India

• Now, one of the top 10 economies in the world, with GDP growth nearly double-digit annually since 2005-06 and annual FDI has grown more than 12 times from 2005-06 to 2010-11, and...

• Proportion of people living below $1.25 a day PPP in 2005 down from 60% in 1981 to 42% in 2005 but people living under $1.25/day up from 421 million in 1981 to 456 million in 2005

Disease Profile: India

<table>
<thead>
<tr>
<th>Communicable Diseases</th>
<th>Non-Communic. Diseases</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Endemic Diseases of major public health importance</strong></td>
<td><strong>Lifestyle Diseases</strong></td>
</tr>
<tr>
<td>Tuberculosis, HIV/AIDS, Malaria, water-borne diseases, acute respiratory infections</td>
<td>- Diabetes</td>
</tr>
<tr>
<td><strong>Endemic Diseases on verge of elimination/eradication</strong></td>
<td>- Hypertension</td>
</tr>
<tr>
<td>Poliomyelitis, Tetanus, Diphtheria, Pertussis, Yaws, Leprosy, Kala Azar</td>
<td>- Obesity</td>
</tr>
<tr>
<td><strong>Reemerging/Resurging Diseases</strong></td>
<td>- Hypercholesterolemia</td>
</tr>
<tr>
<td>Dengue, Chikungunya, Leptospirosis, Japanese Encephalitis, Typhoid, Anthrax, Scrub Typhus,</td>
<td>- Cardiovascular Diseases</td>
</tr>
<tr>
<td><strong>Newly Emerging Diseases</strong></td>
<td>- Stroke</td>
</tr>
<tr>
<td>MDR and XDR Tuberculosis, Nipah, avian and pandemic influenza, Hantavirus pulmonary</td>
<td></td>
</tr>
<tr>
<td>syndrome, Crimean Congo Hemorrhagic Fever</td>
<td></td>
</tr>
</tbody>
</table>

Changing Epidemiological Reality

Dual Burden of communicable diseases & non-communicable diseases, like cancer, diabetes, cardiovascular diseases, stroke, chronic respiratory diseases, which are turning to be an enormous challenge for public health
Total Expenditure on Health as a % of GDP, selected countries

Source: WHO, World Health Statistics 2012

Spending as a % of GDP

China  Brazil  India  USA  UK  Global

5.10%  8.80%  4.20%  17.60%  9.80%  9.40%

Total Expenditure on Health as a % of GDP, selected countries

Source: World Health Statistics 2012
Healthcare Spending in Public and Private Sector

Source: World Health Statistics 2012

Per Capita Spending (US$ )

Source: World Health Statistics 2012
### Out-of-pocket expenditure on health: India versus selected countries

<table>
<thead>
<tr>
<th>Country</th>
<th>Government expenditure on health as % of GDP</th>
<th>Out of Pocket expenditure as % of Total Health Expenditure</th>
</tr>
</thead>
<tbody>
<tr>
<td>India</td>
<td>1.3</td>
<td>60.2</td>
</tr>
<tr>
<td>China</td>
<td>2.7</td>
<td>37.5</td>
</tr>
<tr>
<td>Brazil</td>
<td>3.8</td>
<td>32.3</td>
</tr>
<tr>
<td>South Africa</td>
<td>4.0</td>
<td>16.6</td>
</tr>
<tr>
<td>Russian Federation</td>
<td>4.4</td>
<td>17.2</td>
</tr>
<tr>
<td>Sri Lanka</td>
<td>1.5</td>
<td>44.4</td>
</tr>
<tr>
<td>Thailand</td>
<td>3.1</td>
<td>15.1</td>
</tr>
<tr>
<td>UK</td>
<td>8.2</td>
<td>9.9</td>
</tr>
<tr>
<td>USA</td>
<td>8.4</td>
<td>12.2</td>
</tr>
<tr>
<td>France</td>
<td>9.3</td>
<td>7.3</td>
</tr>
</tbody>
</table>

*Source: World Health Statistics, 2012*
## India Health Systems – Financing

<table>
<thead>
<tr>
<th>Indicators</th>
<th>India (2009)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total per capita expenditure on Health</td>
<td>$ 44</td>
</tr>
<tr>
<td>Percentage of national GDP spent on Health</td>
<td>4.2</td>
</tr>
<tr>
<td>Out of pocket expense as a percentage of private expenditure on health</td>
<td>86.4</td>
</tr>
<tr>
<td>General Government contributions as a percentage of total medical spending</td>
<td>30.3</td>
</tr>
</tbody>
</table>


---

## India’s “Double Burden” of disease

Communicable Diseases still impose a severe toll in terms of death and suffering.

Non-communicable diseases have now become the dominant cause of health problems.
Snapshot of Indian Pharmaceutical Industry (2009-10)

- Industry size: 22 Bn USD approx (Rs.1 Lakh Cr.); industry is growing @ 14 % p.a
- Domestic Market: 11.6 Bn USD (approx.) (58 Thousand Cr)
- Exports: 9 Bn USD approx. (Rs. 42 Thousand Cr) export is growing @ about 10 % p.a.
- Imports: 2.2 Bn USD approx (Rs.12,500 crore)

3rd Largest in world in terms of Volume
Ranks 13th in terms of Value

- 8,000 manufacturing units in the country
- 600,000 Retail & Wholesale Shops in India
- 169 US FDA Approved Manufacturing Facilities
- US Pharmacopeia has office in Hyderabad, India
- USFDA country has office in Delhi & Mumbai
- 153 EDQM certified facilities

Drugs from India are exported to more than 200 countries
Vaccines from India are exported to more than 151 countries

Drug Regulatory System of India

Government of India

- Ministry of Health & Family welfare
  - DGHS
  - CDSCO
  - DCGI
  - DTAB
  - Enforcement & GMP audit Div
  - Quality Control Division-CDTL
  - Registration Div
  - New Drugs Div.
  - Pharmacovigilance
  - Trainings

- Ministry of Chemicals & Fertilizers
  - Department of Chemicals & Fertilizers
  - NPPA

- Ministry of Commerce
  - Department of Commerce
  - Controller General of patents
  - SG

- Ministry of science & Technology
  - DBT
  - CSIR Labs

- Ministry of Environment
  - Environmental clearance to the manufacturing sites
Factors Affecting Access to Medicines in India

- Inefficient and Iniquitous Financing Mechanisms
- High and unaffordable Drug Prices
- Procurement and Distribution Systems
- Need for Strengthening the Regulation of Medicines and Vaccines
- Insufficient Research & Development Focus
- Irrational use of Medicines
- Stringent Product Patent Regime

High Level Expert Group on Universal Healthcare Coverage
Planning Commission of India
Universal Healthcare Coverage

Universal coverage, or universal health coverage, is defined as ensuring that all people can use the promotive, preventive, curative and rehabilitative health services they need, of sufficient quality to be effective, while also ensuring that the use of these services does not expose the user to financial hardship.

WHO Definition of Universal Coverage, 2012

RECENT DEVELOPMENTS AT GOVERNMENT OF INDIA FEDERAL LEVEL

1. Scheme for “Free Medicines for All” in Public Health Facilities under Universal Healthcare Coverage announced by the Hon’ble Prime Minister of India
   • 12th Five year plan – Centrally aided scheme.
   • Quality Generic Medicines.
   • Essential Medicines for all.
   • Total cost Rs.29,968 Crores for five years.

2. National Rural Health Mission (NRHM) has included this in the National Project Implementation Plan (PIP) guidelines for the financial year 13-14.
   • Center will provide 75% fund.
   • State Govt. has to bear 25%.

3. Model being replicated in other states.
States: Large Differences In funding for Medicines

Procurement and Supply Chain Management- Differences in a Few Models of India

<table>
<thead>
<tr>
<th>Key features</th>
<th>Tamil Nadu</th>
<th>Madhya Pradesh</th>
<th>Chhattisgarh</th>
</tr>
</thead>
<tbody>
<tr>
<td>Strong</td>
<td>• Procurement</td>
<td>• Procurement (outsourced)</td>
<td>• Despite need for development, good availability of medicines in health facilities</td>
</tr>
<tr>
<td>Main improvements necessary in:</td>
<td>• Capacity building at district level</td>
<td>• Upgrade Drug Management Manual</td>
<td></td>
</tr>
<tr>
<td>Main constraints</td>
<td>• District capacity building</td>
<td>• Establishing new district warehouses</td>
<td>• Human resources at all levels</td>
</tr>
</tbody>
</table>
Key Observations of Field Visits to States by WHO

1. Corporation model not the only success model
2. Procurement can be outsourced to experienced agents (TNMSC)
3. Distribution requires major investments
   - Capacity (staff)
   - Warehousing
4. Well functioning IT systems available
5. Medicines Management Systems and Procedures weak
6. Monitoring at the point of dispensing weak
7. Financial transfers GoI → States requires caution
8. Major challenge is management capacity (lack of staff)

Rajasthan State Model
Pharmaceutical Sector Scenario & Access To Medicines In Rajasthan

MUKHYAMANTRI NIHSHULK DAVA YOJNA
Rajasthan Free Medicines Scheme

- Rajasthan has extensive healthcare system with trained healthcare personnel.
- The Free Medicines Scheme – Mukhya Mantri Nishulk Dava Yojana, by State of Rajasthan started in October 2011
- Success Factor- Extremely harmonious coordination mechanism among EDL Committee, regulators, supply chain managers, policy makers, and prescribers.
- The model could provide valuable lessons to other states in India and other countries in the region.
- A study planned in collaboration with WHO-India and PHFI to perform a Baseline Evaluation of the Free Medicines Scheme, to document evidence for improving access to medicines and reduced OOP expenses- 150 facilities planned to be sampled.

Key Achievements of the Free Medicines Scheme of Rajasthan

- Highly Cost Effective Procurement of Drugs, medical devices, Equipments and consumables for Government Hospitals
- Prescribing by generic names – a Shift towards “Generics only policy”
- Abundant suppliers – Enormous competition
- Stringent Quality Control – won the confidence of Medical practitioners and people.
- Continuous & adequate supply
- Some charitable hospitals procure drugs from RMSC and provide free to patients.
POOR ACCESS TO DRUGS IN INDIA

- The expenditure on health is the second most common cause for rural indebtedness.
- Expenditure on health is responsible for 3% shift from APL to BPL every year.
- Over 23% of the sick don’t seek treatment because they are not having enough money to spend.
- Expenditure on drug constitute about 50-80% of the health care cost.
- Over 40% of hospitalized patients has to borrow money or sell their assets to get them treated.
- A study by World Bank shows that as a result of single hospitalization 24% of people fall below poverty line in India.

Drug Selection and Use

MAKING DRUGS ACCESSIBLE & AFFORDABLE and RATIONAL USE OF DRUGS

<table>
<thead>
<tr>
<th>LOW COST GENERIC DRUGS</th>
<th>ESSENTIAL DRUGS LIST (EDL)</th>
<th>STANDARD TREATMENT GUIDELINES (STG)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quality drugs at affordable prices.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### FREE GENERIC DRUGS SCHEME OF RAJASTHAN

<table>
<thead>
<tr>
<th>(HARDWARE COMPONENT) AVAILABILITY OF DRUGS IN GOVT. HOSPITALS.</th>
<th>(SOFTWARE COMPONENT) CHANGE IN PRESCRIPTION BEHAVIOUR OF DOCTORS.</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Autonomous centralized procurement agency.</td>
<td>1. Sensitization and orientation about rational use of drugs.</td>
</tr>
<tr>
<td>2. A two-bid open transparent tendering process.</td>
<td>2. Write prescription on self carbonated double prescription slip.</td>
</tr>
<tr>
<td>3. Procurement of all essential and life saving drugs.</td>
<td>3. Diagnosis must be written.</td>
</tr>
<tr>
<td>4. Warehouse at every district.</td>
<td>4. Write Generic / Salt names.</td>
</tr>
<tr>
<td>5. Empanelled laboratories for quality testing.</td>
<td>5. Use out of Essential Drug List.</td>
</tr>
<tr>
<td>7. Transparent and prompt</td>
<td>7. Constitution of Drug and</td>
</tr>
</tbody>
</table>

### ACHIEVEMENTS

- Free essential drugs for the entire population of the State.
- Medicines, Surgical & Sutures are available free of cost to all patients visiting government hospitals.
- Increase in number of patients in govt. Institutes From 2\textsuperscript{nd} Oct 2011 to 31\textsuperscript{st} March 2012.

<table>
<thead>
<tr>
<th>Before MNDY</th>
<th>After MNDY</th>
</tr>
</thead>
<tbody>
<tr>
<td>44 Lac patients per month</td>
<td>62 Lac patients per month</td>
</tr>
</tbody>
</table>

So far 100 Million registered patients benefitted.
ACHIEVEMENTS

MAY 01, 2012

CM’s scheme hits drug sales, 100 stores wind up

FEELING THE HEAT

Chemists say sales of medicines have declined by 50-60%, ask govt to show some mercy

P Singh

JAIPUR: Sales of medicines at chemist shops have declined due to the success of the chief minister’s free medicine scheme.

Rajasthan Chemist Association (RCA) said about 30 to 40 medical shops in rural and remote areas have already been closed down, as businesses were hit by the free medicine scheme.

Mahaveer Sohani, vice president, Jaipur Chemist Association said: “Sales of medical stores situated opposite government hospitals have been affected. They have declined by 50-60% and a few shops in Jaipur have closed down.”

He said the scheme of the chief minister is good and patients are now getting medicines at cheaper rates. “Chemists request the chief minister to help us in some way so that we too get employment. We want the chief minister to have a soft corner for us,” he said.

Bogar suggested that if any patient wants to buy branded medicines from chemist, the government should allow doctors to prescribe them, so that their business continues.

Sanjit Sharma, managing director, Rajasthan Medical Services Corporation said the free medicine scheme is gaining popularity and about 100 medical shops have closed down in the state. Sales have declined by 50-60%.

Chemists should not charge extra rates for medicines and the chemists association can resolve the issue by reinstating their credibility, he added.

The scheme was launched in Jaipur on October 2, 2011. Initially there were problems like medicine not being available in government distribution centres, stocks getting over. But now the situation has improved and medicines are available in sufficient quantities. The number of medicines has increased from 300 to around 800.

• The closed private medical shops at Sawai Man Singh Hospital on Monday.

WHO

Country Cooperation Strategy

India

2012-2017
Strategic priority 1
Supporting an improved role of the Government of India in global health

International Health Regulations
Ensuring the implementation of International Health Regulations and similar commitments

Pharmaceuticals
Strengthening the pharmaceutical sector including Drug Regulatory capacity and Trade and Health

Stewardship
Improving the stewardship of the entire Indian health system

WHO's Position on Generic Medicines

• “WHO not only supports generic products. **We aggressively promote them**, whether through guidelines for conducting bioequivalence studies or through the prequalification programme.

• **Generic products serve public health in multiple ways.** In terms of improving access to medicines, price and quality go hand in hand.

• **Generic products are considerably less expensive than originator products.** And competition among generic manufacturers reduces prices even further.

• **Generics serve the logic of the pocket.** An affordable price encourages good patient compliance, which improves treatment outcome and also protects against the emergence of drug resistance.”

Dr Margaret Chan
28 February 2011
Prequalified medicines according to countries of manufacture (June 2012)

Medicinal products by Indian Manufacturers Prequalified in Tuberculosis in the WHO Prequalification of Medicines Programme

Source: WHO prequalification of Medicines List (http://apps.who.int/prequal/query/ProductRegistry.aspx)
Medicinal products by Indian Manufacturers Prequalified in Malaria in the WHO Prequalification of Medicines Programme

![Percentage of WHO Prequalified Manufacturers - Malaria](http://apps.who.int/prequal/query/ProductRegistry.aspx)

Source: WHO prequalification of Medicines List (http://apps.who.int/prequal/query/ProductRegistry.aspx)

Medicinal products by Indian Manufacturers Prequalified in HIV/AIDS in the WHO Prequalification of Medicines Programme

![Percentage of WHO Prequalified Manufacturers - HIV/AIDS](http://apps.who.int/prequal/query/ProductRegistry.aspx)

Source: WHO prequalification of Medicines List (http://apps.who.int/prequal/query/ProductRegistry.aspx)
Assuring Quality by Strengthening National Regulatory Authorities in India

- Strengthening national regulatory authorities & quality assurance mechanisms for enhanced safety, quality and efficacy of medicines.
- Need for horizontal and vertical collaboration for strengthening the National Regulatory Authority in partnership with well-resourced regulatory authorities.
- Need for a sufficient policy space for Indian pharmaceutical manufacturers to continue their central role in supplying developing countries with low priced, quality-assured generic medicines.
- Capacity building on trade and health and intellectual property rights related to pharmaceuticals, and their impact on public health.

Ensuring quality, safety and efficacy of vaccines

Assessment of the National Regulatory Authority (NRA) of India
### India: National Regulatory system, Status of regulatory functions in 2007 and 2009

<table>
<thead>
<tr>
<th>Regulatory functions</th>
<th>Score 2007</th>
<th>Score 2009</th>
<th>Progress</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regulatory system</td>
<td>64%</td>
<td>NO</td>
<td>YES</td>
</tr>
<tr>
<td>1. MAA &amp; licensing</td>
<td>33%</td>
<td>NO</td>
<td>YES</td>
</tr>
<tr>
<td>2. PMS &amp; AEFI</td>
<td>75%</td>
<td>NO</td>
<td>YES</td>
</tr>
<tr>
<td>3. NRA Lot release</td>
<td>100%</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td>4. Laboratory access</td>
<td>75%</td>
<td>NO</td>
<td>YES</td>
</tr>
<tr>
<td>5. Regulatory inspections</td>
<td>50%</td>
<td>NO</td>
<td>YES</td>
</tr>
<tr>
<td>6. Authorisation/approval of clinical trials</td>
<td>75%</td>
<td>YES</td>
<td>YES</td>
</tr>
</tbody>
</table>

Total FUNCTIONS IMPLEMENTED: 2 No, 6 Yes

---

**1997-2011: WHO assessed 101 out 194 countries**

- 950 regulatory experts, 350 assessors
Major vaccine producing countries, 1997-2011
146 vaccine manufacturers, 95% global production in 15 countries

Developing countries with significant vaccine industry

<table>
<thead>
<tr>
<th>No of trainees</th>
<th>2010 Attendees</th>
<th>2012 Attendees</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drugs Inspector</td>
<td>64</td>
<td>64</td>
</tr>
<tr>
<td>TDA</td>
<td>11</td>
<td>0</td>
</tr>
<tr>
<td>Grand Total</td>
<td>75</td>
<td>64</td>
</tr>
</tbody>
</table>

Budget allocated to CDSCO, 2008-2013

<table>
<thead>
<tr>
<th>Year</th>
<th>Rupees (crore)</th>
<th>USD millions</th>
</tr>
</thead>
<tbody>
<tr>
<td>2007-2008</td>
<td>14</td>
<td>3</td>
</tr>
<tr>
<td>2008-2009</td>
<td>20</td>
<td>4</td>
</tr>
<tr>
<td>2009-2010</td>
<td>20</td>
<td>4</td>
</tr>
<tr>
<td>2010-2011</td>
<td>24</td>
<td>5</td>
</tr>
<tr>
<td>2011-2012</td>
<td>33</td>
<td>7</td>
</tr>
<tr>
<td>2012-2013</td>
<td>78</td>
<td>15</td>
</tr>
<tr>
<td>2013-2014</td>
<td>185</td>
<td>37</td>
</tr>
</tbody>
</table>

Progress 2007-2012

- Budget + 1200%
- Staffing + 189%, + 279%
- Training + 400%
Strengthening Pharmaceuticals with a ‘Trade & Health Approach’

• Enhancing India's role in promoting access to high quality affordable essential pharmaceuticals and other technologies for addressing health challenges globally.

• Identifying opportunities for collaboration within various frameworks to which India has made commitments, such as South-South collaboration, BRICS

Intellectual Property Rights

• Creating an appropriate, TRIPS-compliant intellectual property (IP) regime, consistent with and enabling of the flexibilities reaffirmed in the Doha Declaration, and appropriate to the level of development of its pharmaceutical sector

• Issue of compulsory licenses for increasing access to affordable medicines
Pharmaceutical Policy Environment

- Protect the safeguards provided by the Indian Patents Law and the TRIPS Agreement against the country’s ability to produce essential drugs- Novartis Judgement in India
- Price controls and price regulation especially on essential medicines- Draft National Pharmaceuticals Pricing Policy 2011

Improving Access to Pharmaceuticals and Health Technologies

- Where people have to pay out of pocket, with generic policies, individuals can reduce costs by about 60% and this could make the difference between death or impoverishment and survival.
- Ensure availability of free essential medicines by increasing public spending on drug procurement.
- Strengthening national regulatory authorities & quality assurance mechanism for enhanced safety, quality and efficacy of medicines.
- Supply of Quality Generic Drugs and strengthening ‘Jan Aushadi’ generic medicines’ stores at state level
- Enforcing Rational Use of Medicines - Scaling up Rational Drug Use Initiatives, including use of essential drug lists, standard treatment guidelines, and containing antimicrobial resistance
- Streamlining national and state procurement and supply chain management systems
- Reducing the Price differentials of medicines
BRICS Health Ministers’ Forum
New Delhi

At the 2012 New Delhi summit, the heads of state of the BRICS countries noted that: “Most of BRICS countries face a number of similar public health challenges, including universal access to health services, access to health technologies, including medicines, increasing costs and the growing burden of both communicable and non-communicable diseases”. They therefore directed that the BRICS Health Ministers meetings, first held in Beijing in 2011, “be institutionalized in order to address these common challenges in the most cost-effective, equitable and sustainable manner”.

Renewed Role of WHO in BRICS

Facilitate the country's contribution to global health, especially for universal access to affordable medicines and health commodities of assured quality, and for providing constructive inputs in international forums dealing with possible effects of trade on the health of the population.
Global Role of WHO in Pharmaceuticals

- Pivotal role being played by the **WHO Prequalification of Medicines Programme (PQP)**, which ensures that medicines supplied by procurement agencies meet acceptable standards of quality, safety and efficacy.

- **Importance of innovation for health, and specifically as means to reduce inequities in access to medicines** and other health technologies for priority diseases related to MDG 4, 5 and 6, Neglected Tropical Diseases (NTDs) and Non-communicable Diseases (NCDs).

- **International Conference of Drug Regulatory Authorities (ICDRA)** has been providing drug regulatory authorities of the WHO Member States with a forum to meet and discuss ways to strengthen collaboration and harmonize regulation to improve the safety, efficacy, and quality of medicines globally.

Way forward for BRICS Bloc

- Promoting universal access to medication and strengthening health systems, including through support for the development and implementation of national pharmaceutical policies.

- Strengthening regulatory capacity in activities involving research and development, production and rational use of health technologies that will ensure their quality, safety and efficacy and in a manner that ensures efficiency, accountability, and transparency of regulatory processes.

- Facilitating exchange between national regulatory authorities in key regulatory issues and developing collaborative platforms and networks that promote horizontal cooperation between Member States, including between BRICS health authorities in technology transfer.

- Proposing and accompanying initiatives including universal coverage schemes aimed to rapidly scale up access to medicines within health systems, especially for essential medicines in NCDs, NTDs and diseases related to MDG 4, 5 and 6.

- Strengthening and promoting health technology assessment between BRICS countries.
Acknowledging Contributions from Colleagues from India involved in the BRICS Forum...

• Nilakantha Bhoi, PharmD, MBA, BSc, Technical Consultant, Procurement and Supply Chain Management Expert, IPE Global, DFID Supported Health Sector Reforms Programme, India

• Nirmal Kumar Gurbani, PhD, FIPA, Professor & Associate Dean, Pharmaceutical Management, Indian Institute of Health Management & Research (IIHMR), WHO Collaborating Center, Jaipur, India

Thank You