Study on the Challenges and Opportunities for an Indian Pharmaceutical Company in International De-Addiction Market

By

C. Vasudeva

Dissertation submitted for the partial fulfillment of the

MBA Pharmaceutical Management

Academic year, 2017-2019

The IIHMR University, Jaipur

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IIHMR UNIVERSITY

TO WHOMSOEVER MAY CONCERN

This is to certify that C.Vasudeva, student of MBA Pharmaceutical Management from The IIHMR University, Jaipur has undergone internship training at Rusan Pharma LTD from 1st Feburary 2019 to 3rd May 2019.

The Candidate has successfully carried out the study designated to him during internship training and his approach to the study has been sincere, scientific and analytical.

The Internship is in fulfillment of the course requirements.

I wish him all success in all his future endeavors.

Dr.Sandeep Narula
Dean In-Charge
School of Pharmaceutical Management
The IIHMR University, Jaipur

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Rusan

The certificate is awarded to

C.Vasudeva

In recognition of having successfully completed his
Internship in the department of

International Marketing

And has successfully completed his Project on

STUDY ON THE CHALLENGES AND OPPORTUNITIES FOR INDIAN PHARMACEUTICAL COMPANY IN INTERNATIONAL DE-ADDICTION MARKET.

From **1st February 2019 to 3rd May 2019**

At **Rusan Pharma LTD**

He comes across as a committed, sincere & diligent person who has a strong drive and zeal for learning

We wish him all the best for future endeavors

RUSAN PHARMA MUMBAI 67

Niilesh V Thakkar

Nilesh V Thakkar
SR. Manager-HR&Admin

RUSAN PHARMA LTD. 58-D, Government Industrial Estate, Charkop, Kandivali (W), Mumbai - 400 067.
Tel.: 4238 3000, 2868 7035, 2868 2512, 2868 2515, Fax : 2868 9056, E-mail : rusan@rusanpharma.com
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CIN : U24230MH1994PLC077069

THE IIHMR UNIVERSITY, JAIPUR

CERTIFICATE BY SCHOLAR

This is to certify that the dissertation titled **Study on the Challenges and opportunities for an Indian Pharmaceutical Company in International De-Addiction Market.** and submitted by **C. Vasu Deva** Enrolment No. **IIHMR-U/02/2017-19/0097** under the supervision of **Dr.Ashok Peepliwal** for award of **MBA in Pharmaceutical Management** of the University carried out during the period from **1st Februaru2019** to **2nd May 2019** embodies my original work and has not formed the basis for the award of any degree, diploma associate ship, fellowship, titles in this or any other institute or other similar institution of higher learning.

Signature

Contents

ABBREVATIONS

1. AIDS- Acquired Immuno Deficiency Syndrome.
2. HBV- Hepatitis B Virus
3. HCV-Hepatitis C Virus
4. NCB- Narcotic Control Bureau
5. OST- Opioid Substitution Therapy
6. DOTS- Directly Observed Treatment
7. HIV- Human Immuno Virus
8. NRT – Nicotine Replacement Therapy

Acknowledgement

The success of my study mainly depends on encouragement and guidelines of many people. I take this as an opportunity to express my gratitude for my well-wishers who had helped me in completing this study successfully. I would like to thank specially Mr. Pradeep .P.Oza (director- International Business Development) AND Team for providing me a constant support and guidance throughout my study and also to my Academic Gurus Dr.Sandeep Narula (Dean of Pharmaceutical Management) and Dr. Ashok Peepliwal for their constant mentorship from initiation of study till the finalization of my study. The constant motivation and motivation of all had helped me in successful completion of my project. The main part of this study was All country Managers, Regulatory team and export team had made my study successful completion. Its my luck to work under such a great mentors and excel my knowledge.

C.Vasudeva

Management Trainee- International Marketing.

Rusan Pharma

Abstract

Study on the Challenges and opportunities for an Indian pharmaceutical company in International De-addiction Market.

Background

[1]The pharmaceutical industry is the fastest growing among other industry at $934.8 billion in 2017and was expected to reach at $1170 billion by 2021 at the CAGR of 5.8%[1]and [2]De-addiction Market is around 4 billion in 2016 and is expected at growth rate of 6% by 2025 at 7 billion[2]. In the health care society substance abuse is a bane where different age group of addicts can be seen for substance such as Narcotics substances, alcohol and tobacco.

The main reasons for addiction aretheir friend circle, for experimentation or self-motivation, peer pressures and may be for other reasons also. In the de addiction treatment it's important to monitor that the patients are treated with proper maintenance therapy and also important to create resistance for addiction of drugs among addicts. This study is mainly conducted to understand the various therapies available and challenges faced in Africa, South East Asia and Latin America Markets. In the de-addiction treatment not only pharmacological treatment is important but psychological treatment is very important for a patient. As per National practise guidelines of American society of Addiction Medicine the addict with narcotic substances are treated with Methadone followed by buprenorphine, Naltrexone oral tablets and implants.

Key words: - Maintenance therapy, Resistance, Treatment available, Challenges, Business Key drivers .

Objectives: -

- To know various initiatives taken by governments of each countries.
- To know about various treatments available in different country.
- To know about various challenges faced in market.
- To identify the key drivers in de-addiction market.

Research questionnaire

1. What are the initiatives taken by the government to stop addiction in your country?
2. Which are the various treatments available for drug addiction in your country?
3. Please rate the following (Based on challenges faced in your countries).

Countries	Rating/country						
Knowledge of treatment (Key Drivers)	5						
Registration of product	5						
Political	5						
Economical	5						
Social	5						

Technology	5						

4. Who are the key drivers in de-addiction program?
5. Which are the communities take part in de-addiction program?
6. What are the Challenges faced while exporting the consignment?(Export department)
7. What are the challenges faced during registration of product?(Regulatory)

Methodology

8. Place of study: - Rusan Pharma LTD.
9. Target audience: - Country managers, Regulatory team, Export team, Supportive team.
10. Sampling method:- Purposive sampling
11. Sample size:-20
12. Study tool: - Semi structured questionnaire with five point Likert scale and focus group discussions.
13. Study design:- Descriptive study

Results

14. The responses obtained from the analysis of data revealed that the major initiatives taken by government to stop de-addiction, various treatments available in each country, various challenges faced in country market. The key drivers driving the business, communities involved in de-addiction program, various challenges while exporting, registering of the product.

Conclusion

15. The results have shown the various challenges and bridging gaps that are to be filled for more growth and penetration into the market. The findings of us clarified various key drivers in the market and various forces affecting the growth in market.

About Rusan Pharma LTD

Rusan Pharma, Mumbai Rusan offers a one-stop-shop solution for treating various forms of addictions such as drugs, alcohol and smoking. We are reputed and the largest suppliers of life saving drugs (De-addiction, pain management and anti-TB drugs) to various organizations / ministries like NACO, UNODC, UNOPS, Global Fund, Ministry of Health, Ministry of Justice of countries like India, Europe, UK, Kenya, Tanzania, Uganda, Zimbabwe Russia, CIS, South Africa, Mauritius, Nepal, Myanmar etc.

Since 1994, Rusan has been in the fore-front of making Opioid Substitution Treatment (OST) an acceptable form of treatment in India. Rusan has been working closely with various NGOs, doctors, hospitals, clinics, reputed government institutions such as AIIMS, NIMHANS, KEM funding agencies such as Global fund, DFID and now NACO for scaling up the OST in India. The national program for the treatment of opioid addiction was started at KEM using Methadone syrup manufactured at Rusan.

Rusan Pharma is one of the leading manufacturers and marketers of various narcotics and psychotropic products in India and internationally.

[3]Vision

To bring forward highly innovative and technology driven treatment options for various neglected diseases with the best quality products for our consumers.

Mission

Rusan firmly believes that access to quality healthcare is a right, not a privilege. We will endeavour to ensure the availability of world class, quality medicines at adorable prices, across the globe and are committed to work towards a healthier & happier world**.**

Specialization

Specialist in Narcotics and Psychotropic drugs

One of the 6 notified companies in India to import narcotics

Backward integrations to API

Innovating new delivery system

Core specialization in De-addiction Pain management, Tuberculosis and Parkinson disorder.

Manufacturing Facilities Milestone

- **1994-Rusan Pharma Incorporated**
- **1996- R&D centre Mumbai inaugurated**
- **1998-Ankaleshwar API Unit inaugurated**
- **2000-Kandla SEZ (unit-I) Formulations Unit Inaugurated**
- **2009-Deharadun Formulations Unit Inaugurated**
- **2016-Kandla (unit-II)Transdermal Patch unit inaugurated**
- **2016-NSRT Pvt Ltd R&D centre Mumbai inaugurated**
- **2016-Quanty's clinical Pvt limited CRO centre inaugurated**

Awards and accreditation

1994- International excellence award for the small and medium exporters.

1997- Udyoga Ratna Award by Govt of India.

2000-Chemexcil award for outstanding export performance.

2014/15- 2baconil listed in the "Top 100 Asia's best and fastest growing healthcare and wellness brand by the world consulting and research corporation(WCRC)

2017-Export excellence awards 2017 by Express Pharma.

2017-Trial license for cultivation and extraction of Concentrated poppy straw(CPS) in India.

2018- Permanent license for cultivation and extraction of Concentrated poppy straw(CPS) in India.

DISSERTATION TOPIC

Study on the Challenges and opportunities for a Indian Pharmaceutical Company in International De-Addiction Market.

A.BACKGROUND

Addiction of substances is a bane for the society. The addiction of substances cause severe health problem like AIDS, HCV, Cancer, Liver Sclerosis , Mental health disbalance, Schizophrenia etc. The addiction are mainly classified into three types Drugs addiction, Alcohol addiction and Nicotine addiction. The main reasons for drug addiction are peer groups, pressure, self-experimentation with recreational drugs, availability of drugsand socially unrecognised [4]. Drugs are generally taken by snuffing, self-injecting and oral intake.

Alcohol is the other main addiction in a society. The alcohol is generally considered as the pleasure drink where initially the individual try is for experimenting on one own self and get addicted to it or also he gets addicted due to his peer groups ,peer pressure , unemployment and other factors play a important role in an individual getting addicted. In major of the countries alcohol is not considered as addiction.

Tobacco is another form of addiction which is taken by smoking or by chewing the factors influence for individual are same as common factors for alcohol and drugs.[4]The drug , alcohol and tobacco substances cause poor health unhealthy lifestyle and also poor nutrition. The addiction of drugs leads to homeless ness , suicidal tendency , drug overdose, committing a crime [4].The addiction of all these substances has not only ruined the life of individual but also his family. In the de-addiction program there are key drivers who play a major role in health care society and there role and responsibilities of each of them .

The important thing that is to be understood in manufacturing and handling narcotics are under monitoring of national body NCB and international body INCB. Under the INCB quota each and every country have a restricted quantity of each and every narcotics and psychotropic substances usage. A supplier who is having narcotics license can only import narcotics product.

If the country requires the more amount of narcotics for a year the narcotics control board of particular country should write an application giving proper reasons for more requirement then it is validated by INCB and then it is permitted.

The main purpose of this study is to understand the key drivers who play a important role in de-addiction program and also to know there roles and responsibilities.

B. INTRODUCTION.

The Indian Pharmaceutical market is in third largest by volume and thirteen largest by value. Indian Pharmaceutical market is called as the pharmaceutical hub of the world. The Indian pharmaceutical market is expected to grow by 2020 at 22.2% compound annual growth rate (i.e., $55billion).The Pharmaceutical market of India is mainly constituted by 70% of Generic medicines and reaming percentage are filled by other class products (i.e., 21% of OTC products and 9% Patented products).

The addiction is defined as the physical inability and psychological inability to stop consuming a chemical, drug or substances which cause harm by psychologically or physically. The de-addiction therapy involves psychological therapy and also pharmacological therapy. The De-addiction market in global is estimated to be around four Billion Dollars in 2017 and also expected to reach the market share of seven Billion Dollar at the compound annual growth rate of six percentage by 2025. The three main class of addiction are, Drug addiction, Alcohol addiction andTobacco addiction.

All three together are called as Substance abuse. Drug addiction mainly starts from a range of mild stimulants then move on to higher stimulants like cocaine, codeine till Marijuana LSD, Cannabis, charas, bhang, heroin etc. Alcohol and tobacco like smoking through cigarettes and chewable tobacco. There are many health issues like AIDS, T.B. Hepatitis by addiction to drugs will occur similarly in alcohol addiction the liver failure will occur and also by tobacco addiction it may cause cancer. The over dose of drugs cause 70237 deaths for 100,000 population and the over dose of drugs alcohol and tobacco causes death. 3.3 million People are dead in each year &six million deaths caused by tobacco consumption. There are various initiatives taken by each country's Ministry Of Health and NGOs'. The treatment of de-addiction is mainly classified based on as mentioned classes into drugs-Opioid's substitution therapy; Alcohol is called as Alcohol regular detox and rapid detox and for tobacco nicotine replacement therapy. The drug and alcohol abuse leads to commit crime.

Each and every activity right from processing , manufacturing and till end use is monitored by Country's narcotic body which is governed by international body INCB.

The various country government like Bangladesh,Manymar and other countries have already started OST as an initiative. In few countries like Angola recently de-addiction centre is opened. In countries like Zimbabwe there are no any de-addiction centre.

Majority of the countries are using Methadone as an OST which is long acting opioid where 30-40mg/day initial day dose for a patient is given and maximum dose of 80mg/day is given. The patient dies because of overdose of Methadone. The main reason is the half life of methadone is 24 hours . Buprenorphine is a partial agonist the daily dose is 8mg which is suprabioavailability and half-life of buprenorphine is of…..The Buprenorphine and Methadone are under DOTS therapy. Where Buprenorphine + Naloxone is not under DOTS therapy because Naloxone is having higher affinity towards opioid receptor when Buprenorphine is tried to be misused then Naloxone blocks the activity.

Naltrexone tablet is given for 7 days after that Implant is inserted into body and patient is then followed by counselling.

Consumption pattern of drugs in various countries are as descending order Oceania, America, Africa, Europe and Asia. The study is completely based on the analysis of gap, Opportunities and challenges in the international market by applying analysis such as PESTL, SWOT and Why,where,whom when and how.

C.Addiction and De-addiction.

The addiction is defined as the chronic relapsing disease which involves irresistible urge for intake of drugs which causes physical inability and psychological inability. The function n of brain will be changed by intake of drugs so it is called as brain disorder and the changes in rain may be for long-lasting and lead to harmful behaviour among addicts.

The main reasons for addiction are

1. Curiosity and others are doing.
2. Pleasure
3. To feel more desirable
4. To be effective
5. Availability
6. Peer pressure
7. Home and family etc

The addiction of drugs leads to:-

I. Cardio-Vascular Disease .
II. Stroke
III. Cancer
IV. HIV/AIDS
V. HBV/HCV
VI. Lung disease
VII. Mental disorder
VIII. Aging.

The effects of drugs on Organs

1.Brain-The drugs mainly causes impairment in learning, insomnia, emotional instability, changes in heart rate, body temperature, breathing.

2.Mouth:- By chewing of drugs it mainly causes tooth decaying, gum disease and bad breath.

3.Heart:-Heart attack, stroke, blood clots, heart damage, sudden death.\

4.lungs:-Smoking of drugs causes bronchitis, lung infection and frequent coughing.

Addiction of alcohol leads to:

a. Anaemia and low platelet count
b. Osteoporosis
c. Thiamine deficiency and leads to Wernicke's encephalopathy.
d. **Korsakoff's syndrome**
e. Breast Cancer
f. Blurred vision
g. Decreased vision
h. Coronary artery disease
i. Atherosclerosis

Effects of alcohol on organs

- Brain- Mood and behaviour.
- Heart- Cardiomyopathy, arrhythmias, stroke , blood pressure.
- Liver- Fatty liver, fibrosis, cirrhosis.
- Pancreatitis.

- Immune system- Pneumonia and various types of cancers.

Addiction of Tobacco leads to:

- Skin wrinkles
- Brown teeth
- Gum disease
- Bad breath
- Anxious
- Moody
- Ruin some of the taste bud
- Increase in blood pressure
- Damage of lungs
- Emphysema

Effects of Tobacco on organs

Brain- Makes addictive, headache and dizziness .

Mouth- Bad breath and stains on teeth.

Heart- Increased heart rate, heart attack

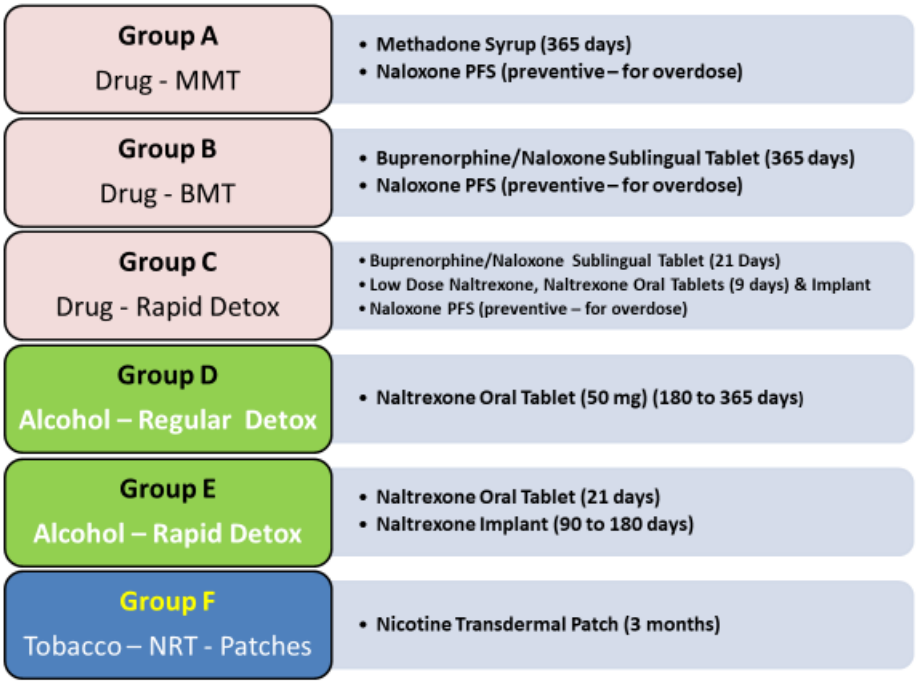
Lungs- Coughing with phlegm and lung cancer.

Skin- Yellow and wrinkled skin.

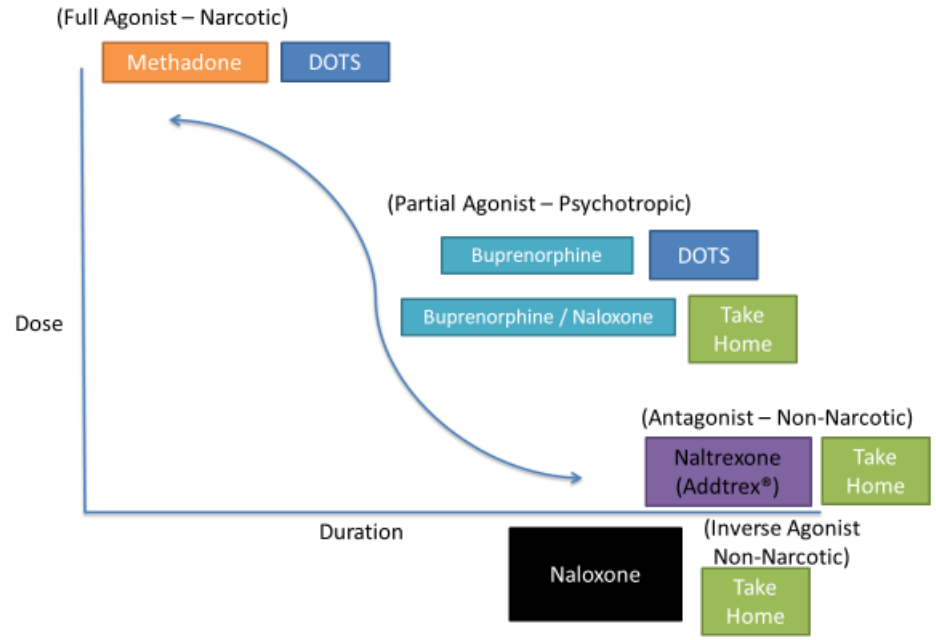
Muscles- Aching of muscles during exercise or playing due to deprivation of oxygen.

De-addiction

The De-addiction of drugs, alcohol and tobacco has 6 major steps of therapy they are as follows,



CONCEPT OF HARM REDUCTION



D.REVIEW OF LITERATURE

1.COMMUNITY AND DRUGS:,A DISCUSSION OF THE CONTEXTS ANDCONSEQUENCES OF COMMUNITY DRUG PROBLEMSIN IRELAND, 1976-2001 By BARRY CULLEN At ADDICTION RESEARCH CENTRE, TRINITY COLLEGE reported as follows.

Community such as under class, structural issues and social disorganization are the communities mainly affected by drug addiction. Underclass community they generally blame drug users their families and their communities. Drug problem and related crime they mainly show the problem of structure in community and society deeper and also physical structure declining and organization of communities that look economic activity.

2.Alcohol-Related Hospital Statistics AT Scotland 2016/17, Publication date – 21 November 2017 *reported as follows.* The effects caused by alcohol on Brain, toxic effects of alcohol and liver sclerosis. The excessive intake of alcohol leads to a condition called as Alcohol related brain damage and can cause problem in cognitive behaviour, learning and memory. There is a steady increase from 1997 -1998 in the general acute setting for 100,000 patients 12.3 was the setting and by 2016-2017 it has raised to 17.1 per 100,000.

E. Research questionnaire

1What are the initiatives taken by the government to stop addiction in your country?

2.Which are the various treatments available for drug addiction in your country?

3.Please rate the following (Based on challenges faced in your countries).

Countries	Rating/country						
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Registration of product	5						
Political	5						
Economical	5						
Social	5						
Technology	5						

4.Who are the key drivers in de-addiction program?

5.Which are the communities take part in de-addiction program?

6.What are the Challenges faced while exporting the consignment?(Export department)

7.What are the challenges faced during registration of product?(Regulatory)

D. Objectives:-

- To know various initiatives taken by governments of each countries.
- To know about various treatments available in different country.
- To know about various challenges faced in market.
- To identify the key drivers in de-addiction market.

E. Methodology

- Place of study: - Rusan Pharma LTD.
- Target audience: - Country managers, Regulatory team, Export team, Supportive team.
- Sampling method:- Purposive sampling
- Sample size:- 20
- Study tool: - Semi structured questionnaire with five point Likert scale and focus group discussions.
- Study design:- Descriptive study
- Survey Instruments:- The questionnaire was semi structured and the focused group discussion was held where each country managers were sharing there experiences in market like the challenges and the ways they converted those challenges into opportunity.

F. Results and conclusion.

Objective 1 :-

1. In countries like Bangladesh, Myanmar, Kenya, Tanzania, Peru Chile Bolivia , Ecuador ,Zambia,Panama and Elsalvador government initiative OST centres are run and act against controlled substances are implemented.

Objective 2 :-

- In Zambia and Kenya- **Buprenorphine** is used in government based OST center.
- In above mentioned other countries – **Methadonesyrup** is used in OST centers.
- In Latin America **Methadone tablets** are used.

OBJECTIVE 3:-

Challenges:-

1. Knowledge about treatment available: - In many of the countries the ministry of health only know Methadone as OST therapy. Since Methadone has a 24hous of half

life the half amount of methadone gets eliminated by next dose and half will be stored in body at certain moment the dose of methadone will be high and it leads to death.

2. In country Like Peru and Bolivia there is a conflict in political where addiction is more due to growth and availability of Coca leaves nearly 35,000 hectare are grown annually.
3. In few countries like Zimbabwe, Angola, Malawi and Madagascar there are no funds in those countries.
4. In each and every country the regulatory requirement varies which consumes large amount of time for entry into product registration
5. The export permit available for narcotics product will be for total volume of purchase order released. In conditions like multiple delivery the document of export could be used once where organization should have to apply for permit again and where resources are spent more either in terms of (cost, time or manpower).
6. Management of Methadone is Very poor in Latin America.
7. Product registration in Latin America is required.
8. Misuse of Methadone by addicts are very high in Kenya.

Opportunities

1. In countries like Bangladesh, Myanmar, Kenya Zambia, Ecuador, Panama, Elsalvador, Peru, Chile, Bolivia and Tanzania has the opioid substitution therapy centres in the countries where buprenorphine can be pitched. In other places apart from Zambia and Kenya OST as Methadone syrup is used in Latin America Methadone tables are used.

2. In countries like Myanmar and Bangladesh the narcotics commission of respected countries are looking forward for an alternative of Methadone management therapy. Since Rusan is having One Stop-Solution a only company having wide range of products for de-addiction will be an opportunity for promoting Addnok and Addnok-N Sublingual tablet having Supra-bioavailability.

3. The patient once treated with all type of management therapy then he/she will be detoxified using Addtrex tablets and then to avoid the condition of craving the **Addtrex implant** are to be inserted.

4. Alcohol and Tobacco addiction is not yet included in program of ministry how ever NRT is available private retailers and hospitals so an effort can be made by meeting official of narcotics department and suggest them for including alcohol and tobacco into deaddiction program.

5. In few part of the country they believe only Psychological therapy is the only way to treat addiction we can meet the responsible person and educate them about our product and convince them to add pharmacotherapy along with psychotherapy.

6. In majority of the country Methadone is used as a gold standard for OST but use of methadone in all kind of addicts is not advisable moreover methadone is a management therapy in order to treat the addicts and make them free from addiction we can suggest them to switch addict to Addnok.

7. Addnok and Addnok-N has an advantage over Suboxone and Subutex because the maximum dose of Suboxone and Subutex are 21 mg /day and poor bioavailability where as Addnok and Addnok-N maximum dose is 8 mg/day.

8. In Latin America countries Addnok, Addnok-N, Addtrex Tab and Implant initiation can be done.

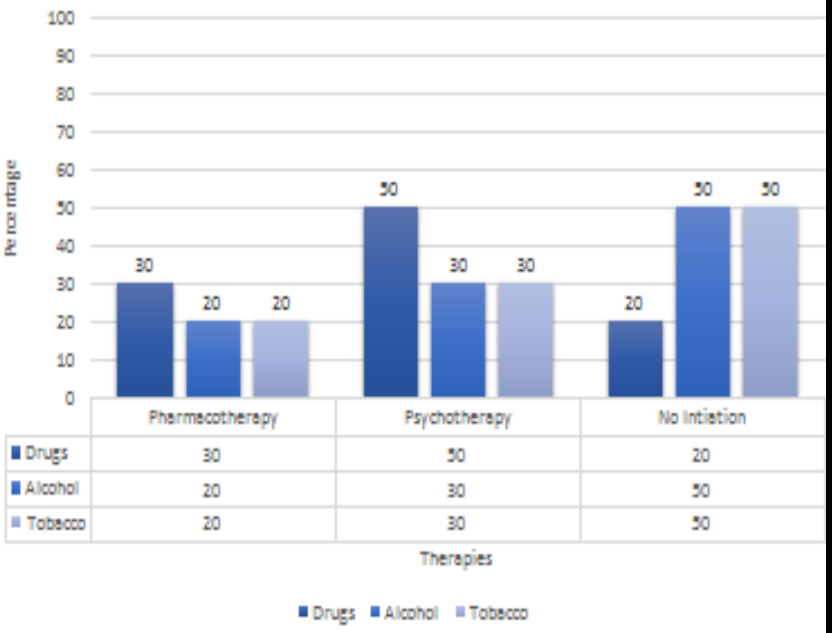
9. In Latin America huge amount of people are not covered under scheme of de-addiction.

10. There are only few registered brands of products available in Latin America for deaddiction program.

11. The products can be exported based on special permit.

12. The Methadone suppress ARV's in drug injecting AIDS patient so buprenorphine can be use

Data Analysis

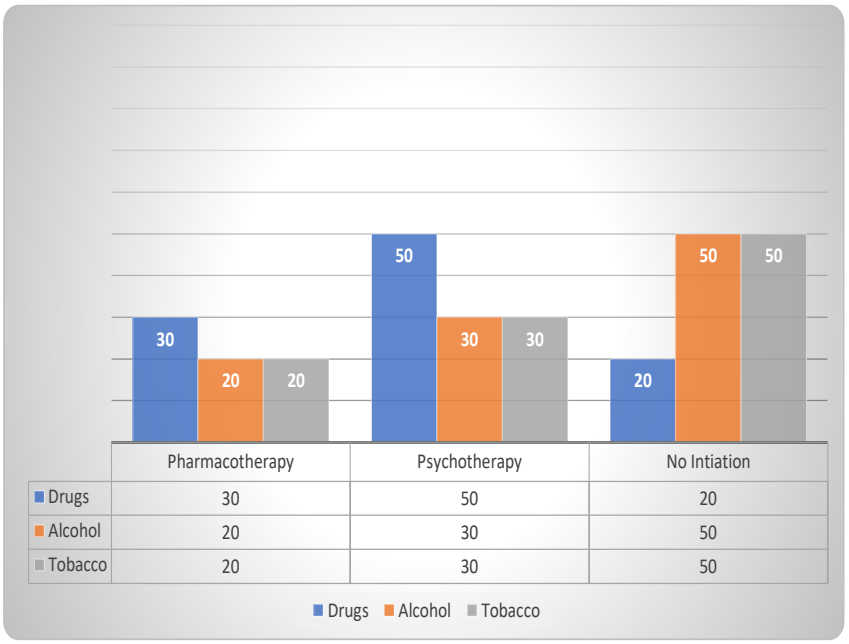


Inference- Drugs-30% of the countries follow Pharmacotherapy, 50% of countries Follow Psychotherapy and 20%no initiatives.

Alcohol-50% of the countries follow Pharmacotherapy, 30% of countries Follow Psychotherapy and 30%no initiatives

Tobacco-20% of the countries follow Pharmacotherapy, 50% of countries Follow Psychotherapy and 50%no initiatives.

Treatments available for substance abuse



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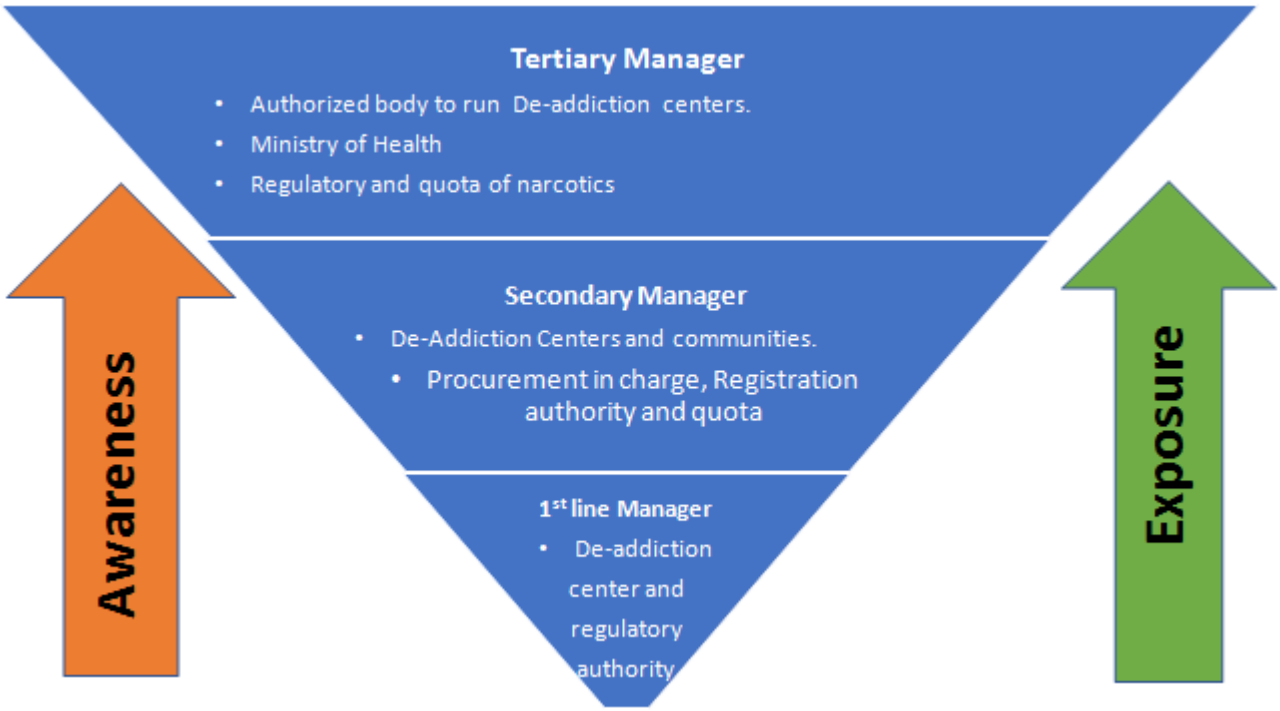
Suggestions

PONS MODEL

P-Prabhudayal ji

O-Oza pradeep

N-Dr.Sandeep Narula



- **Chemicals induce stress on cells turmeric decrease the oxidative stress and avoid conversion of cells into tumor –Turma Boost can be promoted.**
- **2baconil Patch- By PPB It can be promoted internationally.**

Ex:- TATA groups(Public)+Rusan(Private)= Promote anticancer product.

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