MARKET ASSESSMENT OF FIRST LINE ANTI-TUBERCULOSIS MEDICATION USED IN INDIA

Dissertation Submitted to

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for the partial fulfillment for the award of the degree of

Master of Business Administration (MBA)

in

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by

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Under the Supervision and Guidance of

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DECLARATION BY STUDENT

I hereby declare that this dissertation titled **'Market Assessment of First Line Anti-Tuberculosis Medication Used in India'** is the Bonafede record of my original researchwork. I declare that it has not been submitted to any other university or institution for the award of any degree or diploma. Information derived from the published or unpublished workof others has been duly acknowledged in the text.

Signature

Adya Kaul

23June 2021

Completion Certification

CERTIFICATE

This is to certify that Adya Kaul in partial fulfillment of the requirements for the award of the degree of MBA (Pharmaceutical Management) from the IIHMR University, Jaipur has successfullycompleted her internship at (The Enablers) during March 22, 2021, to June 19, 2021.

Vivek Hattangadi
Chief Mentor – The
Enablers29th June 2021,
Ahmedabad

Certificate from Faculty Guide and School Dean

CERTIFICATE

This is to certify that dissertation titled 'Market Assessment of First Line Anti-Tuberculosis Medication Used in India' is a record of the research work undertaken by Adya Kaul in partial fulfillment of the requirements for the award of the degree of MBA PharmaceuticalManagement from the IIHMR University, Jaipur under my guidance and supervision and her approach to the research study has been sincere, scientific, and analytical.

Faculty Guide
IIHMR University, Jaipur

Date

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Date

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ABBREVIATIONS

TB	**Tuberculosis**
HIV	**Human Immunodeficiency Virus**
WHO	**World Health Organization**
DOTS	**Directly Observed Treatment, Short-Course**
MoHFW	**Ministry of Health and Family Welfare, India**
HBC	**High Burden TB Countries**
GDF	**Global Drug Facility**
TB Alliance	**Global Alliance for TB Drug Development**
UHC	**Universal Health Coverage**
FLD	**First Line Drugs**
MDR TB	**Multi Drug Resistant TB**
XDR TB	**Extensively Drug Resistant TB**
CSR	**Corporate Social Responsibility**
CDC	**Centre For Disease Control and Prevention, USA**
US FDA	**Food and Drug Administration, USA**

1.INTRODUCTION/ BACKGROUND

TB IS A PANDEMIC FOUND IN EVERY COUNTRY OF THE WORLD.

Figure 1 WORLD MAP (1)

Tuberculosis (TB) is an infectious illness brought about by a bacterium, mycobacterium tuberculosis. TB is spread through the air. A solitary patient can contaminate a lot more individuals in a year. The microbes normally assault the lungs; however, TB microorganisms can assault any organ of the body like the kidney, spine, brain and gastrointestinal system. Not every person contaminated with TB microorganisms gets the TB disease. Thus, two TB-related conditions exist: Active TB illness and inactive TB illness known as Latent TB (LTBI). TB microorganisms can live in the body without making the person ill which is called Latent TB. Numerous individuals who have dormant TB contamination never foster TB sickness. A few groups foster TB sickness fast, as their immunity levels are low and cannot battle the TB microbes. Others may become ill years later with TB disease, when their body becomes frail due to some other infection.

Global Mortality:

Globally TB is one of the major diseases resulting in fatalities. It accounts for approximately one million and four hundred thousand deaths, which include approximately 208,000 people infected additionally with HIV. **TB** ranked ***seventh*** among the ***top ten*** causes of deaths in 2019.

These death figures do not affect the conscious of average people or the media personnel. This is primarily due to the reason that TB patients, largely belong to the poorer sections of the society who are marginalized, vulnerable and get associated with social stigma. Just compare TB awareness with that of awareness for COVID 19 disease which resulted in ***1.8 million*** deaths in the year 2020 excluding unreported deaths. Due to this pandemic, efforts to end TB menace also reduced significantly. **(2,3)**

Global Morbidity:

Worldwide, the number of people infected with TB in the year 2019 were about ***ten million*** within the expected range of ***eight million nighty thousand to eleven million***.

Age/ Gender incidence: Men (>15yr) account for 56% cases; Women (>15yr) account for 32% cases; Children (<15yr) account for 12% cases. **(2)**

Covid 19 Impact:

Pandemic's impact has shown that Government's across the world must give more importance and funding to Healthcare Sector. For a Nation to have political stability with social and economic development, the good health of a Nation is a prerequisite condition. Pandemic's impact was lesser detection of TB cases and could have led to increase of almost 400,000 people dying from TB in the year 2020. **(2)**

India Morbidity: In 2019, a record of 24 lakh cases including 6.79 lakh notifications from private sector were recorded. The gap 2.9 lakhs between estimated cases 26.9 lakhs (WHO) and notified cases is closing fast. **(4)**

In, 2020, due to Pandemic and Lockdown, notification of cases dropped down to 18.05 lakh. **(5)**

Categories:
TB patients/ TB and HIV patients/ TB and Diabetic patients/ TB and Tobacco chewing patients/ MDR(Multi-Drug-Resistant) TB patients/ XDR- TB(Extensively Drug-Resistent)/Latent TB patients.

TREATMENT TB

Treatment for TB disease starts with four drugs regimens known as **first-line drugs (FLD).** Treatment is for a period of **six to nine months** and these drugs are: ***rifampicin, isoniazid, pyrazinamide, ethambutol***.

The long treatment time and the large quantity of drugs to take, is a difficult task for many of the people, especially for patients of the economically backward strata. Further, these strong medications require that the patients have nutritious diet, which again, many may not be able to afford.

These drugs, if taken as prescribed have a ***success rate of around 85%*** across the globe.

MDR -TB (MULTI- DRUG RESISTANT)

The patients who do not recover from TB disease after taking **FLD** medication for six to nine months fall under the category of **MDR-TB** (**Multi-Drug-Resistant**). In these cases, patients commonly become resistant to the two major antibiotics: ***rifampicin and isoniazid.*** The major reasons for developing **MDR TB** is due to the patients not consuming **FLD** medication daily and as per doctor's prescription. Many patients tend to miss their medication for a few days and some other develop erratic pattern of consuming medication, while non- availability may be a factor for some. All such, cases develop **MDR TB.**

Treatment for **MDR -TB** is with ***Second Line -Drugs***, for a longer duration, two years or more. Treatment includes everyday injections for a period of six months along with other drugs. These ***Second - Line -Drugs*** are more expensive, have more severe side effects as well as have a higher degree of toxicity.

The patients who do not recover from **MDR-TB** disease after taking **SLD** medication for two years fall under the category of **XDR-TB (Extensively- Drug- Resistant)**. For, **XDR-TB** cases, treatment is considerably lengthier, more complex and more costly. In health care facilities with limited resources, **XDR-TB** presents a formidable challenge with very little success rate.

New treatment for **XDR-TB** requires use of new generation drug ***pretomanid*** developed by TB Alliance, which obtained **FDA (Food and Drug Administration, USA)** approval in 2019. This drug ***pretomanid*** is to be used as combination therapy along with ***bedaquiline*** and ***linezolid*** for **XDR-TB. (6)**

2. REVIEW OF LITERATURE

It is anything but an amazing reality that almost 25% (approximately 2 billion) of the total global population (approximately 8 billion) is infected with M. tuberculosis -Latent TB. Of these 2 billion individuals, some (5-10%) are probably going to foster TB infection during their lifetime. Tragically, this TB sickness has a higher event rate in individuals with HIV, lack of healthy sustenance, diabetes, smoking and tobacco consumption habit. **(7)**

Strategy to END TB:

DOTS: Directly Observed Therapy, Short-Course.

In 1993, WHO proclaimed Tuberculosis as a worldwide crisis and began **DOTS** strategy to control Tuberculosis. Nations executing this methodology are more than 180. In **DOTS**., healthcare workers observe patients as they take their medication.

DOTS Plus:

DOTS strategy was improved to **DOTS Plus** strategy in the year 2000. This was done to take care of **MDR-TB.**

RNTCP: Revised National Tuberculosis Control Programme.

India, has been following **WHO** guidelines for control of **TB.** Beginning in the year 1993, India started **RNTCP**, which applied the principle of **DOTS** to the Indian context and covered the entire country by 2005.

In India, as well as in many developing countries, notification of TB cases by private sector is not mandatory. As such, a significant number of new TB cases go unreported especially from private Clinics. Disciplines such as: Pulmonologists; Chest Physicians; General Practitioners; Pediatricians; Orthopedics and Gynecologists treat a large population of patients which go unreported.

HBC:

High TB Burden Countries: 30 HBC countries account for 87% of global cases. Further, eight HBC countries: India, China, Indonesia, Philippines, South Africa, Nigeria, Pakistan, Bangladesh account for about 66% of global TB cases. **(2)**

WORLD TB DAY: Dr. Robert Koch, announced to the Berlin Physiological Society that he had discovered the cause of tuberculosis (**mycobacterium tuberculosis**) on 24th March 1882. He was subsequently awarded Nobel Prize in the year 1905 for his research on tuberculosis.

This day, 24th March, is annually celebrated as World TB Day. Governments and NGOs across the world celebrate this day and try to increase awareness about TB including the fact that TB can be totally cured with proper medication. Publicity is also given about the various government schemes to assist **TB patients. (8)**

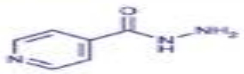
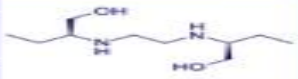
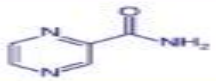
IMPORTANCE OF FIRST- LINE DRUGS:

RIFAMPICIN
ISONIAZIDE
PYRAZINAMIDE
ETHAMBUTOL
OTHERS (STEPTOMYCIN)
.

TB is curable and preventable disease. **TB** patients can be effectively treated with a six-month drug routine. At present, suggested treatment for **TB** disease is a six-month drug routine of the Four–First–Line drugs:

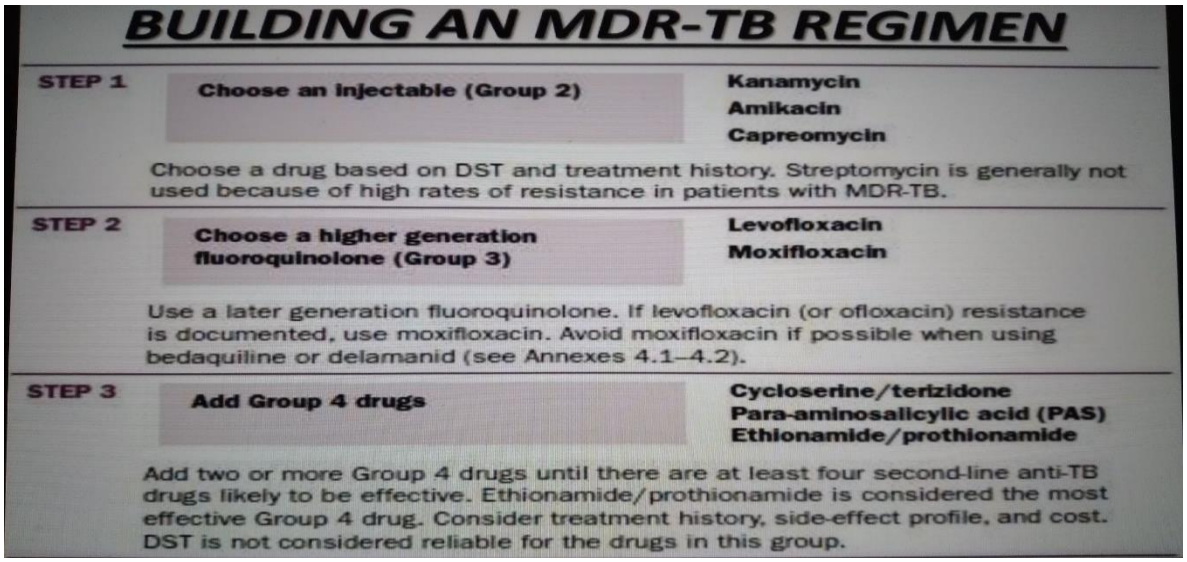
FOUR PRINCIPAL FIRST LINE TB DRUGS
TABLE-2.1(9)

The Four Principal First-Line TB Drugs

Drug Name	Formulation	Chemical Structure
Isoniazid		
Rifampin		
Ethambutol		
Pyrazinamide		

FLD drugs are very effective in the treatment of **TB** provided the complete drug course of six months is taken by the patients. Inputs by 194 member countries of **WHO**, mention **treatment success rate above 85%** with **FLD** drugs.

TABLE 2.2 MDR TB REGIMEN (10)



BUILDING AN MDR-TB REGIMEN

STEP 1	**Choose an injectable (Group 2)**	**Kanamycin** **Amikacin** **Capreomycin**
	Choose a drug based on DST and treatment history. Streptomycin is generally not used because of high rates of resistance in patients with MDR-TB.	
STEP 2	**Choose a higher generation fluoroquinolone (Group 3)**	**Levofloxacin** **Moxifloxacin**
	Use a later generation fluoroquinolone. If levofloxacin (or ofloxacin) resistance is documented, use moxifloxacin. Avoid moxifloxacin if possible when using bedaquiline or delamanid (see Annexes 4.1–4.2).	
STEP 3	**Add Group 4 drugs**	**Cycloserine/terizidone** **Para-aminosalicylic acid (PAS)** **Ethionamide/prothionamide**
	Add two or more Group 4 drugs until there are at least four second-line anti-TB drugs likely to be effective. Ethionamide/prothionamide is considered the most effective Group 4 drug. Consider treatment history, side-effect profile, and cost. DST is not considered reliable for the drugs in this group.	

TABLE-2.3 (2)
WHO END TB STRATEGY

VISION	A WORLD FREE OF TB — zero deaths, disease and suffering due to TB			
GOAL	END THE GLOBAL TB EPIDEMIC			
INDICATORS	MILESTONES		TARGETS	
	2020	2025	SDG 2030[a]	END TB 2035
Percentage reduction in the absolute number of TB deaths (compared with 2015 baseline)	35%	75%	90%	95%
Percentage reduction in the TB incidence rate (compared with 2015 baseline)	20%	50%	80%	90%
Percentage of TB-affected households facing catastrophiccosts due to TB (level in 2015 unknown)	0%	0%	0%	0%

GDF: Global Drug Facility is an organization of WHO.

Is one of the productive organizations leading the challenge against **TB**. Services rendered by **GDF** are:

- Free supply of first line adult and paediatric **anti- TB drugs** to select countries. These countries are economically and industrially backward and are selected based on criterions developed by **WHO** and **UNICEF**.
- Paid supply of first line adult and paediatric **anti-TB drugs** to countries which have adequate finances, but lack technical and administrative skills to obtain these drugs. NGOs and Donors can also avail this facility of paid drugs supply and save on their valuable time.
- Technical service provider.

Some of the suppliers to GDF are:
Lupin Limited, India, www.lupinworld.com
Cadila Pharmaceuticals, India, www.cadillapharma.com
Strides Pharma Science, India. www.strides.com
Swizera Europe B.V. Netherlands. www.svizer.org

GDF is able to negotiate directly with the international pharmaceutical companies and obtain these drugs at bulk rate price.

A complete course of six months first line drugs for a person costs USD 40/- (INR 3,750/-).

A complete course of two years for MDR-TB per person costs USD 1000/- (INR 74,093/-) and above. **(11)**

TB Alliance: Global Alliance for TB Drugs Development

TB Alliance is a not a commercial revenue and profit driven organization. It is committed to the discovery of new generation of **anti-TB drugs**. The objective is to collaborate with universities and pharmaceutical companies for better, faster acting and affordable drugs with lesser side-effects. **TB Alliance** has developed the biggest pipeline of new **anti-TB** drugs in history. These newer drugs enable shorter and effective treatment regimens which helps achieve global objectives of eradicating the TB pandemic.

"We cannot hope to end TB without dramatically shorter, simpler and better treatments."
—Mel Spigelman, M.D. President and Chief Executive Officer of TB Alliance.

BPaL Regimen inclusive of New Drug *Pretomanid*.

TB Alliance discovered new drug ***Pretomanid*** and obtained **US FDA** approval in August 2019. This drug is for treatment of adult **XDR-TB**, to be given as combination drug therapy along with ***Bedaquiline*** and ***Linezolid***, which is referred to as **BPaL Regimen**. These are all oral drugs to be given for a period of six months.

Pretomanid is one of the three new **anti-TB** drugs approved by **US FDA** in more than forty years. **(6)**

Market Data 2019.

Major players operating in the global tuberculosis drugs market include, **Novartis AG, Macleods Pharmaceuticals Ltd., Johnson & Johnson Services, Global Pharma Co., Lupin Ltd., Otsuka Pharmaceutical Co., Ltd., Pfizer Inc., Cadila Pharmaceuticals Ltd, Strides Pharma Science, Swizera Europe B.V.**

Asia Pacific region is expected to have growth in the **ant-TB** drugs market, owing to many high burden **TB** countries, such as China, India, Japan, Phillipines. For instance, according to **WHO**, in 2019 about 2.69 million people suffered from **TB** in India. Also, new cases for **TB** in China exceed one million per annum.

Among therapy, first line therapy segment held the dominant position in TB drugs market during forecasted year 2019, owing to increasing usage of first line drugs in TB treatment which have lesser side effects and higher success rates compared to second line therapy drugs.
India has surplus production of first line-drugs which assists the country to end the menace from TB.

FIGURE 2.3 (7) PRIVATE SECTOR VOLUMES

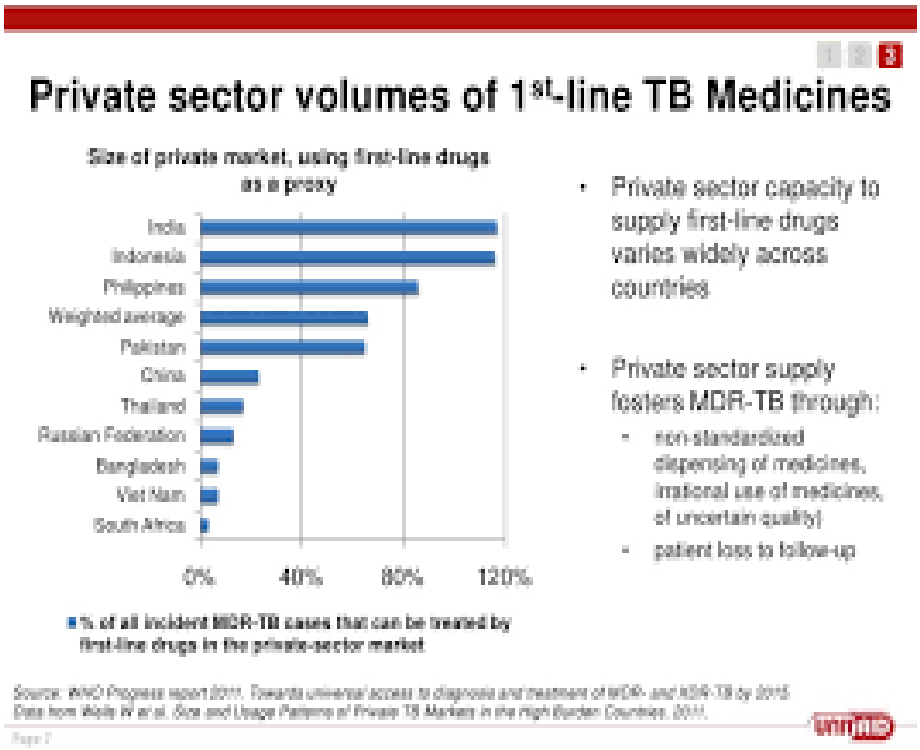
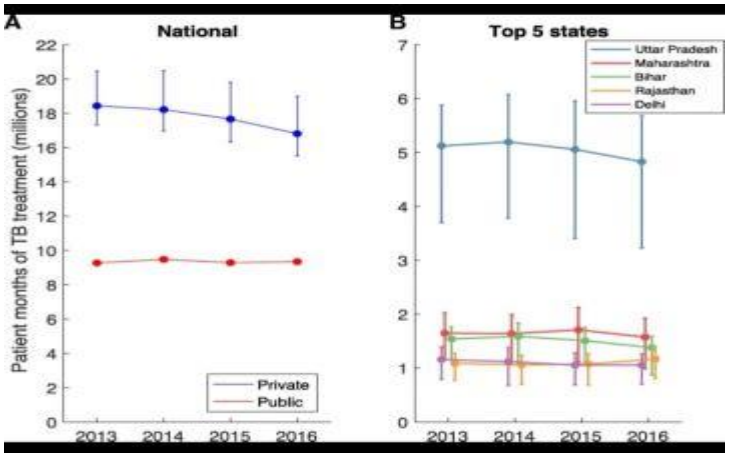


FIGURE 2.5 (14) TB TREATMENT IN PRIVATE HEALTHCARE/GOVERNMENT



ORGANIZATIONS FUNDING ANTI-TB PROGRAMES GLOBALLY.

Organization

Stop TB Partnerships

Centre for Health Research and Innovation (CHRI)

W.J. Clinton Foundation

World Health Partners

Global Health Strategies

Bill and Melinda Gates Foundation (BMGF)

Tata Institute of Social Sciences

T B Alert India

Lepra India

World Vision India

Alert India

Voluntary Health Association of India

3. METHODOLOGY

Objective: To assess the market for First-Line TB medication used in India.

Extent of Study:
>Importance of First-Line TB Drugs.
>WHO, Strategy to End TB.
>MoHFW, India, Strategy to END TB.
>International Organizations active in fight against TB.
>International Donors supporting END TB cause.
>New and upcoming Drugs.
>Market Size TB Drugs
> India Market- Brands and Price Relationship

Study Design: Descriptive Study review through qualitative and quantitative secondary research.

Data Collection: Secondary data gathered from different research articles. Using search engines like Google/ Google Scholar/ SlideShare/ Bing. Keywords selected to search relevant articles and reports.

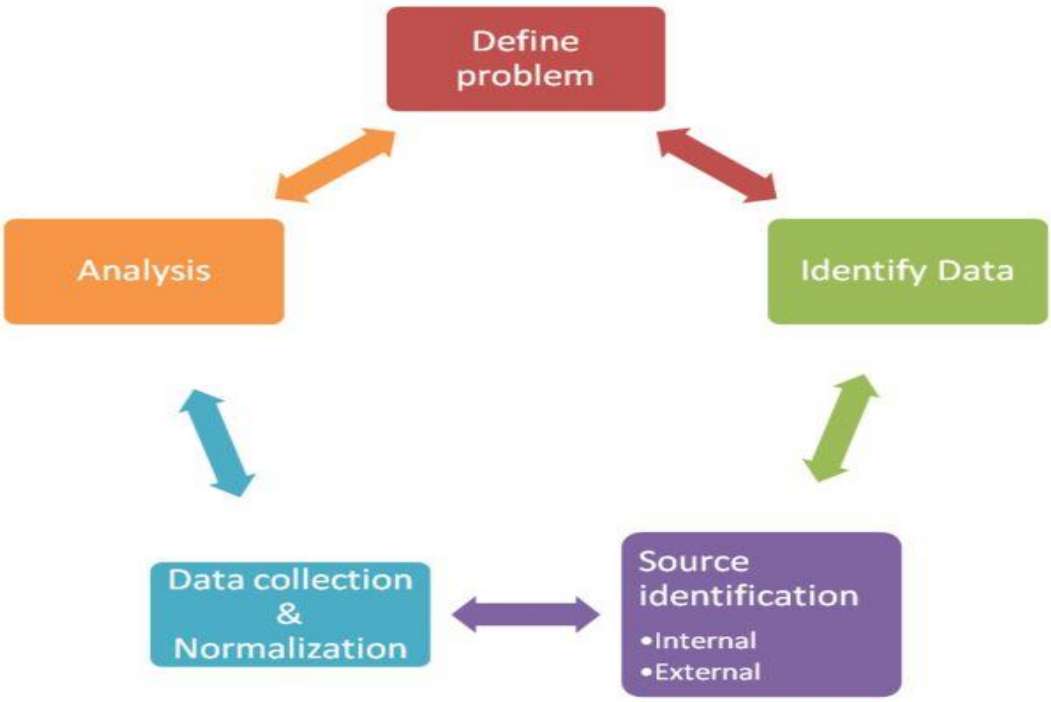
TB Reports by WHO
TB Reports by Ministry of Health & Family Welfare, India
CDC, USA
TB Alliance
GDF Global Drug Facility
Stop TB Partnership

Duration of Study: 22nd March 2021 to 19th June 2021

Source of Information: Research studies and published reports and articles.
Inclusion Criteria: WHO-TB reports, India government TB reports, Professional reports, Press articles and web pages.

Table

FLOW CHART FOR DATA CAPTURE (18)

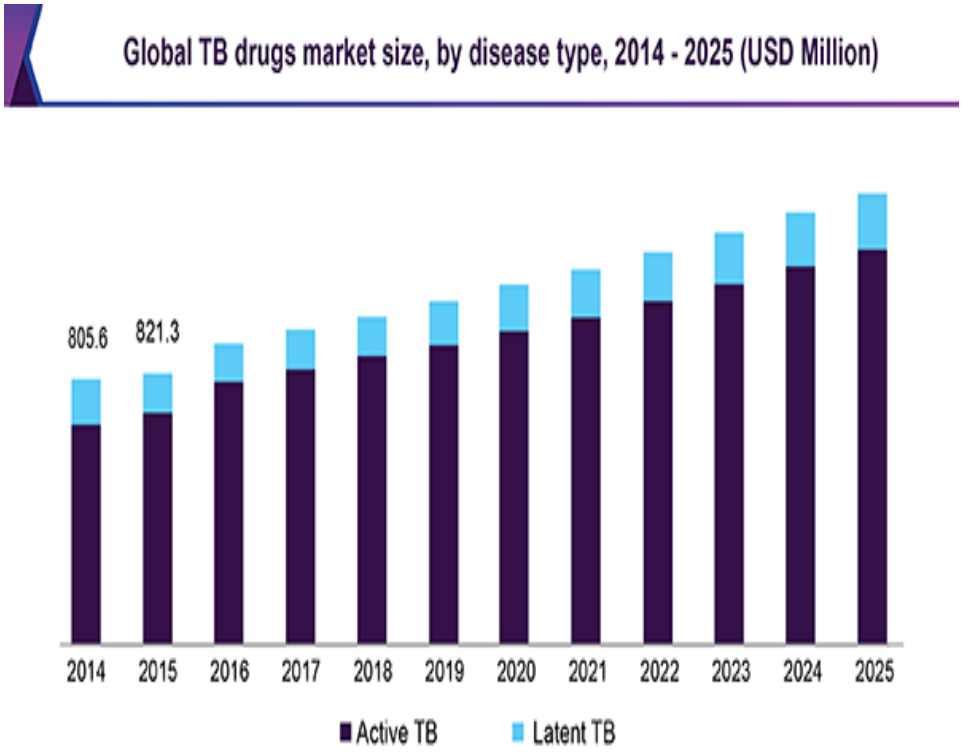


4. RESULTS AND DISCUSSIONS

1.MARKET SIZE

The global tuberculosis market is expected to have a value of about USD 1.38 billion (Rs. 10,228/- Crores) by the year 2025. This market is expected to grow at an annual CAGR of 5.2% from the base year 2016 wherein the market size was estimated at USD 915.6 million (Rs. 6,789 Crores).

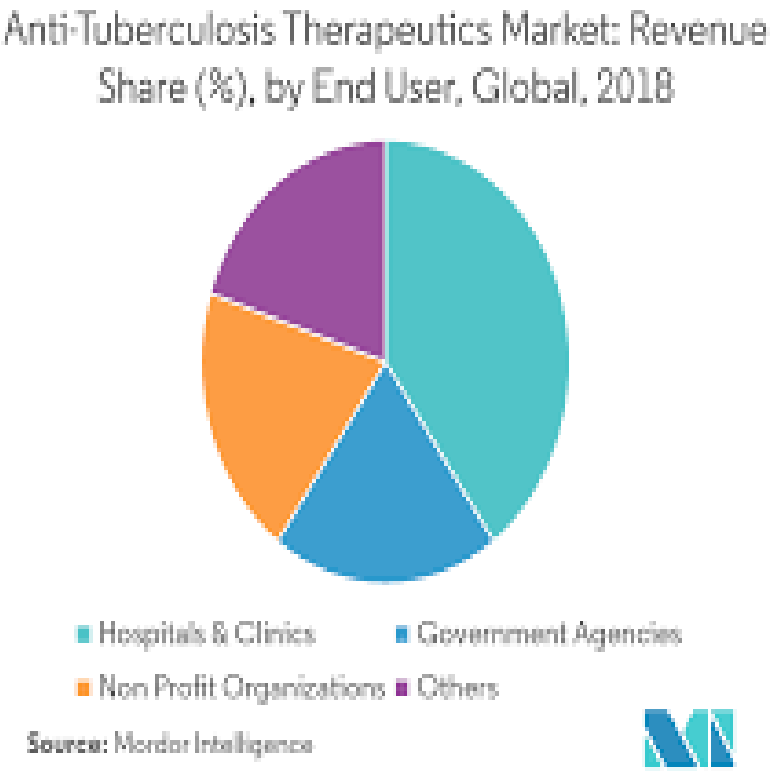
FIGURE-2.2 GLOBAL TB DRUGS MARKET SIZE BY DISEASE TYPE (12)



2. MARKET SEGMENTS

Hospitals and Clinics comprise maximum share of 40% followed by nearly equal 20% share of Government Agencies, Non-Profit Organizations and Others.

FIGURE-2.4 ANTI -TB THERAPUTIC MARKET REVENUE SHARE (13)



3. DRUG ETHAMBUTOL- INDIAN MARKET – BRANDS/ PRICE

TABLE 2.7 (15,16)

S.No.	COMPANY	BRAND	PRICE Rs
1	Merind	Cavibutol1000mg	36
		Cavibutol 600mg	22
		Cavibutol 800mg	29
2	Alkem Laboratory		
3	Stadmed		
		Coxytol 800mg	13
4	AjanthaPharmaceuticals	Anacox- E 800mg	29
5	Geneka H. Care	Cure E	40
6	Macleod'sPharmaceuticals	Ecox 1g	35.90
7	Lark Laboratory	Koxylar1g	36.2
8	PCI Pharmaceutical	Tibitol 1g	40.41
9	Taurus	Taurcox 800mg	34
10	Wyeth Lederle Ltd	Myambutol 800mg	34
11	Finecure Pharmaceuticals	Thamit 800mg	34
12	Concept Pharmaceuticals	Concox 800mg	36
13	Kentreck Labs	Kebitol 800mg	38
14	Eden Healthcare	Den- Butol 800mg	39
15	Acron Pharmaceuticals	EBL 800mg	39.25
16	Emcure Pharmaceuticals	EMTB 800mg	39.60

For drug ethambutol the common dosage is 800 mg. The price range is from Rs 29 Rs to Rs 39.60 per tablet.

4. ISONIAZID DRUG - INDIAN MARKET – BRANDS/ PRICE

TABLE 2.5 (15,16)

S.No.	COMPANY	BRAND	PRICE Rs.
1	Cadilla	Myconax800mgCombination	44.1
2	Novartis	3 Fd Combination	49.00
		4D Combination	139.00
		4D Plus Combination	164.00
3	Acme	Acrifia	52.00
		Acrifia Forte	41.00
4	Lupin	Akt 2	52.00
		Akt 3	8.00
		Akt 4	12.00
		Akt Fd	43,20
		Akurit	11.00
		Akurit Kid	5.00
		Akurit 3	30.00
		Akurit 4	22.00
		Akurit Z	37.00
5	Medispan	Antibin	41.00
		Antibin Kid	10.00
6	Wokhardt	Caviter	30.00
		Caviter FD	30.00
7	Aristo	Coxinex	60.00
8	Cipla	CoxKit 3	10.00
9	Alkem	Coxter 2	64.00
		Coxter 3	20.00

For drug Isoniazid, Lupin is dominating the market with maximum number of product presentations. Novartis is utilizing the concept of high quality, high price and high profits.

5. RIMFAMPACIN DRUG – INDIAN MARKET- BRANDS/ PRICE TABLE 2.4 (15,16)

S.No.	COMPANY	BRAND	Price Rs.
1	Acme Pharmaceutical	A -Cox -450	22.00
2	Aristo Pharmaceutical	Coxid-450	16.72
3	Indian Drugs and Pharmaceutical	Famcin 150mg	7.58
		Famcin 300mg	15.07
		Famcin 450 mg	17.73
		Famcin 600mg	22.15
4	Cadilla Pharmaceuticals	Ls Rif 400mg	50.66
		LS Rif 450mg	50.66
		LS Rif 600mg	66.50
5	Macleods Pharmaceuticals	Macox 100mg	15.61
		Macox 300 mg	18.07
		Macox 450mg	26.59
		Macox 600mg	32.56
6	Overseas Healthcare	Monocin 300mg	33.11
		Monocin 450mg	49.53
		Monocin 600mg	65.31
7	Lupin Pharmaceutical	R-Cin 150mg	20.30
		R-Cin 450mg	53.47
		R-Cin 600mg	21.04
8	Concept Pharmaceuticals	Rifacept 450mg	59.53
		Rifacept 600mg	23.84
10	Biochem Pharmaceuticals	Rifamycin 450mg	53.06
11	Hetero Healthcare	Rimpin 450mg	64.32
12	Themis Pharmaceutical	Ticin 150mg	17.67
		Ticin450mg	49.60
13	Glaxo Smith Kline	Zucox 300mg	18.80
		Zucox450mg	68.93

Lupin has market dominance for Rifampicin with product availability of 150mg, 450mg, 600mg,

6. DRUG PYRAZINAMIDE- INDIAN MARKET- BRANDS/ PRICE

TABLE 2.6 (15,16)

S.No.	COMPANY	BRAND	PRICE
1	Overseas	Actizid 1g	63.45
		Actizid 1.5 g	94.65
		Actizid 750mg	48.46
2	Medispan	Antizide 500mg	42.0
		Antizide 750mg	65.0
3	PCI	Copyrazin 500mg	37.60
		Copyrazine 750mg	55.05
		Copyrazine1000mg	72.10
		Copyrazine1500mg	96.85
4	Alpic	Eumide 1g	75.0
		Eumide 750mg	52.0
5	Zee Lab	Isomide 750mg	55.0
	Macleods	Macrozide1 g	45.0
		Macrozide1.5g	68.0
		Macrozide500mg	22.0
		Macrozide750mg	58.0
		Macrozide1200mg	57.0
6	Aristo	P-Mide 500mg	25.75
		P-Mide 750mg	70.00
7	Cadilla	P-Zide 1g	86.00
		P-Zide 500mg	44.00
		P-Zide 750mg	73.00
8	Emcure	Preeza 750mg	63.00
9	Acme	Pyraface 750mg	62.0
10	Cipla	Pyzid 750mg	55.00

For drug pyrazinamide the most common dosage is 750 mg and the price range is from Rs 73 to Rs.52 per tablet.

7.The extraordinary Covid19 pandemic genuinely impacts individuals with prior ailments. Individuals who have TB will be more defenceless against the novel coronavirus, because of their previous poor condition of lungs. They are at a higher risk of contracting novel coronavirus disease. TB Programmes should guarantee:

*Proper communication with individuals affected by TB and all partners utilizing virtual methods for communication.

* Several months of TB medication should be made available at the residences of TB patients.

* Essential psycho-social, nutritional, and monetary help should be given to TB patients.

* TB care health personnel as well as TB patients, should adhere to fundamental security measures for both TB and Covid19 such as use of masks and hand sanitizers.

8. The BCG vaccine is the solitary TB vaccine which is readily available and widely used for children immunization. It's safety and efficacy is well documented for children.

The effectiveness of this vaccine for adults is not there and as such, this vaccine is not given to adult population.

Research and development activities for adult TB vaccine are an ongoing process, but no success has come as of now.

9. Major sales share of **anti-TB** drugs comprises of the four **FLD** drugs. The drug ***rifampicin*** is leading among the four **FLD** drugs for both the finished product share as well as active pharmaceutical ingredient (API) share.

10. In India, **Lupin Limited**, has the most dominant share of **anti-TB** drugs. This company admitted in the year 2019 that focus of branded drugs business has been showing a declining trend. **(17)**

11. The private market for **anti-TB** drugs has been showing a declining trend. However, institutional sales are showing a growing trend.

12. India goal for eradication of **TB** is by the year 2025, which is somewhat unrealistic. Compared to **WHO** goal of reducing TB cases by 95% in the year 2035 (base year 2015).

CONCLUSION:

TB is a disease which will not totally disappear since a large proportion of people have latent TB, and a small percentage of these people are likely to develop TB disease. As per WHO **(2)** about 25% of world population which is approximately 2 billion people are likely to suffer from Latent TB infection, considering world population of 8 billion.

Further about (5 to 10%) of these 2 billion people are likely to develop Active TB infection during their lifetime. Even considering the lower estimate of 5%, the number of people who will develop Active TB is very significant.

As such, demand will continue to exist for FLD drugs as well as for new generation drugs for cure of TB.

5. RECOMMENDATIONS

1. India and China, both are HBC for TB disease. With large population, the requirement of both countries to treat and cure the annual new TB cases detected will be large. It would be beneficial to both countries to jointly focus on research of new FLD drugs for TB. More effective new drugs are required which can lead to shorter therapy period with lesser side effects. Collaboration can be Government to Government level; University to University level and/or Pharmaceutical Company to Pharmaceutical Company level or of any other possible combination.

2. Indian Pharmaceutical companies can adopt one district in the country under CSR and fund and micro-manage TB control programme in collaboration with private sector hospitals, nursing homes and clinics. This will add to the image of the company and boost its existing drugs sales.

3. Employment protection for at least 1year period should be given to TB patients in private sector. At present, employment protection exists in government sector in our country.

4. For a company, planning to enter the market for FLD drugs for TB, initial product launch can be covered by partnership with some international donor organizations.

5. Need for Adult TB vaccine. Covid19 has driven home the fact that adult vaccinations can be lifesaving and beneficial to public at large. It is necessary, to speed up research and development for Adult TB vaccines.

6. Private TB market in India is substantial, stable, and complicated. Public- Private-Partnership (PPP) will result in greater reach, flexibility, and appeal of TB control programs.

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