ELGA Biotech

Healthcare Pharmaceutical Sciences and Biotechnology: Opportunities for Indo-German Cooperation

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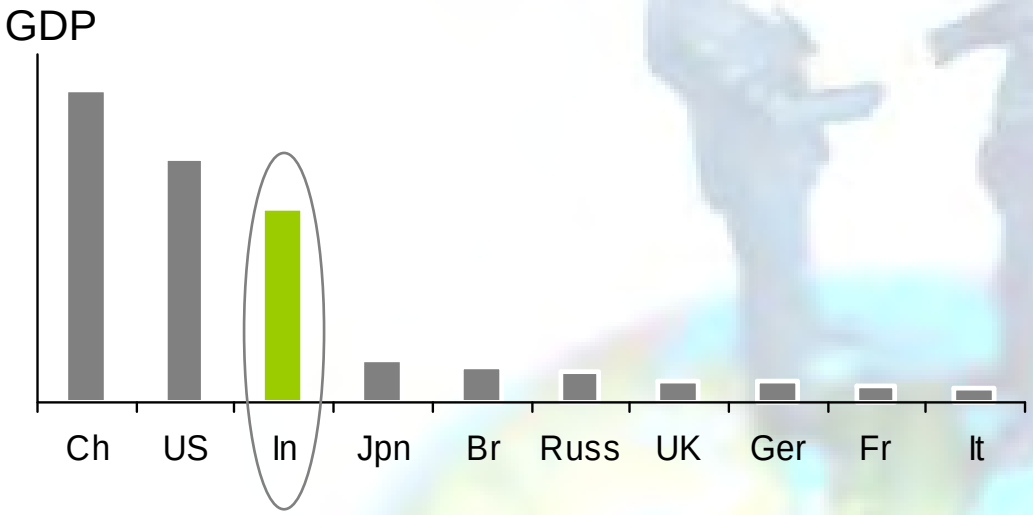
- **General Information**
- **Pharma/Biotech industry in India**
- **Pharma Biotech industry in Germany**
- **What are important areas relevant to Indo-German Cooperation?**
- **What are the available Platforms that support Indo-German Cooperation**

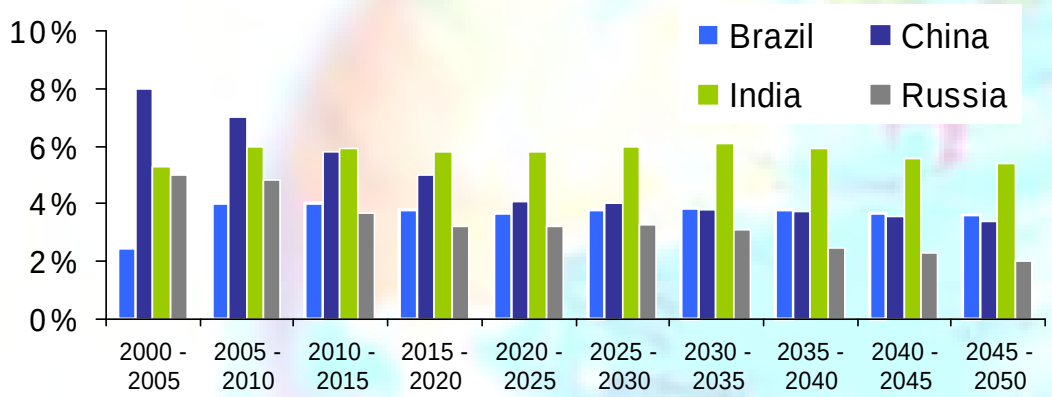
India today – current key figures

- Total population: **1,028 mill.**
- 29 States and 6 Union Territories.
- GDP: nearly **US$ 1,000 bn. (+ 9%)**
- Chemical Ind. in GDP: **13%**
- Average inflation rate: **4.5% (2007)**
- Exports: **US$ 124 bn.**
- Imports: **US$ 170 bn.**
- Interest rate: **7.5 %**
- Forex Reserves: **US$ 247 bn**.
- Literacy: **68%**
- Developing health care system @ **13%** (Source: CII Report)
- **$ 30.8 bn** Chemical Industry expected to grow to **$ 60 bn** by FY 2010. (*Source: ICMA*)
- Pharma export to regulatory market on the rise.
- R&D is witnessing high investments
- Rapid growth of new markets as Clinical / Custom Research Organizations

India is poised to become a strong economy over the next 15-20 years



India is projected to be the third largest economy by 2050



Of the BRIC countries only India maintains 5% GDP growth through 2050

Source: “India: Realizing BRICs Potential”, Goldman Sachs

Healthcare Challenges & Opportunities in India

- Obesity is a serious problem in India. Seventy-six per cent of women in the capital, New Delhi, are suffering from abdominal obesity, according to a survey by the All-India Institute of Medical Sciences. Authored by Anoop Misra.
- The issue of obesity bring other related problems along, from diabetes to heart failure. An estimated 25 million Indians have diabetes, and this is forecast to grow to 57 million by 2025.
- According to a WHO study 60% of Indian population will suffer from coronary heart diseases.
- Infectious diseases remain prevalent.
- Modern day diagnostic technology is available only to a fraction of the population.
- With the growth in middle-income population, demand for good health services is increasing.
- Medical tourism requires top of the line medical facilities.

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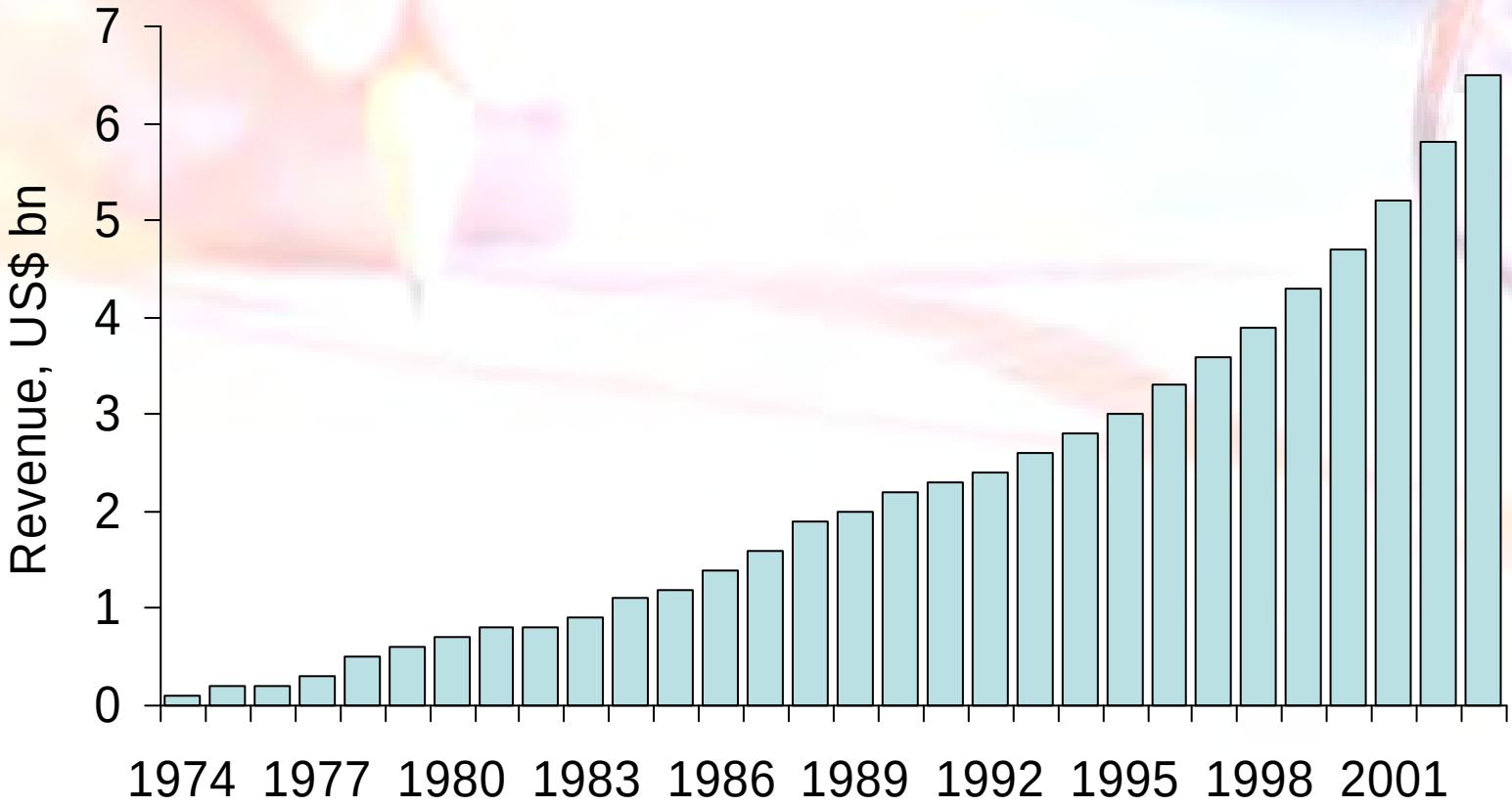
Facts about Indian Healthcare Industry

- Well developed pharmaceutical industry with strong manufacturing base, growing close to 10% annually.
- Climbing the value chain from bulk drugs to formulation.
- Global no. 4 with 8% in volume and 2% in value. The largest number of USFDA approved manufacturing facility in any country outside USA.
- More than 45% (close to € 4 bn) exported to 200 countries incl. U.S. and Europe.
- The industry with over 10,000 manufacturing units remain fragmentary but consolidation is taking roots.
- Clinical Laboratory Services dominated by few big players.
- Laboratory equipment manufacturing is rudimentary.
- Most equipments for clinical and R&D services are imported.
- With new hospitals coming up like mushrooms, the demand for equipments is expanding rapidly.
- India is emerging as the global hub for contract research and manufacturing services (CRAMs) due to its low cost advantage and world class quality standards.

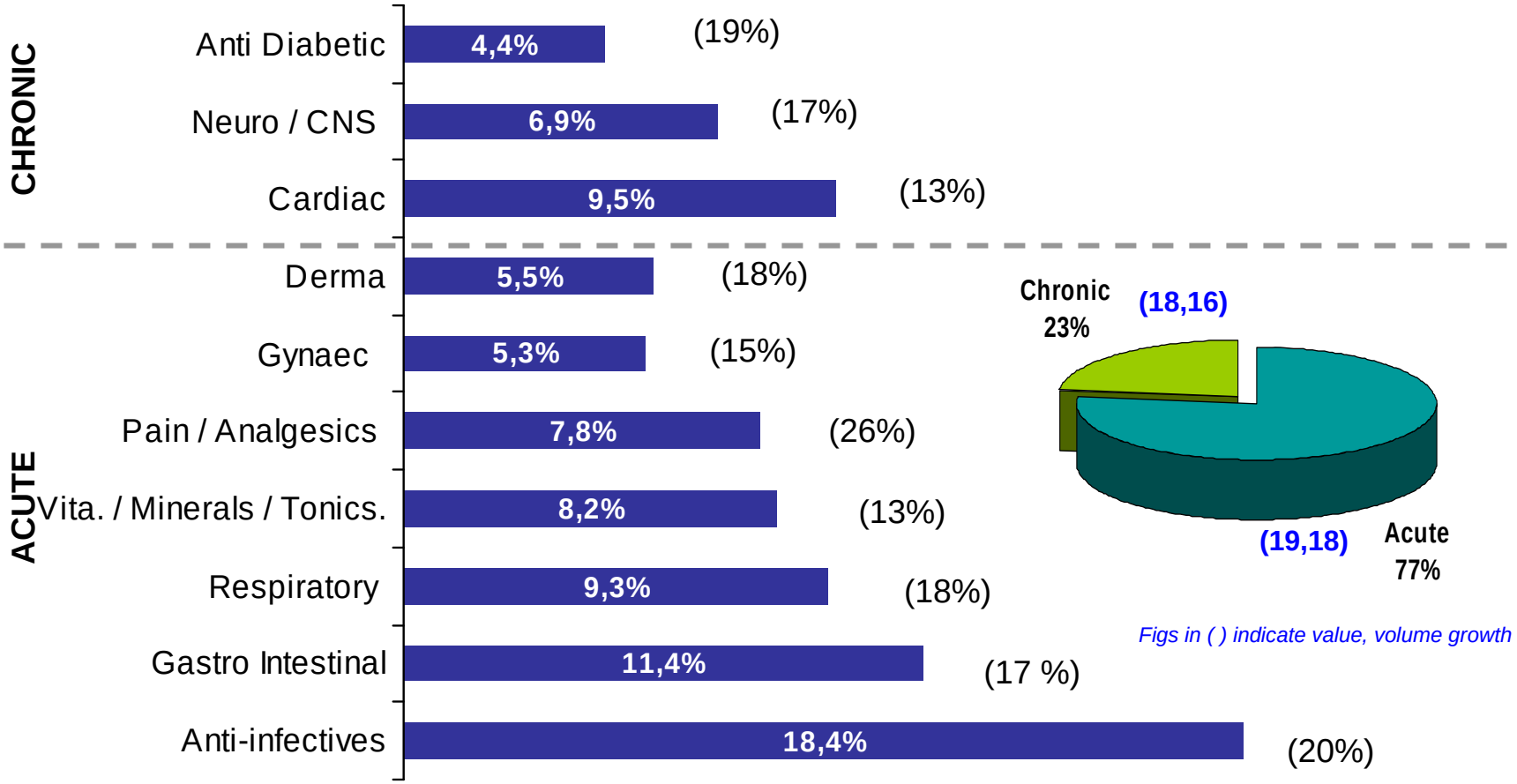
  Nicholas Piramal, Shasun Chemicals, Divi's Lab, Dishman Pharma, Cadila Healthcare, Lupin, Matrix Lab and Aurobindo Pharma are some of the companies which have witnessed impressive growth in revenues from their CRAMs business under various tie-ups with global pharmaceutical majors.

Growth in Drug Production in India



Therapy Split

Although there is a steady shift to chronic therapy, both therapies have shown similar GR this year

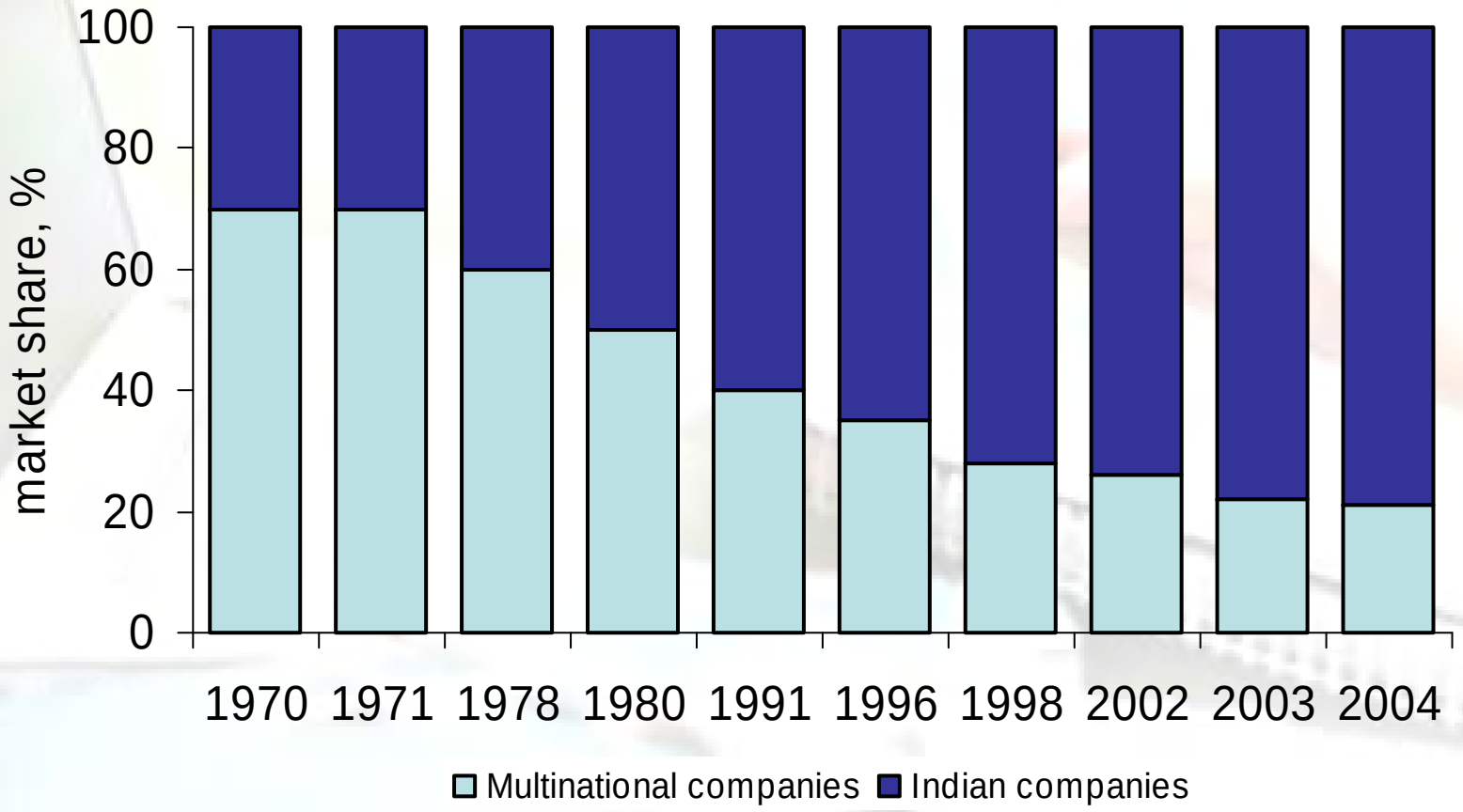


*Source ORG-IMS SSA Jan 07; selected therapeutic areas only From Dr. Dziki

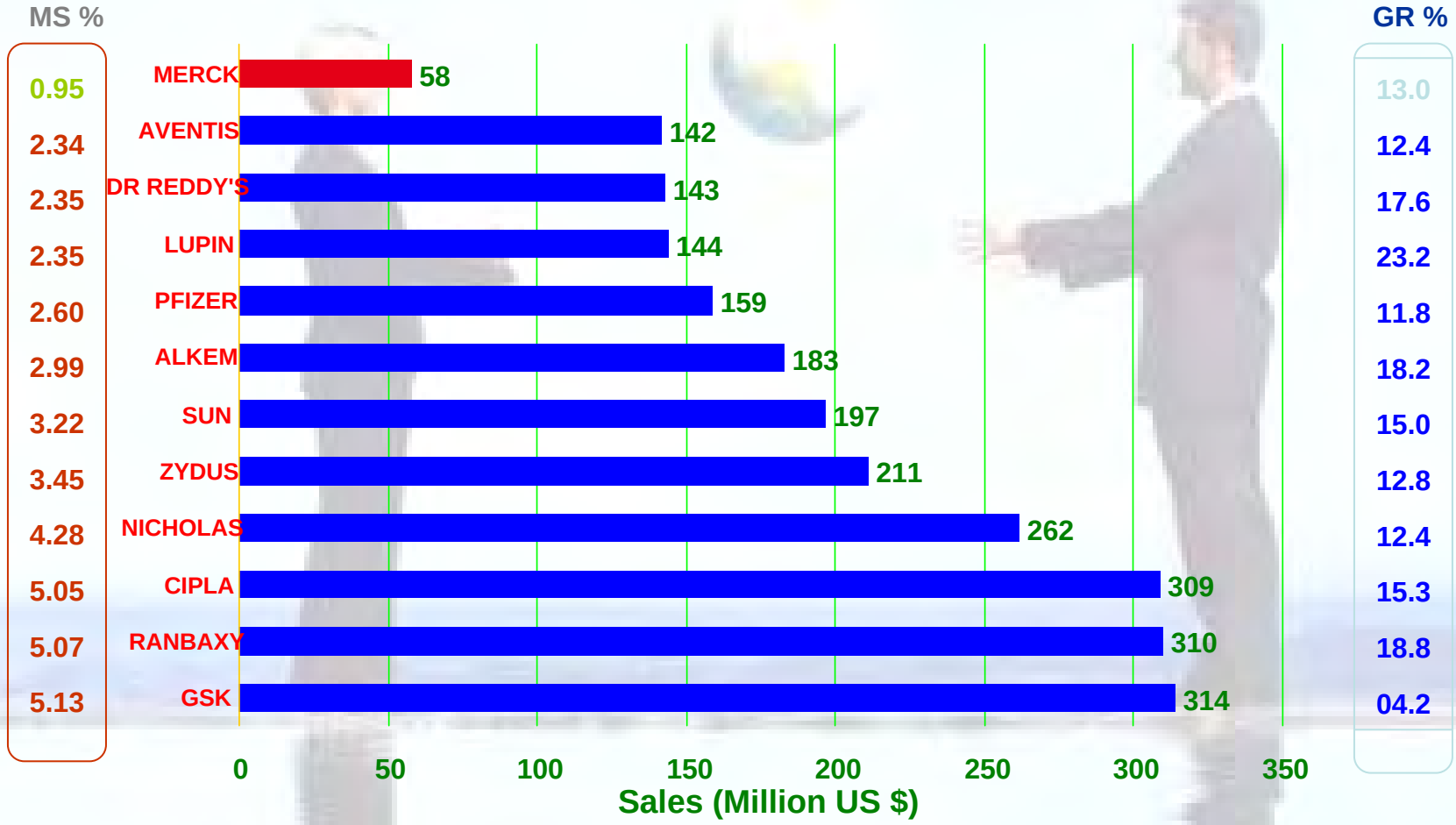
Liberalisation → Innovation → Growth

- Liberalisation and globalisation initiated in 1991 has produced a pressure on Indian Pharmaceutical and biotechnology industry to innovate.
- New IPR regime in compliance with TRIPS agreement under WTO: Shift from Process patent to Product patent regime – will protect all New entrants / entities from 2005.
- New patent regulations is causing a major structural shift with the entry of foreign players.
- Foreign Direct Investment (100 %) has been allowed without prior Govt. approval in most of the cases.

Native Companies dominate India‘s Pharmaceuticals Market



Only three MNCs rank among the Top 10 companies taking 36% share of the Indian Pharma Market



Source : Dr. Dziki and ORGIMS SSA Jan 2007

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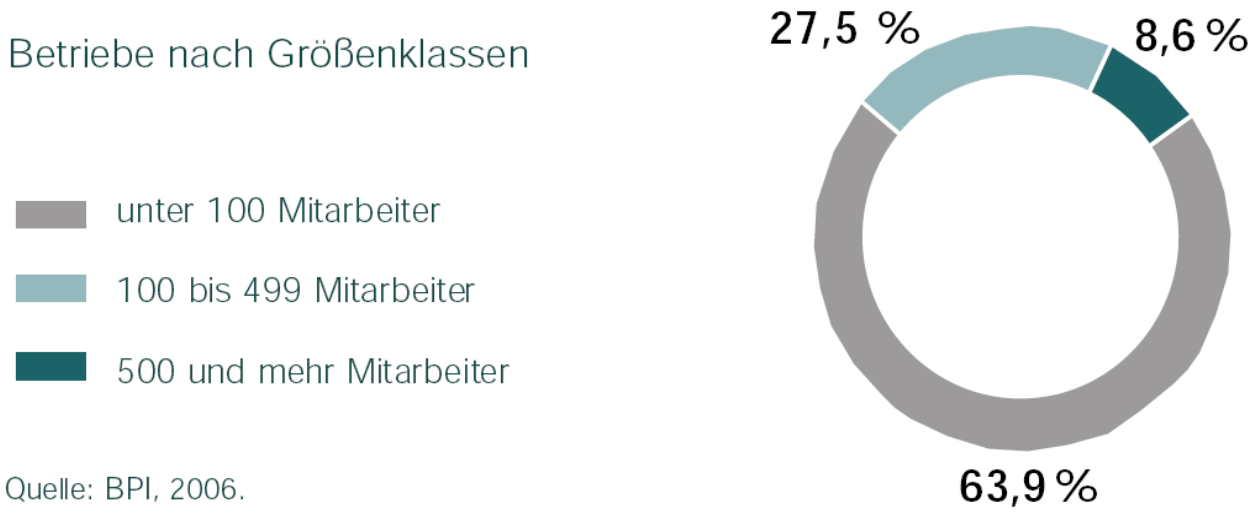
German Pharma Market

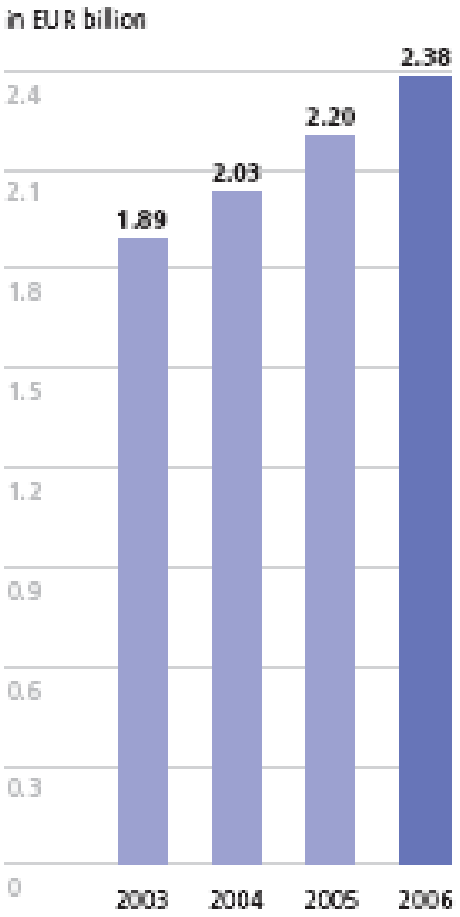
Industry Structure

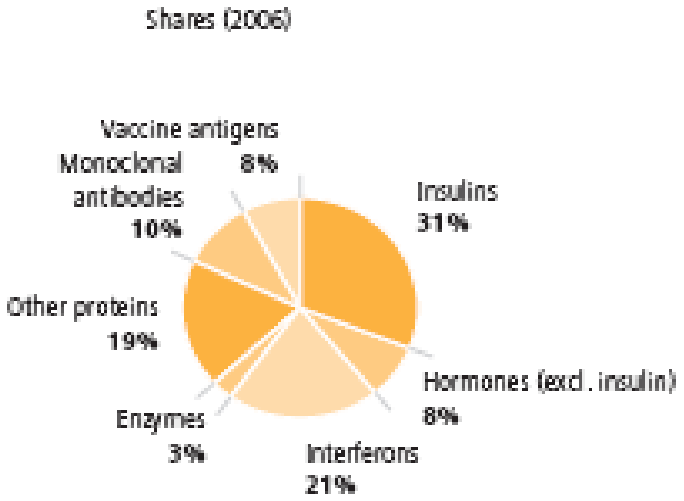
Germany is the largest pharma market in the EU and the third largest in the World after USA and Japan

- **1,024 companies, ranging from SMEs with < 20 (336) staff to MNC affiliates thereof 391 biotech companies.**
- **Pharmaceutical market volume is 37.8 billion Euro**
- **More than 90% of the companies have < 500 staff.**
- **Nearly 90% have international activities.**
- **In most cases, however, the revenue is generated in the domestic market.**



Sales of Genetically Manufactured Pharmaceuticals





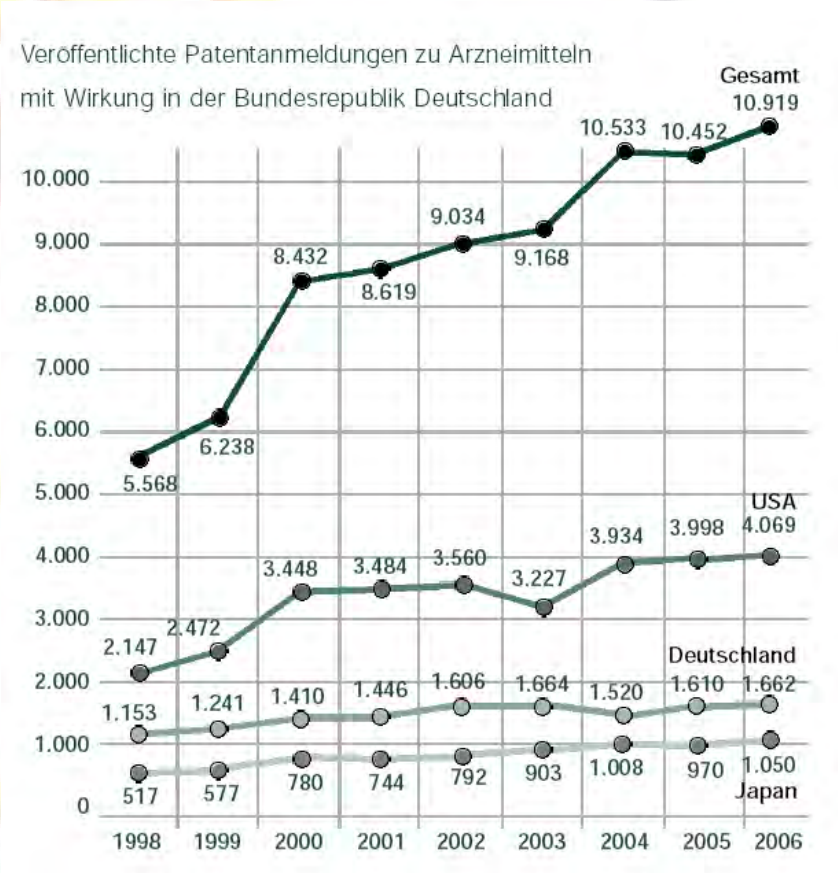
Sales at manufacturers' prices in the pharmacy market

Source: InsightHealth, VFA

No. of European patent applications is constantly growing

- Total no of patent applications for new drugs: 10,919 (+4.5%)
  - German applications accounted for in total: 1664 (= 5.2%)
  - German applications for NBEs:146 (-7.0%)
- 4.552 patents were assigned
  - Germany accounted for 765 (=6.9%)

High R&D expenditures over the past few years made it possible to launch 23 new molecular entities (NMEs) in the German market in 2005, most of which focused on innovative therapeutic drugs for cancer.



German Pharma Market
R&D

- **Consolidation in German Pharma Industry:**
  - ongoing concentration of European Pharma Industry
    - merger Bayer / Schering
    - acquisition Merck KGaA / Serono
    - acquisition Nycomed /Altana
    - acquisition UCB / Schwarz Pharma

  and

  - increase in investmen in R & D from EUR 2.3 bn (1980) to EUR 22.5 bn (2006)

→ the number of new drugs has considerably shrunk

- Key risk factors for new drugs
  - regulatory approval (centrally ruled in Europe)
  - reimbursement by health insurances (country specific)

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Solution to growth?

Co-operation between Pharmaceutical industry and innovative biotechnological companies

Synergy in Biotech/Pharma R & D through Cross-Border Partnership

Competitiveness = Innovation

- Innovation is a social process
- Innovation is NOT just technology – it is networking through partnership to make optimal use of knowledge
- Thus innovative scenario is created by partners each providing a cutting edge technology
- Globalisation of innovation is the answer to problems faced by many pharma/biotechnology companies

Globalisation of Innovation: Trends and opportunities in India

Can India be a worthy partner for Europe?

- **Strengths**
  - Highly qualified and less expensive manpower
  - Strong knowledgebase supported by highly developed IT-enabled services
  - Well net-worked laboratories at Universities and research Institutes
  - Rich biodiversity with highly homogenous ethnic population pockets
  - Well developed pharmaceutical and agro industries
  - Access to intellectual and capital resources from Indian scientific diaspora
- **Weaknesses**
  - Research and commercialisation remain apart
  - Lack of venture capital
  - Relatively less R&D emphasis and expenditure
  - Lack of innovative R&D culture and poor IPR protection
  - Poor brand name of Indian industries

Potential areas of collaboration

Drug Discovery
-Target validation
-Animal studies
-Genomics
-In silico computational modelling
-Biologics

Drug candidates
-Custom synthesis
-Combinatorial synthesis
-Library of plant products
-Biopharmaceuticals

cGMP manufacturing
-Chemical compounds
-Vaccines
-Biogenerics
-Biologics

Clinical Trials
-CROs
-Safety & Toxicity
-Multi-centre trials
-Anti-infectives

Indian companies can become strong partners for developing therapeutically active biologics

Human proteins and peptides

- Insulin, Epo, Growth Hormone etc.
- Peptide antagonists

Enzymes and Cytokines

- tPA, Streptokibnase, Interferon,Interleukins

Therapeutic antibodies

- Humanised antibodies for cancer
- Anti-angiogenic molecules

Vaccines

- Hepatitis, Dengue virus, Smallpox, Anthrax
- TB, Malaria
- Cancer vaccines, DNA-based vaccines

Diagnostics

Major constraints for a fast track Biotechnology development in India:

- Limited Venture capital support
- Unclear legal framework with respect to the export of genetic material and genetically altered organisms
- Uncertainity in data security
- IPR protection

Examples of Recent R&D Deals between Indian and Foreign Companies:

- License Agreement between **Torrent Pharmaceuticals Ltd. and Novartis Pharma AG**, for global rights to its patented AGE (Advanced Glycosylation Endproducts) breaker compound. AGE breaker compounds have potential in the treatment of heart disease and diabetes related vascular complications.
- **Glenmark Pharmaceuticals Inc (GPI)**, has signed a $27 million royalty deal with international healthcare investment fund Paul Capital Partners' Royalty Fund to finance the development of 16 dermatological products by GPI for the US market.
- **Merck KGaA and Glenmark Pharmaceuticals** announce Collaboration Agreement on DPPIV (Dipeptidyl peptidase IV) enzyme Inhibitor for Type 2 Diabetes.
- Indian company **Advinus Therapeutics** has signed a deal with **Merck & Co. (USA)** to jointly develop two metabolic drugs. Advinus expects to gain $74.5 million for each product and has also received an undisclosed up front payment. Additionally, Advinus will receive royalty payments on sales of the drugs.

“India is positioned to grow into a major R&D center for biotechnology companies”

G Steven Burrill is CEO of Burrill & Company, a life sciences merchant bank engaged in three core activities - venture capital investment, strategic partnering and strategic advisory services.

Pharmabiz.com, June 2004.


Thank You!