Dissertation On

INNOVATIVE PRICING & MARKET ACCESS STRATEGIES IN PHARMA EMERGING MARKETS

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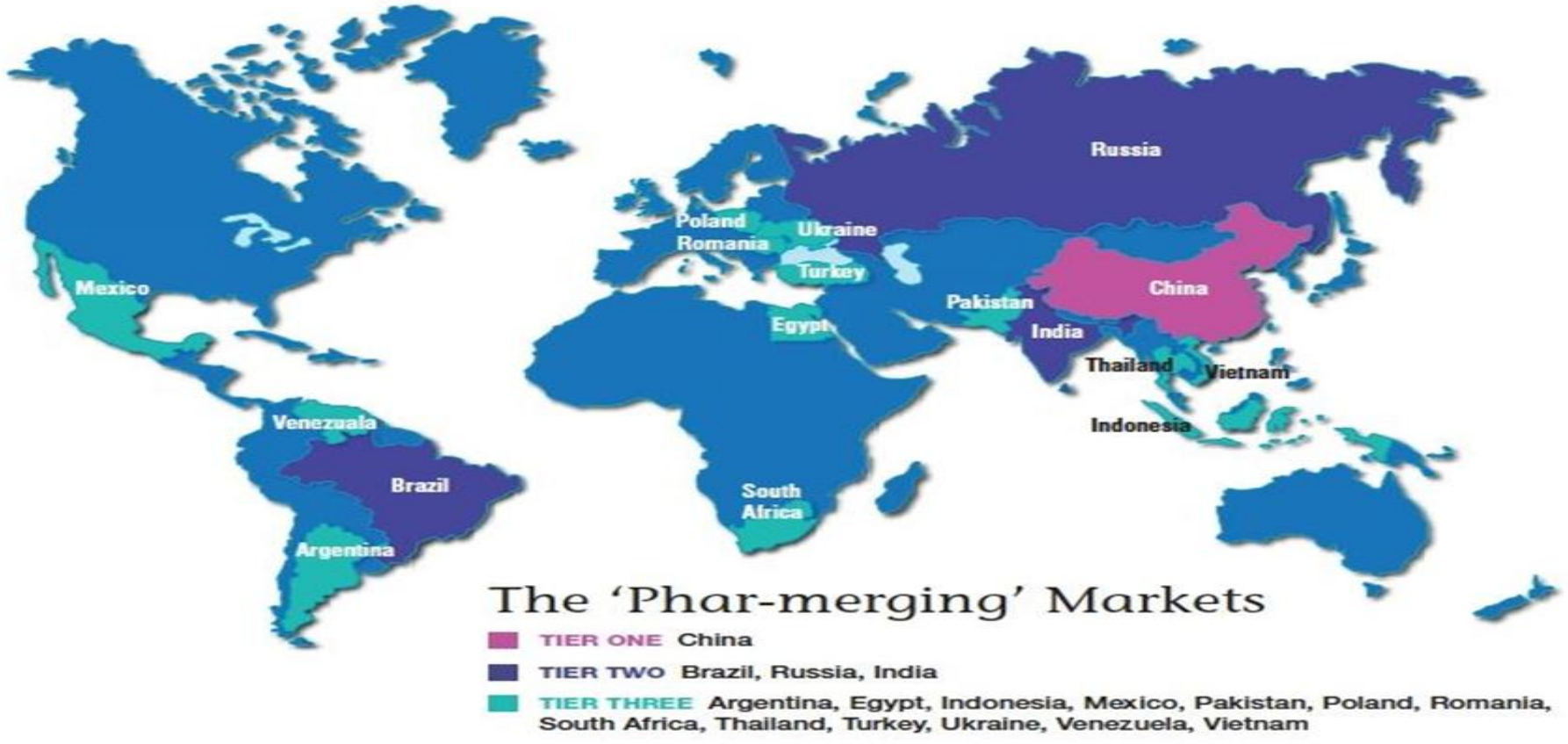
Why this Study??

- As most of the “mature markets” are getting saturated, Pharmaceutical companies are shifting their focus on the Emerging markets to get their revenues
- This study takes a look at what Strategies Global Pharmaceutical companies adopt to make their drugs successful. The areas tried to covered under this study-
  - The innovative access and pricing models
  - The way companies approached emerging markets
  - The disparity between emerging markets & mature markets
  - What needs to be done to explore potential of emerging markets.

Introduction

- IMS Health defined the ‘Pharmerging’ markets i.e. 17 key geographies based on macroeconomic metrics and pharmaceutical market forecasts; it has been increased to 21 countries with the addition of Algeria, Colombia, Saudi Arabia and Nigeria



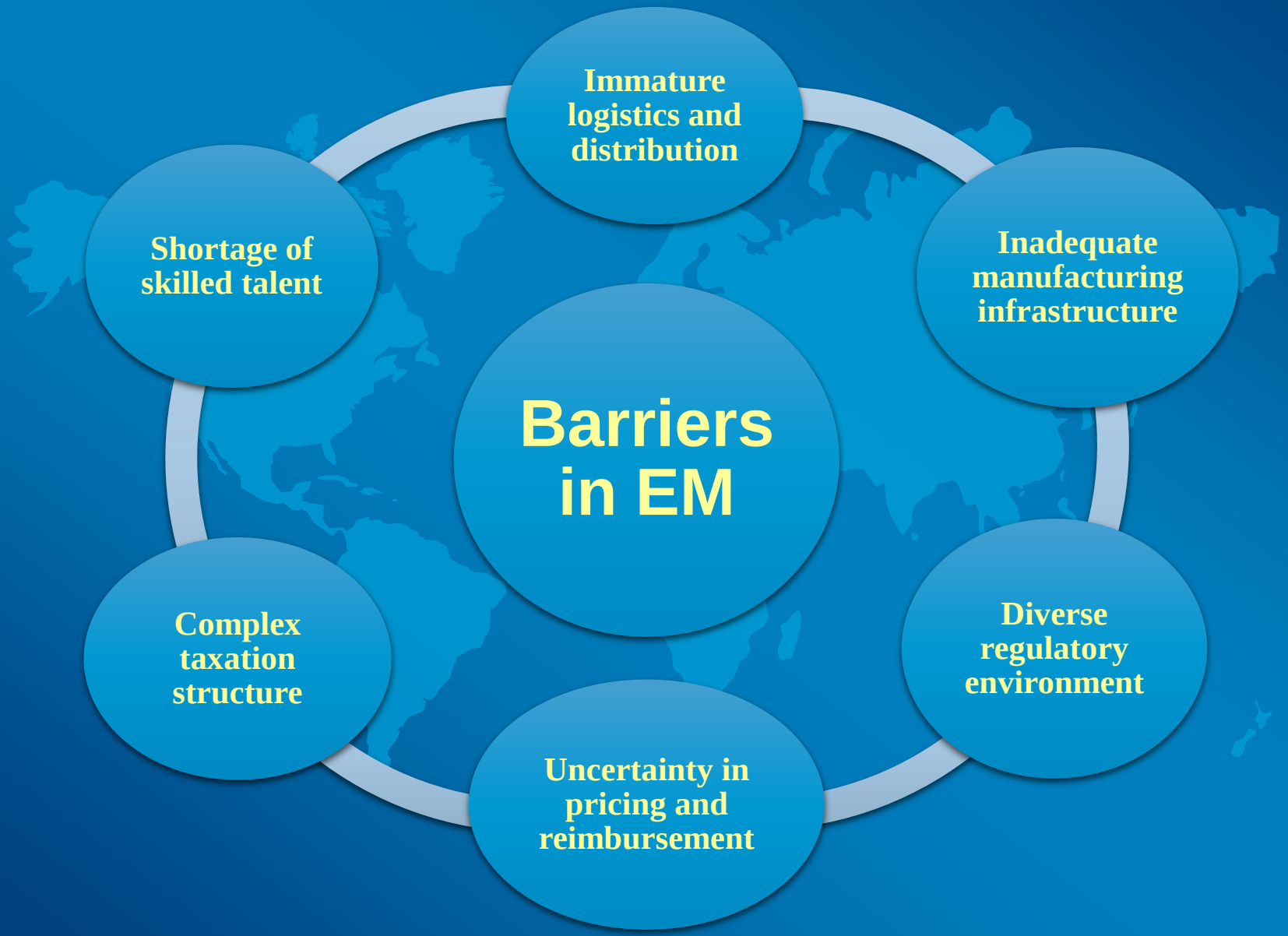
- Forecasts Expects Pharmerging countries will together add $300bn+ sales between 2012 and 2017 i.e. 1/3rd of global pharma & will increase share from 23% in 2012 to 33% in 2017, with all 4 BRIC countries in the top 10 by sales value.

Source: IMS Health Global Market Prognosis, May 2013, at ex-manufacturer price levels, constant local currency (LC) $. Contains Audited + Unaudited data

Between 2012 and 2017, Pharmerging markets have growth rates far higher than in mature markets: forecast 13% CAGR 2012-2017 vs. 2% for the top 8 mature markets.

Challenges to Growth in Emerging Markets

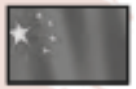
(It's not as simple as it sound)



Regulatory Environment for emerging markets

In **Russia**, the price ceiling for "essential drugs" means a reduction in price for many products. The outpatient DLO reimbursement program is, therefore, expected to cover more of the population with its capped budget.

China has introduced a more unified pricing measure to reduce the gap between local generics and off-patent international brands. Collaboration with the U.K.'s NICE could pave the way for economic analysis of new drugs.



Nigeria wants to improve access by implementing the National Health Insurance Scheme to establish universal healthcare for all citizens by 2015. The strengthening of the National Agency for Food and Drug Administration and Control will reduce counterfeit medicines and increase consumer confidence in new drugs.

In **India**, a further erosion of patent jurisdiction can be observed. An extension of direct price control to all drugs to stop free pricing is possible.

Vietnam is implementing a centralized annual tendering program in 2013 and has introduced a price cap. The objective is to make drugs more affordable, given out-of-pocket payments of approximately 60% of the market's healthcare spending.

In **Brazil**, the creation of an economic evaluation agency (CITEC) has become a big barrier to market access. New fast-track approval for biosimilars is expected.

In **South Africa**, the introduction of national health insurance will lead to tendering of drugs with downward pressure on prices. A new reference pricing scheme will look at each therapeutic class as a whole and possibly take the lowest price instead of the average price.

Source: IMS Health; UNIDO; SCRIP; Strategy& analysis

Reimbursement comparison in emerging markets

Reimbursement	Brazil	Russia	India	China
Scope of government reimbursement	Vast coverage with full reimbursement for a range of life saving and chronic therapy drugs	Limited drug coverage (affects only 5% of the population)	Only inpatient coverage for government employees	Widespread coverage with a mix of full reimbursement and patient copayments
Private health insurance coverage (outpatient costs)	Few plans provide coverage for outpatient drug usage	No coverage for outpatient drug usage	No coverage for outpatient drug usage	No coverage for outpatient drug usage

Price pressure is aggravated by domestic competition, as they get support from their governments

Examples

- Despite valid patent protection, Bayer's Nexavar, for HCC is facing competition from Natco Pharma, Compulsary Licensing granted by GoI .Therapy costs of around $170 per month, while Bayer's Nexavar therapy costs amount to $5,500 per month.

- Roche entered a partnership with Emcure Pharmaceuticals in 2012. It include Roche's breast cancer drug Herceptin (Biceltis) and its lymphoma and RA treatment MabThera (Ikgdar) for domestic sale under different names & lower prices

What can be done in Emerging markets?

- **Think customer clusters: The importance of submarkets**

Companies should consider plotting their access strategies by thinking of customers & “submarkets” rather than focusing only on countries and continents. This approach can enable companies to have more targeted and effective customer centric strategies

- **Find cross-border similarities-**

Firms may benefit from creating solutions that are better positioned to cross geographic borders by exploiting these similarities.

- **Establish global reach with local relevance-**

It is important to standardize globally whenever possible to gain economies of scale, but also to customize where appropriate to achieve local relevance

- **Create effective and rapid execution capabilities-**

The ability to understand the customer and to execute solutions across markets that are aligned with customer needs in a timely and cost-efficient manner can be a key to success and competitive differentiation

Methodology

- **Type of study**: Secondary, Desk Research was carried out on existing models and precedents in emerging markets to identify the best practices
- Analysis of five markets (BRICS) was also carried out to get deeper insights
- Augmentin, Mabthera, Januvia, and Galvus were used as an example (Drugs present in all 5 markets), analyzed for success factor, price cut, disease area, business model etc.
- Other than these Published reports, Expert Interviews & other confidential resources & Databases.
- **Study duration**: 3 months

Market Analysis- BRAZIL

- Largest market in Latin America &10th-largest in the world
- Pharma sales are forecasted to $48.7 billion by 2017

- Pricing pressure occurs on two fronts:
  - Manufacturers must submit all proposed drug prices to an independent organization, the Regulation Drug Market Committee (CMED).
  - Another Brazil has a strong local generics industry, which is supported by government policies aimed at extending the availability of medicines to low income consumers

- Brazil's product registration and launch process through ANVISA, the national health agency, is also complex and expensive

Market Analysis- RUSSIA

- Almost 80 percent of drugs in Russian market are imported
- Annual pharmaceutical sales are to rise to $32 billion by 2017, @ CAGR 16.7% per year
- Government's target program, "Development of the pharmaceutical and medical industry of the Russian Federation," details the goals to achieve by 2020.
- The government has already introduced and plans a series of measures to restrict access to state tenders for imported medicines — particularly in the hospital segment
- Most multinational pharma companies have constructed or are in the process of constructing factories in Russia to avoid losing their share in the hospital segment.

Market Analysis- CHINA

- Pharmaceutical sales forecasted to grow an average of 17.7 percent per year in 2013-17, reaching $166 billion in 2017
- Central government spent an additional $125 billion in health care expenses over the past three years.
- China’s rapid rise in both internet and mobile phone usage is changing patient access and awareness of different types of care
- The proportion of urban population has grown from 36 percent in 2010 to 52.6 percent in 2012
- By 2016, the value of pharma sales in China is expected to be greater than that in Japan, currently the world’s second-largest market.

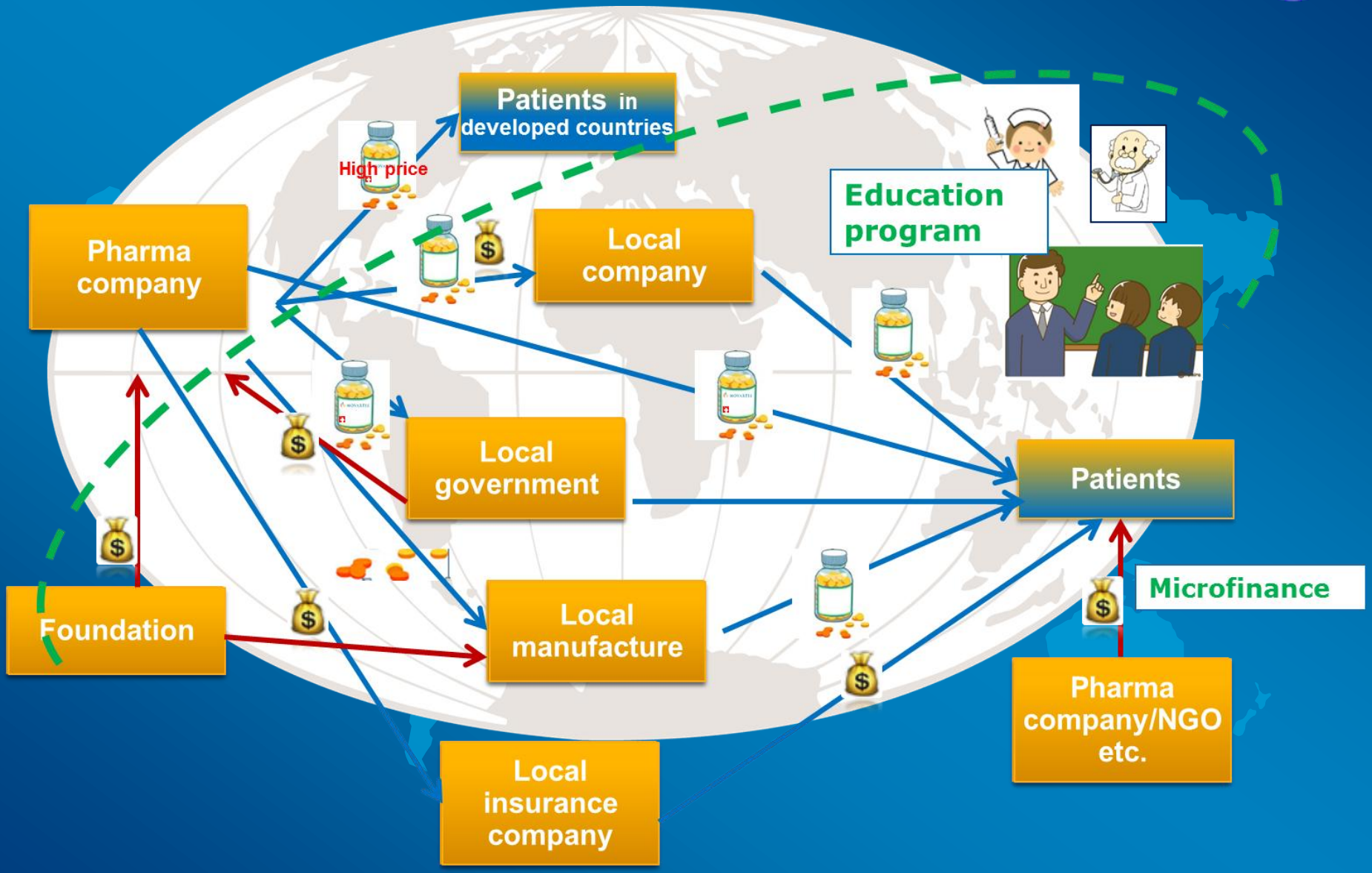
Market Analysis- INDIA

- Market was $23.6 billion in 2013 and reach $27.0 billion by 2016
- It is estimated that Indian companies will benefit by about $40 billion as 46 U.S. drug patents expire in 2012-15
- With over 60,000 generic brands across 60 therapeutic categories; manufactures more than 400 APIs.
- Nation’s low cost of production and R&D will boost the efficiency of Indian pharmaceutical companies in 2016.
- Competitive pricing, Generic Dominance, Poor healthcare Infrastructure, Fragmented Supply chain, Highest FDA approved plants in any foreign nation, etc. are some of the factors affecting overall market

Market Analysis- AFRICA

- African market is expected to achieve a year-on-year growth rate of 10.6 percent by 2020, resulting in pharmaceutical sales of $45 billion in 2020.
- Nearly 70 percent of HIV/AIDS patients live on the African continent. This is a huge burden on a growing economy and an impediment to more rapid economic development.
- The lack of healthcare infrastructure and the unaffordability of medication are the biggest hurdles to growth in the African markets
- Lack of availability and reimbursement accounts to High out-of-pocket healthcare expenditure
- Country still in phase of struggling with Infectious Disease treatment

PRICING AND MARKET ACCESS MODELS



Tiered Pricing

- Companies adjust prices to assure affordability of products in different social segments. It can be either in the same market (Intra Country Tiered Pricing) or between countries or regions (Inter Country Tiered Pricing).
- Gilead’s system for pricing its ARVs, Viread and Truvada has two primary tiers, charging a monthly price of $17.00 for Viread and $26.25 for Truvada in low-income countries and charging a monthly price of $30.00 for Viread and $45.00 for Truvada in lower middle-income countries.
- GSK launched Avamys (an allergy remedy) in Mexico at a 50% discount and, with that cut-rate price, won over a 50% share of that drug's market

Micro- Finance

- Aims to make treatment affordability. Generally companies allows a monthly installment systems for a treatment on yearly basis.

- GSK is introducing a microfinance program to extend access yet further in Indonesia and Philippines.
- It extends the cost of the 24-week pegylated interferon regimen for patients over a period of 24 to 36 months via equal monthly installment payments of a maximum of INR 5400 ($89) per month.

Micro-Insurance

- There is limited health coverage which means that the bulk of costs are paid out-of-pocket by patients or their families
- Companies tie up with local insurance players, to develop & launch Policies to provide appropriate and affordable care to patient.
- Roche is working closely with local insurance companies in countries such as China, Brazil, the Philippines, Hong Kong, Mexico, Peru and Russia for cancer care
- Uplift India Association, implemented the UpLift Health Mutual Fund (HMF), The fund decreases financial shock of an unexpected health emergency for community members. The scheme allows people to share risk by contributing a small amount. When an emergency occurs, a lump sum amount can be made available.

Patient assessment program (PAP)

- Pharmaceutical companies now run PAPs to provide free or discounted medications to people who cannot afford to buy their medicine. This increased the access of their drugs in market and also, reputation building for further growth
- **The few PAP model used by companies are:**
- Structured PAP:
  - 1: Fixed-Quantity Model: In this type of structured PAP, the number of vials/doses given free is fixed regardless of a patient's financial state.
  - 2: Financial Model: The patient's ability to pay for the drug determines the assistance he or she can get.
- Unstructured PAPs: based purely on doctor recommendation.

- **Pfizer:** Oncologists praised this program for delivering the drugs to patients on time. Initial treatment is given for free, and the duration depends on the longevity of patient. The entire treatment is free for patients who live below the poverty line.

- **DRL**: The Sparsh PAP is based on doctor recommendation; they decide who is eligible for assistance. Poor patients get the second vial free after paying for the first one.

- **Novartis**: GIPAP is the pioneer in PAPs in India and is the most widely publicized assistance program, with a large patient base. Patients are screened based on their ability to pay and are offered different schemes, e.g., pay for three months and get nine months free or pay for two months and get nine months free

Loyalty Cards

- To keep the patient adherence to the treatment companies introduced loyalty card that results in gaining incentives or discounts by patients.
- Pfizer launched the eCard, the customer receives discounts as rewards for adherence to Pfizer's medicines. The eCard programme affords customers a 30% – 60% discount on prescription medicine, and also includes educational materials aimed at helping a patient understand and manage their conditions, as well as to understand the importance of adherence
- eCard was launched six years ago in the Philippines, where 2.2 million patients are now in the system. It was subsequently replicated in Indonesia and Malaysia,

Dual branding

- Companies launch versions of same drug with different names & price in same/different geographic regions.

- Sanofi has used a variant of the "second brand" strategy to keep costs down in poorer countries. For instance, it sells both branded Plavix and its generic version, clopidogrel, in Indonesia, and it's experimenting with two malaria drug pricing tiers in Morocco.

Local players involvement

- Roche entered a partnership with India's Emcure Pharmaceuticals in 2012. It include Roche's breast cancer drug Herceptin (Biceltis) and its lymphoma and RA treatment MabThera (Ikgdar) for domestic sale under different names & lower prices

- In January 2014, Biogen Idec and UCB announced that they have signed exclusive agreements granting UCB the right to commercialize Biogen Idec products in South Korea, Hong Kong, Thailand, Singapore, Malaysia and Taiwan, and to develop and commercialize Biogen Idec products in China.

Capital investment

- Companies are now investing in emerging countries as a long term investment., so that instead of seeking ROI in just 1 or 2 years, They plans for 3/4 year time horizons, and perhaps even longer for large programmes
- In November 2012, Sanofi laid foundation for an industrial facility in Saudi Arabia. It would be the first global pharmaceutical company to establish a manufacturing plant with 100 percent FDI in the country
- Recognizing that a weak health care infrastructure is a significant barrier to access, GSK reinvests 20% of its profit into African health care infrastructure, through partner NGOs such as Save The Children, the African Medical and Research Foundation (AMREF), and CARE.

Govt. partnerships

- Government partnership is among the top 5 strategies as per the PWC report
- MSD, and the government of Rwanda launched a comprehensive national cervical cancer prevention program in 2011. MSD provided more than 2 million doses of the vaccine Gardasil at no cost. In exchange, MSD was included in the publicly funded routine vaccination scheme.
- The Swiss drug maker Roche signed a cost-sharing deal with Chinese Government to provide Herceptin, an expensive, breakthrough drug at a 75 percent discount.
- GSK struck a deal with the Brazilian government. In exchange for knowledge and technology transfers, the state guarantees GSK both a set price and set volumes for its pneumococcus vaccine for children

Voluntary licensing

- Many companies are now sharing their patent rights through voluntary licensing with generic manufacturers. It helps them to increase their medicines access in developing markets
- In June 2011, Merck granted two VLs to, Emcure Pharmaceuticals Ltd. and Matrix Laboratories Ltd., for the manufacture and commercialization of raltegravir in 60 Low Income and sub-Saharan African countries. In March 2012, Merck granted two licenses for diabetes medicines to Sun Pharmaceuticals.
- GSK plans to share more than 800 drug patents with others seeking new cures for neglected tropical diseases and is cutting prices of more than 100 patented medications by 45% in the world's poorest countries.

Joint Venture

- Joint venture helps in penetration into the market. To get into the emerging markets, it seems to be a good strategy. It has become a trend in pharmaceutical world
- Pfizer Inc. and Zhejiang Hisun Pharmaceuticals (China), launched Hisun-Pfizer Pharmaceuticals Co., Ltd. to develop, manufacture and commercialize off-patent pharmaceutical products in China and global market.
- Regeneron has joint venture with Bayer for marketing & selling EYLEA, an ophtha product, outside US
- Simcere is also working on a heart drug that BMS had let go idle in its pipeline. If approved, Simcere has exclusive rights to sell it in China but will share proceeds with Bristol-Myers on sales in the rest of the world.

Ensure Proper Distribution

- Accessibility to medicines is most important factor still to be developed in Emerging Markets.

- Novartis' SMS for Life pilot project is a PPP with the Roll Back Malaria Partnership, Vodafone, IBM, Google and the Ministry of Health in Tanzania.
- Its objective is to minimize stock-outs of life-saving malaria drugs, utilizing mobile phones, SMS, Google mapping, and websites to track and manage the supply of drugs.
- In pilot districts, stock-out rates have been reduced from 87% –93% to 0% –47% within 21 weeks.

Education and Information

- The problem with the emerging countries is lack of awareness. People in rural area are not aware of the treatments available in the market which affect both the people and the pharmaceutical companies
- MSD has embellished its promotional efforts through a comprehensive disease management approach for diabetes using the "Sparsh“, helpline that follows-up with patients for glycemic controls and helps them manage their disease
- Novo Nordisk has established an exceptional reputation in the diabetes arena in markets like China, India and Russia, where it has achieved major reach with physician and patient disease awareness programs including a ‘diabetes bus’ and mobile test centers (in Russia).

Business-NGO Partnership

- Aims to reduce poverty, improve general conditions, increase access and quality of healthcare and to reduce counterfeit.

- **Unilever**-In India, teamed up with NGOs to create Shakti, a rural network that sells products adapted to rural customers in more than 100,000 villages, employing 31,000 women. In Indonesia, it teamed up with Oxfam to research and assesses the impact of production and distribution processes on poor communities.

Collaboration with Mobile Phone Companies

- mHealth initiatives for data collection, monitoring and treatment support. 59% of patients in emerging markets use mHealth, compared to 35% in developed markets.

- Novartis has ConTacto APP in LACan region.
  - Patient will be able to purchase through ConTacto APP
  - Enrolment through this app will allow patients to have a faster way of registration.
  - Pharmacy Location: Real time information on the location of the nearest pharmacy to patients.
  - Basic Screening Tests: Trough APP.
  - Pill Reminder: this notification will remember patients to take their medication.

RESULT- 3A Strategy Model

Affordability	Availability	Awareness
1. Tiered pricing 2. Micro- Finance 3. Micro- Insurance 4. Patient assistance program 5. Loyalty Cards 6. Dual branding	1. Local Players 2. Capital Investment 3. Govt. Partnership 4. Voluntary Licensing 5. Joint Venture	1. Education 2. Information

For success in Pharmerging markets, these must be followed in combination, not in parts (mistake done by many big pharma). Our research suggests 3A's strategies to achieve success in this part of the world.

3A Strategy

The drug to be launched in EM must be made affordable as there is very low purchasing power parity of people in EM. The companies should focus on the volume not on the value.

Companies should put their efforts on ensuring proper distribution in EM to increase patient access

People in rural area are not aware of the treatments available in the market which affect both the people and the pharmaceutical companies.

There are definitely more chances of success for Pharma companies in EM

Sanofi- The 3A follower

- Sanofi and the Drugs for Neglected Diseases Initiative (DNDi), entered into a PPP for ASAQ a FDC for malaria.
- **Affordability:** From the partnership's inception, acceptable price levels were set at $1 for three-day adult treatment and $0.50 for children. No patent would be issued.
- **Availability:** The partnership was set up to produce ASAQ mainly for institutional buyers such as the Global Fund, which typically work through national governments or NGOs to make it available to patients
- **Awareness:** Information and education tools for patients and health care providers give guidance on using the drug safely and effectively along with other services provided by Sanofi's Impact Malaria Program

Key Learnings

- It was found that the difference in emerging and the mature markets is huge. Therefore, most of the companies did not get the desired success in emerging markets as they went with **“one size fits all”** approach.
- The study suggests some innovative pricing and access models under all the three sections- Availability, Affordability and Awareness which can be used in combination to eliminate the hurdles in EM
- It was also found that Emerging markets are changing very fast; therefore, the Pharma Company which enters these markets much early with proper pricing strategy will get more benefitted than others.

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- ……Many more…….

Anyone feeling like this???

Am Feeling like this!!!

Questions are guaranteed in life; Answers aren't.

THANK YOU ALL

FOR LISTENING

& Being Awake