Sustaining Health with innovative R&D and Health Infrastructure

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&
Vice-Chairman & Managing Director
Novartis India Limited

Presentation for CIPIH at New Delhi, India on November 4, 2004
Organisation of Pharmaceutical Producers of India (OPPI)

- Founded in 1965
- Over 70 Members
- Research-based International & large Indian Pharma Companies
- Affiliated to IFPMA, Geneva and WSMI, France
- 3 Fundamental Beliefs
  - Adherence to TRIPs Compliant IPR
  - Ethical Sales Promotion based on IFPMA Guidelines and Code of Conduct
  - Adherence to International GMP & Quality Standards
Neglected Diseases - Neglected Populations

- Why is the health of some populations neglected?

- Which health needs are neglected?

- Why and what new medicines are needed?

- Are new drugs on their way?

- Is the level of financing sufficient to sustain current R&D efforts?
Why?

- Neglected diseases because of their localisation and entrenchment in the world’s poorest regions do not represent a direct threat for developed countries population.

- This removes most incentives from both public and private sector research – the source for pharmaceutical innovation.
Disease Burden in India

- 16% of world wide POPULATION
- 18% of world wide MORTALITY
- 20% of world wide MORBIDITY
- 2% of world wide GDP
- 1% of world HEALTHCARE INVESTMENT

—but only—
Health Challenges ahead for India

- Malaria staging a resurgence with ~50% rise in incidence of P-Falciparum Malaria.
- No significant decline in TB infection with growing incidence of drug resistance
- HIV/AIDS an epidemic in making –
  - from a few thousand in the early 1990s to a working estimate of 5.1 million children and adults living with HIV/AIDS in 2003 of whom ~39.6% are women/children.
  - Globally India is second only to South Africa in terms of the overall number of people living with the disease
- High Morbidity due to incidence of Water-borne infections
- Growing mortality through Life style diseases

Source: [http://www.avert.org/aidsindia.htm](http://www.avert.org/aidsindia.htm); [http://www.avert.org/indiaaids.htm](http://www.avert.org/indiaaids.htm)
<table>
<thead>
<tr>
<th>Goal</th>
<th>Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eradicate Polio and Yaws</td>
<td>2005</td>
</tr>
<tr>
<td>Eliminate Leprosy</td>
<td>2005</td>
</tr>
<tr>
<td>Eliminate Kala Azar</td>
<td>2010</td>
</tr>
<tr>
<td>Achieve Zero level growth of HIV/AIDS</td>
<td>2007</td>
</tr>
<tr>
<td>Reduce Mortality by 50% on account of TB, Malaria and other Vector and Water Borne diseases</td>
<td>2010</td>
</tr>
<tr>
<td>Reduce Prevalence of Blindness to 0.5%</td>
<td>2010</td>
</tr>
</tbody>
</table>
Efficacious Pharmaceutical Innovation

- Successful Healthcare Systems
- Efficient Markets
- Effective Use of Intellectual Property
- Adequate and Predictable Regulatory Requirements
The Reality is ....

- Most diseases that disproportionately affect low income countries can be treated with medicines from the WHO Essential Drugs List

- The biggest challenge is getting the interventions to the people who need them
## Current Status of Drugs for Neglected Diseases

<table>
<thead>
<tr>
<th>Disease</th>
<th>Existing Medicines</th>
</tr>
</thead>
<tbody>
<tr>
<td>African Trypanosomiasis</td>
<td>Yes</td>
</tr>
<tr>
<td>Chagas Disease</td>
<td>Yes</td>
</tr>
<tr>
<td>Leishmaniasis</td>
<td>Yes</td>
</tr>
<tr>
<td>Dengue Fever</td>
<td>No</td>
</tr>
<tr>
<td>Malaria</td>
<td>Yes</td>
</tr>
<tr>
<td>Tuberculosis</td>
<td>Yes</td>
</tr>
</tbody>
</table>
Factors that Impede R&D in Neglected Diseases

- Lack of sustained financing mechanism
- Scientific hurdles
- Costly clinical trial and regulatory requirements
- Poor infrastructure
- Weak IP protection
Partnership is the key to unlocking the barriers

Funders
- supply the money!
- e.g. NIH, Gates, DFID, Wellcome Trust

Product Development PPPs
- facilitate partnering between funders and project participants
- stewardship of funders’ contributions
- e.g. GATB, MMV, WHO/TDR

Development NGOs
- pick up on opportunities from industry
- e.g. DNDi, IOWH

Academia & Public Sector
- ideas, expertise, contacts & networks
- e.g. LSTM, LSHTM, WRAIR, WHO/TDR
## Examples of Product Development PPPs for Neglected Diseases

<table>
<thead>
<tr>
<th>Disease</th>
<th>Organizations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Malaria</td>
<td>Medicines for Malaria Venture (MMV)</td>
</tr>
<tr>
<td></td>
<td>Malaria Vaccine Initiative (MVI)</td>
</tr>
<tr>
<td></td>
<td>European Malaria Vaccine Initiative (MMV)</td>
</tr>
<tr>
<td></td>
<td>Japanese Pharmaceutical, Ministry of Health, WHO Malaria Drug Partnership (JPMW)</td>
</tr>
<tr>
<td></td>
<td>Lapdap™ Antimalarial Product Development (Lapdap)</td>
</tr>
<tr>
<td>Tuberculosis</td>
<td>Global Alliance for TB Drug Development (TB Alliance)</td>
</tr>
<tr>
<td></td>
<td>Global TB Vaccine Foundation (Areas)</td>
</tr>
<tr>
<td></td>
<td>Foundation for Innovative New Diagnostics (FIND)</td>
</tr>
<tr>
<td>African trypanosomiasis</td>
<td>Drugs for Neglected Diseases Initiative (DNDI)</td>
</tr>
<tr>
<td></td>
<td>Gates Foundation/University of Carolina Partnership (GFUNC)</td>
</tr>
<tr>
<td></td>
<td>Infectious Disease Research Institute (IDRI)</td>
</tr>
<tr>
<td></td>
<td>Institute for One World Health (IOWH)</td>
</tr>
</tbody>
</table>

Source: IFPMA
**We are seeing results**

<table>
<thead>
<tr>
<th>Disease</th>
<th>Discovery &amp; Preclinical Development</th>
<th>Phase I</th>
<th>Phase II</th>
<th>Phase III</th>
</tr>
</thead>
<tbody>
<tr>
<td>African trypanosomiasis</td>
<td>3</td>
<td>1</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Chagas disease</td>
<td>5</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Leishmaniasis</td>
<td>3</td>
<td>1</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Dengue fever*</td>
<td>5</td>
<td>2</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Malaria</td>
<td>21</td>
<td>1</td>
<td>3</td>
<td>5</td>
</tr>
<tr>
<td>Tuberculosis</td>
<td>18</td>
<td>2</td>
<td>2</td>
<td></td>
</tr>
</tbody>
</table>

*For Dengue fever, most project are vaccine candidates; for other diseases vaccines are not included.*
### Pharma Industry Contribution 2003

Combined Aid of Pharma corporation in 2003 over USD 2 billion which exceeds those of budget of public sources:

<table>
<thead>
<tr>
<th>Source</th>
<th>USD billion</th>
</tr>
</thead>
<tbody>
<tr>
<td>WHO annual health budget</td>
<td>1.37</td>
</tr>
<tr>
<td>UNICEF</td>
<td>1.3</td>
</tr>
<tr>
<td>EU bilateral disbursement for HIV/AIDS</td>
<td>0.9</td>
</tr>
<tr>
<td>USAID global health budget</td>
<td>1.4</td>
</tr>
<tr>
<td>Disbursement from global fund for HIV/AIDS, Malaria, TB</td>
<td>0.2</td>
</tr>
<tr>
<td>EU disbursement for HIV/AIDS, Malaria, TB</td>
<td>0.5</td>
</tr>
</tbody>
</table>

Source: Hudson Institute paper “A review of Pharma Companies Contribution for HIV/AIDS, TB, Malaria and other Infectious diseases”
New Research & Discovery for Neglected Diseases

AstraZeneca
Bangalore Research Institute

Efficacious in treatment of TB which would shorten the Treatment course to less than 4 months. An investment of $ 40 million and 100 scientists. First drug candidates can be expected in three years.
New Research & Discovery for Neglected Diseases

Novartis Novartis Institute for Tropical Diseases (NITD)

A collaborating project between Novartis and the Government of Singapore, NITD is a $122 million research institute employing about 100 scientists. It focuses on research and discovery of novel drugs for Dengue fever and TB.
Novartis and Shanghai Institute of Materia Medica extend collaboration for use of natural products from Chinese medicinal plants in drug discovery
GlaxoSmithKline Tres Cantos Centre for Diseases of the Developing World Drug Discovery

GSK’s Diseases of the Developing World (DDW) Initiative at Spain to assess Disease targets and identify Candidate compounds for Malaria and TB. Tres Cantos facility is a principal location for discovery projects within the joint GSK/MMV portfolio of four malaria discovery programs.

Source: IFPMA
Poverty – Health Vicious Circle

- Health Risk factors
- Disease Profile
- Impact of poor Health on Economics
- Availability of Resources
- Health Interventions
- Health Outcomes
### Global Daily Deaths per Major Communicable Diseases

<table>
<thead>
<tr>
<th>Disease</th>
<th>Deaths</th>
</tr>
</thead>
<tbody>
<tr>
<td>Respiratory Infection</td>
<td>10,814</td>
</tr>
<tr>
<td>HIV/AIDS</td>
<td>7,852</td>
</tr>
<tr>
<td>Diarrhoeal</td>
<td>5,482</td>
</tr>
<tr>
<td>Tuberculosis</td>
<td>4,504</td>
</tr>
<tr>
<td>Childhood Disease</td>
<td>3,611</td>
</tr>
<tr>
<td>Malaria</td>
<td>3,079</td>
</tr>
<tr>
<td>Neglected Diseases*</td>
<td>378</td>
</tr>
</tbody>
</table>

*Neglected diseases are defined as African trypanosomiasis, Chagas disease and Leishmaniasis

Number of Compounds in Development by Major Disease Categories

<table>
<thead>
<tr>
<th>Disease Category</th>
<th>Compounds</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sense organ disorder</td>
<td>22</td>
</tr>
<tr>
<td>Digestive diseases</td>
<td>33</td>
</tr>
<tr>
<td>Respiratory diseases</td>
<td>44</td>
</tr>
<tr>
<td>Diabetes</td>
<td>50</td>
</tr>
<tr>
<td>Musculoskeletal diseases</td>
<td>55</td>
</tr>
<tr>
<td>HIV/AIDS**</td>
<td>86</td>
</tr>
<tr>
<td>Cardiovascular disease</td>
<td>123</td>
</tr>
<tr>
<td>Infectious diseases+**</td>
<td>185</td>
</tr>
<tr>
<td>Respiratory Neuropsychiatric diseases</td>
<td>271</td>
</tr>
<tr>
<td>Cancers</td>
<td>395</td>
</tr>
</tbody>
</table>

* Excluding HIV/AIDS; including 61 vaccines. ** Including 15 vaccines

Source: PhRMA Medicines in Development Survey 2003/2004
Global Annual Spend on Health Research

- 1991 $ 30 bn
  2001 $ 106 bn
- Continuing under investment in the developing world
- Inspite of a marked shift in the pattern of diseases and illness across the world
- Developing Countries Industrialised Nations
  Life style health issues Communicable diseases HIV / AIDS
  obesity
- HIV and severe acute respiratory syndrome have shown that diseases can move rapidly from the developing to the developed world
## Spend on Health Research

### Countries:
- **USA**: 49%
- **Japan**: 13%
- **UK**: 7%
- **Germany**: 6%
- **France**: 5%

### Source:
- **Private Sector**: 48%
- **Public Sector**: 44%
- **Not for Profit Private Sector**: 8%

High cost of developing drugs has prompted pharma companies to go for blockbuster drugs.
HIV/AIDS, Malaria, Tuberculosis

- WHO
- UN Millennium Development Goals
- These three diseases account for
  10% of Global Deaths
  18% of Disease Burden in least developed countries
- Other diseases
  - Viral, Bacterial, Parasitic & Fungal infections
  - Acute respiratory infections
  - Diarrhoeal diseases of children
- Neglected diseases
  - Chagas disease
  - African trypanosomiasis
  - Onchocerciasis
  - Leishmaniasis
  - Schistomiasis
  - Leprosy
  - Lymphatic Filarisis
  - Dengue Fever
  - Guinea Worm
  - Blinding Trachoma

Many of these diseases can be treated with existing cost effective therapy
Diseases for which Effective Medicines Exist

<table>
<thead>
<tr>
<th>Disease Current</th>
<th>Disease Status</th>
<th>Existing Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Childhood diseases</td>
<td>1.12 million children die each year</td>
<td>Effective, low cost vaccines exist for all major childhood diseases, including pertussis, polio, diphtheria, measles and tetanus</td>
</tr>
<tr>
<td>Diarrhoeal diseases</td>
<td>1.8 million deaths result from diarrhoea each year</td>
<td>Oral rehydration therapy (ORT), once considered the most important medical advance in this century, can prevent about 90% of child deaths from Diarrhoeal dehydration at the cost of 10 cents per treatment</td>
</tr>
</tbody>
</table>
### Diseases for which Effective Medicines Exist

<table>
<thead>
<tr>
<th>Disease Current</th>
<th>Disease Status</th>
<th>Existing Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Malaria</td>
<td>1.3 million deaths result from malaria each year</td>
<td>Effective prevention and treatment tools exist, which if applied properly, could lead to elimination of malaria</td>
</tr>
<tr>
<td>Schistosomiasis</td>
<td>200 million people are affected globally, of which 85 percent in Africa</td>
<td>Schistosomiasis can be treated with Praziquantel at the cost of 30 cents per child, per year, including delivery costs</td>
</tr>
</tbody>
</table>
## Diseases for which Effective Medicines Exist

<table>
<thead>
<tr>
<th>Disease Current</th>
<th>Disease Status</th>
<th>Existing Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Vitamin A deficiency</strong></td>
<td>140 million children at risk of blindness</td>
<td>Vitamin A is low cost and can be easily administered as a food supplement</td>
</tr>
<tr>
<td><strong>Onchocerciasis</strong></td>
<td>Merck has donated over one billion tablest of Mectizan with more than 300 million cumulative treatments distributed</td>
<td>Over 25 years, protected 11 million children against onchocerciasis – and around 1 million people have been saved from blindness.</td>
</tr>
</tbody>
</table>

Merck has donated over one billion tablest of Mectizan with more than 300 million cumulative treatments distributed.
Diseases for which Effective Medicines Exist

<table>
<thead>
<tr>
<th>Disease Current</th>
<th>Disease Status</th>
<th>Existing Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Leprosy</td>
<td>Novartis donates $35 million in multi-drug treatment for leprosy and works with WHO</td>
<td>Over 13 million people have been cured of leprosy and the prevalence rate has dropped by over 90% since 1985 and the number of countries considered endemic has been reduced from 122 to 15.</td>
</tr>
<tr>
<td>Lymphatic Filariasis</td>
<td>GlaxoSmithKline donates albendazole and Merck donates ivermectin (Mectizan®). To date 250 million treatments of albendazole and 20 million treatments of Mectizan® have been donated.</td>
<td>By 2003 almost 80 million people in 37 countries had received treatment for lymphatic filariasis.</td>
</tr>
</tbody>
</table>
### Diseases for which Effective Medicines Exist

<table>
<thead>
<tr>
<th>Disease Current</th>
<th>Disease Status</th>
<th>Existing Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guinea Worm Eradication Program</td>
<td>Johnson &amp; Johnson has donated medical supplies to treat more than 3,000 villages in the endemic countries</td>
<td>The number of people suffering from guinea work has dropped from 10-15 million at the start of the 1980s to 32,000 in 2003.</td>
</tr>
<tr>
<td>Blinding Trachoma</td>
<td>Pfizer has donated more than $130 million in product donations (Zithromax(^R)) and health educational grants</td>
<td>Over 5 million people have been rid of trachoma and more than 70,000 cases of blindness prevented.</td>
</tr>
<tr>
<td>African trypanosomiasis WHO program to eliminate Sleeping Sickness</td>
<td>Aventis has supplied some 1.2 million drug ampoules and worked with WHO on a new formulation</td>
<td>During the past three years, more than 60,000 people have benefited from this initiative.</td>
</tr>
</tbody>
</table>
But...Challenges Remain

- More financial resources need to be mobilised in a sustainable way to create a strong and sustainable pipeline of drug candidates.
- Joint effort of global scientific community need of the hour to translate accumulated basic scientific knowledge into applicable information.
- Streamline development of new drugs to bring down overall cost of R&D for neglected diseases.
- Efforts needed to accelerate capacity building in developing countries to facilitate late stage clinical trials.
- Mobilisation of additional resources to ensure that new medicines for neglected diseases reach the actual beneficiaries. Experience of successful disease control programs can serve as a base for this.
Positive Features

- Patent protection of 20 years extended to all areas of technology
- Reversing burden of proof on infringers
- Post-grant opposition in place of pre-grant opposition
- Simplified and Expeditious Patent grant procedure
Patents (3rd Amendment) Bill

Areas of Concern

- Compulsory Licensing
- Importation as Working of Patent
- Patentability
- Post Vs. Pre Grant Opposition
Patents (3rd Amendment) Bill – Areas of Concern

Compulsory Licensing

• Should be restricted to true NATIONAL EMERGENCY situations.

• Only for NON-COMMERCIAL USE.

• Interests of the Licensee can never be placed above those of Inventor.

• Broad based Compulsory Licensing only

• Helps the Copier and not the Patient.
Patents (3rd Amendment) Bill – Areas of Concern

Compulsory Licensing

Language **ambiguous** and establishes **very low and subjective thresholds** for commercial entities to invoke Compulsory Licensing.
Patents (3rd Amendment) Bill – Areas of Concern

Importation

- Should be allowed as Working of Patent
- All over the world Manufacturing Activities are consolidated in countries which are Best Cost Producers (including India)
- Mfg. Facilities involving Advanced Technologies and High GMP Standards cannot be spread all over the world.
Patentability

- TRIPS Allows NCEs, Polymorphs, Chiral Isomers, New Indications etc.

- Domestic Companies insisting on only NCEs
Post Vs Pre Grant Opposition

- Should retain Post-grant Opposition as given in 3rd Patent Amendment Bill

- Pre-grant Opposition can result in frivolous objections delaying the grant of patent.
Patents (3rd Amendment) Bill – Areas of Concern

Data Exclusivity

- Terminology used Data Protection
- Not included in 3rd Amendment
- Recommendation – minimum 5 years (from the date of marketing approval)
- Amendment of Schedule Y of the Indian Drugs Act to include Data Protection.
## The world's rising innovation hot spots

<table>
<thead>
<tr>
<th></th>
<th>China</th>
<th>India</th>
<th>Israel</th>
<th>Russia</th>
<th>Singapore</th>
<th>South Korea</th>
<th>Taiwan</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>U.S. patents</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1993</td>
<td>60</td>
<td>30</td>
<td>306</td>
<td>62</td>
<td>39</td>
<td>764</td>
<td>62</td>
</tr>
<tr>
<td><strong>U.S. patents</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2003</td>
<td>366</td>
<td>354</td>
<td>1,188</td>
<td>268</td>
<td>438</td>
<td>3,952</td>
<td>5,300</td>
</tr>
<tr>
<td><strong>R&amp;D spending</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(% of GDP)</td>
<td>1.2</td>
<td>1</td>
<td>4.7</td>
<td>1.2</td>
<td>2.2</td>
<td>2.9</td>
<td>2.3</td>
</tr>
<tr>
<td><strong>Science &amp; engineering</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>grads (1,000)</td>
<td>337</td>
<td>316</td>
<td>14</td>
<td>216</td>
<td>5.6</td>
<td>97</td>
<td>49</td>
</tr>
</tbody>
</table>

Source: BusinessWeek, Oct. 11, 2004
Creating global Research Community

... new patent regime and abundant and competitively priced knowledge industry could catapult India into a global knowledge production centre.

..... R.A. Mashelkar

Financial Times
7th September 2004
Concluding Thoughts

- Serious disease burden threatens the poor despite the availability of effective medical tools.
- A small number of diseases affecting the poor require increased R&D, mostly to improve existing treatments.
- A new wave of initiatives and activities is emerging with a potential to tackle this problem – additional incentives are required.
- Several critical gaps should be addressed to facilitate R&D efforts for neglected diseases and that requires mobilisation of the entire global public health community.
Concluding Thoughts

We are each looking at the same problem

Innovation is the solution

Current system is not perfect but
IP incentives for innovation
must be preserved to
meet the needs of the developing world

Other elements of access and affordability
must be addressed in parallel and across
sectors

This can only be achieved in partnership and
through communication

IP, Public Health and Innovation must
be looked at comprehensively

We hope today begins a continuing dialogue

We must balance IP, Innovation and Public Health Goals
BACK UP SLIDES
# How Expensive are Medicines?

<table>
<thead>
<tr>
<th>Per Day treatment cost for common ailment</th>
<th>Rs.</th>
<th>Average cost of common goods &amp; services of daily consumption (one time)</th>
<th>Rs.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Asthma</td>
<td>0.45</td>
<td>Banana</td>
<td>1.00</td>
</tr>
<tr>
<td>Angina (Chest Pain)</td>
<td>0.55</td>
<td>Public Telephone</td>
<td>1.00</td>
</tr>
<tr>
<td>Diabetes</td>
<td>0.70</td>
<td>Egg</td>
<td>1.70</td>
</tr>
<tr>
<td>Common Allergy</td>
<td>0.75</td>
<td>Newspaper</td>
<td>2.00</td>
</tr>
<tr>
<td>Common Headache</td>
<td>1.00</td>
<td>Inland Letter</td>
<td>2.50</td>
</tr>
<tr>
<td>Amoebiasis</td>
<td>1.10</td>
<td>Cup of Tea</td>
<td>3.00</td>
</tr>
<tr>
<td>Diarrhoea</td>
<td>1.20</td>
<td>Bus Fare (Minimum)</td>
<td>3.00</td>
</tr>
<tr>
<td>Anti ulcer</td>
<td>1.40</td>
<td>Milk (half litre)</td>
<td>7.50</td>
</tr>
<tr>
<td>Common Cold</td>
<td>1.50</td>
<td>Suburban train ticket</td>
<td>10.00</td>
</tr>
<tr>
<td>Arthritis</td>
<td>1.50</td>
<td>Thali Meal</td>
<td>20.00</td>
</tr>
<tr>
<td>Blood Pressure</td>
<td>1.75</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Common Myths – Medicine Costs are too High

Reality: **Medicines = Small %age of Healthcare Expenditure**

<table>
<thead>
<tr>
<th>Category</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Doctor’s Fees</td>
<td>9%</td>
</tr>
<tr>
<td>Medicines</td>
<td>15%</td>
</tr>
<tr>
<td>Diagnostic Investigations &amp; Pathological Tests</td>
<td>24%</td>
</tr>
<tr>
<td>Hospitalisation</td>
<td>17%</td>
</tr>
<tr>
<td>Transport</td>
<td>20%</td>
</tr>
<tr>
<td>Miscellaneous</td>
<td>8%</td>
</tr>
<tr>
<td>Others</td>
<td>7%</td>
</tr>
</tbody>
</table>
R&D spend of top 10 Indian pharma companies

Average R&D spend of top 5 Indian pharma companies ~ 4.25%

Source: ASK RJ & Associates
Innovation-led Global Opportunities (R&D)

Low Costs, Faster Output Of Formulations Lure Drug Majors To Set Up Base Here

Global pharma cos eye India as R&D hub

Writankar Mukherjee
KOLKATA 20 FEBRUARY

HOW much does it cost an international pharma giant to develop a new blockbuster drug? Close to $850m per drug, of which nearly 70% is spent on clinical research and trials. And it is in this area that India, with its vast and diverse 'disease patient population', is now showing competence at nearly a third of the costs compared to the west.

Consequently, more and more pharma MNCs are stressing on India for their 'low-cost' R&D hub. Companies like Eli Lilly, Pfizer, Aventis, Novo Nordisk, GlaxoSmithKline, Merck, to name a few, are now leveraging their drug development activity through their Indian subsidiaries. The advantage — compression of the development cycle time of drugs. This allows for faster output of final formulations. After all, each day of delay to market a drug can cost more than $1m in sales.

"There is growing recognition for India as a centre contributing world-class quality data acceptable to major regulatory agencies worldwide, including the US FDA," Dr RS Nadig, medical director, Eli Lilly India, told ET. "There has also been a considerable improvement in the research environment in India," Chandrashekhar N Potkar, director, clinical research, Pfizer India, said.

Hence, Eli Lilly is increasing its R&D budget from Rs 8.5 crore in '02 to Rs 11 crore in '03. This calendar year may see the budget go up to Rs 11 crore. The company is mainly focusing on Phase II-IV work in therapeutic areas of diabetes, oncology, infectious diseases, critical care and women's health. It is also eyeing other allied activities, like developing central labs for clinical research.

Similarly, Aventis, which had earlier focused more on Phase II and IV studies in India, is now going for Phase III work as well in therapeutic areas of diabetes, cardiovascular and oncology. And Pfizer India has started to figure high on the priorities of Pfizer.

This is simply because, of the three phases of clinical research (start up, execution and close out), Pfizer has found that its Indian operations have a competitive advantage over the other global hubs in the study execution phase. Pfizer India is engaged in the full range of clinical research, from Phase II-IV studies to even biometric activities.

Industry sources informed that a few companies like Lundbeck, which have only marketing outfits in India, are now planning to set-up R&D centres. A few others, like Roche, still rely on the vast network of clinical research organisations in the country, but investment in the near future cannot be ruled out.
Ideal IPR policy for India

NATIONAL INTEREST

SCIENCE & TECHNOLOGY AND R&D

INTELLECTUAL PROPERTY RIGHTS

AVAILABILITY & MEDICINE PRICES

HEALTHCARE NEEDS
Ideal IPR policy for India

National Interest

• Increased Foreign Direct Investment
• Employment Generation for Knowledge Workers
• Improved International Credibility
• Accelerate GDP growth through Wealth Creation
• Alleviate Poverty thru` Growth in GDP/Capita
• Compliment Healthcare Aims of the Nation
Ideal IPR policy for India

- Availability & Prices Drugs
- Indian Pharma Market is 100% Generic today & even by 2005 will be 97% + Generic
- Over 95% of drugs in the WHO Essential List are out of Patent
- Even for Patented Medicines Several Therapeutic Equivalents available (e.g. over a dozen Antihypertensive categories)
- Competition, monitoring by National Pharmaceutical Pricing Authority (NPPA) and abundant availability of generics will stabilise prices
- Availability and Access are functions of Health Infrastructure and have no co-relation to Patents
Ideal IPR policy for India

Healthcare Needs of the Nation

• Medicines form only 15% of the Total Healthcare spend.

• Focus should be on Prevention (e.g. Sanitation, Hygiene, Immunisation, Vaccination, Clean Air, Water & Nutrition).

• Healthcare budget only 1.7% of the total Outlay (WHO Recommendation 8-10%).

• Modern Medicines can significantly contribute to Cost Effective Healthcare (Pharmacoeconomics).
Science, Technology and R&D

- Our own Scientists need protection for the Knowledge they create. India has highest Intellectual Capital per dollar.
- India has 3rd largest Scientific & most Cost Competitive Brainpower.
- Over 15% of Scientists in US Pharma Industry are of Indian Origin – can help Networking & Reverse the Brain Drain.
Role of the Industry

- Research expertise and resource
  - Target identification, HTS, optimisation, chemistry
- Experience in Clinical Development
  - Clinical trials, dosing, safety, efficacy
- Regulatory and manufacturing skills
  - Dossier preparation, process development
- Supply
  - Medical training, distribution
Development for “ALL” and “not FEW”
They deserve a “better tomorrow” …