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*INDIAN PHARMA-  
GLOBAL  
CONNECTION*

*p.u.m.rao*  
*Dept. of Chemicals & Petrochemicals*  
*Govt. of India*

# Quality

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The race for quality  
has no finish line.....

# *World Pharma Market 2006*

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- ⌘ **Global pharma revenues \$ 643 billion- growing by 7%.**
- ⌘ **Increase in biotech products. 10% of global sales.**
- ⌘ **Top five European markets- \$ 123 billion, Japan \$ 64 billion.**
- ⌘ **With USA, all the three make up 80% of market.**

## *World Pharma Market 2006(contd.)*

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- ⌘ **31 new molecular entities introduced.**
- ⌘ **Top 10-12 research based MNC pharma companies from US and Europe dominate the market.**
- ⌘ **One fourth of the 2300 products developed are biologicals.**
- ⌘ **Pfizer is at the top with \$ 50 billion sales.**

## *World Pharma Market 2006(contd.)*

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- ⌘ **High potential launches – Gardasil (vaccine for cervical cancer), Januvia (first in class for type II diabetes), Sutent for Renal cancer.**
- ⌘ **Major therapeutic classes sold –  
Lipid regulators (\$ 35.2 Bil.), Oncology products (\$ 34.6 Bil.) and Respiratory agents (\$ 24.6 Bil.)**
- ⌘ **Products losing patent production in 2006- excess of \$ 18 Bil.**

# *Leading Brands- 2006*

## *(Source-IMS Health)*

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<b>S.N</b>	<b>Brand</b>	<b>Company</b>
1	<b>Lipitor (atorvastatin)</b>	<b>Pfizer</b>
2	<b>Plavix (clopidogrel)</b>	<b>BMS</b>
3	<b>Nexium (esomeprazole)</b>	<b>Astra Zeneca</b>
4	<b>Seretide/Advair (fluticasone+salmeterol)</b>	<b>GSK</b>
5	<b>Zocor (simvastatin)</b>	<b>Merck</b>
6	<b>Norvasc (amlodipine)</b>	<b>Pfizer</b>
6	<b>Zyprexa (olanzapine)</b>	<b>Eli Lilly</b>
7	<b>Risperdal (risperidone)</b>	<b>J&amp;J</b>
8	<b>Ogastro(lansoprazole)</b>	<b>Abbott</b>

# *Recent Mergers and Acquisitions*

<b>Acquirer</b>	<b>Acquires</b>
<b>UCB, Belgium</b>	<b>Schwarz, Germany</b>
<b>Serono, Switzerland</b>	<b>Merck KGaA, Germany</b>
<b>Nicomed, Denmark</b>	<b>Altana Pharma, Germany</b>
<b>TEVA, Israel</b>	<b>Ivax, USA and Sicor Italy</b>
<b>Watson, USA</b>	<b>Andryx, USA</b>
<b>Sandoz, Europe</b>	<b>Hexal, Germany</b>
<b>Barr Labs. USA</b>	<b>Plica Croatia</b>
<b>Actavis Iceland</b>	<b>Amide Pharma USA</b>
<b>Hospira USA</b>	<b>Mayne Australia</b>

## *R&D Investment by Global Pharma Industry*

<b>2005 Rank</b>	<b>Company</b>	<b>Pharma R&amp;D Spend (\$ Bil)</b>	<b>% of Sales</b>
<b>1</b>	<b>Pfizer</b>	<b>7.4</b>	<b>16.7</b>
<b>2</b>	<b>Johnson &amp; Johnson</b>	<b>6.3</b>	<b>28.3</b>
<b>3</b>	<b>GlaxoSmithKline</b>	<b>5.7</b>	<b>16.8</b>
<b>4</b>	<b>Astra Zeneca</b>	<b>5.4</b>	<b>22.5</b>
<b>5</b>	<b>Sanofi-Aventis</b>	<b>4.8</b>	<b>14.9</b>
<b>6</b>	<b>Novartis</b>	<b>4.5</b>	<b>18.0</b>
<b>7</b>	<b>Roche (includes Chugai)</b>	<b>4.2</b>	<b>26.8</b>
<b>8</b>	<b>Merck</b>	<b>3.8</b>	<b>17.3</b>
<b>9</b>	<b>Eli Lilly</b>	<b>3.0</b>	<b>20.4</b>
<b>10</b>	<b>Amgen</b>	<b>2.3</b>	<b>19.2</b>

# *Global Pharma Developments*

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- ❑ **Investment Activities**
- ❑ **Mergers & Acquisitions.**
- ❑ **Prohibitive R&D costs**
- ❑ **Changing Regulatory environment**
- ❑ **Threat from generics**
- ❑ **Compulsions for outsourcing**



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*Indian Pharmaceutical  
Industry*

*Retail pharma sales Basket*  
*ORG IMS- JAN. 2006*

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<b>Group</b>	<b>Share %</b>
<b>Antibiotics, Anti bacterials</b>	<b>16</b>
<b>GI Related</b>	<b>11</b>
<b>Cardiovasculars</b>	<b>11</b>
<b>Respiratory</b>	<b>10</b>
<b>Vitamins, Mineral Supplements</b>	<b>10</b>
<b>Pain management</b>	<b>10</b>
<b>Dermatological</b>	<b>6</b>
<b>CNS Related</b>	<b>5</b>
<b>Others including Gyane</b>	<b>21</b>

# ***Indian Pharma Industry Profile contd.***

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- ⌘ **Country ranks 4<sup>th</sup> world wide accounting for 8% of world's production by volume.**
- ⌘ **Excellent performance in Gold standard market.**
- ⌘ **Strength of industry- developing cost effective technologies, excellent human resource skills**
- ⌘ **Maintain SHE requirements in production**

# ***Indian Pharma Industry Profile contd***

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- ⌘ **Sourcing by original innovator cos.**
- ⌘ **India emerging as the hub for collaborative research, Co development and Co-marketing**
- ⌘ **The global presence in the critical antiretroviral supply is now part of history.**
- ⌘ **Development of cost effective non infringing processes.**
- ⌘ **India emerging as the hub for collaborative research, Co development and Co-marketing**

# *INDIAN PHARMA INDUSTRY IN STATE OF TRANSITION*

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- ❑ Bringing new products at a never before frequency.
- ❑ Bigger players have gone on a brand acquisition spree to strengthen their brand portfolios and positions.
- ❑ Mergers and alliances at a never before pace.
- ❑ Creating world class R&D centres for new drug discovery R&D.
- ❑ Spending significant proportion of profits on R&D.

## *Region wise share of pharma exports 2005-06*

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<b>Region</b>	<b>Destinations</b>	<b>Share%</b>
<b>Europe</b>	<b>39</b>	<b>25 . 0</b>
<b>Asia</b>	<b>29</b>	<b>20 . 7</b>
<b>North America</b>	<b>11</b>	<b>18.7</b>
<b>Africa</b>	<b>50</b>	<b>13. 0</b>
<b>West Asia</b>	<b>15</b>	<b>7. 0</b>
<b>CIS</b>	<b>10</b>	<b>7. 7</b>
<b>South America</b>	<b>13</b>	<b>5. 5</b>
<b>Australia Pacific</b>	<b>17</b>	<b>0. 9</b>
<b>Caribbean</b>	<b>18</b>	<b>0. 9</b>

# *Export of Drugs, Pharmaceuticals & Fine Chemicals from India (2005-2006)*

## *Leading regulated markets*

<b>Country</b>	<b>Value (US \$ Mil)</b>	<b>% Share Dosage exports</b>
<b>USA</b>	<b>680</b>	<b>40</b>
<b>Germany</b>	<b>236</b>	<b>22</b>
<b>Russia</b>	<b>233</b>	<b>36</b>
<b>UK</b>	<b>182</b>	<b>63</b>
<b>China</b>	<b>169</b>	<b>12</b>
<b>Brazil</b>	<b>137</b>	<b>46</b>
<b>Nigeria</b>	<b>114</b>	<b>87</b>
<b>Canada</b>	<b>110</b>	<b>11</b>
<b>South Africa</b>	<b>98</b>	<b>51</b>
<b>Turkey</b>	<b>95</b>	<b>29</b>
<b>Ukraine</b>	<b>95</b>	<b>97</b>
<b>Italy</b>	<b>91</b>	<b>7</b>
<b>Vietnam</b>	<b>89</b>	<b>55</b>
<b>Netherlands</b>	<b>86</b>	<b>53</b>
<b>Singapore</b>	<b>84</b>	<b>16</b>
		<b>\$ 1 equiv. to Rs. 45</b>

# ***LIST OF NEW BULK DRUGS EXPORTED***

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- ❑ Amlodipine
- ❑ Valdecoxib
- ❑ Saquinavir
- ❑ Pantaprazole
- ❑ Ramipril
- ❑ Glimiperide
- ❑ Nateglinide
- ❑ Paroxetine
- ❑ Olanzapine
- ❑ Sertraline
- ❑ Lorazepam
- ❑ Clopidogrel
- ❑ Gatifloxacin

- Zopiclone
- Lisinopril
- Paclitaxel
- Sibutramine
- Quinapril
- Venlafaxine
- Fexofenadine
- Trovalfloxacin
- Buflomedil
- Efavirenz
- Didanosine
- Candesartan
- Quetiapine

- Ritanovir
- Fluvastatin
- Irinotecan
- Alendronate
- Carvedilol
- Anastrozole
- Tioconazole
- Cilastatin
- Citalopram
- Losartan
- Zaleplon
- Zolpidem
- Fosinopril

## *Major API Exports(2005-06)*

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<b>Product group</b>	<b>Rs. Crores</b>
<b>Menthol</b>	<b>477</b>
<b>Erythromycin</b>	<b>273</b>
<b>Amoxycillin</b>	<b>188</b>
<b>Cephalexin</b>	<b>132</b>
<b>Ibuprofen</b>	<b>124</b>
<b>Ciprofloxacin</b>	<b>114</b>
<b>Ranitidine</b>	<b>113</b>
<b>Cefadroxyl</b>	<b>89</b>

*Major Dosage Form exports  
(2005-06)*

<b>Product group</b>	<b>Rs. Crores</b>
All anti infectives	4440
Pencillin group	1288
Nutritional group	916
NSAIDS, Analgesics	614
Cardiovasculars	412
Anti Ulcers	397
Ayurveda products	248
Hormonals	184

# Pre and Post 1970 Scenario

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- \* **Prior to 1970**

- \* **85% market with foreign companies**

- \* **15% market with domestic companies**

- \* **1970 – Process Patents introduced for pharmaceuticals**

- \* **At present**

- \* **85% market with domestic companies**

- \* **15% market with foreign companies**

# ***Regulatory Framework***

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- \* Drug (Price Control) Order, 1995 – for control of prices of specified drugs**
- \* Indian Patents Act, 1970 – As on 1<sup>st</sup> January 2005 provides product patent for drugs, food and agro-chemicals**
- \* New drugs, imports, clinical trials, drug standards approved by Central Government Enforcement by States**
- \* Registration system streamlined for import of drugs – both site and product registration**
- \* Cabinet approval for forming Central Drugs Authority.**
- \* Draft Pharma policy with GOM.**

# ***Recent Changes in Drugs & Cosmetics Act and Rules***

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- \* Upgraded Schedule M in place**
- \* Schedule "Y" amended for multi-centric concurrent clinical trials as per GCP**
- \* GMP – realigned as per international guidelines GCP – India's requirements on GCP published as guidelines**
- \* GLP – monitoring authority set up for pre- clinical (toxicological) studies**

# MNC-India partnership

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- ❁ MNCs who left earlier are back on Indian shores with WOS .
- ❁ World generic companies like TEVA, Apotex , Hexal Pharma, Altana Pharma have also set up bases in India specially for carrying out R&D in Pharma.



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# *Research & Development*

# Research & Development

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- ⌘ **Global R&D costs.**
- ⌘ **India an attractive destination for R&D**
- ⌘ **Positive effects from introduction of product patents.**
- ⌘ **Government initiatives.**

# **Research & Development (contd.)**

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- ⌘ Now 10-12 leading Indian companies engaged in drug discovery.**
- ⌘ Some are spending over 6% to 10% of their sales turnover towards R&D.**
- ⌘ The areas covered are Cancer, diabetic, anti infective, asthma segments**

# Some promising candidates

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<b>Company</b>	<b>Molecule</b>	<b>Indication</b>
<b>Ranbaxy</b>	<b>RBX11160</b>	<b>Malaria</b>
<b>Dr. Reddy's Labs</b>	<b>DRF10945</b>	<b>Obesity</b>
<b>Dr. Reddy's Labs</b>	<b>DRF1042</b>	<b>Cancer</b>
<b>Glenmark</b>	<b>GRC8200</b>	<b>Diabetes</b>
<b>Wockhardt</b>	<b>WCK771</b>	<b>Infection</b>

# Indian drug R&D pipeline

<b>Company</b>	<b>Categories worked on</b>
<b>Dr. Reddy's Labs</b>	<b>Cardiovascular, Infections, Diabetes and Cancer</b>
<b>Ranbaxy</b>	<b>Infectious, Respiratory, Urinary disuses and Diabetes</b>
<b>Orchid Pharma</b>	<b>Inflammatory and infectious diseases, Cancer and Diabetes</b>
<b>Glenmark</b>	<b>Respiratory and Inflammatory, Diabetes and Obesity</b>
<b>Zydus Cadila</b>	<b>Diabetes, Inflammation, Obesity, Novel Drug Delivery</b>
<b>Nicholas Piramal</b>	<b>Inflammation and Diabetes</b>
<b>Dabur Pharma</b>	<b>Oncology</b>
<b>Torrent Pharma</b>	<b>Obesity, CVD</b>
<b>Wockhardt</b>	<b>Infections</b>
<b>Sun Pharma</b>	<b>Allergy, Drug delivery systems</b>



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*Opportunities for Indian  
companies*

# Contract Research

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- ⌘ **Indian specialist API producers work with innovator pharma giants abroad for supply of NCEs, advanced intermediates for discovery compounds (custom synthesis).**
- ⌘ **Contract Research at \$ 19 Billion to go up to \$ 40 Billion in 2010.**
- ⌘ **Drugs Discovery outsourcing \$ 4 Billion in 2005 to go up to \$ 7 Billion in 2009**
- ⌘ **India's drug discovery services in 2005 reportedly valued at \$ 470 Million in 2005.**

**Source- Frost & Sullivan report**

# CLINICAL TRIALS

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- ⌘ **Western Clinical Research Organisations(CRO) identified India as an important set up for clinical trials.**
- ⌘ **International CROs Quintiles, Icon clinical, Pharma Olam are already in India to conduct clinical trial, ECG services and data management.**
- ⌘ **Leading MNCs like Pfizer, J&J, GSK, Eli Lilly, Novartis, Altana Pharma have made India a hub for clinical trials and running their Phase II & Phase III clinical trials.**

# *Discovery Services in India*

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<b>Company</b>	<b>Area of Work</b>
<b>Avra Labs., Hyderabad</b>	<b>Product chemistry, Organic synthesis, Chiral synthesis</b>
<b>Bhairavi Labs, Bangalore</b>	<b>Medicinal chemistry, Drug discovery services</b>
<b>Innovasynth, Mumbai</b>	<b>Medicinal chemistry , CRAM</b>
<b>Sai Lifesciences, Hyderabad</b>	<b>Medicinal chemistry services</b>
<b>Shasun Chemicals, Chennai</b>	<b>CRAMS, Medicinal chemistry</b>
<b>Suven LS Hyderabad</b>	<b>CRAM discovery services, Clinical trials and collaborative research</b>

# Cooperation areas

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- ❑ Sourcing APIs, Dosage forms from India to cut down healthcare costs.
- ❑ Joint Venture Cooperation.
- ❑ Other areas

# Conclusion

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**To conclude, for global companies who have their vision focused right on any activity in the entire gamut of Drug Development to manufacturing, India is a must- not- miss destination for them.**



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**Thank You !**