



# U.S.-India Business Council

## India and the United States:

### Opportunities & Challenges in the Pharmaceutical Sector



November 17, 2014





# What is USIBC?

The U.S.-India Business Council is a business advocacy organization representing America's top companies investing in India, joined by global Indian companies, with an aim to deepen trade and strengthen commercial ties.

USIBC was formed in 1975 at the request of our governments to involve the private sectors of both countries to enhance investment flows between the United States and India. Our primary mission is to serve as a direct link between business and government leaders, resulting in increased trade and investment.



Current USIBC Chairman, Ajay  
Banga, President & CEO  
Mastercard





# To Start, Some Thoughts...

“Fight against the Indian way of doing things, wish that things were different, and the only result will be tears. Just as you have to turn your watch forwards by half an hour when landing in India, just as you have to check in the batteries from your camera as separate pieces of luggage, just as it can prove impossible to find a working Internet connection in a proud center of high-tech like Hyderabad, so every foreigner has to surrender and realize that things will get done their own, unexpected ways. The very qualities that make India culturally alive, textured and itself make it uncommonly reluctant to adjust to the economic rules and geopolitical norms of the world.” -**Pico Iyer**





# To Start, Some Thoughts...

“Western Executives unfamiliar with India’s history sometimes ask me why there appears to be an undercurrent of disdain and concern toward the power of foreign companies in India. The answer is simple: India’s early experience with foreign company had its unpleasant side. The memory of that pain casts a shadow event today.” - Gunjan Bagla *Doing Business in 21<sup>st</sup> Century India*





# History of India: A Brief Review

- The East India Company 1600-1847 started a period of British Rule
- Gained independence from the British in 1947 and constitution came into effect in 1950
- Independence movement started long before 1947 and the Indians have constantly been colonized by the West:
  - Dutch India: 1604-1825
  - Danish India: 1620-1869
  - French India: 1759-1954
  - Portuguese India: 1510-1961
  - British India: 1613-1947





# License Raj & Socialism

- Nehru was a student of socialism, so when India became independent, socialism influenced his economic and political thinking
- From the beginning there have been FDI limitations on investment
- Permits to do everything: get a car, get a phone, sell land (“license raj”)
- Principle of Swadeshi: principle of Indian self-sufficiency
- Economic liberalization in 1991 due to a balance of payment crisis







# About India: Some basics

- **Diversity of religion and Language:** Hindu, Muslim, Christian, Sikh, Buddhists, Jain. 23 official languages in India (including English), but 122 languages are spoken by more than 10,000 people
- With 1.2 billion people, India is the world's largest democracy with:
  - 5 national recognized parties and 45 state recognized parties
- **Vibrant Free Press:** 30,000+ newspapers in India with 2,000 daily newspapers. The Times of India which is the largest English newspaper in the world 88 percent of men (15-24 years) are literate while 74 percent of woman (15-24) are literate. Between 10-33% can read and speak English.
- There are 900 million mobile phone users in India, or about 75% of the population; about 625 million have access to closed toilet or about 50 percent of the population; there are 120 million internet users in India, or about 10% of the population





# About India: some basics

- India ranks 6<sup>th</sup> in the world for the number of billionaires it has: (56) and 8<sup>th</sup> in the world for multimillionaires (14,800).
- According to the World Bank, the world had 872.3 million people below the poverty line, of which 179.6 million people lived in India. In other words, India with 17.5% of total world's population, had 20.6% share of world's poorest in 2013.
- “You have a Switzerland and a Sub-Saharan Africa in the same country.”
- India is the world’s 3<sup>rd</sup> largest economy, but still very low when the GDP is calculated per capita, at about \$2,000 a year





# Jugaad: An Indian Management Theory

"There is sometimes a tendency for Western companies to over-engineer products - to make them perfect, account for all possible use cases, and make them last forever," he continues. "Jugaad thinking helps us focus on the essence, the real requirements, and often leads to taking the mental leap that is required for a disruptive new design or product."

Wido Menhardt, CEO of the Philips Innovation Center.





# Doing Business in India:

## Some Basics

- Bargaining and negotiating skills are important
- Affordability is paramount (in some sectors)
- Yes does not necessarily mean yes and disagreement may not be acceptable
- Time is flexible
- Strong rule of law, but outcome of decisions (such as breach of contract) can take years or decades to decide
- The importance of hierarchy and elders
- Family business houses versus government versus new business
- Women in business – a new phenomenon
- Multitasking during a meeting – not a sign of disrespect
- Insisting means you really mean it -asking once may mean you do not really want it
- Scarcity of resources sometimes means that's its necessary to be somewhat forceful (don't be bashful!)





# Doing Business in India:

## Some Basics

- **Its important for Companies to have appropriate expectations for the Indian market**
  - Margins may be lower in the entry period of 5-10%. But many companies can achieve returns of +10%
  - Delays in operations, patience is required
  - Long-term vision of India is needed – 1.2 Billion people with expanding economy
  - Be aware of the valley – and do not get stuck.
  - Work around lack of infrastructure – how to succeed without reliable roads, sterile warehouses, or similar challenges
  - FCPA compliance issues means that it is not easy doing business in India
  - Upper management understands commitment to India





# Doing Business in India

## DOING BUSINESS IN INDIA

	2013 RANK	2012 RANK
India's Overall Ranking	132	132

### TOPIC RANKINGS

Starting a Business	173	169
Dealing with Construction Permits	182	183
Getting Electricity	105	99
Registering Property	94	97
Getting Credit	23	23
Protecting Investors	49	46
Paying Taxes	152	149
Trading Across Borders	127	125
Enforcing Contracts	184	184
Resolving Insolvency	116	109

Source: World Bank

- India ranks 132 out of 185 nations in the Ease of Doing Business Index
- India ranks last in the BRICS. South Africa is ranked 39, China is 91, Russia is 112 and Brazil is 130.





# Communication in India

- Yes English is spoken but the accent may be difficult to understand (both ways) and there is a bit of Indian English you'll have to get used to.
- Americans tend to take charge and to tell others how it should be done. In India, asking for input and advice may be better.
- Hierarchy may also be important to your communication strategy.
- In general, Indians prefer a more subdued, subtle form of communication.





# Key Legal & Accounting Issues

- The Indian Courts – takes a long time. The importance of the Supreme Court
- Arbitration
- A contract is only a small part of the overall relationship between parties
- Laws about forms of enterprise are consistent across India, so you don't have to worry about what state to incorporate
- IP Laws- still working this one out
- Employment Laws- very difficult to lay off and fire
- Indian fiscal runs April 1-March 31 and assets are usually shown on the right side. Less than 1% of Indians pay income tax. But there are customs duties, VAT, Additional duties. Is Goods and Service Tax coming?





# Civil Services of India

- Indian Administrative Service – the premier administrative civil service of the Government of India. IAS officers hold key strategic positions in the GOI and public sector undertakings.
  - Like many government agencies they are overworked and underpaid.
  - Patience and respect is required





# National versus State Dynamics

- **States with most growth potential?**

- Madhya Pradesh (now leading the pack) followed by Uttarakhand, and Bihar.
- Gujarat continues to be rated as one of the easiest states to do business.
- Rajasthan (good government)
- Opening of Burma – what does it mean for North Eastern states?





# Overarching Economic Developments

- The Economy is taking a hit but we may have hit the bottom: **GDP for India grew a mere 4.7%** year-on-year 2013, compared with almost 10% growth 2010.
- **The Rupee has stabilized** at about INR 60 to 1 USD but was as high as INR 68 to 1 USD last year.
- Modi's Make In India Campaign?

Source: World Bank





# The Pharmaceutical Market

- Overall, the Pharmaceutical Growth Story is positive
  - The market is worth \$22 Bn and could go to \$45BN by 2020.  
Likely growth at 15% a year
- Types of Pharmaceutical Investment Key
  - Innovative Company that imports and distributes, generic looking to manufacture, “Gilead Model”, or other partnerships.
- Expanding private health insurance, particularly for pharma reimbursement, should boost buying
- But expanding Price Controls could be a deterrent
- Domestic Market is largely generic and export focused
- Less reliance on IP as a tool for controlling health care costs; more reliance on price controls





# The Pharmaceutical Market

- But IP still is a concern...
  - Center/State Confusion
  - Section 3(d)
  - Pre & Post Grant Oppositions
  - Compulsory Licenses?
- Guidelines for Interpretation of Pharmaceutical Patents
- New IP Thank Tank and Draft IP Policy
- Clinical Trials – The Government is not approving them
- Domestic versus Foreign Companies
- Export regulations – Serialization issues
- Distribution issues due to infrastructure
- Understanding your market and customer: are you targeting private hospitals or public hospitals?





# The Pharmaceutical Market

- Several Government Agencies regulate the pharmaceutical industry – so can be confusing. DCGI, DoP, NPPA...
- The Principal Legislation controlling the industry is the Drugs and Cosmetics Act of 1940 (DCA), which is implemented at both the Central and State level (State FDAs).
- For drugs that have never been sold in India before (e.g. patented drugs), phase III clinical trials are usually required. You may also need import certificates and licenses in order to bring the drug in to the country.
- The Government has a Drug Master File system, which is where you file the key information regarding manufacturing of API, etc.





# Thank You!

**Amy Hariani**

Director and Legal Policy Counsel

U.S.-India Business Council

[ahariani@uschamber.com](mailto:ahariani@uschamber.com)

+ 1 202 270 4146



**USINDIA** Business Council