Summer Training at
Blueberry Pharma Advisory, Mumbai.
(April 15- June 15, 2013)

To Identify the Opportunity and Market from Matured Molecules Which are Still Growing

By
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Under the guidance of
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Certificate

This to certify that Aleti Goutham student of Post Graduate Diploma in Pharmaceutical Management (PGDPM) from Institute of Health Management Research, Jaipur, Batch 4^{th} has successfully undergone his summer training in Blueberry pharma Avisory, Mumbai and has done projects on:

- "To Identify opportunities and market from Matured Molecules which are still growing"
- Worked on secondary data collection of Anti Hypertensive ,Anti Diabetic and Oncology molecules

The candidate has successfully carried out the mentioned studies assigned during his summer training from 15 April 2013 – 15June 2013 and his approach towards the study was sincere, scientific and analytical.

We wish him success in all his future endeavors.

Dr. Nirmal K Gurbani

Professor and Dean
IHMR, Jaipur

Dr. Ashok Kaushik

Dean Academics and Student Affairs,
IHMR, Jaipur

ACKNOWLEDGEMENT

I express my sincere gratitude to Mr.Subhash Seth. (CEO) for giving me an opportunity to undergo summer training at Blueberry pharma advisory.

I am very thankful to Dr.Nirmal K Gurbani and Mr.Subhash Seth for their support, cooperation and motivation provided to me during summer training for constant inspiration, presence and sharing their knowledge .The task of summer training would have been never completed without their valuable suggestions, which had helped me a lot, in completing my project.

I also extend my sincere appreciation to college & the staff, who had helped me in placing for summer training program in such a well encouraging organization, which had helped me in accomplishing my project and, to reach myself a step head.

Lastly I would like to thank my parents and the almighty for their moral support in working towards my dreams, and my friends with whom I shared day- to- day experience and received lot of suggestions that improved my level of my knowledge and quality of work.

ALETI GOUTHAM

DECLARATION

I ALETI GOUTHAM student of PG Diploma in Pharmaceutical Management studying at college IIHMR Jaipur, hereby declare that the summer training report on "To Identify Opportunities from Matured Molecules which are Still Growing" submitted to IIHMR Jaipur and Blueberry Pharma Advisory, Mumbai.

The information and the data given in the report is authentic to the best of knowledge

ALETI GOUTHAM

COMPANY PROFILE

Mr.Subhash Seth is Chief Executive Officer and Owner of Blue Berry Pharma Advisory, Mumbai. He has over 39 years of global pharmaceutical experience. He was previously the Senior Vice President of International Business at USV Limited. He had global responsibility of sales and marketing of Active pharmaceutical ingredients (APIs) and Finished Dosage business. He has also worked with leading Indian pharmaceutical companies including Zydus Cadila and Torrent Pharmaceuticals. He has extensively travelled across the globe and has worked with innovators and top global generic companies.

ABOUT COMPANY:

Blue Berry Pharma Advisory was established on the April 1, 2011 in Mumbai, India. It is an independent consultancy company advising Indian & Overseas pharmaceutical companies with different business interests. It advises healthcare product companies in developing strategies for the companies that can take them to next level of the horizon. He advises clients mainly in the areas of Strategic Planning, Business Development, and Sales & Marketing.

CURRENT PROJECTS:

It advising mid-size Indian Pharma Companies & assisting US & EU companies to develop products from scratch & preparation of ANDAs, EU Dossiers & supply of Finished Dosages to clients.

EXECUTIVE SUMMARY

Pharmaceutical sector is one of the fastest growing sectors all over the world. Revenues are increasing year by year. The investments are also increasing at a very high rate and at the same time many players are entering into the market, there has been the cut–throat competition between various drugs manufacturing companies, all the companies are manufacturing products of different therapeutic segments. There is need to manufacture drugs which have demand in the market and have to know the gaps of market and develop strategies to increase sales by penetrating into the market, but most of the companies don't take initiate to start production because they face the problems of marketing strategies for the business development. So there were particular organizations approach consulting companies, for whom they provide strategic planning in the areas of sales, marketing and business development.

The consulting agencies provide strategies to companies are totally based on the primary and secondary data. In present scenario the drugs which are used are large in number and drug molecules are also very numerous in number. In order to increase the sales & market, identifying the therapeutic segments is very important .and most of the API manufacturing companies have to identify the molecules which have high growth and sales, and the companies must know the current market scenario of particular molecules before manufacturing the API product. The main scope of this study is to identify the molecules which still have potential and major share in the market. The potential of molecules has determined by the sales figures of last past years and the combination of molecules which are widely using since past years.

So, here analysis has been done in various aspects like volume, price, players, and market share of players in different countries. The analysis has done by using MS Excel. The source of secondary data is IMS DATA 2012

OBJECTIVES

-To identify the mature molecules which are still having potential and growth in the market.

-To identify the market for matured molecules

METFORMIN

INTRODUCTION

Metformin is an oral anti diabetic drug used in the biguanide class. It is the first line drug used for the treatment of type 2 diabetes and it has been used since past 40 years. It produces helpful side benefits that can protect against the lethal complications of type II diabetes. Combination therapy using two differently acting oral anti diabetic agents at the time of diagnosis or early thereafter is becoming increasingly common in order to reach glycaemic targets. The combination of metformin and pioglitazone in an early stage of type 2 diabetes enables greater likelihood that these targets can be attained without the risk of hypoglycaemia associated with insulin secretagogues. A greater use of alogliptin and other DPP-4 inhibitors will occur if long-term studies show reduced cardiac events .The initial treatment with glyburide/metformin tablets provides superior glycemic control at lower doses than individual monotherapies.Glycosylated hemoglobin levels, fasting plasma glucose levels, insulin sensitivity, and β-cell function improved significantly with metformin-rosiglitazone therapy in a dose-dependent manner.

Metformin was mostly used in combination with other drugs because of its less adverse effects and effective in action. It has lower risk of hypoglycemia than the other drug. It has potential to maximize glycemic control in diabetic patients without increasing gastrointestinal effects. First synthesized and found to reduce blood sugar in the 1920s, metformin was forgotten for the next two decades as research shifted to insulin and other antidiabetic drugs. Interest in metformin was rekindled in the late 1940s after several reports that it could reduce blood sugar levels in people, and in 1957, French physician Jean Sterne published the first clinical trial of metformin as a treatment for diabetesThe most common adverse effect is gastrointestinal upset, including diarrhea, cramps, nausea, vomiting and increased flatulence.

The most serious potential side effect of metformin use is lactic acidosis; this complication is very rare, and the vast majority of these cases seem to be related to comorbid conditions, such as impaired liver or kidney function, rather than to the metformin itself. It has also been reported to decrease the blood levels of thyroid-stimulating hormone in people with hypothyroidism, The clinical significance of this is still unknown. . It was introduced to the United Kingdom in 1958, Canada in 1972, and the United States in 1995. It is now believed to be the most widely prescribed antidiabetic drug in the world; in the United States alone, more than 48 million prescriptions were filled in 2010 for its generic formulations.

DATA INTERPRETATION

Figure no: 1

1. Global share of Metformin volume in percentage

COUNTRY	PERCENTAGE
Usa	14
India	11
Australia	9
Germany	5
Portugal	5
France	4
Turkey	4
Italy	3
Uk	3
Spain	3
Czech	3

Interpretation:

USA has the highest market share 14 % out of 100%

India has the second highest market share 11%

Australia stood in third place with a market share 8%

Germany has the market share 5%

Figure no: 2

Countries with maximum price of Metformin in Dollars

Puerto Rico	11712
USA	9110
UK	8063
Uruguay	3853
Taiwan	3848
Mexico Retail	2903
UAE Retail	2640
Singapore	2457
Peru retail	2438
Colombia retail	2406
Brazil retail	2200

Interpretation :

Ireland has the highest price of 1718 dollars

Venezuela has the second highest price of 747 dollars

Peru has the third highest price of 644 dollars

Mexico has the fourth highest price of 613 dollars

Japan has stood in tenth position with the price of 412 dollars

Figure no: 3

Countries with minimum price of Metformin in Dollars:

Country	Price
Estonia Retail	2
Indonesia total market	3
Portugal combined	5
Sweden combined	7
Czech combined	8
China Hospital	8
Thailand Combined	13
Australia	14
Pakistan	14
S.Africa combined	16
Venezuela Retail	18
Denmark combined	21

Interpretation:

Estonia retail has the lowest price of 5.81 dollars

Slovakia combined has the second lowest price of 12.04 dollars

Newzeland has the third lowest price of 25.45 dollars

Australia has the fourth lowest price of 29.63 dollars

Czech Republic has the fifth lowest price of 34.2 dollars

Figure no: 4

Top players of metformin according to market share

Country	Total players	Top players	% share
UK combined	27	1	14
Vietnam combined	84	1	23
India combined	101	1	23
Korea combined	87	1	33
China hospital	93	1	40
Germany combined	60	2	42
C.america retail	58	2	43
Peru retail	20	2	44
Mexico retail	54	3	47
Taiwan combined	38	3	47

Interpretation:

UK has the lowest market shared by top player among 27 market players

India has the 101 market players, with 1 top player with a market share of 23%

China has the 93 Market players, with 1 top player with a market share of 40 %

Mexico Retail has the 54 players with 3 top players sharing market of 47%

Taiwan combined has 47 market players with 3 top players sharing a market of 47%

Figure no: 5

Countries in which top players have low market share have the following average prices:

Country	Average Price
UK Combined	131
Vietnam combined	114
India total sales	108
Korea combined	230
China Hospital	166
Germany Combined	220
C,America Retail	459
Peru retail	645
Mexico Retail	613
Taiwan combined	160

Interpretation:

India has the lowest average price 108

Mexico has the highest average price 613

UK has the average price 114

China has the average price 166

Korea has the average price 230.

AMLODIPINE

INTRODUCTION:

Amlodipine is a long-acting calcium channel blocker (DHP) of class Dihydropyrridine.It is used alone or in combination with other medications to treat high blood pressure and chest pain (angina). It is well absorbed by the oral route with a mean oral bioavailability of approximately 60% and its concentrations in plasma declined with a mean half-life of 33 h.The combination of amlodipine/valsartan 5/160 mg produces less peripheral oedemaAmlodipine and olmesartan is a medication that is used for treating high blood pressure.It is a type of combination medication that works by relaxing the blood vessels, which helps to improve blood flow and makes it easier for the heart to pump blood.Beneficial effect of combining CCBs with statins has now been replicated in transgenic atherosclerotic mice, where the combination of amlodipine and atorvastatin produced.

Amlodipine is the 2 billion dollar drug of brand name norvasc which was patented by the Pfizer.The patent of these Pfizer's block buster drug was expired in 2007. The metabolism and excretion of amlodipine have been studied in healthy volunteers following oral administration of C-labelled drug and Renal elimination is the major route of excretion with about 60% of an administered dose recovered in urine, largely as inactive pyridine metabolites. The major metabolite identified was 2-([4-(2-chlorophenyl)-3-ethoxycarbonyl-5-methoxycarbonyl-6-methyl- 2-pyridyl]methoxy) acetic acid, and this represented 33% of urinary radioactivity. Amlodipine concentrations in plasma declined with a mean half-life of 33 h, while elimination of total drug-related material from plasma was slower.

Figure no: 6

1. Global share of Amlodipine volume in percentage

Country	Percentage
USA	19
India	14
Japan	10
Germany	6
UK	3
Korea	3
Russia	3
Italy	3
France	2
Poland	2
Thailand	2

Interpretation:

USA has the highest market share of 19%

India has the second highest market share of 14%

Japan has the third highest market share of 10%

Germany has the fourth highest market share of 6%

UK had stood in fifth place with a market share of 3%

Figure no: 7

Countries with maximum price of Amlodipine in dollars per kg

Country	Price
Puerto Rico combined	49720
Colombia	40557
USA	40383
Venezuela	31621
Japan	31621
Mexico	25854
Peru	25736
Domnican Republic	19157
Canada	18578
Kuwait	17807

Interpretation:

Puerto Rico has the highest price of 113993 dollars

Kuwait has the second highest price of 112126 dollars

C.America has the third highest price of 105170 dollars

Japan combined has the fourth highest price of 100101 dollars

Venezuela combined had stood in fifth place with a price of 84945 dollars.

Fig no: 8

Countries with Amlodipine lowest price per kg in dollars

Denmark	2416
Newzeland	2985
Sweden	3911
India	7365
Bangladesh	8392
United kingdom	9161
Pakistan	9482
Thailand	10264
Netherland	10338
Uruguay	10495
Vietnam	10603

Interpretation:

Denmark has the lowest price of 2416 $

Newzeland has the second lowest price of 2985 $

Sweden has the third lowest price of 3911 $

India has the fourth lowest price of 7365 $

Bangladesh has the fifth lowest price of 8392 $

Figure no: 9

Market share of Amlodpine among top players

Country	Total players	Top players	Top player share %
India	99	1	15
Vietnam	96	1	15
Spain	39	1	27
Indonesia	38	1	27
Domnican republic	51	2	30
Portugual	40	3	36
Luxemburg	9	1	43
Morraco	16	2	46
Czech republic	26	3	47
Italy	37	1	50

Interpretation:

India has 99 players, among which only 1 top player has a market share of 15 %

Spain has total 39 market players; among that 1 top player has 16% market share

Portugal has 40 market players; among that 3 players have 36% market share

Morraco has 46 market players; among that 2 players have 16% market share

Italy has 50 market players; among that 1 player have 37% market share.

Figure no: 10

Countries which have lowest market share by top player have the following average prices

COUNTRY	AVERAGE PRICE
India total sales	7359
Vietnam Combined	10603
Spain combined	50863
Indonesia total market	35509
Domnican Rep	64054
Portugal combined	50786
Luxembourg Retail	56670
Morraco Retail	33603
Czech combined	14820
Italy combined	26253

Interpretation:

India has the lowest average price of 7359

Spain has the average price of 50863

Portugal combined has the average price of 50786

Moracco retail has the average price of 33603

Italy combined has the highest average price of 26253

OBSERVATIONS:

The Observations of this project are

- The entire market is based on volume, number of players, Price and Market share attained by all the players of particular country.
- Price of molecules varies from country to country
- There is a large price differentiation in different countries
- In some countries only few players have a major share
- There is complete segregation of Markets in various countries
- High variation on usage of volumes of drug by different companies
- Countries with segregated market and few top players which have low market share, were the best markets for the new players

KEY LEARNINGS

Market Scenario

Analysis of international markets

Technical skills for analyzing Data