

**Summer Training at
KEE Pharmaceuticals Ltd.
(16th April – 26th June, 2012)**

Pre-Market Survey for Topical Cream in Arthritis

**By
Garima Bhatia**

**Under the guidance of
Dr. Nirmal Gurbani**

**Post Graduate Diploma in Pharmaceutical Management
2011-2013**



**Institute of Health Management Research,
Jaipur
2012**

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Certificate

This is to certify that Garima Bhatia has undergone summer training in KEE pharmaceuticals ltd., New Delhi from 16th April to 26th June, 2012

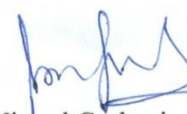
The candidate carried out all the studies related to summer training herself. Her approach to the studies has been sincere, scientific, and analytical. This summer training in partial fulfillment of the course requirement is recommended for the award of Post Graduate Diploma in Pharmaceutical management.

I wish her success in all future endeavors.



Dr .P. R.Sodani

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CERTIFICATE

This is to certify that **Ms Garima Bhatia** from **INDIAN INSTITUTE OF HEALTH MANAGEMENT RESEARCH**, Jaipur has completed the summer training with **KEE PHARMA LTD.** New Delhi On the project **PRE MARKET SURVEY FOR TOPICAL CREAM IN ARTHRITIS** for two months from 16th April,2012 to 26th June,2012..

She has successfully completed the assigned project. We wish her all the best in her future career.

Her conduct and dedication was excellent.

DATE 30th June,2012
DELHI


(S.B. AGGARWAL)
VICE PRESIDENT

ACKNOWLEDGMENT

I would like to express my heartfelt thanks to management of **KEE Pharmaceuticals Ltd.** for granting me an opportunity to undergo summer training in their esteemed organization. It would have not been possible without the kind support and help of many individuals and organizations. I would like to extend my sincere thanks to all of them.

I am highly thankful to **Mr. Praveen Kumar (President) and S.B. Aggarwal (Vice President)** for their guidance and constant supervision as well as for providing necessary information regarding the project and also for their support in completing the project. Their expert guidance, advice, timely suggestions, personal interest and attention had been a privilege for me.

I would like to express my gratitude towards my mentor **Dr. Nirmal Gurbani** for his kind co-operation and encouragement which helped me a lot in completion of this project.

I would also like to thank **Ms. Priyanka Walia** (Executive Secretary) for her valuable guidance and time.

My thanks and an appreciation also goes to my colleagues in developing the project and people who have willingly helped me out with their abilities.

GARIMA BHATIA

DECLARATION

I hereby certify that, I carried out the project titled “**PRE MARKET SURVEY FOR TOPICAL CREAM IN ARTHRITIS**” under the supervision of Mr. **S.B.Aggrawal (Vice president, Marketing)**, KEE Pharma Pvt.Ltd. New Delhi. This project is submitted in partial fulfilment of the requirement for the post graduation diploma of pharmaceutical management to Institute of Health Management and Research, Jaipur.

PLACE: New Delhi

GARIMA BHATIA

DATE: 26/06/2012

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SECTION - 1

INTRODUCTION

ABOUT THE ORGANIZATION

Company Overview:-

Kee Pharma limited is a well-established Delhi based pharmaceutical company that was started in 1957 by C.R.Motihar.Today; KPL has a strong work force that is made up of professional and dynamic individuals working together as a team to ensure that KPL is an efficient and professionally run organisation.

KEE Pharma is an innovative, dynamic and caring organisation. We strive to provide the best that modern medicine has to offer be it new dosage forms, revolutionary pharmaceutical molecules or biotechnologically engineered cures. Innovative attitude to life drives us to always look for better and more effective cure. Our dynamism allows us to cross our nation's boundaries and forage into global market to find these cures. Our caring outlook makes us ensure that these cures are available to the people of India through an effective and extensive distribution network and careful pricing. Being a well established 45 year old company, we have our feet firmly planted on the ground. We know the importance of quality, purity and effectiveness of medicine. Above all else, we know what it takes to achieve all three and we make sure that we do every person at KEE pharma understands the importance of quality, purity and effectiveness and in this understanding, knows at the very bottom of his or her heart that – Life matters....People matter.

KPL is made up of two SBU's –

- KEE Pharma
- KEE biogenetics

- 1) **KEE Pharma:** - This is the oldest division of the company which deals mainly in prescription and life saving drugs. In this division doctors segments that are visited and to whom the products are promoted are the gynaecological, orthopaedic, dentist, surgeon and practitioner segments. Hence the entire range of KEE pharma's products is aimed at these three segments of doctors, thus enabling us to concentrate our efforts and provide these segments with the best and latest in allopathic healthcare. The products that are promoted in this division are REVICI inj. (for haemostats), SALSOL(for asthma) and DISER(for Pain and inflammation).

- 2) **KEE GAD Biogen Pvt. Ltd.** – This is a high-tech biopharmaceutical enterprise which is engaged in manufacturing, marketing and research, of high tech diagnostics reagent and devices, drug delivery system and nano-medicines that are used for the diagnosis, treatment, mitigation, and cure of wide range of human diseases. The R&D unit of KEE Gad is recognized by the department of Scientific and Industrial research of ministry of science and technology, Govt, of India. KEE GAD is owned and run by professional stock holders. The production facilities meet the c GMP standards of FDA. The company has put a plant to manufacture and market Clinical chemistry Reagents at A-8, Third Floor Naraina Industrial area phase II , New Delhi . License under Drugs act has obtained for the manufacture of over 30 analytes in the body fluids including blood and urine. The Company went into commercial production from 2011.

FUTURE PLANS:-

At present Kee Pharma is looking forward to opening a new production facility which is currently under development as per the revised schedule (CGMP). This production unit will have state of the art equipments and will follow the latest manufacturing techniques for the in-house production of Oral and Parenteral dosage forms. On the export front, Kee Pharma is in the process of registering its drugs in SriLanka, Nepal, Iraq & Bangladesh and we are confident that we will have our products available in these markets by the end of the year 2005.

Disease Profile

OSTEO ARTHRITIS

It can affect both the larger and the smaller joints of the body, including the hands, feet, back, hip or knee. The disease is essentially one acquired from daily wear and tear of the joint; however, osteoarthritis can also occur as a result of injury. Osteoarthritis begins in the cartilage and eventually causes the two opposing bones to erode into each other. Initially, the condition starts with minor pain while walking but soon the pain can be continuous and even occur at night. The pain can be debilitating and prevent one from doing some activities. Osteoarthritis typically affects the weight bearing joints such as the back, spine, and pelvis. Unlike rheumatoid arthritis, osteoarthritis is most commonly a disease of the elderly. More than 30 percent of females have some degree of osteoarthritis by age 65. Risk factors for osteoarthritis include: prior joint trauma, obesity, and a sedentary lifestyle.

Osteoarthritis, like rheumatoid arthritis, cannot be cured, but one can prevent the condition from worsening. Physical therapy to strengthen muscles and joints is very helpful. Pain medications are widely required by individuals with osteoarthritis. For some patients, weight loss can reduce the stress on the joints. When the disease is far advanced and the pain is continuous, surgery may be an option.

RHEUMATOID ARTHRITIS

This is a disorder in which the body's own immune system starts to attack body tissues. The attack is not only directed at the joint but too many other parts of the body. In rheumatoid arthritis, most damage occurs to the joint lining and cartilage which eventually results in erosion of two opposing bones. Rheumatoid arthritis often affects joints in the fingers, wrists, knees and elbows. The disease is symmetrical (appears on both sides of the body) and can lead to severe deformity in a few years if not treated. Rheumatoid arthritis occurs mostly in people aged 20 and above. In children, the disorder can present with a skin rash, fever, pain, disability, and limitations in daily activities. Often, it is not clear why the rheumatoid arthritis occurred. With earlier diagnosis and aggressive treatment, many individuals can lead a decent quality of life. The drugs to treat rheumatoid arthritis range from corticosteroids to monoclonal antibodies given intravenously.

PRODUCT DETAILS

Algaea-X

This is a **topical cream for joint pains and arthritis** available for the first time in India. This product is especially beneficial to those who experience discomfort in their muscles, Joints or other areas that impact movement, mobility, strength, and flexibility as a result of Aging, work or other activities. **Approved by the US FDA**, it is the result of more than 15 Years and over \$35 million dollars of developmental research. It **contains Mitol, an extract From brown seaweed**. Algaea X also treats joint stiffness, muscle soreness, neck and back Pain, strains and sprains, arthritis, tendonitis, frozen shoulder and other inflammation associated diseases or conditions.

Key Features

- Delivers soothing topical relief from aches interfering with everyday living and Activities.
- Penetrates deep below the skin into muscles and tissue to soothe and heal stiff, sore
- Muscles and joints.
- Non-greasy formulation does not irritate skin and has a mild, pleasant short-lived Odour.
- Utilizes potent anti-inflammatory and circulatory promoting properties of a Patented algae extract (Mitol) that is the result of more than 15 years and over \$35 Million dollars of developmental research.
- Long-lasting anti-inflammatory, anti-oxidant, and other healing properties Supported by extensive research.
- Studies have shown Algaea-X to be as effective as some widely prescribed Products in providing relief to joint discomfort and stiffness.

Healing Properties

- Strong anti-inflammatory effects that both heal and protect.
- Significant blood circulation improvements and overall promotion of vascular Health.
- Heals joint, muscles and surrounding tissue.
- Strong anti-oxidant scavenging of free radicals promotes healthy cellular function.

SECTION – 2

RESEARCH METHDOLOGY

2.1 PROBLEM STATEMENT

The project is to know about the preferences of the doctor for prescribing natural topical product with help of various factors.

2.2 RESEARCH OBJECTIVE

Given below are the objectives of our study:-

- To **know about the preferences** of the natural product by Orthopedicians and Rheumatologists in RA and OA patients.
- To **find out the competitor brands** available in the market and are prescribed by the doctors.

2.3 RESEARCH DESIGN

Questionnaire was designed by analyzing various factors which were required for collection of data and full fill our study objective. Questionnaire consists of both open ended and close ended questions.

2.4 SAMPLE DESIGN

Target Population: - A specified **Rheumatologists and Orthopaedicians** were chosen.

Sample Size: - 51 Doctors

2.5 DATA COLLECTION

The collection of data was done through field work. **Field work was done in different cities of Uttar Pradesh to know about the views of the doctors.**

Following areas covered in U.P.:-

- **Kanpur**
- **Lucknow**
- **Allahabad**

SECTION-3

DATA ANALYSIS AND INTERPRETATION

3.1 DATA ANALYSIS:-

Data entry and data analysis was done in Microsoft Excel spread sheets. The program has inbuilt tools which are used for various calculations.

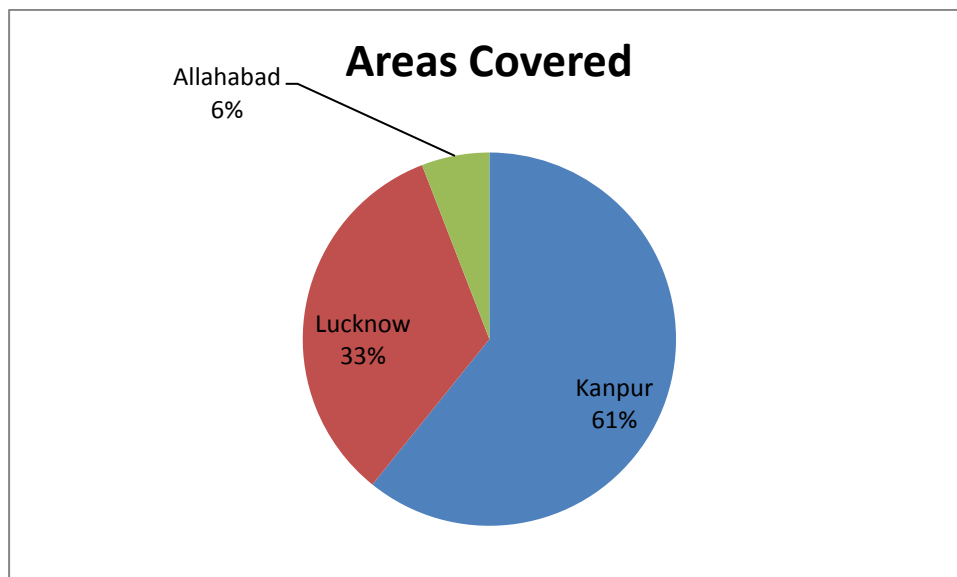
3.2 DATA INTERPRETATION:-

Sample distribution for the survey:-

Sample size taken for the study was **51** and covering **three regions of Uttar Pradesh** namely:-

City	No of doctors
Kanpur	31
Lucknow	17
Allahabad	3

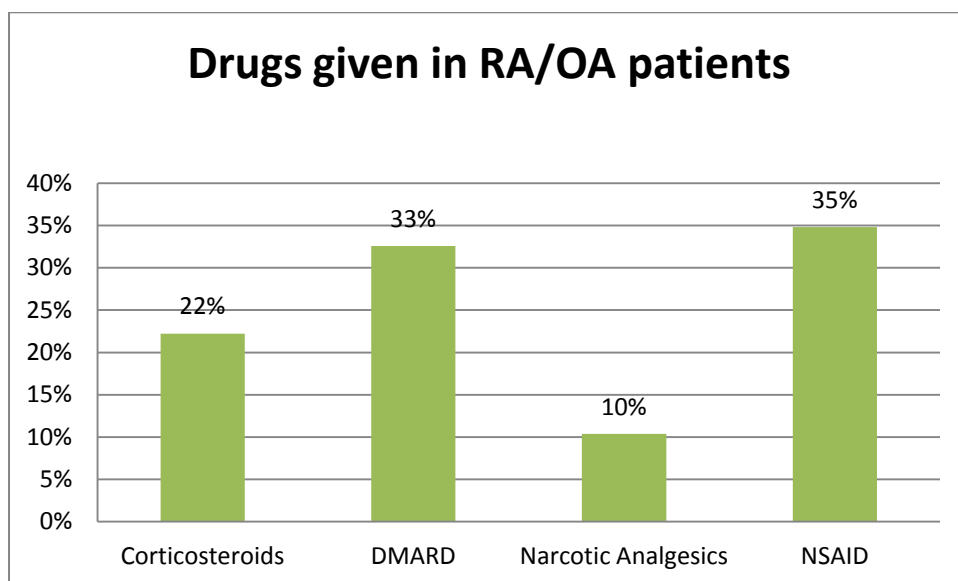
- Kanpur
- Lucknow
- Allahabad



- 61% doctors were covered from Kanpur region.
- 33% orthopaedicians was covered from Lucknow and remaining 6% samples was covered from Allahabad city.

3.3 Drugs used in patients of RA/OA by orthopaedicians:-

Corticosteroids	30	22%
DMARD	44	33%
Narcotic Analgesics	14	10%
NSAID	47	35%
Grand Total	135	



The drugs mainly given by Orthopaedicians in RA/OA patients for control of pain and inflammation were mainly:-

- NSAID
- DMARD
- Narcotics Analgesics
- Corticosteroids

Observation: -

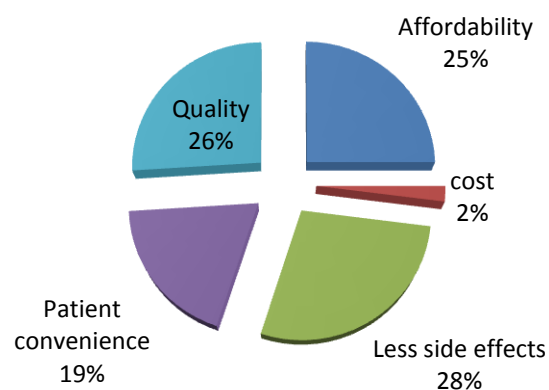
- Most of the doctors prefer giving NSAID drugs to RA/OA patients.
- Most of the doctors prefer giving drugs in combinations.
- After NSAIDs preference given by doctors is for DMARD.
- 22% Doctors go for corticosteroid in case of RA/OA.
- 10% doctors prefer narcotic analgesics drugs.

3.5 Main Influencing factors while Prescribing a drug :-

Affordability	46	25%
cost	3	2%
Less side effects	52	28%
Patient convenience	35	19%
Quality	48	26%
Grand Total	184	

Affordability	46	25%
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Quality	48	26%
Grand Total	184	

Influencing factors while prescribing a drug

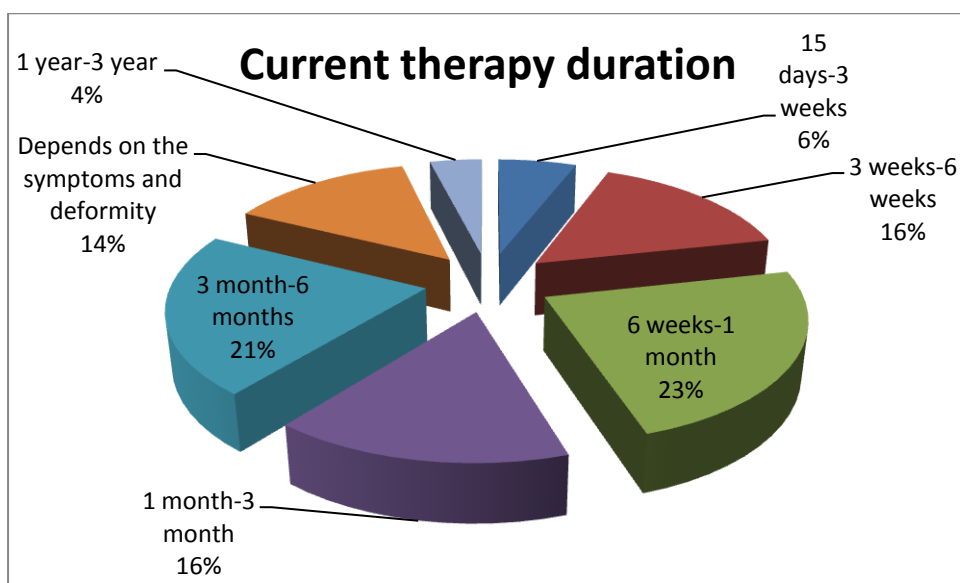


Observations: -

- Most of the doctors preferred that the drug should have less side effects and affordable and within the reach of the patients
- 26% doctors look upon the Quality factor while prescribing a drug.
- Another factor which came up was the patient convenience as per told by the doctors.
- Other factors like cost and easy availability also came up by doctors.

3.8 Time needed by current therapy to show the results:-

15 days-3 weeks	3
3 weeks-6 weeks	8
6 weeks-1 month	12
1 month-3 month	8
3 month-6 months	11
Depends on the symptoms and deformity	7
1 year-3 year	2

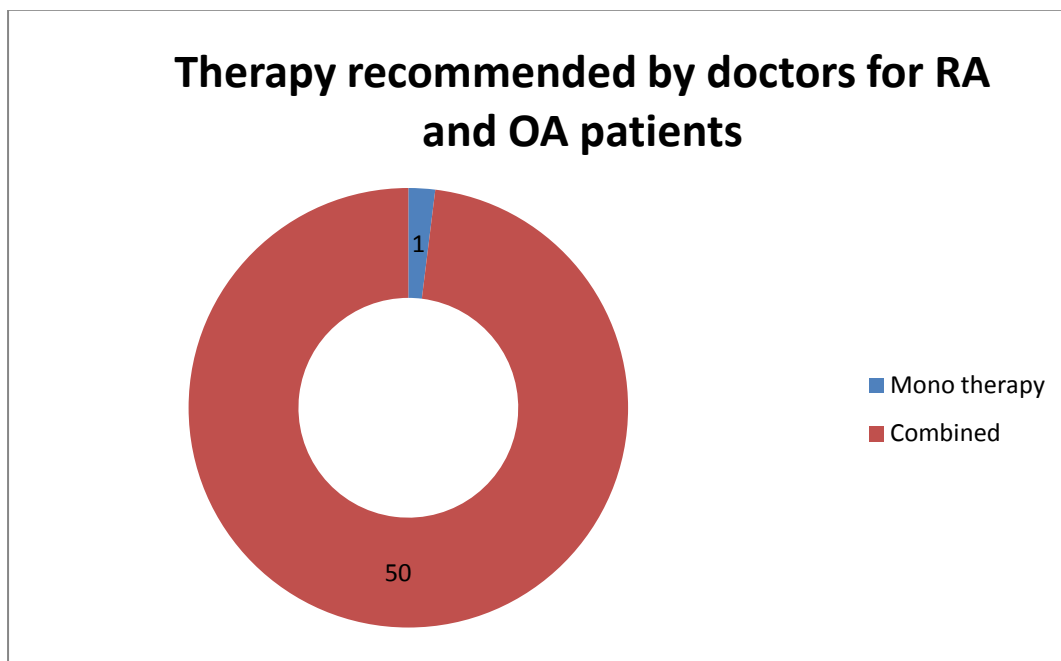


Observations:-

- About 14 % of doctors say that time taken by current therapy to show results is 2-3 months.
- According to 13 % doctors 6 months duration is taken for current therapy to show its results.
- Some of the doctors said that duration of therapy also depends upon the symptoms and deformity.

3.9 Therapy recommended for RA/OA patients:-

Type of therapy recommended by doctors	Therapy recommended by doctors
Mono therapy	1
Combined	50

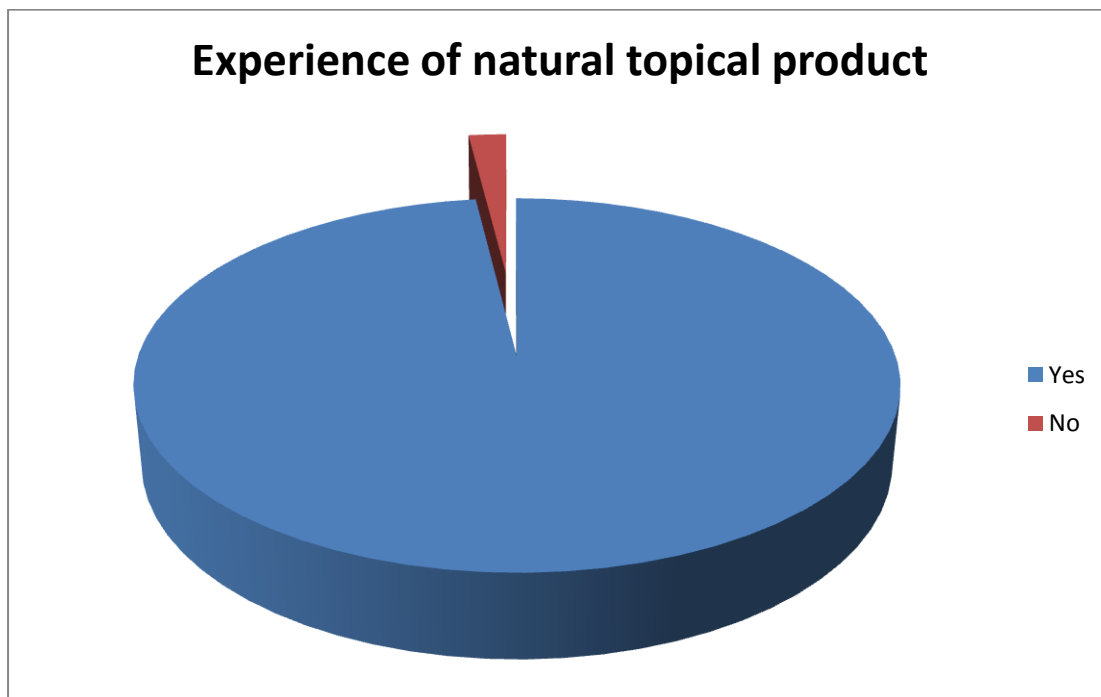


Observation:-

- About 50 % of the doctors prefer combined therapy for RA/OA patients.
- Only 1 % of the doctors go for monotherapy.

3.9 Experience of any natural brand:-

Reply	Experience of natural topical product
Yes	50
No	1

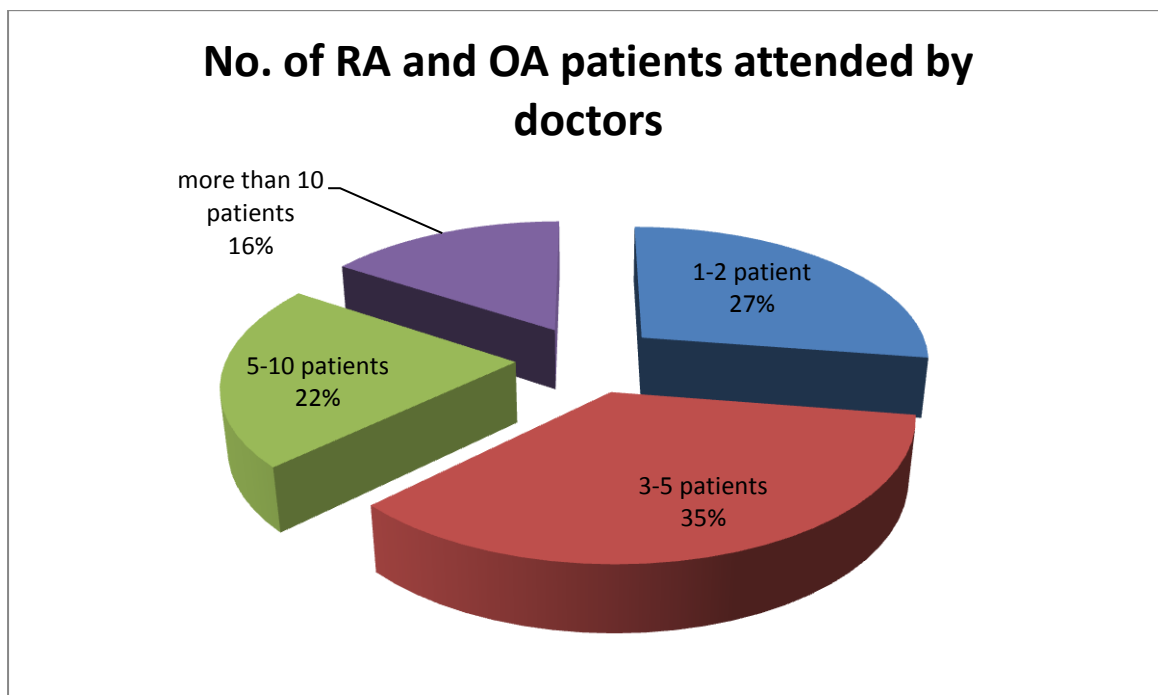


Observation: -

Only 1 doctor out of 51 doctors has experienced a natural product before. The brand was from the HIMALAYA Company but doctor was not satisfied with the performance of the product of this company. Rest 50 doctors did not have any natural brand experience yet.

3.10 Number of RA/OA patients attended by a doctor in a day:-

No. of patients attended by the doctor	Total No. of patients
1-2 patient	14
3-5 patients	18
5-10 patients	11
more than 10 patients	8

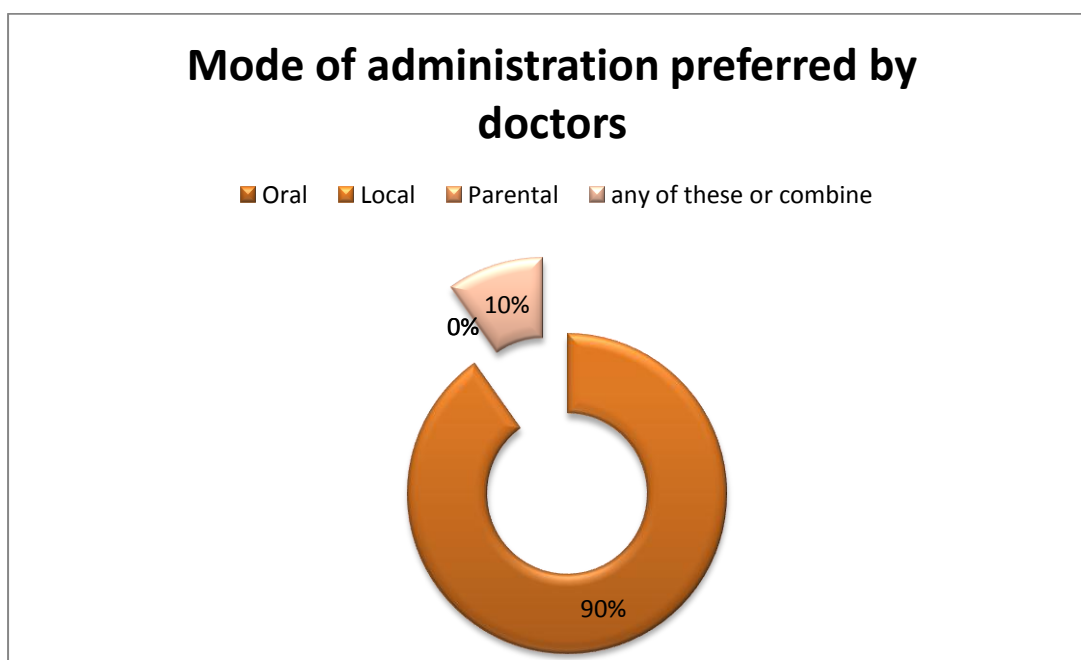


Observation:-

- 35% of the doctors attend 3-5 patients in a day.
- 27% doctors attend 1-2 patients in a day.
- About 22% of the doctors attend 5-10 patients in a day.
- Only 16% of the doctors attend more than 10 patients in a day.

3.11 Mode of administration preferred by doctors for RA/OA patients:-

Mode of administration	Preference of doctors
Oral	46
Local	0
Parental	0
any of these or combine	5

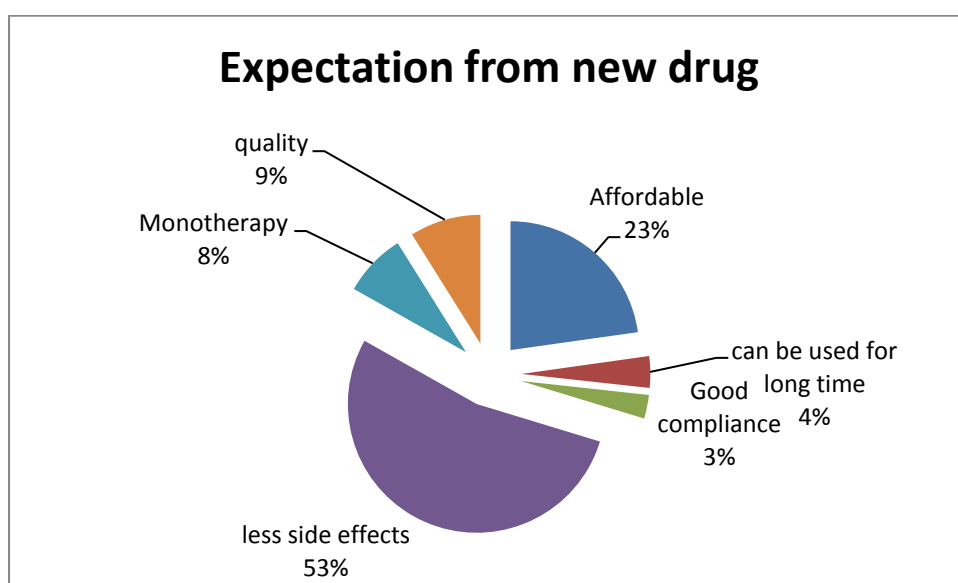


Observation:-

- Majority of the doctors prefer Oral route of administration in patients.
- Only 10% of the doctors prefer to give combinations and that depends upon the condition of the patient.

3.12 Expectation from new drug of RA/OA:-

Affordable	23%
can be used for long time	4%
Good compliance	3%
less side effects	54%
Monotherapy	8%
quality	9%



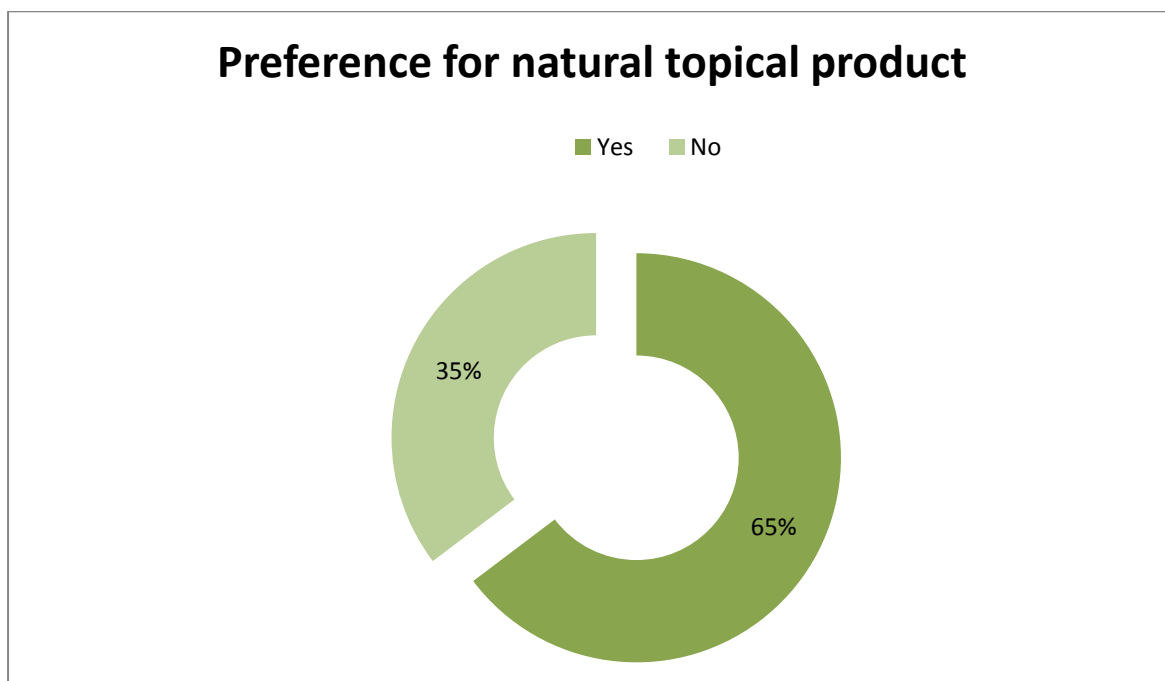
Observation:-

Expectations of doctors from new drug of RA/OA:-

- Less side effects
- Effective
- Economical
- Quality
- Monotherapy
- Affordable
- Can be used for long time
- Good compliance

3.11 Preference of natural topical product by the doctors:-

Doctors reply	Preference for natural topical product
Yes	33%
No	18%



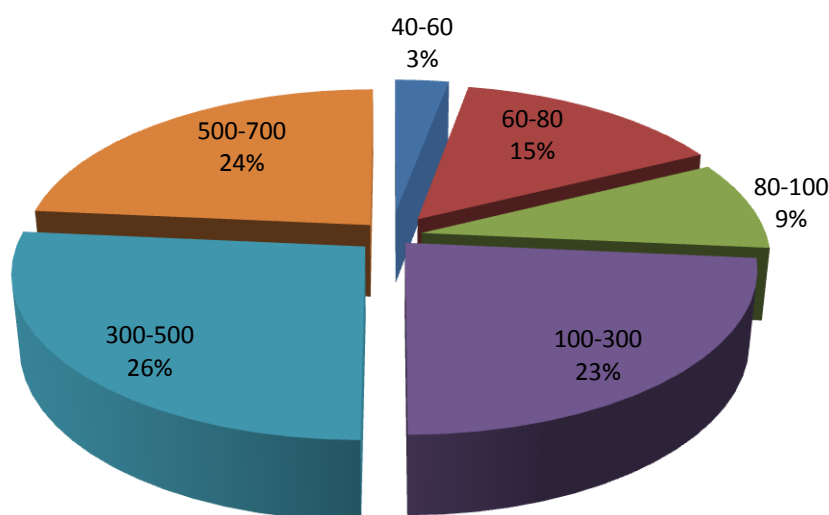
Observation:-

- Around 65% of the doctors prefer using natural topical product.
- Only 35% of the doctors do not prefer natural topical product because their previous experience was not good.

3.12 Recommended price for natural topical product:-

Price	Recommended price for natural topical product by doctors (in %)
40-60	3
60-80	15
80-100	9
100-300	23
300-500	26
500-700	24

Recommended price for natural topical product by doctors



Observation:-

- Majority of the doctors recommended the price range of the product should be up to Rs. 300-500.
- As per the doctors if the effectiveness of the product is more than price range can be increased and it can extend up to Rs. 500-700.
- 23% of the doctors recommended 100-300 price range for the product.
- About 15% of the doctors given a range of 60-80 Rs.

SECTION – 3

QUESTIONNAIRE

PRE MARKETING ASSESSMENT FOR LAUNCHING NEW NATURAL PRODUCT FOR TREATMENT OF RA/OA ARTHRITIS

Name of Doctor _____

Specialization MD/MS Rheumatology/Orthopedician

Address of doctor with Phone No and Email ID

Email _____

Phone No./Mobile No. _____

1. What kind of drug is used in patient of RA/OA for control of inflammation and pain?
2. What is the main influencing factor while prescribing a drug?
 - A) Quality B) Less side effect higher bioavailability C) Affordability
 - D) Patient convenience E) Other _____ (Pl tick whichever is applicable)
3. How much time the current therapy needs to show results?
4. Which therapy you recommend for such patients? a) Mono b) Combined
5. Have you experience any natural product? Yes/No
6. If experienced what is brand and satisfaction with results
 - a) Very satisfied b) satisfied c) Not satisfied

7. Number of RA/OA patient you attend in day

a) 1-2 b) 3-5 c) 5-10 d) more than 10

8. What mode of administration you prefer for such patient?

a) Oral b) local c) Parental d) any of these or combine

9. What is your expectation from new drug in RA/OA cases for control of pain and Inflammation?

10. Will you prefer a natural topical product which takes care of pain, inflammation And has scientific data to back up? Yes/No.

11. What should be the monthly recommended price for such product?

SECTION – 4

KEY FINDINGS

Key findings:-

- Most of the doctors prefer giving drugs in combination of NSAID and DMARD.
- Most of the doctors give **preference to less side effects ,quality of the drug and affordability** while prescribing any drug. If the quality of the drug is good then it can perform better in the market.
- As per the doctors says the current therapy duration is 2-3 months and if there is any drug which can **show its action in short period of time** then it will be preferred by the doctors.
- Majority of the doctors prefer in giving **combined therapy instead of monotherapy**.
- There is less competition in market for natural products because the products available in the market before are also not giving satisfactory results.
- As per the doctors says they **prefer oral route of administration** the most rest of the route of administration are used depending upon the condition of the patients.
- Majority of doctors said that the new product which is going to be launched in the market **should have less of the side effects and should be affordable**.
- There are **more chances that natural topical product can perform better** in the market as doctors are also interested in experiencing such product.
- Depending upon the effectiveness of the product price range can be set.

SECTION-5

RECOMMENDATIONS & SUGESSTIONS

Suggestions:-

- Most of the doctors prefer giving drugs in combination the most preferred combination is NSAID and DMARD.
- Most of the doctors give preference to less side effects, quality of the drug and affordability while prescribing any drug. If the quality of the drug is good then it can perform better in the market.
- As per the doctors says the current therapy duration is 2-3 months and if there is any drug which can show its action in short period of time then it will be preferred by the doctors.
- Majority of the doctors prefer in giving combined therapy instead of monotherapy.
- There is less competition in market for natural products because the products available in the market before are also not giving satisfactory results.
- Most of the doctors prefer oral route of administration.
- Majority of doctors said that the new product which is going to be launched in the market should have less of the side effects and should be quick and effective.
- **Among topical products majority of doctors prefer using natural topical product.**
- Depending upon the effectiveness of the product price range can be set.

Recommendations:-

- If the quality of the drug is good then it can perform better in the market.
- If there is any drug which can show its action in short period of time then it will be preferred by the doctors.
- The natural topical products can perform better in the market as doctors are also interested in experiencing such products.

CONCLUSION

- After the pre marketing assessment done on the natural topical product it was found that most of the doctors are interested in trying the natural topical product and want to have an experience of this product therefore there is a brighter chance that the new product can perform better in the market.
- Doctors who have said “NO” for the natural topical product is also because their experience for the existing product was not good therefore according to me this new product can perform better in the market as there are less competitor for this product in the market and the existing products are not able to satisfy the needs of the customers.

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