERENCES

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ANNEXURE

Questionnaire

Market Survey to retail pharmacies-

Q1. What were the major devices customer purchased in 2nd wave of covid?

During Covid-

Post Covid-

Q2. What were the devices customer started purchasing when 3rd wave of covid was about to outbreak?

Q3. What was their buying behavior while preparing themselves for covid waves (advanced purchasing of devices)?

Q4. What were the increments in sales during, & post covid?

Q5. Were you able to manage the supplies?

If not, then what time it took to fulfill the supply gap-?

Q6. What was the selling price of the devices as follows?

Thermometer-

Vaporizer-

Pulse oximeter-

Blood glucose meter-

Gloves-

Masks-

Sanitizers-

Covid rapid test kit-

Small oxygen concentrators-

Oxygen cylinders-

Digital BP monitor-

3-ball lung exerciser pump-

Q7. What all were the covid rapid test kit sold? (Their name with their brand)

Q8. How did a distribute on network allowed you to pay the remaining bills in case of no funds

Name of the firm with address-

Contact no.-

Remarks-
