Drug Regulations in India

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Meeting With Ambassadors / High Commissioners of African Countries

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Flow of presentation

- About Indian Pharma Industry
- India's export to Africa
- Indian Regulatory System
- Standard of Drugs in India
- Initiatives taken by Government of India
- Counterfeit Drugs – India's Steps
- Quality of Drugs in India
- Areas to be focused
- Conclusion

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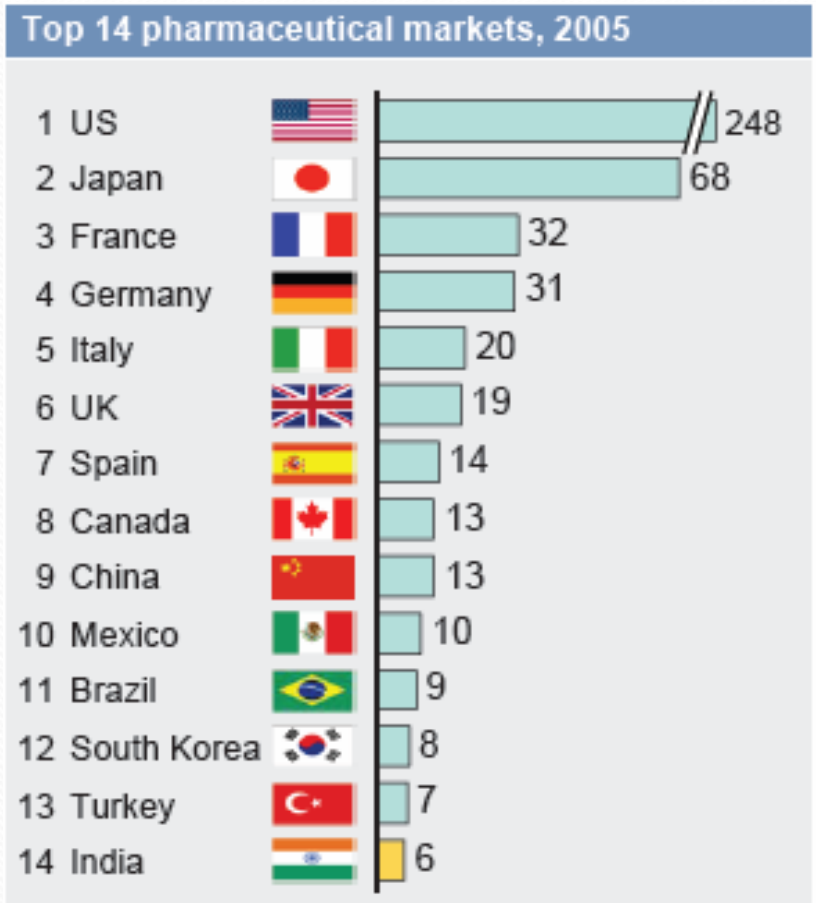
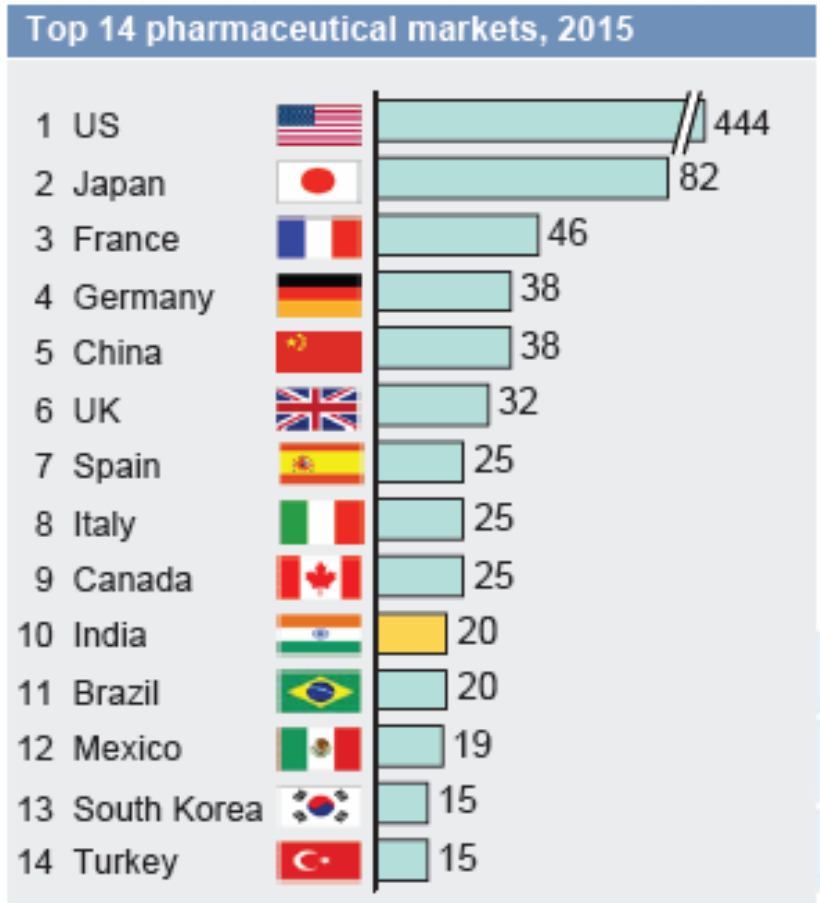
Indian Pharmaceutical Market

Indian Pharmaceutical market – $18 bn year	**Growth – 12-14% per**
Export - 6.7 bn	**Import - 905 m**
14th largest in value	**4th largest in volume**
~ 100 US FDA approved manufacturing sites	
Total number of manufacturing licenses issued: ~ 10000	
MNC's contribution to Pharma for domestic use – 20%	

10th Largest Market by 2015





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CURRENT GLOBAL STATUS

- Emerging as tough competitor to Europe as a growing Pharma R&D Hub
- An emerging hub for collaborative R&D in drug development , biotechnology and process developments
- Shift from business driven research to research driven business
- Topped in drug fillings with US FDA (more than 150 DMFs)
- A preferred destination for several multinationals (Roche, Aventis, Chiron) for sourcing of APIs
- Fast growing clinical research activity with increased activity of MNCs like Pfizer, Novartis, Astra Zenica, Eli Lilly etc.)
- Largest number of US FDA approved plants outside US.

Final ANDA Approvals by Country (2008) (figs. in Nos.)

Country	Numbers
USA	169
India	132
Israel	40
Germany	25
Canada	24
Switzerland	19
Iceland	14
Jordan	11
Other	25

- *Source: Thomson Scientific,*

Trade with African Countries

	US billion	% Growth
• Total Pharma Export	6.7	12.78
• African Countries	0.87	17.81
Share of Exports to African Countries	13.53%	

Sorted by Share of Market Region Wise

Southern Africa		North Africa	
South Africa	62.08%	Sudan	34.23%
Zambia	12.02%	Egypt	30.41%
Angola	10.12%	Algeria	23.69%
Mozambique	4.80%	Morocco	6.58%
Namibia	3.72%	Libya	3.33%

East Africa		West Africa	
Kenya	36.71%	Nigeria	53.37%
Tanzania	19.54%	Ghana	16.36%
Uganda	18.58%	Guinea	8.50%
Ethopia	14.26%	Benin	4.01%
Mauritius	6.18%	Senegal	3.01%

Central Africa

Chad	4.18%	Gabon	3.75%
Cameroon	33.31%	Congo Rep	0.68%
		Equtl Guinea	0.28

Legal Enactments to Regulate Import, Manufacture & Sale of Drugs

Drugs and Cosmetics Act, 1940

Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954

Drugs and Cosmetics Rules, 1945 made under the Act

Drug Price Control Order (DPCO), 1995

Objective

The overall objective of a National Regulatory Authority (NRA) is to ensure that medicinal products are of acceptable quality, safety and efficacy, are manufactured and distributed in ways which ensure their quality until they reach the patient/consumer, and their commercial promotion is accurate.

Standards of Drugs In India

The Drugs and Cosmetics Act has laid down that `standards of quality of drugs shall be as given in the second schedule to the Act.

- Any drug including API should conform the specification of the prescribed pharmacopoeias or those claimed on the label. In addition patent and proprietary medicines are required to comply with the requirements of Schedule V of the rules.
- Surgical designs are required to comply with standards laid down in Schedule F(II)
- Medical Devices are required to comply with the standards laid down in schedule R-I
- Mechanical Contraceptives are required to comply with the standards laid down in Schedule R.

Myth – Reality
About Spurious drugs in India

- A study of a samples of drugs tested all over the country in last 4 to 5 years, reveals that about 0.3% to 0.4% of around 40,000 samples fall within the category of spurious drugs
- The figures quoted by media range from 10% to 25% of drugs in country being spurious / counterfeit drugs

Facts and Figures

As per feedback from the state Drug Controllers Percentage of spurious Drugs reported yearwise-

Year	Samples Tested	Spurious Drugs	Percentage of Spurious Drugs
2007-2008	34,725	46	0.13
2006-2007	35,189	51	0.14
2005-2006	38,704	124	0.32
2004-2005	49,287	144	0.29
2003-2004	40,862	118	0.28
2002-2003	43,138	129	0.29
2001-2002	38,824	96	0.25

Study conducted

- Study to assess the extent of spurious drugs in country
- Study designed by Indian Statistical Institute, Hyderabad
- Initially it included testing of 31,000 drug samples of 62 various popular brands from therapeutic categories like anti-TB, Anti allergic, ant-infectives, anti-malarials, antihistaminics etc.
- The collection of samples from various parts of the country is currently in the final stage.
- As on date, approx. 26,500 samples collected from different zones
- Collection of samples would be an ongoing activity for year 2009 also.

Initiative taken by Govt. of India

- Specific definition of spurious drugs and cosmetics was introduced in 1982
- Enhanced penal provisions up to life imprisonment provided under sec 27 amended on 5th Dec 2008
- Norms of GMP have been upgraded by amending Schedule M to the rules to ensure production of quality drugs through out the country.
- Financial assistance was provided to states for augmentation of drug testing facilities under World Bank assisted Capacity Building Project (CBP)
- Formation of IP commission in January 2009
- Efforts going on for NABL accreditation of drug testing laboratories.

Approval of Clinical Trials, Import, & Manufacture of New Drugs

Requirements and Guidelines - Schedule Y

Rule 122 A — Permission to import new drug

Rule 122 B — Permission to manufacture new drug

Rule 122 DA — Definition of Clinical trials

Rule 122 E — Definition of New Drugs*

- **New substance having therapeutic indication**
- **Modified or new claims, new route of administration for already approved drug**
- **Fixed Dose Combination**

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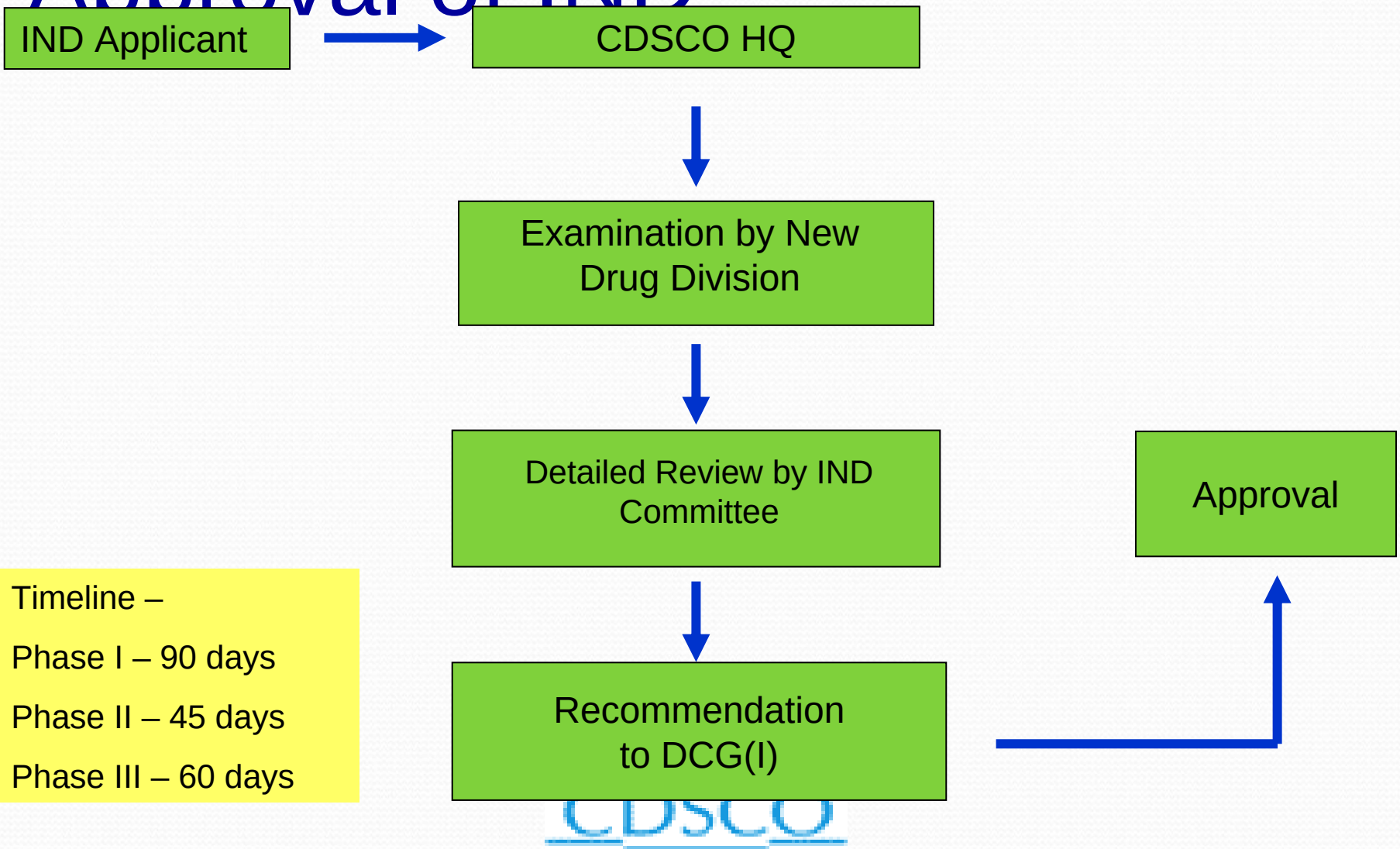
Data Requirements under Schedule Y

- Chemical and Pharmaceutical Information
- Animal Pharmacology
- Animal Toxicology
- Human Clinical Data (Phase I / II / III)
- Worldwide Regulatory Status
- Labeling
- Prescribing Information

Approval of IND



Timeline –

Phase I – 90 days

Phase II – 45 days

Phase III – 60 days

Import, Registration and Licensing

Mfg sites and Products are required to be Registered

Issue of Import License in Form 10 / 10A

Rules 21 to 30 → Rules related to grant of Registration Certificate and Import License

Schedule DI & DII → Information required for registration of Mfg site and Product

Timeline

For RC: As per D& C Rules, 9 Months ,However in practice, 2 months

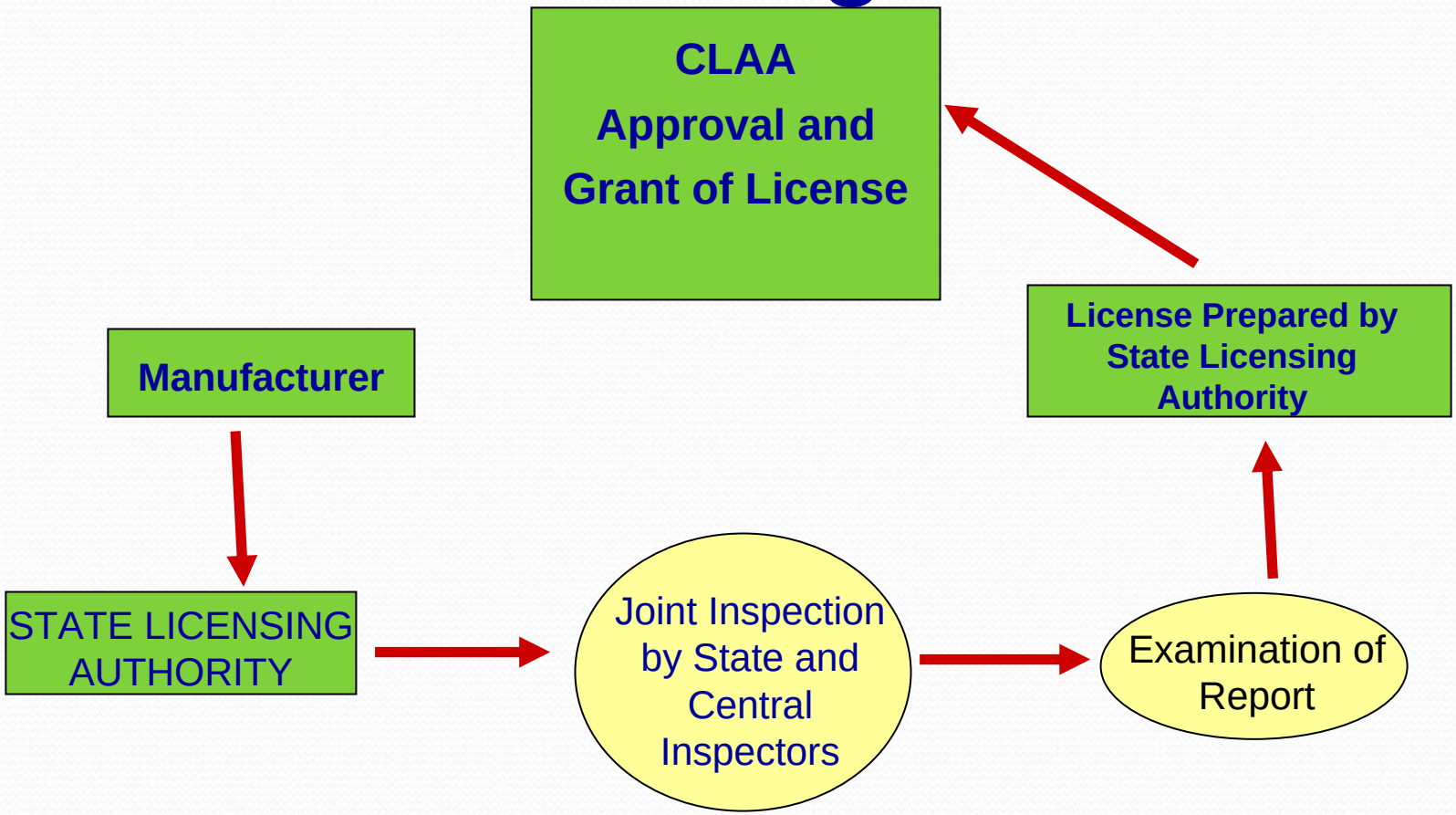
For Import License

2 -3 weeks

Registration Certificate(RC) and Import License - Valid for 3 years

As per Rule 24A (5), there is provision to inspect overseas manufacturing site for which manufacturer has to pay 5000 USD

Central Licensing*



* **For Biologicals, Large volume parenterals (LVP), Blood bank and blood products & Some Medical Devices**

Counterfeit Drugs - Indian Government Initiatives

- Issues related to counterfeiting of medicines were discussed in with IBSA working group meeting held on 29th July 2008
- India on behalf of South East Asia Region (SEARO) objected to draft resolution 7-8th August 2008
- Meeting of all the pharmaceutical manufacturer association called on 3rd September, 2008 by DCG(I).
- Final recommendations discussed in next SEARO Regional Committee meeting on 8th to 11th September 2008.
- Meeting with the Indian Pharmaceutical Industry representative on 14th Nov 2008.
- ADHOC working group of IMPACT meeting on 25th & 26th Nov 2008 at Bonn, Germany.

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Counterfeit Drugs - New Definition

THE REVISED DEFINITION PROPOSED AT BONN, GERMANY

Counterfeit medical product:

A medical product is counterfeit when there is a false representation in relation to its identity[1], or source[2] . This applies to the product, its container or other packaging or labelling information. Counterfeiting can apply to both branded and generic products. Counterfeits may include products with correct ingredients/components,[3] with wrong ingredients/components, without active ingredients, with incorrect amounts of active ingredients, or with fake packaging.

Quality defects or non-compliance with Good Manufacturing Practices/Good Distribution Practices (GMP/GDP) in legitimate, authorized medical products should not be confused with counterfeiting.

[1] e.g. any misleading statement with respect to name, composition, strength, or other elements,

[2] e.g. any misleading statement with respect to manufacturer, country of manufacturing, country of origin, marketing authorisation holder, including use of falsified documentation in the manufacture or trade of the product

[3] this refers to ingredients or any other component of a medical product”

Revised Definition- Suggestions addressed

- The focus should be protection of public health rather than IPR or trade related aspects.
- The prime victims of counterfeit drugs are patients rather than the IPR holders.
- The definition should not hinder the availability of legitimate / generic drugs / medicines.
- Patent disputes should not be confused with counterfeiting.
- A distinction may be made between counterfeiting and unauthorized drugs (unauthorized drugs / medicines are such which authorized in some countries whereas unauthorized in some other countries).
- There is a specific suggestion from Indian Drug Manufacturers Association that the words “Patent disputes” may be replaced by “IPR related issues”.

Quality of Drugs

- India has always maintained quality of Drugs which has not only being accepted by Domestic market but also accepted Globally.
- Indian Regulatory Agency has taken appropriate steps to consistently maintain quality of drugs manufactured throughout India
- India is only country which produces international quality drugs at a affordable cost.
- Indian companies like Cipla, Ranbaxy are credited with bringing down the prices of life saving drugs for HIV, Oncology, TB drugs etc.

Collaborations

- WHO, Health Canada and US FDA to strengthen
  - **Functioning in several areas including monitoring drugs for adverse reactions, regulating medical devices, clinical practices and biological drugs**
- Also with Brazil, South Africa and AFSAAPS-France

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WHO NRA Assessment- April 2009

- NRA of India has qualified the WHO NRA Assessment for vaccines with score of 100% in all the critical indicators
- WHO auditors were from USFDA, AFSAPPS-France, Belgium, WHO HQ, Egypt, Senegal, Thailand and Iran

Conclusion

- India is among the top three generic producers and top three API producers globally.
- Quality of Indian Pharma industry is well accepted well wide,
- The key strengths of the Pharma market are a well-developed industry with strong manufacturing base, well-established network of laboratories and R & D infrastructure, highly trained pool of scientists and professionals, world class quality products, strong marketing and distribution network, very strong reverse engineering skills, cost competitiveness and rich bio-diversity.
- The FICCI paper notes that the Indian market offers several advantages for African pharma market. The reasons are:
  - Setting up plants in India is 40% cheaper compared to the costs in the developed countries
  - Cost of bulk drug production in India is 60%-70% less compared to western nations
  - Regulations in India are also in alignment with global IPR regime

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Conclusion (contd.)

- Further, apart from offering world-class quality, Indian drug prices are among the lowest in the world – in some cases as low as 1/10th of international prices.
- In addition to this, India has strong talent pool with respect to healthcare professionals.
- The talent pool equipped with strong chemistry skills, which are key strengths for the growth of pharmaceuticals and healthcare industry of any country.
- Because of these advantages India is now increasingly becoming an integral part of the global value chain in the pharmaceutical and healthcare sector. Not only have the Indian pharma companies performed exceptionally well in the Indian market, but they have also left a mark in the international market place as well.

THANK YOU