Summer Training at

(April 20- June 20, 2014)

Market Scenario of Clopidogrel as a Molecule

By
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Under the guidance of
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MBA-Pharmaceutical Management (MBA-PM)
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The IIHMR University, Jaipur
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CERTIFICATE

This is to certify that Mr. PRASHANT DAGAR student of Institute of Health Management Research University; Jaipur has undergone summer training at **Dr. Reddy's Laboratories Ltd, Jaipur** from April 20, 2014 to June 20, 2014.

The candidate has successfully carried out the project "Market scenario of Clopidogrel" assigned to his during summer training & his approach to study has been sincere scientific & analytical.

This summer training is in partial fulfillment of the course requirements.

We wish his success in all his future endeavors.

Mr. Abhishek Dadhich
Assistant Professor & Mentor
IIHMR University, Jaipur

Col. (Dr.) Ashok Kaushik
Dean Academics& Student Affairs
IIHMR University, Jaipur

DR. REDDY'S

To Whom So Ever It May Concern

This is to Certify that Mr. PRASHANT DAGAR S/o Mr. SUKHBIR SINGH from Institute IIHMR University have undergone for Marketing Project under my Inspection and guidance for Dates .To Date 16th April to 20th June

On Product CLOPIDOGREL

I wish him for his successful Career in future.

Nikhil

With Regards
Nikhil Andleigh
Manager- Dr. Reddy's
Jaipur

CERTIFICATE

This is to certify that Mr. PRASAHANT DAGAR, student of **POST GRADUATE DIPLOMA IN PHARMACEUTICAL MANAGEMENT** (1ST YEAR) OF INDIAN INSTITUTE OF HEALTH MANAGEMENT RESEARCH has done accompanying project work entitled "**Market scenario of CLOPIDOGREL as a molecule"** under the supervision of **Mr. Navendu Sharma,** area sales manager in **Dr. Reddy's Labs,** JAIPUR.

PRASHANT DAGAR

PGDPM (BATCH-05)

IIHMR, JAIPUR

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PRASHANT DAGAR

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INTRODUCTION:

- **Introduction of the organization*:***

Dr. Reddy's Laboratories Ltd is a pharmaceutical company based in Hyderabad, Andhra Pradesh, India. The company was founded by **Kallam Anji Reddy**, who had previously worked in the mentor institute, Indian Drugs and Pharmaceuticals Limited, of Hyderabad, India. Dr. Reddy's manufactures and markets a wide range of pharmaceuticals in India and overseas. The company has over 190 medications, 60 active pharmaceutical ingredients (APIs) for drug manufacture, diagnostic kits, critical care, and biotechnology products. It has the revenue of $2.1 billion (2012) and net income of $300 million (2012).

Dr. Reddy's began as a supplier to Indian drug manufacturers, but it soon started exporting to other less-regulated markets that had the advantage of not having to spend time and money on a manufacturing plant that would gain approval from a drug licensing body such as the U.S. Food and Drug Administration (FDA). By the early 1990s, the expanded scale and profitability from these unregulated markets enabled the company to begin focusing on getting approval from drug regulators for their formulations and bulk drug manufacturing plants in more-developed economies. This allowed their movement into regulated markets such as the US and Europe. By 2007, Dr. Reddy's had six FDA plants producing active pharmaceutical ingredients in India and seven FDA-inspected and ISO 9001 (quality) and ISO 14001 (environmental management) certified plants making patient-ready medications – five of them in India and two in the UK.

Dr. Reddy's - India today is more than a 200 million dollar venture with presence in almost all major therapeutic areas. Their finished dosage business in India started in 1986 with launch of Norilet (norfloxacin). Their market penetration through nearly 3000 sales force who connect to more than 3,00,000 doctors on a regular basis has yielded us reaching all corners of the country and providing affordable and innovative medicines in all major therapeutic areas like gastro-intestinal, oncology, pain management, cardiovascular, dermatology, diabetes, etc. Eight of their brands feature in the top-300 brands in India that include drugs like Stamlo, Reditux, Omez and Ketorol. Apart from manufacturing and distribution of medicines they also provide patient care through their various initiatives like Sparsh, Life at your Doorstep, etc. (where patients are given free treatment and medicines), and educate and create awareness among healthcare professionals through DRFHE to cater to the millions who are in need of proper treatment across the country.[3]

BACKGROUND OF THE STUDY:

The definite or predictable market scenario for particular pharmaceuticals is a key motivator for future innovation: it determines whether, and how vigorously, a profit-based enterprise will further investigate an area for new, improved drugs. An understanding of market dynamics is also critical to determining how drugs can be distributed efficiently. By determining the market scenario of a drug companies can identify the upcoming opportunities for the companies.

Market scenario can be tracked by the collection of specific database in case of pharmaceutical industries in India Doctors and pharmacists are the primary target of industries. Scenario ideation is a very necessary part of business. Every strategy is based on assumption of those factors which are able to affect the market environment.

Heart disease is the number one killer in the world and India carries more than its share of this burden. Moreover, the problem is set to rise: it is predicted that by 2020, India will have 100 million heart patients, amounting to approximately 60% of people suffering from heart disease, globally. Indian pharmaceutical market is very much attractive and full of opportunities.

Clopidogrel (INN) is an oral, thienopyridine-class **antiplatelet agent used to inhibit blood clots in coronary artery disease, peripheral vascular disease, and cerebrovascular disease.** The drug works by irreversibly inhibiting a receptor called $P2Y_{12}$, an adenosine diphosphate (ADP) chemoreceptor on platelet cell membranes. Adverse effects include hemorrhage, severe neutropenia, and thrombotic thrombocytopenic purpura.

Not even in India it is the problem at global level now so it opens some gates of opportunities for pharmaceutical industries in this sector. CLOPIDOGREL has lots of opportunities in this market the main aim of this study is to explore those opportunities and to determine that present market scenario of CLOPIDOGREL. By determining the scenario the market of CLOPIDOGREL it will be easier to predict that what is the current market situation of CLOPIDOGREL and what are the opportunities are there for CLOPIDOGREL in different markets and situations. What are the threats and what are the holdups factors existed in the market which may influence the market of CLOPIDOGREL. Due to the large number of hypertension cases in India and at global market, generate an attractive market for antihypertensive drugs and CLOPIDOGREL like new and effective medicine can make its position here very well and industries who wants to introduce it in the market it is a good sign for them. In Indian market CLOPIDOGREL is a new entrant it is growing very rapidly and most o the companies are focusing on this molecule.

Scenarios organize the market uncertain characters into sets of competing assumptions about the future environment which a company will face. The first step of applying the Strategic Framework is to determine the drivers of change, define the range of possible futures, and develop scenarios that describe these futures. The following pages explore four likely scenarios; their impact on the Indian market and the potential opportunity for industry. Developing strategic responses for each scenario is dependent on the unique capabilities and challenges of each company. It is my hope to spur industry to abandon the notion of a single, silver bullet, "best" strategy and to adopt a new perspective on strategic planning for India's complex pharmaceutical market. The strategic flexibility approach start with anticipating strategic questions and mapping of those factors that could change the direction of the Indian pharmaceutical market. Only thing is constant in the pharmaceutical market that it is uncertain and dynamic in nature to handle these challenges industry needs to identify them make plans according to them.

Doctors are considering being the first consumer of the pharmaceutical industries in India. More the prescription with specific brand's name more will be its market. To determine the exact market scenario and opportunity in the market prescription patterns of doctors should be analyze. Which factor is motivating most to write a drug in his prescription can be determine and if a company establish its brand according to it then it will surely hit a high growth rate. That factor can be price of the drug, quality or effectiveness of drug, safety of drug or company's image there are so many factors which can influence the prescription of a doctor. to determine the marketing scenario of a drug it is necessary that company must know about the perceptions of the doctors because market is totally depend on it.

LITERATURE REVIEW:

Brief introduction of Indian pharmaceutical market:

Although the Indian pharmaceutical market is attractive, it is more than a little bit crowded with over 20,000 pharmaceutical firms, 60,000 distributors and 700,000 to 800,000 retailers competing for the pharmaceutical dollar. The top 10 companies control about 30% of the market and 250 companies control 70% of the market. Fortunately for MNCs, whose limited portfolios make brand-building essential, there are still opportunities to build and sustain brands in the market despite intense competition and fragmentation. In a market where doctors are free to prescribe any drug (whether branded or generic), any broad shifts in prescription patterns will radically impact revenues. Pharmaceutical sales are rising faster than growth in real private consumption and will continue to grow, driven by both increased healthcare spending per capita and a larger proportion of spend going toward pharmaceuticals. While acute therapies have historically dominated the market and epidemics provide spurts of growth, chronic therapies are growing at a faster rate and have witnessed significant price increases at a time when overall pricing in the domestic pharmaceutical industry has been fairly stable. The price increase can be attributed to increasing disposable income among chronic patients, prescription "lock in" with few equivalent brands, and novel technologies that differentiate treatments and deliver increased value to patients.

Before the expiry of its patent, Clopidogrel was the second-most prescribed drug in the world. In 2010, it grossed over US$9 billion in global sales.

Antiplatelets drugs:

An **antiplatelet drug** (antiaggregant) is a member of a class of pharmaceuticals that decrease platelet aggregation and inhibit thrombus formation. They are effective in the arterial circulation, where anticoagulants have little effect.

They are widely used in primary and secondary prevention of thrombotic cerebrovascular or cardiovascular disease.

Introduction of Clopidogrel:

- An ADP receptor antagonist that competitively inhibits ADP from binding to platelet receptors, preventing ADP-mediated up-regulation of glycoprotein (GP) IIb/IIIa receptor, again blocking amplification of platelet aggregation.

- Direct comparison of clopidogrel may indicate that it is a slightly more effective antiplatelet drug than aspirin - for example, when compared head-to-head in the Clopidogrel versus Aspirin in Patients at Risk of Ischemic Events (CAPRIE) trial. But a high NNT (200) to prevent one additional event and high incremental cost (given aspirin's low cost) have meant that use of clopidogrel alone is limited to those who cannot tolerate aspirin prophylaxis. More importantly, clopidogrel is routinely used in the treatment of acute coronary system (ACS) and post-percutaneous coronary intervention (PCI) stenting in conjunction with aspirin.

Medical use:

Clopidogrel is used to prevent myocardial infarction (heart attack) and stroke in people who are at high risk in certain people at elevated risk of these events, including those with unstable angina, myocardial infarction (heart attack) with or without ST elevation, and those with established peripheral artery disease, recent heart attack, or ischemic stroke.

Plavix is marketed worldwide in nearly 110 countries, with sales of US$6.6 billion in 2009. It had been the second-top-selling drug in the world for a few years as of 2007 and was still growing by over 20% in 2007. U.S. sales were US$3.8 billion in 2008.

In 2006, generic clopidogrel was briefly marketed by Apotex, a Canadian generic pharmaceutical company before a court order halted further production until resolution of a patent infringement case brought by Bristol-Myers Squibb. The court ruled that Bristol-Myers Squibb's patent was valid and provided protection until November 2011. The FDA extended the patent protection of clopidogrel by six months, giving exclusivity that would expire on May 17, 2012. The FDA approved generic versions of Plavix on May 17, 2012.

In June 2009, the European Medicines Agency gave authorisation to six generic versions of clopidogrel bisulfate, and the drug is now available in several European countries, including the United Kingdom.

Generic clopidogrel is produced by several pharmaceutical companies in India and elsewhere, and often sold under its INN.

It is marketed by Dr. Reddy's under the trade name PLAGRIL.

It is marketed by Cipla under the trade name Clopivas, by Sun Pharmaceuticals as Clopilet, by Ranbaxy Laboratories as Ceruvin, as Clavix by Intas Pharmaceuticals, and

as Deplatt by Torrent Pharmaceuticals. In India, it is sold as Clopivas AP by Cipla, Clopigrel A by USV, and Clopitab A by Lupin(mixed with aspirin).

Competitors of CLOPIDOGREL:

Ten generic versions of the anti-clotting drug clopidogrel (Plavix) were approved en masse by the FDA.

Two dosage forms for the generics were approved: 300 mg, produced by Gate, Mylan, and Teva; and 75 mg, manufactured by Apotex, Aurobindo, Mylan, Roxane, Sun Pharma, Teva, and Torrent.

Uppsala, Sweden - Results of a phase 2 trials suggests that the new thienopyridine antiplatelet drug **prasugrel** (Lilly/Sankyo) may be more effective than **clopidogrel**, with a greater inhibition of platelet aggregation and fewer nonresponders.

Available brands of Clopidogrel:

Plagerine - Micro Carsyon [Clopidogrel]

Strength	Volume	Presentation	Price*
Plagerine 75mg	10	Plagerine FC-TAB	50.00

Plagerine-A - Micro Carsyon [Clopidogrel + Aspirin]

Strength	Volume	Presentation	Price*
Plagerine-A Aspirin (EC)75mg, Clopidogrel 75mg	10	Plagerine-A CAP	28.88
Plagerine-A Aspirin (EC)150mg, Clopidogrel 75mg	10	Plagerine-A CAP	29.13

Plagerine-A - Micro Carsyon [Clopidogrel]

Combination	Volume	Presentation	Price*
Plagerine-A Aspirin (EC) 75 mg, Clopidogrel 75 mg.	10	Plagerine-A CAP	28.88
Plagerine-A Aspirin (EC) 150 mg, Clopidogrel 75 mg.	10	Plagerine-A CAP	29.13

Plagril Gold - Dr. Reddy's [Clopidogrel]

Strength	Volume	Presentation	Price*
Plagril Gold 75mg	10	Plagril Gold FC-TAB	120.00

Plagril-A - Dr. Reddy's [Clopidogrel + Aspirin]

Strength	Volume	Presentation	Price*
Plagril-A Clopidogrel 75mg, Aspirin 75mg	10	Plagril-A CAP	33.75
Plagril-A Clopidogrel 75 mg, Aspirin 75 mg.	10	Plagril-A FC-TAB	30.90

Plagril-A - Dr. Reddy's [Clopidogrel]

Combination	Volume	Presentation	Price*
Plagril-A Clopidogrel 75 mg, aspirin 75 mg.	10	Plagril-A CAP	33.75
Plagril-A Clopidogrel 75 mg, Aspirin 75 mg.	10	Plagril-A FC-TAB	30.90

Platfree - Medley [Clopidogrel]

Strength	Volume	Presentation	Price*
Platfree 75mg	10	Platfree TAB	145.00

Platfrin - Medley [Clopidogrel]

Strength	Volume	Presentation	Price*
Platfrin 75mg	10	Platfrin TAB	60.00
Platfrin 150mg	10	Platfrin TAB	70.00

Platloc - Unichem [Clopidogrel]

Strength	Volume	Presentation	Price*
Platloc 75mg	10	Platloc TAB	31.90

Platloc-AS - Unichem [Clopidogrel + Aspirin]

Strength	Volume	Presentation	Price*
Platloc-AS Aspirin 75mg, Clopidogrel 75mg	10	Platloc-AS TAB	26.68
Platloc-AS Aspirin 162.5mg, Clopidogrel 75mg	10	Platloc-AS TAB	26.98

Platloc-AS - Unichem [Clopidogrel]

Combination	Volume	Presentation	Price*
Platloc-AS Aspirin 75 mg, Clopidogrel 75 mg.	10	Platloc-AS TAB	26.68
Platloc-AS Clopidogrel 75 mg, Aspirin 162.5 mg.	10	Platloc-AS TAB	26.98

Platocas - Unichem [Clopidogrel + Aspirin]

Strength	Volume	Presentation	Price*
Platocas Aspirin 75mg, Clopidogrel 75mg	10	Platocas TAB	26.68
Platocas Aspirin 162.5mg, Clopidogrel 75mg	10	Platocas TAB	26.68

Preva-AS - Intas [Clopidogrel]

Combination	Volume	Presentation	Price*
Preva-AS Clopidogrel 75 mg, Aspirin 75 mg.	10	Preva-AS FC-TAB	25.94
Preva-AS Clopidogrel 75 mg, Aspirin 150 mg.	10	Preva-AS FC-TAB	26.19

Preva-AS - Intas [Clopidogrel + Aspirin]

Combination	Volume	Presentation	Price*
Preva-AS Clopidogrel 75 mg, Aspirin 75 mg.	10	Preva-AS FC-TAB	25.94
Preva-AS Clopidogrel 75 mg, Aspirin 150 mg.	10	Preva-AS FC-TAB	26.19

Psygrel - Psycorem [Clopidogrel]

Strength	Volume	Presentation	Price*
Psygrel 75mg	100	Psygrel TAB	360.00

Stagrel-A - Invision [Clopidogrel + Aspirin]

Strength	Volume	Presentation	Price*
Stagrel-A Aspirin (EC)150mg, Clopidogrel Bisulfate 75mg	10	Stagrel-A TAB	33.83

Need of the study:

Indian pharmaceutical market is full of uncertainties every company has to exploit those uncertainties and has to determine the opportunity size in the market. This research is to determine what is the present market scenario of market of CLOPIDOGREL drug which a cardiovascular drug and basically a beta-blocker in nature. This study will give an account of direct and indirect competitors in the market. There is a lot of opportunity for cardiovascular drugs that can be seen by the following report.

The huge increase in the patient population, patent expiry of popular blockbuster drugs, increase in disposable income and introduction of newer and better drugs is helping the market to grow. Above figure has shown that there is a lot of growth and profit in antiplatelet market and CLOPIDOGREL which is a beta blocker primarily used for strokes is new entrant in Indian market and now all the companies are focusing on it. CLOPIDOGREL is rapidly growing. Companies are watching a safe investment and lot of profit in it. So CLOPIDOGREL is a emerging market in India.

The uncertainties are common in a complex, growing market like Indian make forming and committing to one strategy difficult because then assumptions the strategy was built on may well change. A company that has been committed to a breakthrough strategy may face unexpected problems if the market environment changes. Strategic risk is the danger of change so profound that a company's basic approach to creating and capturing value is threatened. The challenge is not to look for a superior prediction of the future, because it doesn't exist—most of the uncertainty is outside the company's control. The challenge is to manage the strategic risk. Scenario analysis is a process of analyzing possible future events by considering alternative possible outcomes. Thus, the scenario analysis, which is a main method of projections, does not try to show one exact picture of the future. Instead, it presents consciously several alternative future developments. Consequently, a scope of possible future outcomes is observable. Not only are the outcomes observable, also the development paths leading to the outcomes. it tries to consider possible developments and turning points, which may only be connected to the past. In short, several scenarios are demonstrated in a scenario analysis to show possible future outcomes.

The ability to exploit the uncertainty in the Indian market may well differentiate the winners from the losers. The size of the opportunity for MNCs varies widely depending upon the condition of key market drivers. While scenarios are independent of the company, the most effective strategies to address those scenarios are unique to each company. Breakthrough Results require committing to the most appropriate strategy for the expected future while maintaining the ability to adjust and respond quickly should the future not turn out as expected. There are lots of factors which are able to affect the product's market.

RESEARCH QUESTIONS:

1. **What is the market scenario of CLOPIDOGREL?**
2. **What is the perception of doctors about CLOPIDOGREL?**

OBJECTIVES:

1. **To determine doctors perception about CLOPIDOGREL on different parameters.**
2. **To determine market scenario of CLOPIDOGREL.**

Methodology:

Study design: Descriptive study.

Source of Data: Primary data

Sampling technique: Non probability sampling.

Data collection tool: Semi-structured questionnaire

Study area: South and West Delhi

Sample size: 50 doctors (CARDIOLOGISTS)

Data Analysis: Microsoft excel has been used to analyze the data quantitatively.

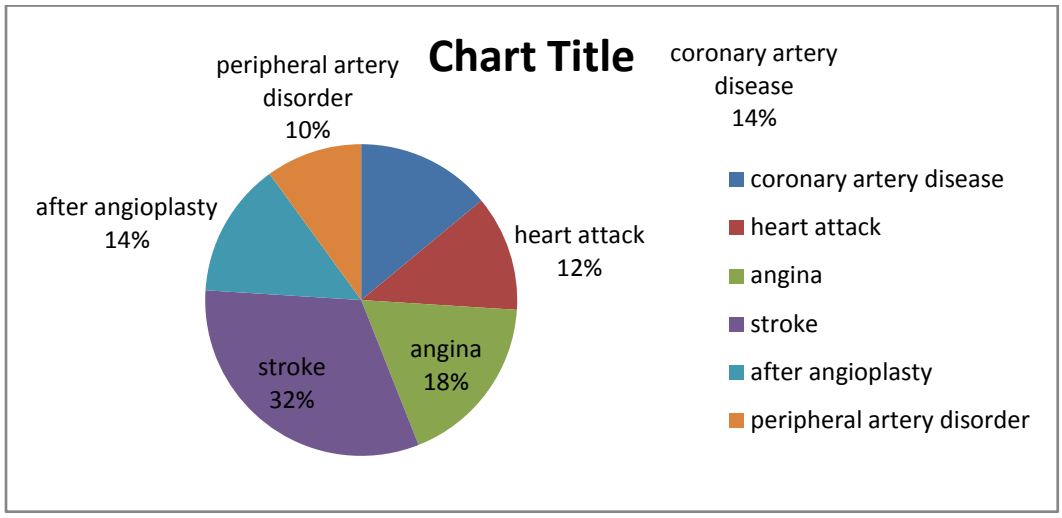
Ethical considerations:

- Respondent was fully aware about the study.
- All the respondent has fill the questionnaire with their own interest.

Results:

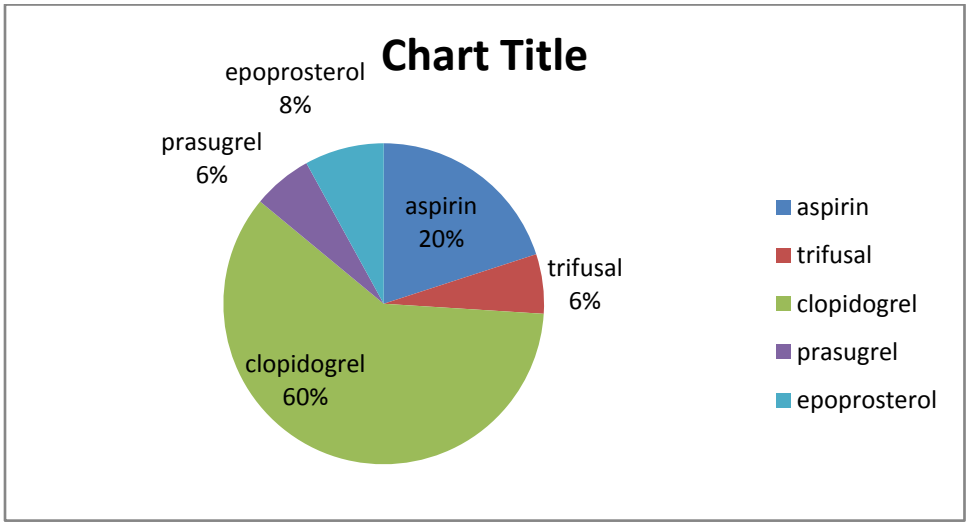
Data collected from 50 doctors are compiled in this section. . The data are analyzed and presented under.

1. Major symptoms for which Clopidogrel is prescribed more:



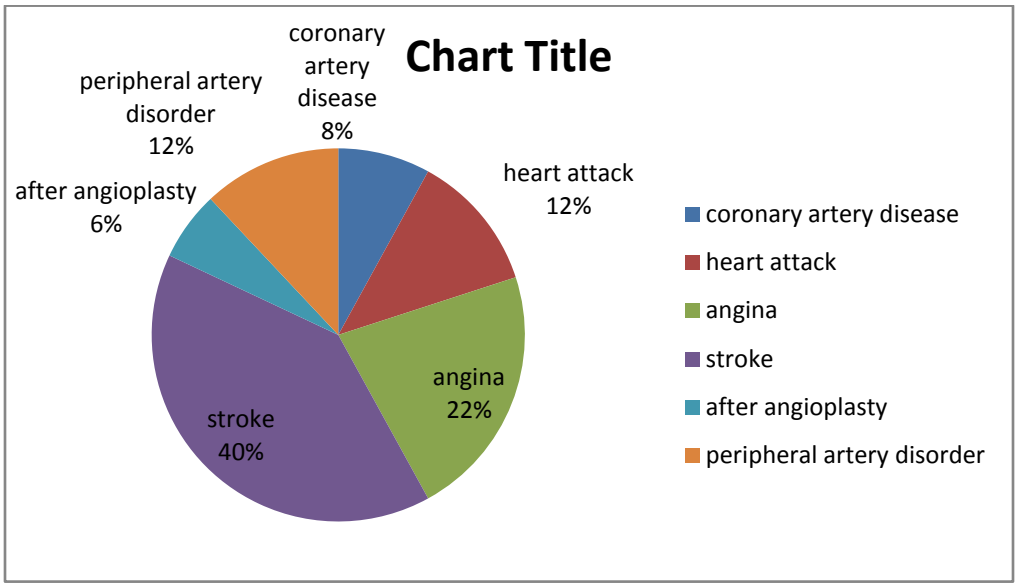
Findings: Clopidogrel is prescribed most in Heart Strokes followed by Angina and then Coronary Artery disease and after Angioplasty.

2. Antiplatelet drug preferred more:



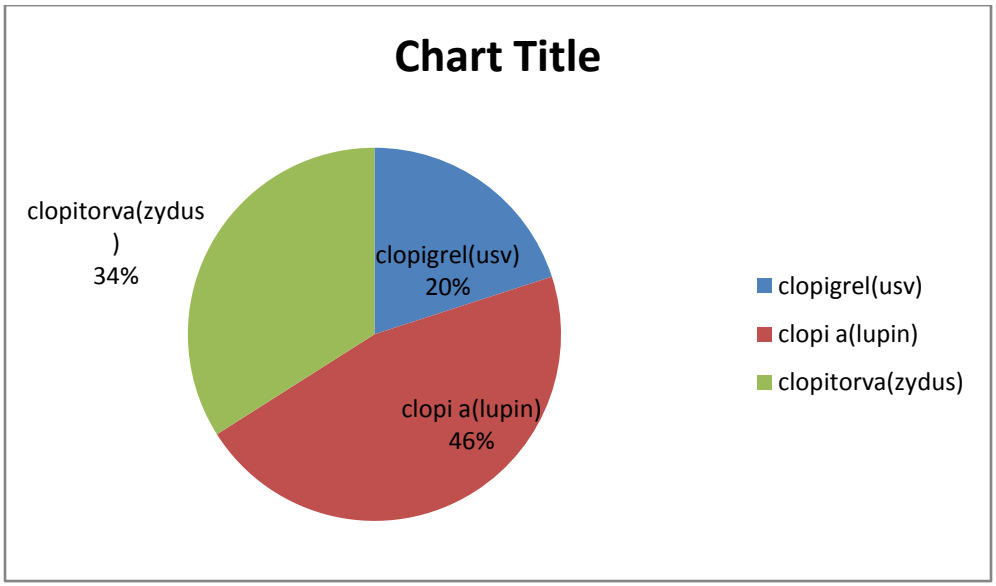
Findings: Doctor's preferred choice is Clopidogrel i.e 60% doctors followed by Aspirin i.e. 20%.

3. Case in which Clopidogrel preferred more:



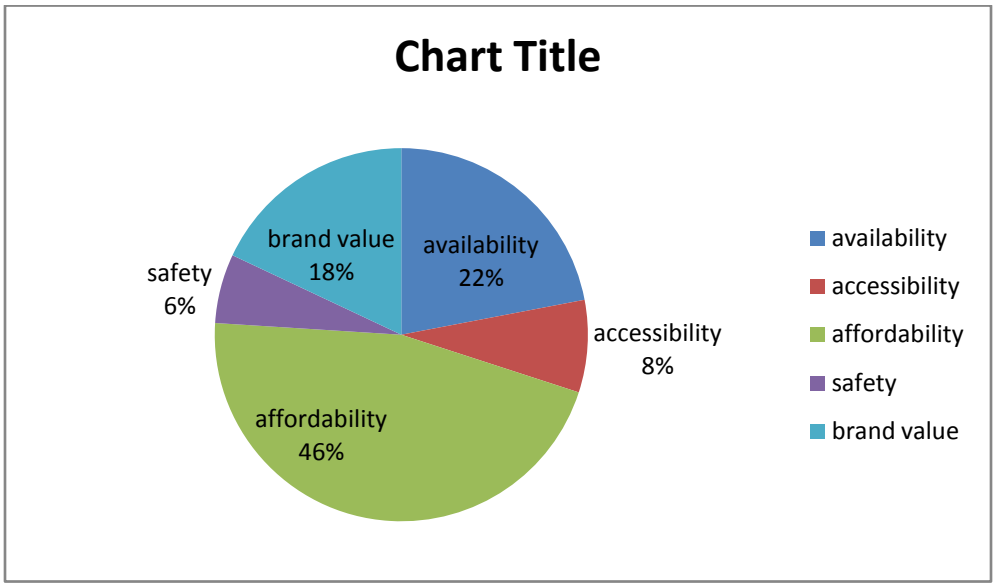
Findings: Clopidogrel is mainly used for Heart Strokes i.e. 40% followed by Angina 22% then Peripheral Artery Disorder 12%.

4. Most preferred brand of clopidogrel:



Findings: Clopi A (LUPIN) is preferred most i.e. 46% followed by Clopitorva(ZYDUS) i.e. 34% and then Cloigrel(USV) i.e. 20%.

5. This brand is preferred because:



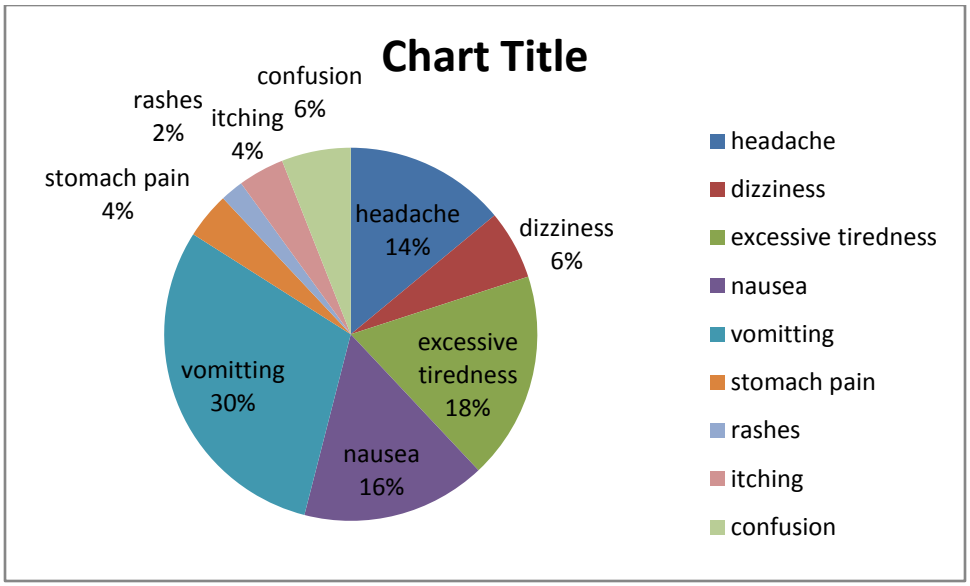
Findings: This brand is preferred because of Affordability followed by Availability and then Brand value.

6. Drug is safe or not:

YES	45
NO	5

Findings: 90% of the doctors agreed that the drug is safe.

7. Side Effects seen in patients:



Findings: Mostly Vomiting occurred followed by Excessive tiredness, Headache, Nausea etc.

8. Satisfaction with Clopidogrel:

YES	48
NO	2

Findings: 48 doctors are satisfied with the results of Clopidogrel.

CONCLUSION:

This study has the main objective of determining the market scenario of CLOPIDOGREL and what the perceptions of doctors about CLOPIDOGREL. In order to answer the core research question 50 doctors of WEST and SOUTH Delhi are attributed during the period from 20 April to June 20, 2014.

CLOPIDOGREL hasn't any tough competition in market so to compete their direct and indirect competitors companies has to focus on the **affordability** of the drug which is consider as the most motivational factor for doctors when they prescribe CLOPIDOGREL. Market scenario of CLOPIDOGREL is full of opportunities and growth. Other motivating factors like **availability of drug** which is totally depend on **distribution channel** of the company.

Here it is clear that in **Pharmaceutical market, Cardiovascular segment** has lots of opportunity because it has a large number of cardiac patient so pharmaceutical companies should focus on CLOPIDOGREL which has a very fine market not even In India but also in U.S. market which is said to be largest pharmaceutical market. Key strength of CLOPIDOGREL is not only to be an **effective drug** according to the doctors it very much **affordable** and its demand is constantly increasing. That means companies have a good opportunity in this segment and they need to grab this opportunity.

Adverse effect of CLOPIDOGREL can be neglect because they are not up to the serious level and adverse effects are only seen in very small percentage of patients. Adverse effects due to CLOPIDOGREL can be taken care by different other medication support. So it can be said ADRs of CLOPIDOGREL is not going to be a serious hurdle on the way of its growth.

All these factors are supporting CLOPIDOGREL to be a very attractive market. By this research finally concluded that CLOPIDOGREL's market scenario is full of opportunities and growth. CLOPIDOGREL market can be concluded as full of profits and by taking some smart step any company can grab this opportunity.

RECOMMENDATIONS:

On the basis of the study I will recommend that an affordable and accessible clopidogrel brand may give lots of opportunities to the industry and increasing size of cardiac market in India will bring lots of opportunities for this molecule so I will recommend industries to take a look on this market and after patent expiration there is lots of opportunity for generics. An effective, safe and affordable drug which can be easily available will open some new gates of growth for the companies.

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ANNEXURE-1

QUESTIONNAIRE

a. For which major symptom you prescribe antiplatelet drug the most?
   i. Coronary Artery Disease
   ii. Heart attack
   iii. Angina
   iv. Stroke
   v. After Angioplasty
   vi. After Heart bypass or valve replacement
   vii. Peripheral artery disorder
   viii. Others (specify)

b. For these symptoms which antiplatelet drug you preferred more?
   i. Aspirin
   ii. Trifusal
   iii. Clopidogrel
   iv. Prasugrel
   v. Dipyridamole
   vi. Epoprosterol

c. In which case you preferred CLOPIDOGREL more?
   i. Coronary Artery Disease
   ii. Heart attack
   iii. Angina
   iv. Stroke
   v. After Angioplasty
   vi. After Heart bypass or valve replacement
   vii. Peripheral artery disorder
   viii. Others (specify)

d. Which brand of CLOPIDOGREL you preferred more?
   ……..

e. Why you preferred this brand?
   i. Availability
   ii. Accessibility
   iii. Affordability
   iv. Safety
   v. Brand value

f. IS CLOPIDOGREL IS SAFE OR NOT?
   i. Yes
   ii. No

g. WHICH SIDE EFFECTS YOU PROBABLY SEEN IN CLOPIDOGREL?
   i. Excessive tiredness
   ii. Headache
   iii. Dizziness
   iv. Nausea
   v. Vomiting
   vi. Stomach pain
   vii. Rashes
   viii. Itching
   ix. Confusion
   x. Pale skin

h. Are you satisfied with CLOPIDOGREL?
   i. Yes
   ii. No