Summer Training
at
Jolly Healthcare

(01th APRIL –31 MAY 2020)

A Report

by
Krishna Agrawal

MBA Pharmaceutical Management
2019-2021

ACKNOWLEDGEMENT

It is great pleasure for me to acknowledge all those who have contributed towards the conception, origin and nurturing of this project.

This work was carried out at the School of Pharmaceutical Management, The IIHMR University, Jaipur, Rajasthan.

It is a delightful moment for me, to put into words all my gratitude to my esteemed guide and preceptor **Dr. Saurabh Kumar Banerjee** , Dean, School of Pharmaceutical Management, The IIHMR University, for his inestimable guidance, valuable suggestions and constant encouragement during the course of this study. It is with affection and reverence that I acknowledge my indebtedness to him and his outstanding dedication, often far beyond the call of duty. Apart from guiding me, his unwiring moral support and advice.

I am also thankful to **SALMAN KHAN** of MBA PM 10 Batch at School of Pharmaceutical Management for their valuable support.

At this moment, last but not least, express my heartiest regards to **My Family** for their energetic, moral and economical support that boosted my spirits. It was the blessing of them that gave me courage to face the challenges and made my path easier. It is because of them I have reached the place where I am today.

Krishna Agrawal

Contents

Company Profile

Jolly Healthcare-Bridging the Unmet Medical Needs!!

From the beginning, the founders envisioned a company that consistently generates fresh intellectual capital to combat challenging diseases.

"Jolly Pharmaceuticals started operations in 1996- the year Dr Krishna M. Ella and Mrs. Suchitra Ella returned from the US to set up a company dedicated to creating innovative vaccines and bio-therapeutics. Dr Ella was returning from a research and teaching stint in the US and he wanted the new company to be an intellectual capital powerhouse. In the years that followed, he assembled a team of bright scientists and led the creation of path-breaing vaccines. Today; Jolly Pharmaceuticals has **over 50 patents**. As a leading biotechnology company, we seamlessly straddle the worlds of product research and manufacturing to create effective vaccines and therapeutics for patients around the world."

"Jolly Healthcare is one of the fastest-growing Pharma Exporter in India with a wide range of pharmaceutical formulations with an assurance of quality and reliability for both Domestic and Export (Indian Subcontinent & Africa) market. The Company has contract-manufacturing tie-up with a state-of-the-art WHO-GMP certified manufacturing Unit at Haridwar. Jolly Healthcare observes Safety Health Environment (SHE), U.K.-M.H.R.A. and U.S.-FDA. Norms. Our product portfolio covers almost all therapeutic segments like Anti-malarial, Analgesics, Anti-diabetics, Gastro-intestinal, Anti-allergic, Cough & cold preparations, Anti-fungal, Antibiotics, Sedatives, Tranquilizers, Anti-amoebic, Anti-diarrheal, Erectile Dysfunction

tablet, Hypertension tablets, Anti-fungal, Anti-HIV, Anti-Cancer, Vitamins, Corticosteroids, Anti-ulcers, Hormonal Preparations, Ointments & Cosmetics and Herbals and Nutraceuticals & Food Supplements. At Jolly Healthcare we supply formulations in practically all dosage forms, i.e. Tablets, Capsules, Soft Gels, Dry Syrups, Liquid Orals, Powder in Sachet, Dry & Liquid Injections, Pre-filled Syringes, Large Volume Parenteral, Eye / Ear / Nasal Drops. JOLLY HEALTHCARE strengths lie in developing Quality & Affordable Products with QC certificates-COA report and COPP certificates. We have the finest team for the Product Dossiers and have 100% success rate in Dossier Approval. We have developed a new drug delivery system for 100 % Timely Delivery of Products to our Valuable Importers. Our pharmaceutical formulations have gained huge acknowledgement for their unsurpassed effectiveness and highly competitive rates."

Our Mission- To become No. 1 shortage and orphan drug company in India by 2020.

Our Vision- Availability of life-saving drugs and diagnostics for the neglected across the globe.

Our USP- Essential ingredients of Exports possessed by Jolly Healthcare-

1. Quality
2. Capacity & Timely delivery
3. Competitive price
4. Sound Financial Status
5. Well defined systems of production
6. WHO-GMP, ISO-9001, ISO-14001, SHE & International Bar Coding.
7. Exports to Bhutan, Sri Lanka, Africa etc
8. Manufacturing & Marketing Shortage & Orphan Drugs

Our strengths-

1. WHO-GMP Approved & UKMHRA Compliant Manufacturing Unit
2. Anabolic Steroid Manufacturer
3. Best ACTD/CTD dossier
4. Timely Delivery
5. Comfortable payment terms
6. Affordable Pricing

Our plant is approved by the following authority:

- WHO GMP CERTIFICATE- With more than 900 COPP
- NAFDAC, Ministry of Health, Nigeria
- MOH-ZAMBIA
- DOMINIC REPUBLIC
- MOLDOVA
- SRILANKA
- ANVISA

Trade affiliations-

- PHARMEXCIL
- DGFT
- Company of Registrar
- Indian Pharmaceutical Association
- WHO-GMP

Trade show we participate-

- CPhi India
- CPhi SEA
- Middle East Gateway for the Medical & Pharmaceutical Industries

Transparency in Dealings-

1. Transparent & honest dealings
2. Ethics of business
3. Corporate governance
4. Fair dealings
5. Fast communication
6. 100% Dossier approval
7. QC certificates-COA report and COPP certificates

100 % Timely Delivery of Products

Product Portfolio

Anti-HIV

Cytoflu (Flucytosine)

Valgaids (Vanganciclovir)

Antibiotics

Jolltrim (Trimethoprim + Sulfamethoxazole)

Jolclo (Cloxacillin)

Jollpen (PenicillinG)

Huelin (Benzathine Penicillin)

Nostof (Cefazolin Sodium)

Sulphaz (Sulphadiazine)

Analgesic

Cabaza (Pentoxifyline)

Antifungal

Mycoflu (Amphoterecin-B)

Diagnostics

Exacto (HIV test kit)

Abstract

The point of the investigation is to do the market survey of Diazoxide molecule in different cities across India. In this study, I have surveyed 90 doctors comprises of Pediatricians and Neonatologists. By this survey, I tried to know the various preferences of doctors concerning the diazoxide molecule. I have done my survey in around 10 cities through visit/telephonic/online medium and questions to doctors are asked via questionnaire. The results obtained from the survey are helpful and informative.

Introduction

Neonatal hypoglycemia happens when the neonate's blood glucose level is not exactly the infant's body prerequisites for components, for example, cell vitality and digestion. There is irregularity globally for indicative limits. In the US, hypoglycemia is the point at which the blood glucose level is underneath 30 mg/dl inside the initial 24 hours of life and beneath 45 mg/dl from that point. In the UK, in any case, lower and progressively factor edges are utilized (<18 mg/dl whenever OR infant with unusual clinical signs and a solitary worth <45 mg/dl OR infant in danger of disabled metabolic adjustment however without irregular clinical signs and an estimation <36 mg/dl and remaining <36 mg/dl at next estimation). The neonate's gestational age, birth weight, metabolic requirements, and health condition of the infant substantially affect the neonate's blood glucose level. There are realized hazard factors that can be both maternal and neonatal. This is a treatable condition. Its treatment relies upon the reason for the hypoglycemia. Even though it is treatable, it very well may be lethal whenever gone undetected. Hypoglycemia is the most widely recognized metabolic issue in infants.

Hyper-insulinemichypoglycaemia (HH) has continuously been seen as an explanation behind headstrong hypoglycemia in neonates and infant youngsters. HH happens on account of uncontrolled discharge of insulin from β-cells of islets of Langerhans in the pancreas. Small for gestational age (SGA) babies and macrocosmic infant of diabetic mothers (IDM) are the two most essential social affairs of infant kids at risk for hypoglycemia in the neonatal period. Glucose is crucial essentialness hotspot for the new-born cerebrum and hypoglycemia is known to cause irreversible neuronal injury when it is dreary and genuine; so

speedy affirmation and treatment of these infant youngsters with HH is indispensable.

His of two kinds i.e. transient and congenital. Data on blood glucose homeostasis and fitting assessments for centre individual metabolites throughout a scene of hypoglycemia is the establishment for investigation and the administrators of HH. The organization of therapeutically dormant HH regardless of everything remains a test. Data on genetic changes, more forward-thinking imaging modalities like Fluorine 18L-3, 4 dihydroxyphenylalanine positron transmission tomography (18F-DOPA-PET) yield and availability of histological division of focal and diffuse kinds of consistent HH has streamlined the organization of Congenital Hyperinsulinism (CHI).

I] what causes hypoglycemia in an infant?

Hypoglycemia can be brought about by conditions, for example,

1. Poor sustenance for the mother during pregnancy
2. Making an excessive amount of insulin in light of the fact that the mother has inadequately controlled diabetes
3. Incompatible blood classifications of mother and child (extreme hemolytic sickness of the infant)
4. More insulin in the child's stool for different reasons, for example, a tumor of the pancreas
5. Birth imperfections
6. Congenital metabolic maladies or hormone insufficiencies. A portion of these disagreement families.
7. Not enough oxygen during childbirth (birth asphyxia)
8. Liver malady
9. Infection

II] Which babies are in danger for hypoglycemia?

Infants are bound to have hypoglycemia include:

1. Babies destined to moms with diabetes
2. Babies who are little for gestational age or development confined
3. Preterm infants, particularly those with low birth loads
4. Babies brought into the world under critical pressure
5. Babies with moms rewarded with specific medications, for example, terbutaline
6. Babies who are huge for their gestational age

III] What are the indications of hypoglycemia in an infant?

Indications of low glucose may not be clear in infants. The most well-known signs include:

1. Shakiness
2. Blue color to skin and lips (cyanosis)
3. Stopping breathing (apnea)
4. Low internal heat level (hypothermia)
5. Floppy muscles (poor muscle tone)
6. Not keen on taking care of
7. Lack of development and vitality (laziness)
8. Seizures

IV] Management of Hyperinsulinemic Hypoglycemia with Diazoxide

Diazoxide, a Potassium-Adenosine Tri Phosphate channel activator, its pillar of clinical treatment in delayed HH. Diazoxide forestalls alpha-cell layer depolarization, what's more, represses insulin discharge by keeping a Potassium-

Adenosine Tri Phosphate channels open. It is administered via oral routewith a dose of 5-20 milligram per kg per day in three partitioned dosages. Once utilizing diazoxide in babies having hepatic brokenness or hypoalbuminemia, use lower dosages of3 milligrams per kg per day as it is profoundly protein-bound (more than 90%). Additionally, lower dosages are more secure in SGA babies as they are touchy to diazoxide. Diazoxide is ordinarily joined with thiazide diuretics to balance its most normal reaction of liquid maintenance in neonates. Hypertrichosis is also a significant normal intricacy of this molecule which for the most part returns following the end of treatment. Diazoxide effect is noted when baby can quick properly for age, keeps up ordinary glucose levels and shows ascend in serum unsaturated fats and ketone bodies toward the finish of quick. Nifedipine, a Ca^{+2} channel antagonist, has been utilized in barely any diazoxide inertinstances of CHI, however, a lot of such patients fails to show any response.

V] About the product – BALILA

Diazoxide enables the release of insulin from pancreas by opening the potassium channel. Hence it increases the potassium ion permeability through the membrane and causes the hyperpolarization eliciting the relaxation of the local smooth muscles (because of which voltage-gated calcium ion channel switches off leading to inhibition of action potential generation).

It also acts as a peripheral vasodilator hence used for hypertensive emergencies (it relaxes articular smooth muscles and decreases the vascular resistance).Diazoxide is an antidiuretic hence increase the reabsorption or retention of sodium and water/fluid in the body (therefore it may precipitate the CHF in cardiac patients).

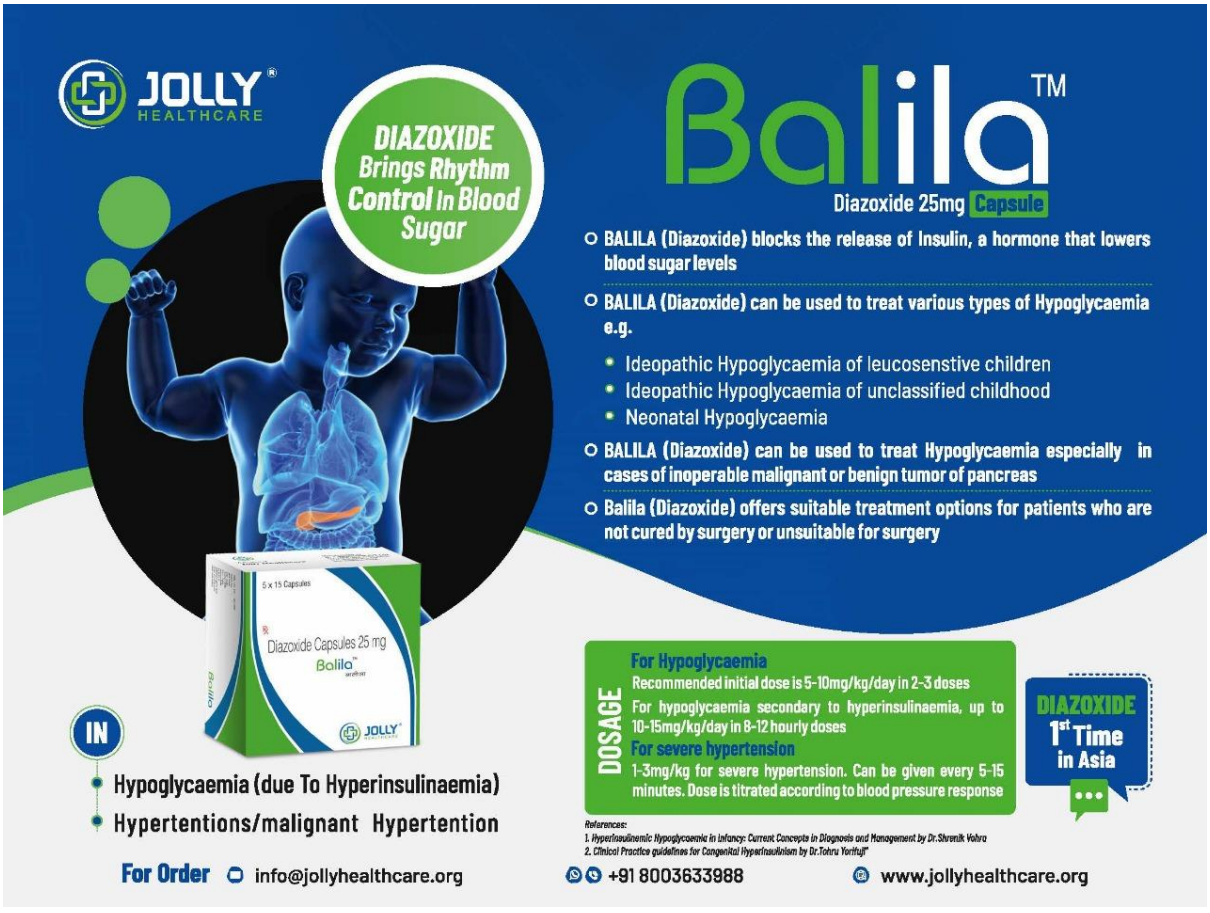

Fig.1-Balila Pamphlet

The pharmacokinetics of the drug is as follows-

1) Absorption- readily absorbed in the body following the oral route of administration.

2) Distribution- Dispersed all through the body; the most significant level is found in kidneys, liver, and adrenal organs; it passes through the placental barrier and blood-cerebrum barrier. It has high protein-philic affinity i.e. around 90% to serum proteins, in this manner, it has a half-life of around 25 to 35 hours in typical grown-ups.

3) Metabolism- partially metabolised in the liver.

4) Excretion- discharged gradually by the kidneys in urine.

Consecutive administration of benzothiazide and in presence of hypokalaemia condition the hyperglycaemic activity of diazoxide gets enhanced.The hyperglycaemic activity of diazoxide can be antagonized by the administration of insulin, tolbutamide and alpha-blockers (like prazosin terazosin and doxazosin etc).

Diazoxide is commonly recommended for grown-ups who have inoperable islet cell adenoma or carcinoma or extrapancreatic danger. It can likewise be utilized in babies and youngsters which are experiencing leucine affectability, islet cell hyperplasia, nesidioblastosis and extrapancreatic danger.

It is contraindicated in patients with hypersensitivity towards diazoxide or to other thiazides. It should also not prescribe in case of improper renal functioning, functional hypoglycaemia, pregnancy (due to severe teratogenic effects).

Diazoxide requires close clinical oversight with cautious checking of blood glucose and clinical reaction so portion alteration should be possibleappropriately.

Some ADR's related to the drug is as follows-

1) Hirsutism
2) Diabetic ketoacidosis
3) Hyperosmolar non-ketonic coma
4) Na+ ion and water retention
5) GI intolerance like nausea, vomiting.
6) Hypotension
7) Cataract
8) Fever
9) Gout
10) Acute Pancreatitis

Overdose of diazoxide can be treated with prompt insulin administration and Restoration of electrolyte balance and fluid. It also requires prolonged surveillance for up to 7 days due to the long half-life of the drug.
It shows a drug-drug interaction with a diuretic, coumarin anticoagulants, diphenylhydantoin, and chlorpromazine.

Usual daily dosage for adults and children is 3 to 8 mg per KG and for infants and new-borns, it is 8-15 milligram per kilogramseparated into 2 or 3 equivalentquantities every 8 or 12 hrs.To maintain its stability ideally it must be stored at room temperature ranging between 15-30 C.

Literature Review

Shrenik Vora, Suresh Chandran, Victor Samuel Rajadurai And Khalid Hussain

"Assessment of blood tests, assembled at the hour of hypoglycemic scenes, for delegate metabolites and hormones is essential for finding and treatment. Extended care among clinicians about infant youngsters "in harm's way" of hypoglycemia and late advances in the genetic investigation has made an imperative responsibility to the assurance and the leading body of hyperinsulinism. Increasingly flow drugs like lanreotide (long-acting somatostatin straightforward) and sirolimus (mammalian target of rapamycin (mTOR) blocker) appear to be encouraging as patients with the diffuse ailment can be managed adequately without subtotal pancreatectomy, restricting the long stretch sequelae of diabetes and pancreatic lack. More state-of-the-art bits of information in understanding the sub-nuclear and histological reason and upgrades in imaging and cautious systems will change the best approach to manage patients with natural hyperinsulinism."

Objective: - To investigate the market of Diazoxide in multiple cities of India.

Research Methodology

Mode of data collection:

Study type: Descriptive Study

Type of data: Quantitative data

Sampling technique: Purposive sampling

Data collection: Field and online survey using a questionnaire

Study Timeline: Two months (April 2020 - May 2020)

Sample size: The sample size was 90.

Data Analysis and Interpretation**:**

Analysis and interpretation of the data have been carried out to deduce the conclusions with the aid of appropriate statistical tools.

Results & Discussions

1) No of Doctors responded?

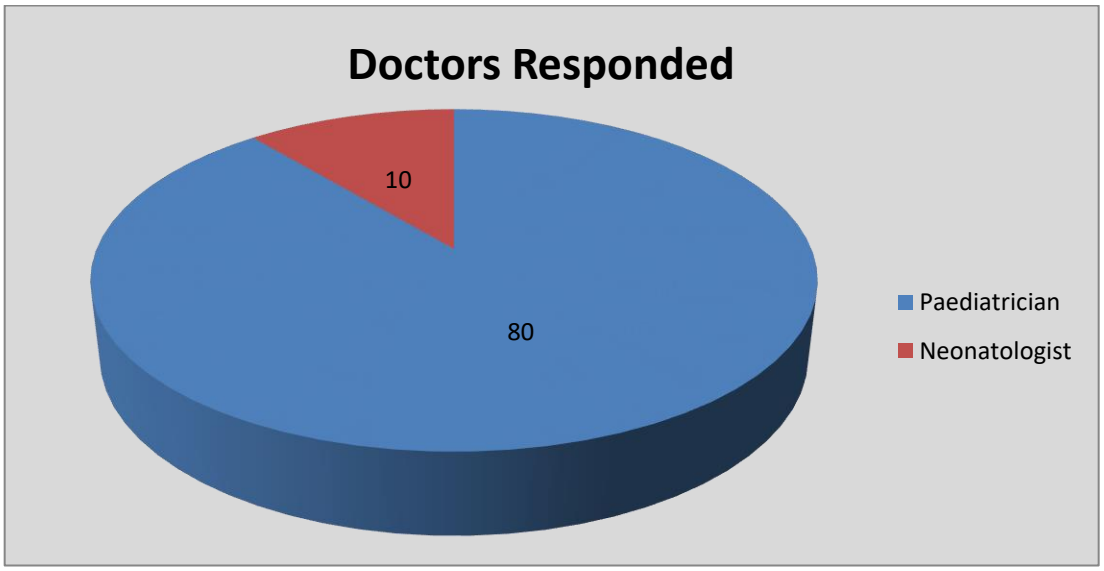

Fig.2- Depiction of Doctor's responded to the survey questionnaire.

Interpretation–From fig.2 it was observed that 80 paediatrician and 10 neonatologist responded.

2) Type of hospitals covered?

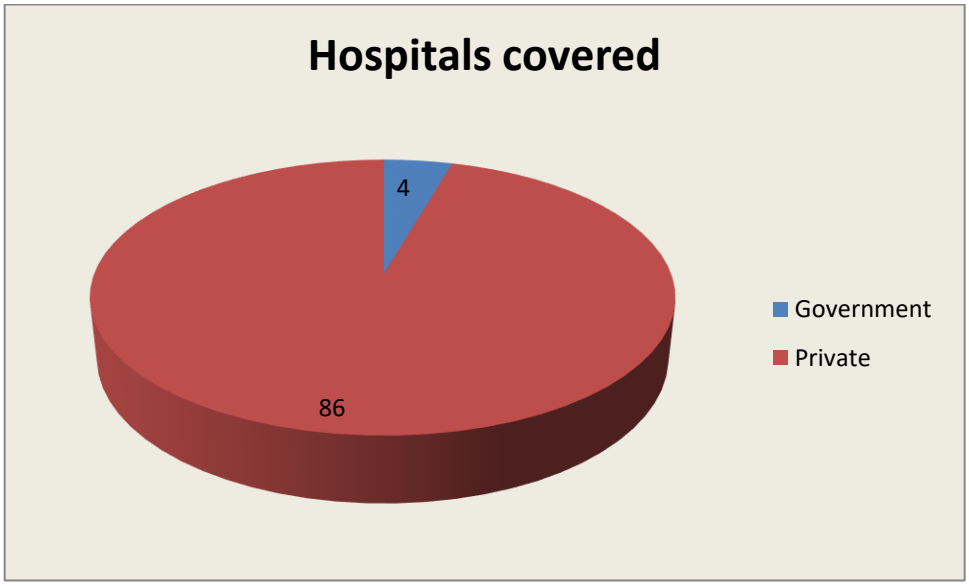

Fig.3 – Depiction of Hospitals Covered during the survey.

Interpretation – From fig.3 it was observed that 86 were Private hospitals and 4 were Government hospitals.

3) In which condition(s) doctors will preferred the diazoxide molecule.

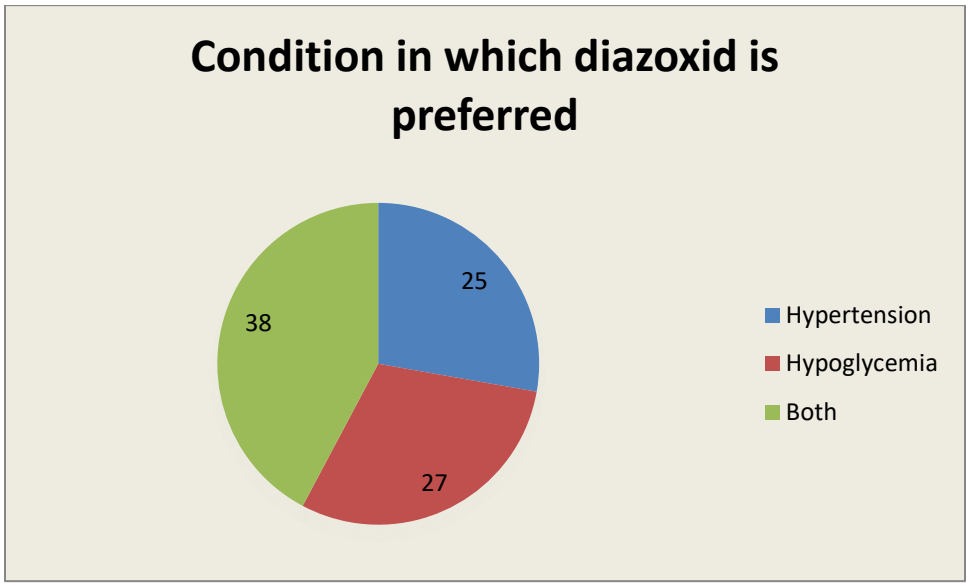

Fig.4 – Depiction of indications used for Diazoxide

Interpretation – From fig.4 it was observed that diazoxide was preferred by 27 responded for Hypoglycemia followed by 25 respondent for Hypertension.

4) No of hospitals with NICU beds facility.

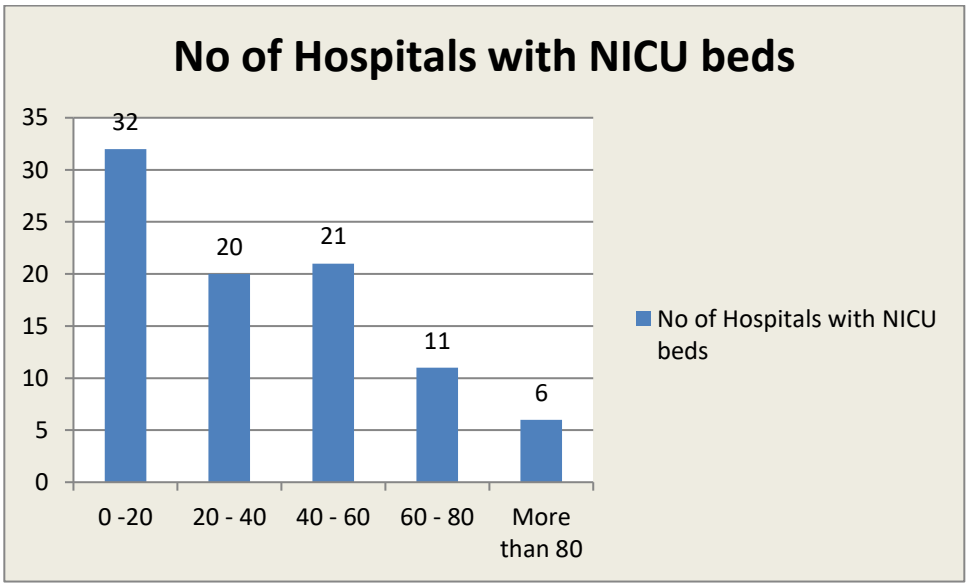

Fig.5 – Depiction of the No of hospitals with NICU beds facility

Interpretation – From fig.5 it was observed that most of the hospitals have NICU beds facility not more than 20.

5) Which is the most preferred dosage form administered by patients?

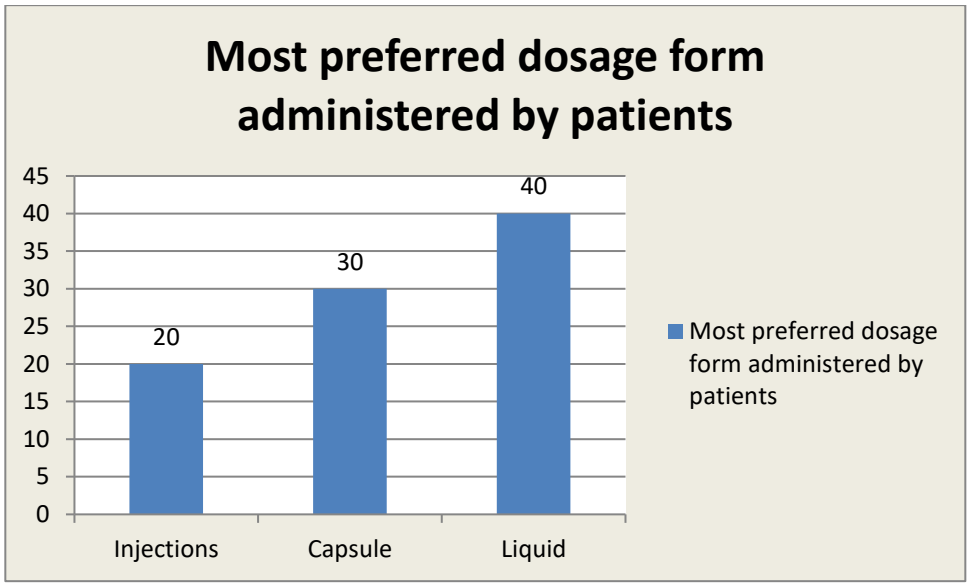

Fig.6 – Depiction of preferred dosage forms.

Interpretation – From fig.6 it was observed that most preferred dosage form by the patient was liquid followed by capsule and then injection form.

6) Which of the following attributes influences your prescription?

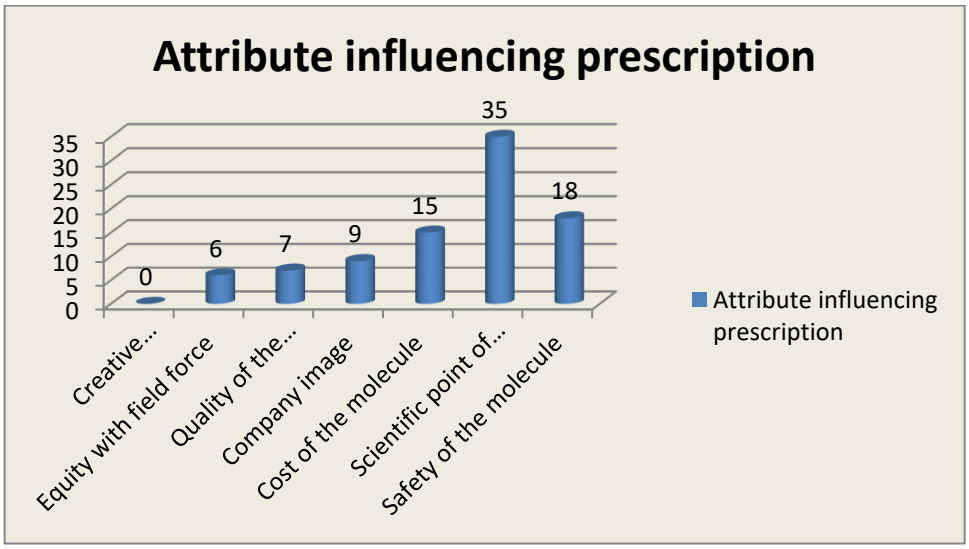

Fig.7 – Depiction of attributes influencing the prescriptions.

Interpretation – From fig.7 it was observed that Scientific point of the molecules and Safety of the molecule are two major attributes that influence the prescription of respondents.

7) Which of the following activity will help doctors in prescribing the drug molecule?

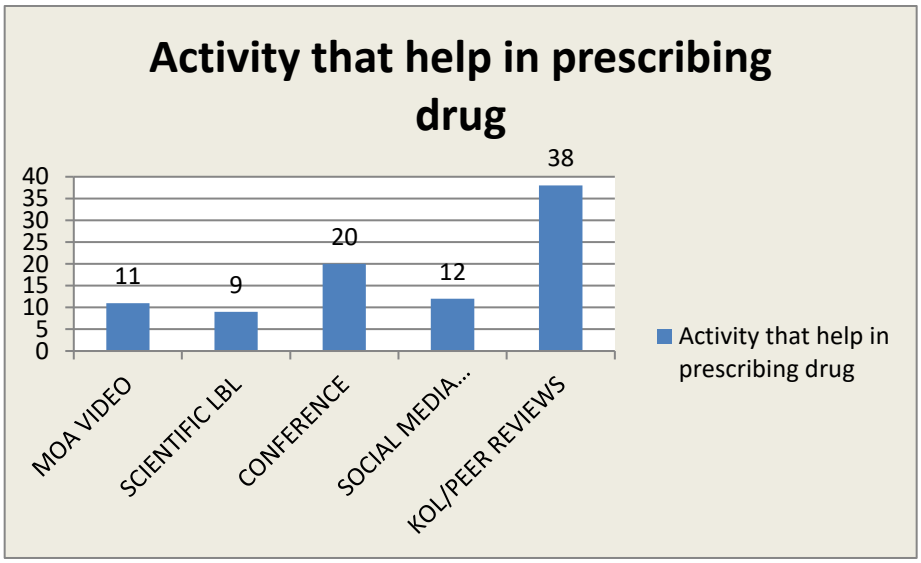

Fig.8 – Depiction of activities that help in prescribing Diazoxide.

Interpretation – From fig.8 it was observed that the KOL/Peer reviews followed by conference is the two major activities that help in prescribing the drug.

8) How to mostly treat severe Hypoglycemia patients?

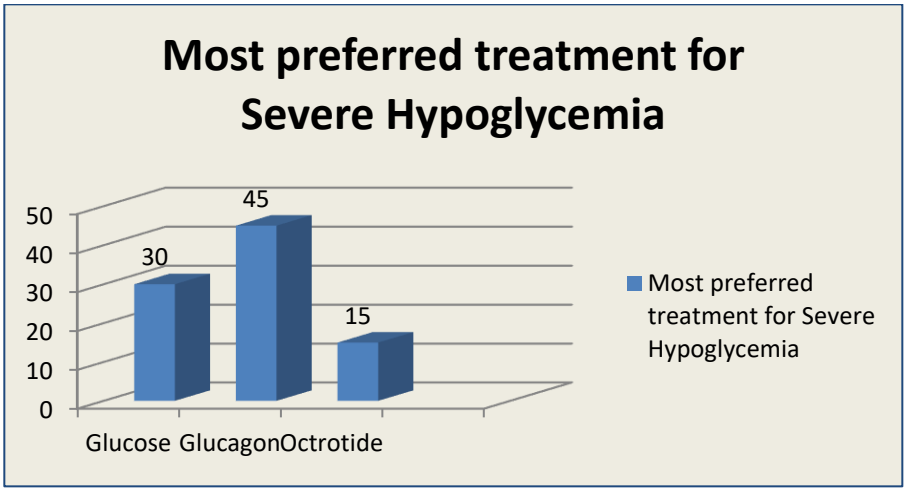

Fig.9 – Depiction of preferred treatment for severe hypoglycemia

Interpretation – From fig.9 it was observed that Glucagon and Glucose (IV) are most preferred for severe hypoglycemia conditions.

9) How do you mostly treat mild hypoglycaemia?

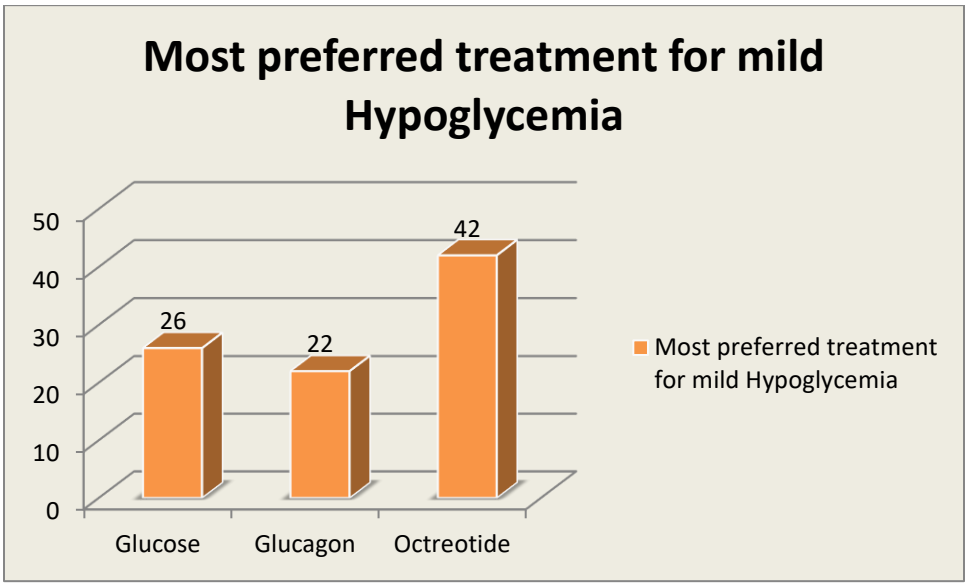

Fig.10 – Depiction of preferred treatment for severe hypoglycaemia.

Interpretation – From fig.10 it was observed that octreotide is most preferred for severe hypoglycaemia conditions.

Conclusion

To conclude diazoxide is an effective treatment for Hyperinsulinemichypoglycemia and malignant hypertension. Hyperinsulinemichypoglycemiamajorly occurs due to excessive endogenous or injected insulin. Malignant hypertension has a BP that is commonly over 180/120 while the normal range is 120/80. Malignant hypertension ought to be treated as a health-related crisis or a medical emergency. India can be a hub of malignant hypertension due to a large number of Hypertensive patients and its association with Diabetic pool in the country. Hence there can be a potentially untapped market for this molecule. Jolly Healthcare is one of the best companies in the orphan drug market which provides quality and efficacious products to doctors and patients at a competitive price. And there are less competitors present in the market for orphan drugs which provide quality and effective drugs to the doctors.

Recommendation

- According to respondents, Diazoxide is a potent molecule which can be use as a severe hypertension.
- As per the scientific data diazoxide has less side effect than octreotide due to which it can be use as long therapy in hypoglycaemia.
- According to respondents, KOL opinions can drive prescription behaviour.
- Strong scientific knowledge backed representative can bring good Top line growth.
- The dosage form of the drug can play a pivotal role since the drug can be targeted to all age segments i.e. from Neonates to Adults.

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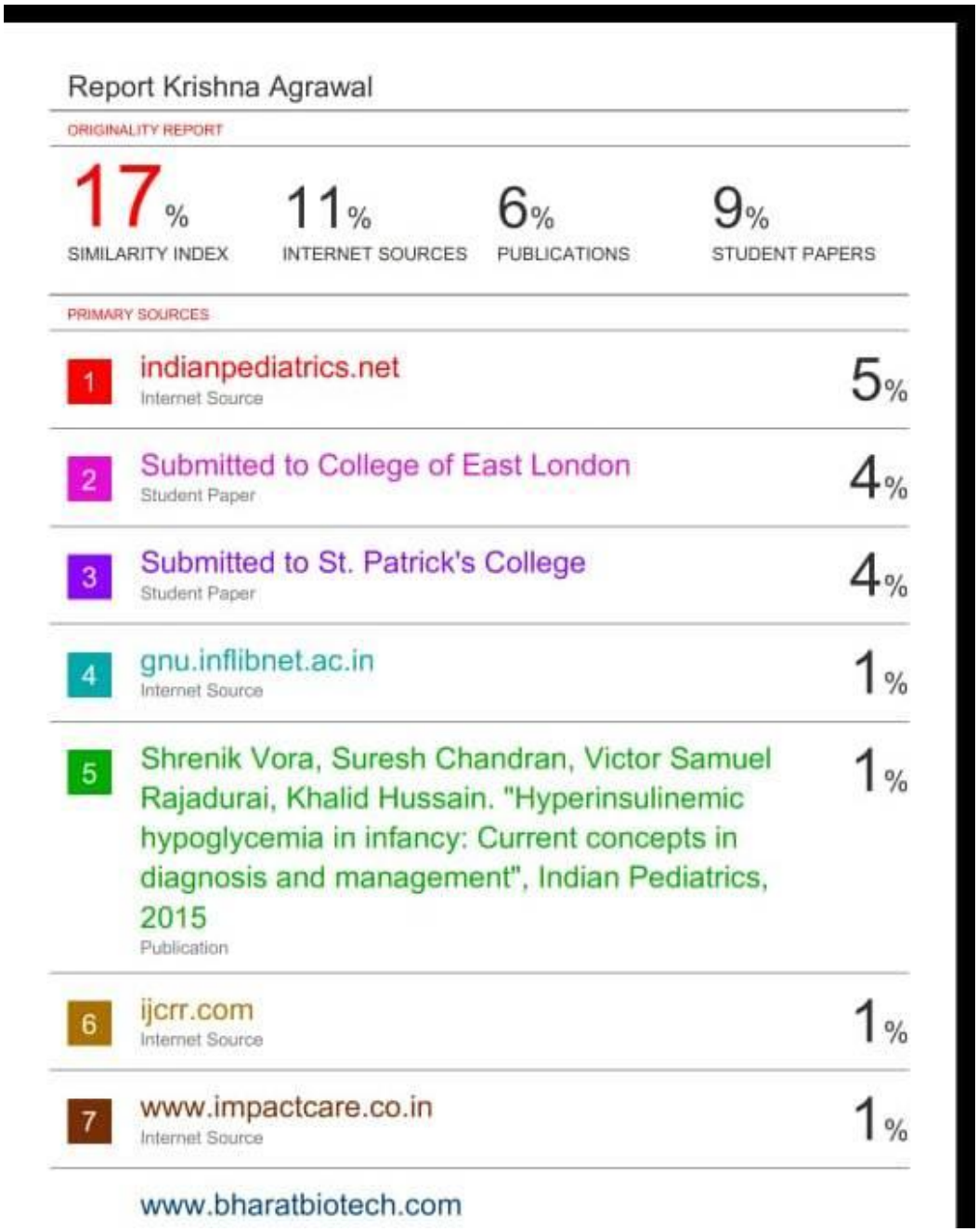

Report Krishna Agrawal

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Online Course Report

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Krishna Agrawal

Table of Content

Contents

Course Name - Pharmaceutical Management

Introduction

Pharmaceutical management mainly deals with the four managements in the organization.

- Brand Management
- New Product Launch
- Sales Team Management
- Customer Management

Objective

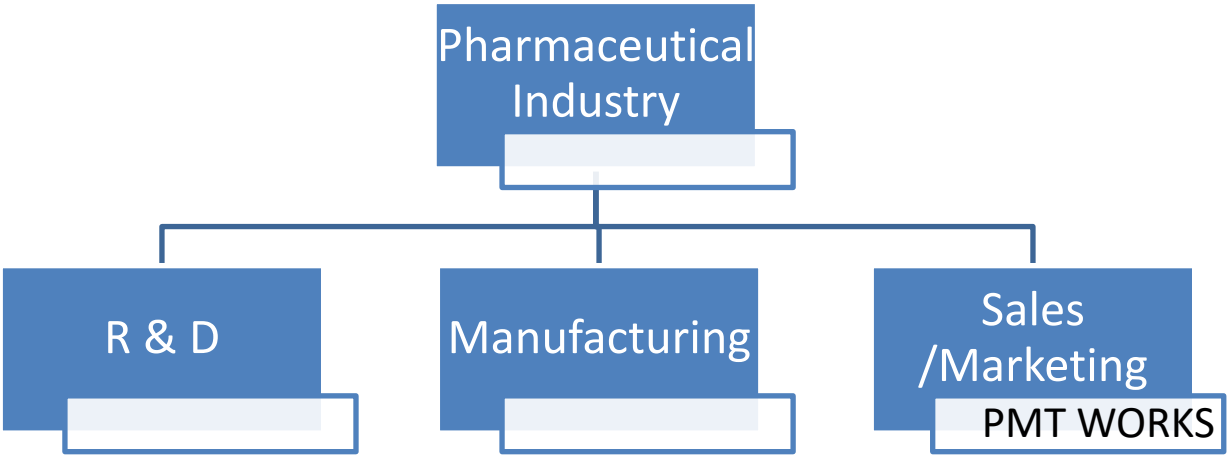
- Pharmaceutical Management
- Analysis of Indian Pharmaceutical Market
- How to make Brand Plan

Course Contents

WEEK 1

Pharmaceutical Management

It is the combination of pharmaceutical science with marketing and management concept. To make business & financial decision to launch a new product, in term of their marketing and sales aspects.

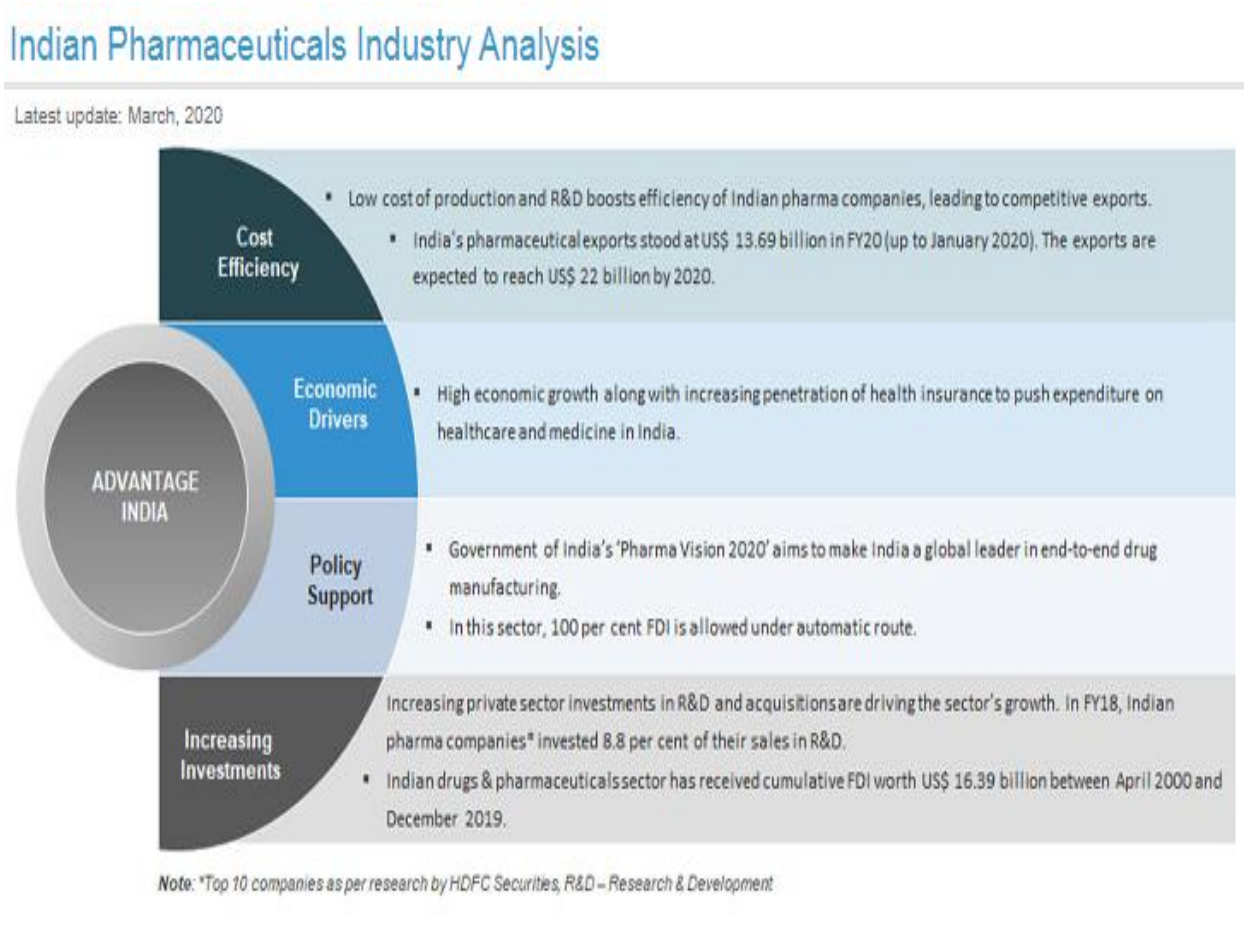


Market Data

Market data is taken in two ways

- Value Sales and Unit Sales (AWACS,IMS)
- Prescription and Prescriber (SMSRC,IMS)

Indian Pharmaceutical Industry Analysis



Week 2

Indian Pharmaceutical Market Segment

Indian Pharmaceutical Market is divided into three segments.

- Chronic Segment
- Sub Chronic Segment
- Acute Segment

Chronic Segment: All long life therapy comes under this segment.

1. Anti Diabetic
2. Immunomodulator
3. Cardiac
4. Nuro/CNS
5. Anti Cancer
6. Respiratory
7. Urology

Sub Chronic Segment: Mainly up to one year therapy comes under this segment.

1. Anti TB
2. Anti Infective
3. Anti Viral
4. Gynecology

Acute Segment: Mainly short therapy comes under this segment.

1. Anti Malarial
2. Anti Parasitic
3. Derma
4. Analgesic
5. Anti Pyretic

IPM SEGMENT

ACUTE CHRONIC	Sum of MAT JAN'20	Rank	MS %	GR%
ACUTE	95380.65	1	64.5	10.10
CHRONIC	52591.47	2	35.5	11.23

Plan and Combination Segment

Plain/Combination	Sum of MAT JAN'19	Sum of MAT JAN'20	MS%	GR%
Grand Total	133910.95	147972.12	100	10.50
Plain	67590.67	75113.78	50.76	11.13
Combination	66320.22	72858.28	49.24	9.86

Top Therapy of IPM

SUPERGROUP	Sum of MAT JAN'19	Sum of MAT JAN'20	Rank	MS
Grand Total	133911.0	147972.1	100	
Anti-infectives	16119.3	18103.1	1	12.2
Cardiac	15787.3	17508.8	2	11.8
Gastro Intestinal	13875.0	15028.2	3	10.2
Anti Diabetic	12614.4	14114.3	4	9.5
Respiratory	10694.5	11892.6	5	8.0
Vitamins / Minerals / Nutrients	10489.4	11587.3	6	7.8
Pain / Analgesics	10257.3	11467.4	7	7.7
Derma	10199.7	11140.5	8	7.5
Neuro / CNS	7879.5	8570.2	9	5.8
Gynaec.	6684.2	7374.0	10	5.0

Week 3

Brand Plan

Brand Plan Contain

- Brand History and Market Analysis
- Brand Strategy Drivers
- Clinical Trials
- Brand Strategic and Promotional Plan

Brand History and Market Analysis

- Product Fact File
- Market Trend
- Defining Market
- Brand History – AWACS/SMSRC Analysis
- Prescription Analysis

Brand Strategy Drivers

Defining communication strategy

- Customer insights
- Communication Task
- Brand portrait wheel & Brand Positioning

Matrix

- SWOT Analysis
- Trend Analysis
- Assessing competition
- Segmentation-Targeting-Positioning

Clinical Trials

- Jupiter Trial
- Steller Trial

- Lunar Trial
- Hope 3 Trial
- Asteroid Trial

Brand Promotional Plan

- Marketing Objective
- Brand Positioning
- Key strategic directions & tactical plans/initiatives
- Tactical plans/initiatives dash board
- Annual activity/input plan phasing
- Contingency measures

Week 4

Brand Positioning

Element of Positioning

1. Brand Name
2. Market definition
3. Category definition
4. Patient segment
5. Customer target
6. Insights
7. Brand essence
8. Competitive advantage
9. Supporting evidence
10. Brand positioning summary statement
11. Key messages

Learning Methodology

Web session was conducted by Lokesh Kumar two days in a week from 8 June to 5 July 2020 and some data were given to learn and to analyze it.

Key Learning

- Basic structure of Indian Pharmaceutical Market.
- How to analyze the pharmaceutical market.
- Overview of brand plan.
- Brand positioning.
- Visulates forming.