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PHARMACEUTICALS

September 2009

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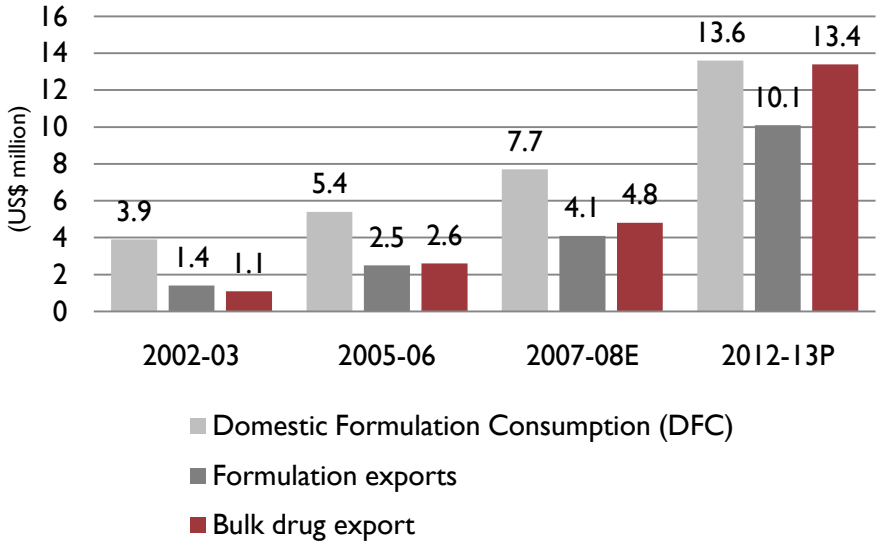
The focus of this presentation is to discuss…

- Market overview
- Policy
- Key trends and drivers
- Key players
- Key opportunities

Indian pharmaceutical market — US$ 7.3 billion opportunity

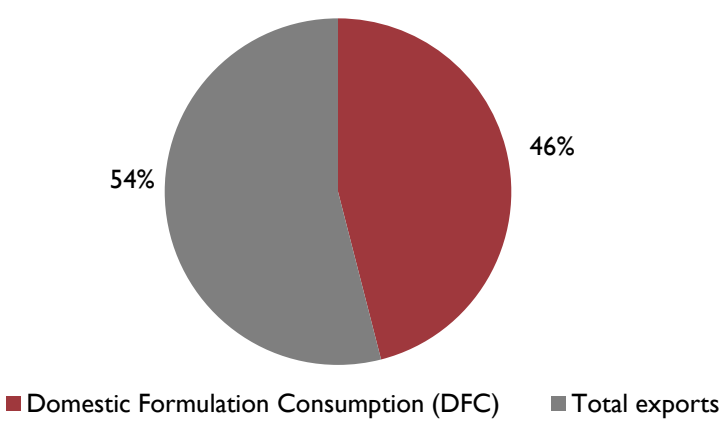
- India is among the fastest growing pharmaceutical markets in the world.
- The pharmaceutical market was worth US$ 16.6 billion in 2007–08; the domestic retail market is expected to cross the US$ 10 billion mark in 2010 and reach an estimated US$ 12 billion to US$ 13 billion by 2012.

Domestic pharma retail market



Source: Pharmaceuticals: industry profile, Dec 2008, CRIS INFAC

Break up of Indian pharma industry

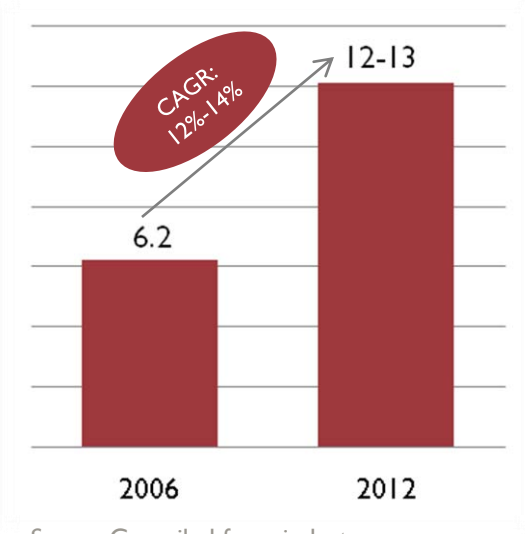


Source: Pharmaceuticals: industry profile, Dec 2008, CRIS INFAC

Indian pharmaceutical market — US$ 7.3 billion opportunity

- The outsourcing opportunity is set to grow to US$ 53 billion in 2010 from US$ 26 billion in 2006.
- Retail sales of pharmaceuticals were US$ 7.7 billion in 2007–08.
- Domestic consumption accounted for nearly 46 per cent and exports for the remaining 54 per cent of total industry revenues.

Forecasted Indian pharmaceutical retail market in US$ bn



Source: Compiled from industry sources

Anti-infectives — largest therapeutic category

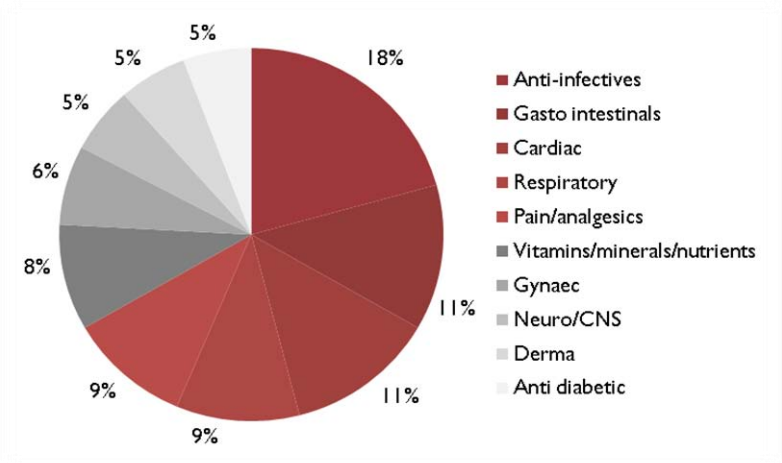
- The anti-infectives segment was the highest contributor (18 per cent) to total domestic sales in 2007–08.
- Cephalosporins, penicillins and quinolones are key drug classes among anti-infectives.
- Gastrointestinal and cardiac are the second- and the third-largest therapeutic categories, respectively.
- Oral anti-diabetics and anti-peptic ulcerants are the fastest growing therapeutic segments under alimentary and metabolism therapeutic categories.

Source: Pharmaceuticals: industry profile, Dec 2008, CRIS INFAC

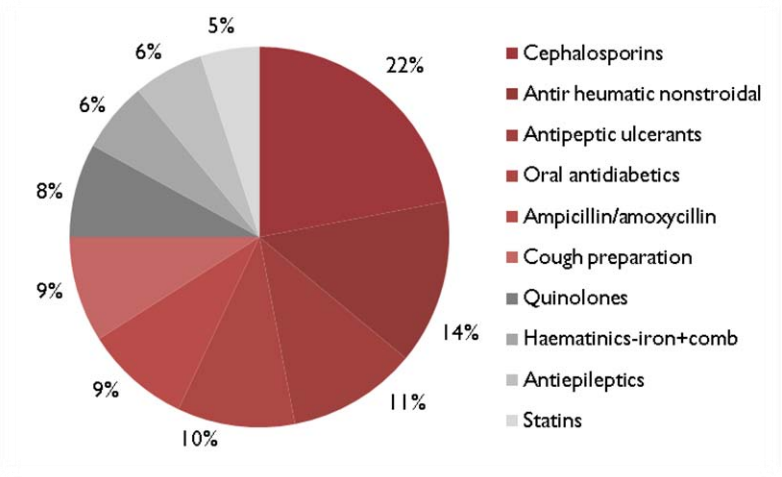
Anti-infectives — largest therapeutic category

- Cholesterol reducers have emerged as a key class of cardiovascular drugs in the last few years.
- Anti-epileptics accounted for 35 per cent of total revenues of the central nervous system (CNS) segment in 2007–08.

Market share of key therapeutic categories (2007–08)



Market share of key drug classes (in %, 2007–08)

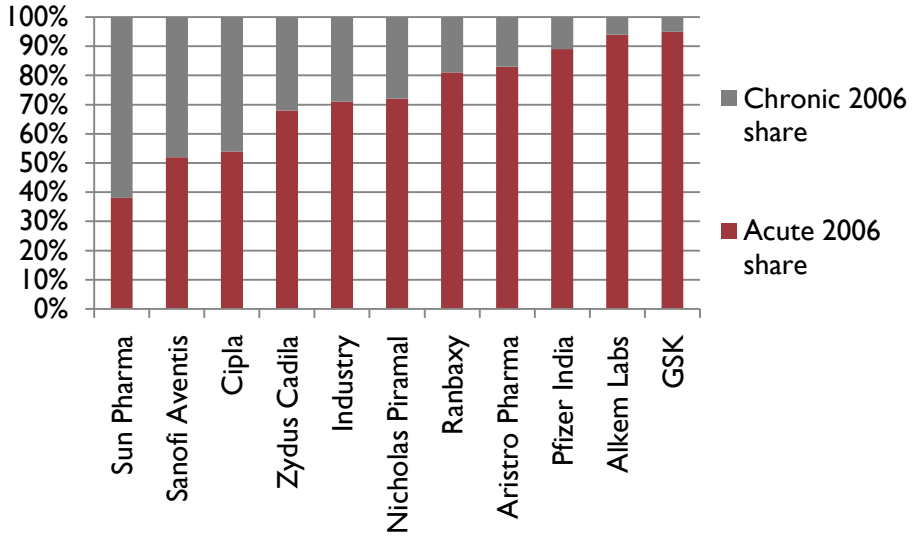


Source: Pharmaceuticals: industry profile, Dec 2008, CRIS INFAC

Acute therapy dominates sales, chronic segment to fuel growth

- Chronic therapy contributes 22 per cent to total revenues and acute therapy dominates with a share of 78 per cent.
- New products launched in the chronic therapy segment outnumbered acute segment launches in 2006.
- The acute segment is expected to grow at a steady pace due to its mass therapy nature and unresolved issues of sanitation and hygiene in the country.

Acute vs. chronic sales mix of top 10 Indian pharmaceutical companies



Source: Pharmaceuticals: industry profile, June 2008, CRIS INFAC

Acute therapy dominates sales, chronic segment to fuel growth

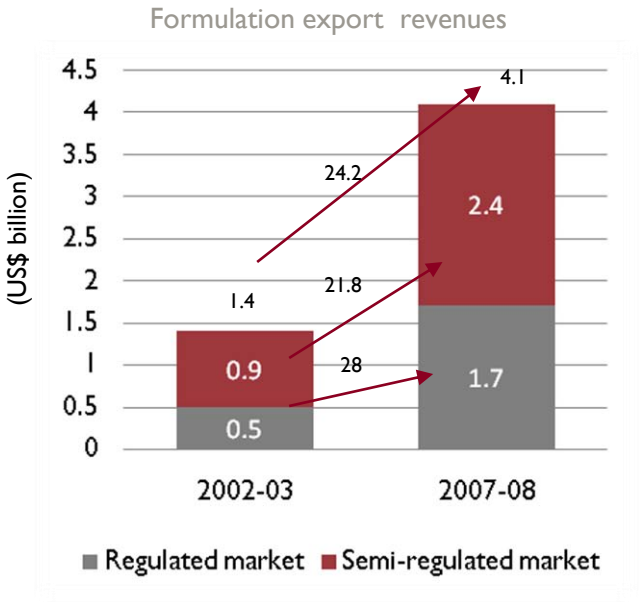
Key drivers of chronic therapy segments

- **Growing geriatric population:** 4.9 per cent of the total Indian population in 2005 consisted of the 65+ age group. This is further expected to increase to 6.4 per cent by 2015 and 7.5 per cent by 2020.

- **Rapid urbanisation**: An increasing number of people are suffering from lifestyle diseases such as diabetes, obesity, depression, etc., due to rapid urbanisation. The urban population has grown by 31 per cent in a decade — from 217 million in 1991 to 285 million in 2001 — as against 18 per cent population growth in rural areas.

Indian pharmaceuticals exports

- For 2007–08, export revenues are estimated to be around US$ 8.9 billion.
- Formulation exports are estimated to constitute 46 per cent of total revenue, while bulk drugs are estimated to account for 54 per cent.
- Revenues from formulation exports are expected to surpass those from bulk drugs by 2010–2011.
- By 2012, exports are expected to top US$ 23.5 billion, with most of the value generated by generics and active pharmaceutical ingredients (API).



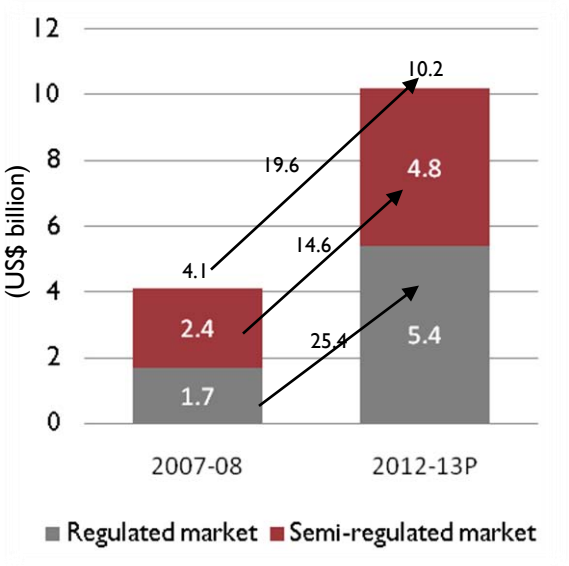
Source: Pharmaceuticals: industry profile, Dec 2008, CRIS INFAC

Indian pharmaceuticals exports

Demand from regulated markets bound to increase

- Exports to regulated markets are expected to surge at a compound annual growth rate (CAGR) of 25.4 per cent between 2007-08 and 2012-13. In comparison, exports to semi-regulated markets clocked a CAGR of 14.6 per cent from 2000 to 2005.
- Formulation exports to regulated markets are expected to grow at a high CAGR of over 25.4 per cent to reach US$ 5.4 billion by 2012-13.
- Demand from semi-regulated regions is estimated to grow at a modest CAGR of around 14.6 per cent and reach US$ 4.8 billion in the same period.

Formulation exports demand outlook

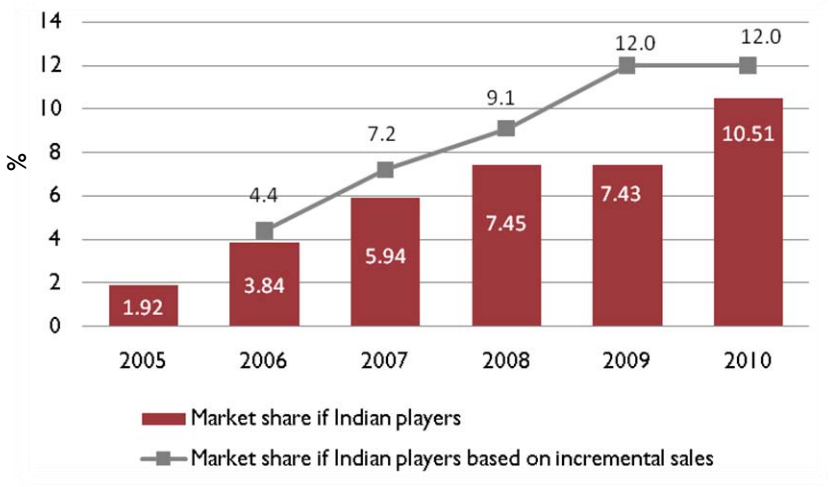


Source: Pharmaceuticals: industry profile, Dec 2008, CRIS INFAC

Generics to drive growth of exports from India

- By 2011-12, the share of Indian players in the US generic market is expected to cross 6 per cent from 2.1 per cent in 2006-07.
- Formulation exports to the US are expected to grow at a CAGR of 38 per cent and reach around US$ 3.03 billion in 2011-12.
- Exports of generic drugs to Europe are likely to grow at a healthy CAGR of 20 per cent to reach US$ 1.8 billion by 2012-13.

Expected market share of Indian players in the US generics market

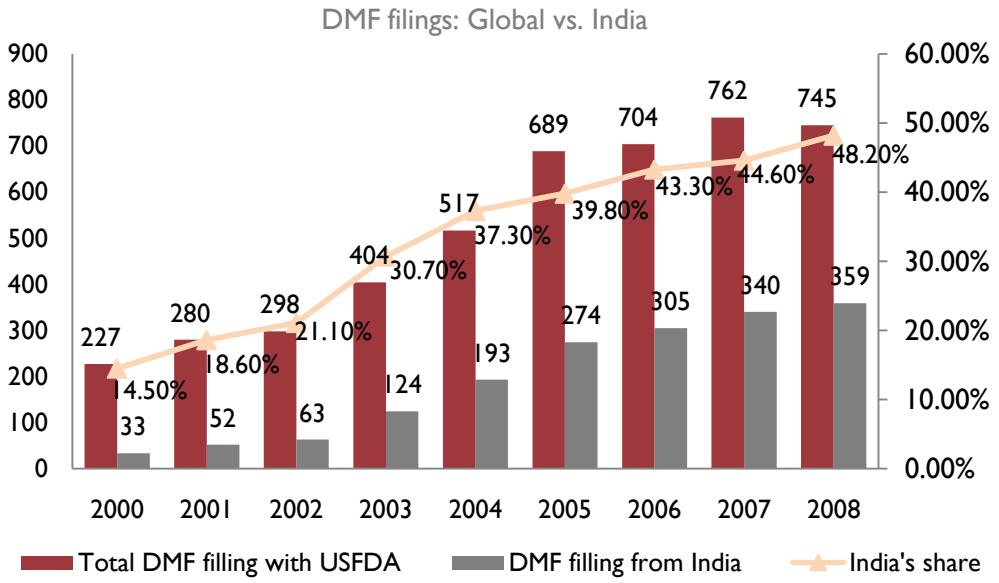


Source: Pharmaceuticals: industry profile, Dec 2007, CRIS INFAC

Generics to drive growth of exports from India

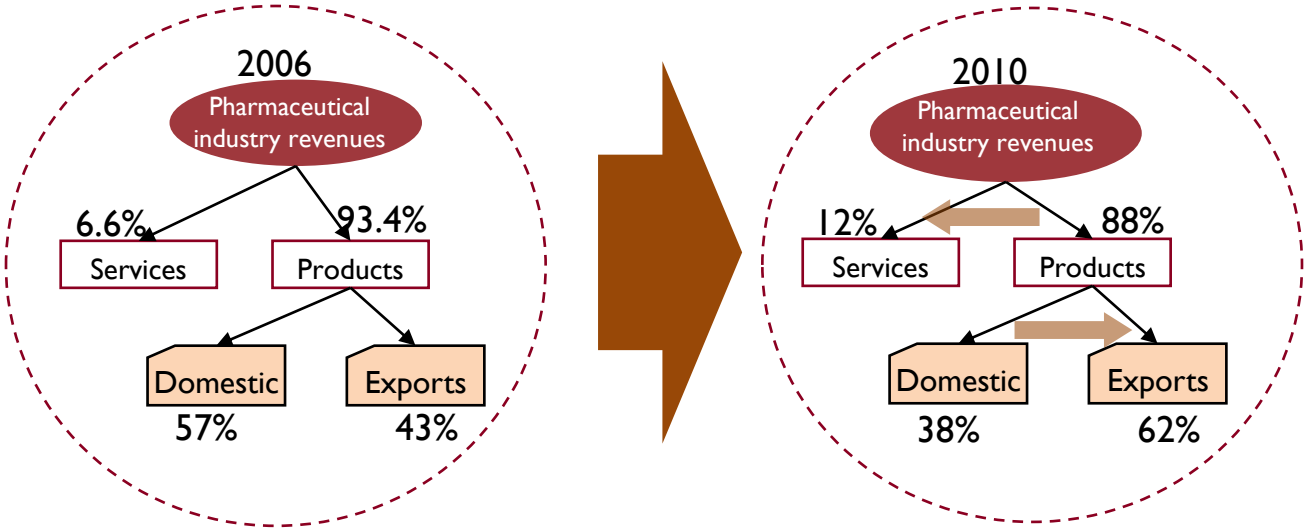
- India is the world's fifth-largest producer of bulk drugs.
- Demand for bulk drugs has grown at a CAGR of 31 per cent since 2000–01 to reach US$ 4.8 billion in 2007–08.
- The share of Indian companies in the total drug master files (DMF) filed with the USFDA* increased from 14.5 per cent in 2000 to 48 per cent in 2008.
- Semi-regulated markets account for a majority of bulk drugs' exports with a 50 per cent share.

India to maintain focus on bulk drug export



Source: Pharmaceuticals: industry profile, Dec 2008, CRIS INFAC
* USFDA: United States Food and Drug Administration

Changing paradigm: Indian pharmaceutical industry



Source: Ernst & Young analysis

- Although revenues from the domestic market dominated total pharmaceutical revenues in 2006-07, exports contribution surpassed the domestic turnover in 2007-08.
- The pharma sector is expected to witness an upswing in revenues from the service segment due to the increase in outsourcing of contract research and manufacturing services (CRAMS) to India.

Advantage India: Significant cost arbitrage

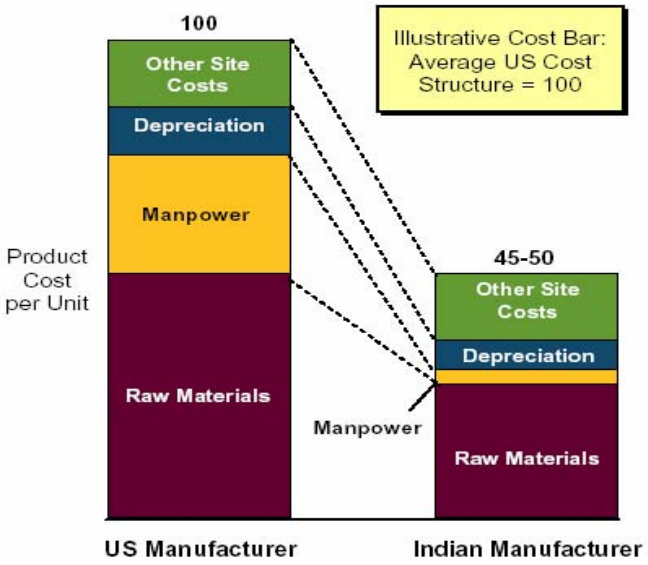
The basic production cost in India is up to 50 per cent lower than costs in the US.

- 30 per cent to 50 per cent lower depreciation
  - FDA-approved plants can be constructed in India at 30 per cent to 50 per cent lower costs
  - Higher utilisation of equipment due to improved processes (not quantified)
- 85 per cent to 90 per cent manpower cost savings
  - Labour costs in India typically 10 per cent to 15 per cent of the cost in the US
  - Savings applicable across all hierarchal levels (e.g., operators, research scientists, etc.)
  - Improved, more efficient processes contribute to lower labour costs per unit (not quantified)

Advantage India: Significant cost arbitrage

- 40 per cent to 50 per cent savings in raw materials
  - Bulk drugs can be manufactured in-house at 40 per cent to 50 per cent of ethicals' cost
  - Excipients and intermediates sourced locally at 20 per cent to 30 per cent lower costs
  - Most other raw materials can be sourced internally and from China

India's cost arbitrage



Source: OPPI – Adapted from Monitor Group, Study on Outsourcing Opportunities in Indian Pharmaceutical Industry

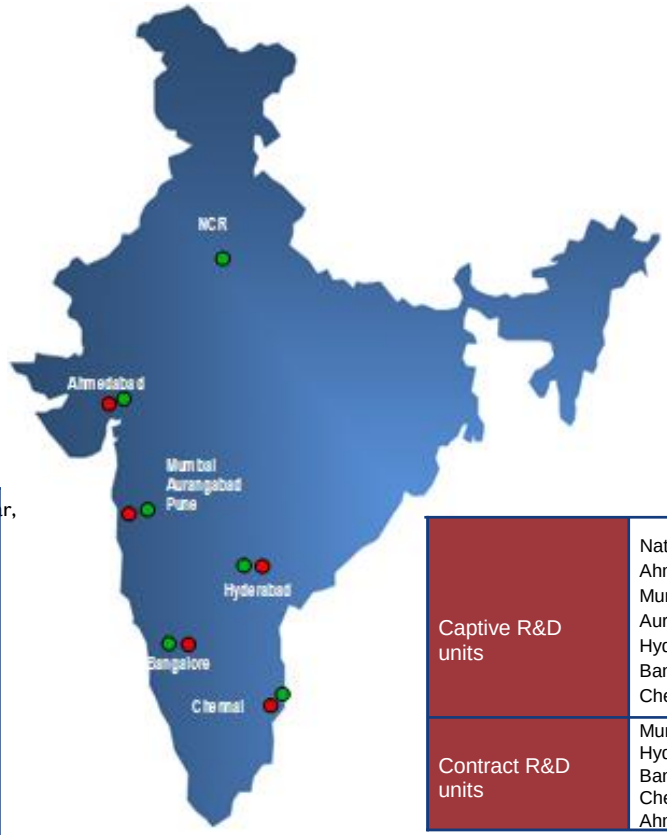
Established infrastructure for pharma R&D and manufacturing

Key manufacturing clusters

Traditional bulk drugs cluster	Gujarat — Ahmedabad, Ankleshwar, Vapi, Vadodara Maharashtra — Mumbai, Tarapur, Aurangabad, Pune Andhra Pradesh — Hyderabad Tamil Nadu — Chennai Pondicherry Karnataka — Mysore, Bangalore Goa — Panaji
Traditional formulation cluster	Goa Mumbai Pune Hyderabad
Emerging bulk drugs cluster	Andhra Pradesh— Visakhapatnam
Emerging formulation cluster	Himachal Pradesh — Baddi Uttarakhand — Pantnagar

Source: Ernst & Young analysis

Key R&D clusters



Captive R&D units	National Capital Region Ahmedabad Mumbai Aurangabad Hyderabad Bangalore Chennai
Contract R&D units	Mumbai Hyderabad Bangalore Chennai Ahmedabad

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Enabling research infrastructure

- The country has over 450 institutes/colleges and departments imparting pharmacy education.
- More than 25,000 pharmacy graduates pass out from these institutes every year.

Key research institutes in India
• Central Drug Research Institute (CDRI), Lucknow
• National Institute of Pharmaceutical Education and Research (NIPER), Mohali
• Indian Institute of Chemical Technology (IICT), Hyderabad
• Centre for Cellular & Molecular Biology (CCMB), Hyderabad
• Indian Institute of Chemical Biology (IICB), Kolkata
• Indian Toxicology Research Institute (ITRI), Lucknow
• Institute of Genomics and Integrative Biology (IGIB), New Delhi
• Institute of Microbial Technology (IMTECH), Chandigarh
• National Chemical Laboratory (NCL), Pune
• National Centre for Biological Sciences (NCBS), Bangalore
• Jawaharlal Nehru Centre for Advanced Scientific Research (JNCASR), Bangalore
• Centre for DNA Fingerprinting and Diagnostics (CDFD), Hyderabad
• Indian Institute of Science (IISc), Bangalore
• National Institute of Immunology (NII), New Delhi

Enabling research infrastructure

Talent statistics

- Around 1,000 biotech and biochemistry postgraduates pass out every year
- Around 10,000 chemistry postgraduate students graduate every year
- Around 2,500 chemical engineering students pass out every year. India had a pool of around 50,000 chemical engineering graduates until 2004–05
- Around 4,500 students pursue PhDs in various science streams
- 1,000 students pursue PhDs in engineering stream
- 1,000 students pursue PhDs in chemistry

Source: Pharmaceuticals: industry profile, Dec 2007, CRIS INFAC

Case study: Government introduces four more NIPERs

The National Institute of Pharmaceutical Education and Research, India, was established by the Government of India (GoI) to cater to the long-standing demand for setting up a dedicated nodal institution for quality higher education and advanced research in pharmaceutical sciences. The benefits delivered by NIPER prompted the government to set up four new NIPERs at Kolkata, Ahmedabad, Hyderabad and Hajipur (Bihar) in 2007.

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Regulatory framework

- The main regulatory body in India is the Central Drug Standard Control Organization (CDSCO) under the Ministry of Health and Family Welfare.
- CDSCO is presided over by the Drug Controller-General of India (DCGI), who is in charge of approval of licenses for drugs at both the Central and state levels.
- India introduced the product patent regime, in accordance with the TRIPS agreement, in January 2005 with an amendment to the patent act.
- Foreign direct investment (FDI) up to 100 per cent is permitted through the automatic route in drugs and pharmaceuticals.
- For licensable drugs and pharmaceuticals manufactured by recombinant DNA technology and specific cell/tissue targeted formulations, FDI needs prior government approvals.

Source: "India Pharmaceuticals and Healthcare Report Q2 2008," Business Monitor International

Regulatory framework

- The industry is undergoing consolidation due to recent legislation and policy updates:
  - Manufacturing units should adhere to good manufacturing practices (GMP) outlined in Schedule M of the Drugs and Cosmetics Act
  - Manufacturing units are required to comply with the WHO and international standards of production.
- The National Pharmaceutical Pricing Authority (NPPA) is responsible for fixing and controlling the prices of 74 bulk drugs and formulations under the Essential Commodities Act.

Source: "India Pharmaceuticals and Healthcare Report Q2 2008," Business Monitor International

Drug regulatory environment in India in transition

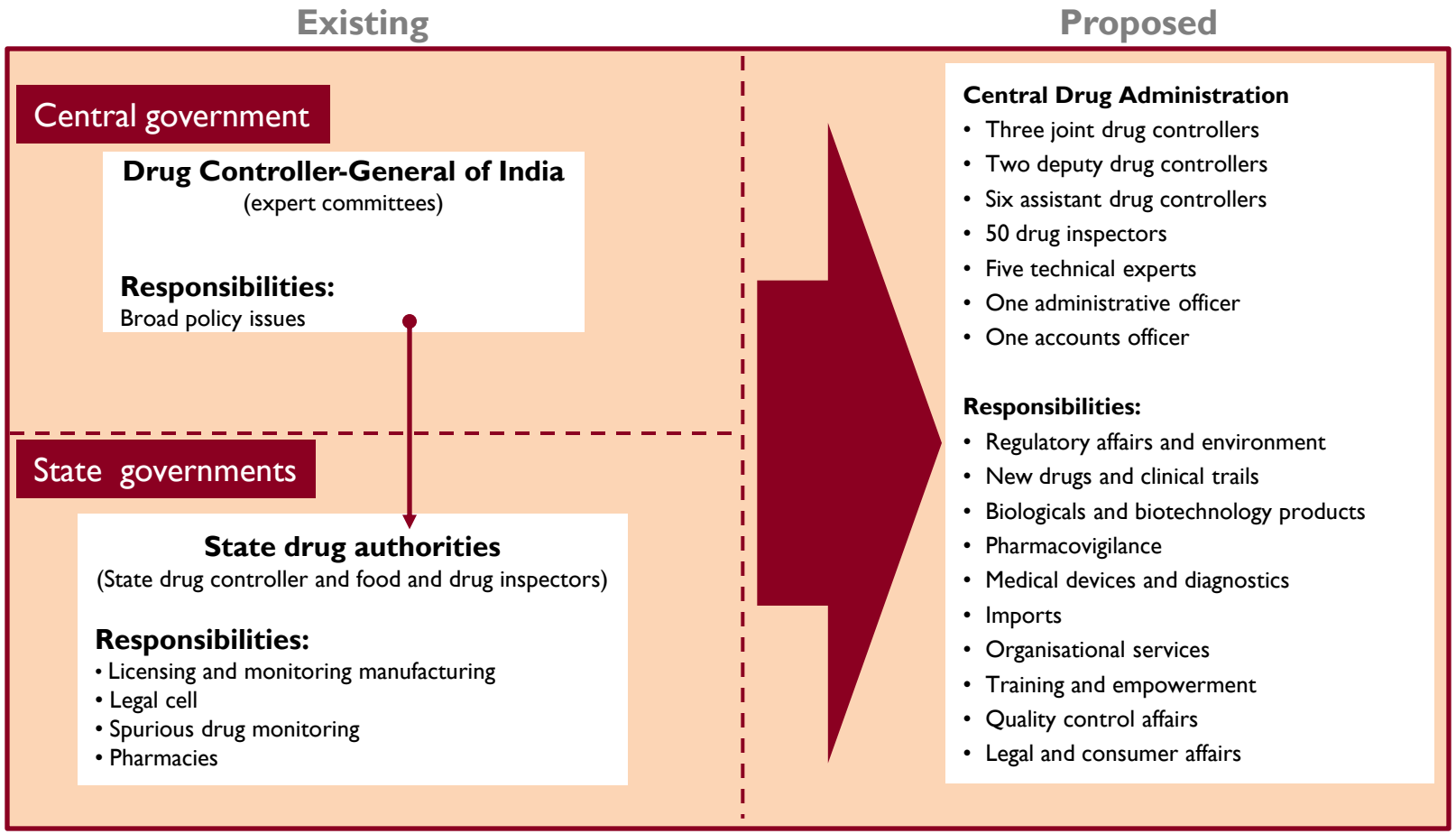
Existing drug regulatory system

- India has a bifurcated drug regulatory system — regulatory functions are divided between the Centre and state authorities.
- Existing infrastructure at the Centre and in states is inadequate to perform the assigned functions of drug administration with efficiency and speed, though there is a renewed focus on the same.

Proposed new system

- The Central Cabinet approved the formation of the Central Drug Authority (CDA) in January 2007.
- The proposed organisational structure of the CDA is to be analogous to the USFDA.
- It will be a strong, well-equipped, empowered, independent and professionally managed body.
- It is expected to facilitate upgradation of the national drugs regulator, uniformity of licensing, and enforcement and improvement in drug regulations.
- The efficiency and efficacy of drug administration is expected to be much higher after this transition.

CDA — India's new drug regulator



Budget 2009–2010 and policy changes

Budget measures:

- Budget 2009–2010 reduced the customs duty from 10 per cent to 5 per cent on imports of select life saving drugs and their bulk drugs for treating ailments such as breast cancer, hepatitis, rheumatic arthritis, etc.

- Customs duty has been reduced from 7.5 per cent to 5 per cent on two specified life saving devices used in the treatment of heart conditions. These devices are now fully exempt from excise duty and countervailing duty (CVD) also.

Source: India Budget 2009, Ernst & Young 2009

Budget 2009–2010 and policy changes

Policy changes:

- The government has approved the Drugs and Cosmetic (Amendment) Bill, 2008, which inter alia enhances the term for imprisonment from five years to at least 10 years, which may extend to lifetime, and raises the fine from Rs. 10,000 to Rs. 10,00,000 or three times the value of the drug confiscated, for manufacturers of spurious and adulterated drugs.

- The DCGI has directed state drug regulators not to allow companies to sell drugs that have undergone a composition change under their old brand names. Such drugs will be treated as new drugs and the companies would have to go through scrutiny before getting fresh approvals.

- The DCGI has made the registration of all clinical trials compulsory for trials initiated after June 15, 2009. Earlier, the registration of clinical trials by various institutions and companies was voluntary.

- The DCGI has withdrawn the powers given to state-level regulators to issue Certificate of Pharmaceutical Product (CoPP).

- The DCGI has discontinued issuance of the WHO-GMP certificate for both pharmaceutical products and plant audits.

Source: India Budget 2009, Ernst & Young 2009

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Changing growth fundamentals of the domestic market

Increasing penetration driving growth	Expansion of private sector healthcare driving accessibility	Increasing penetration of medical insurance
• Expansion of healthcare facilities in the rural and far-flung areas has enhanced accessibility. • Increased government spending on roads, telecommunication and health infrastructure has facilitated the foray of pharmaceutical companies into relatively distant pockets of the market. • With sales revenues of US$ 1.4 billion, the Indian pharmaceutical market in rural areas witnessed a growth of 39 per cent as compared to the growth of 18 per cent in the overall domestic market in November 2006.* • New product launches in 2006–07 accounted for only 1 per cent of the market, while 15 per cent of the growth was contributed by volume growth.	• Medical value travel has led to an investment spurt in private healthcare services in the country. • There has been accelerated investment from the private sector in healthcare facilities across tier-I and tier-II cities in the country. • An estimated one million beds would be added by 2012, taking the total beds available in the country to over two million.** • An estimated US$ 69.7 billion would be invested by the private sector in healthcare infrastructure by 2012. • The number of patients visiting Indian hospitals is expected to rise by 30 per cent to 22 million by 2015.	• Penetration of medical insurance would grow at a higher pace due to the increasing influx of foreign players. • Favourable regulatory changes such as permitting FDI of up to 51 per cent in stand-alone health insurance companies and setting the minimum capital requirement at US$ 5.4 million would drive growth in this segment. • The Indian middle class, with its increasing purchasing potential, is expected to become a major buyer segment. • Increasing penetration of customised insurance plans would drive affordability, influencing the consumption of medical and healthcare products.

*Source: The Economic Times, January 26, 2007 **Source: Ernst & Young FICCI healthcare report

Rising disposable income to drive drug consumption

- There were 16.4 million middle-class households with an annual income ranging between US$ 4,849 and US$ 24,242 in 2006.
- The segment is expected to grow at a CAGR of 14 per cent; it is likely to touch 28.4 million by 2010 and be the key driver of consumption.
- There were 1.7 million households in the upper-income group with an annual income greater than US$ 24,242 in 2006.
- The aggregated household expenditure on healthcare services increased at a CAGR of 9.3 per cent between 1993–94 and 2001–02.*
- Healthcare expenditure is expected to rise by 15 per cent per annum.*
- The high purchasing potential of the burgeoning Indian middle class is set to drive the consumption of healthcare services, including pharmaceuticals which constituted 22.6 per cent of the total healthcare expenditure in 2007.**

Rising disposable income to drive drug consumption

Income distribution across households

	FY1996	FY2002	FY2006	FY2010	CAGR
Rich (Annual income greater than US$ 24,242)	268,000	807,000	1.7 million	3.8 million	21%
Middle Class (Annual income between US$ 4,849 - 24,242)	4.5 million	10.7 million	16.4 million	28.4 million	14%
Aspirers (Annual income between US$ 2,182-4,849)	28.9 million	41.3 million	53.3 million	75.3 million	7%
Deprived (Annual income less than US$ 2,182)	131.2 million	135.4 million	132.2 million	114.4 million	1%

Source: "The Great Indian Market", August 2005, National Council of Applied Economic Research

**Source:* Ernst & Young FICCI healthcare report

***Source:* Espicom

Focus of Indian companies shifting from the US

- Pricing pressures and shrinking margins in the generics space and increasing litigation instances in the US are compelling Indian companies to consider opportunities beyond the US.
- Indian companies have invested more than US$ 1.2 billion in European markets.

Increasing focus on Japan

- Japan is the world's second-largest pharmaceutical market after the US.
- With sales worth US$ 60 billion in 2006, it constitutes around 11 per cent of the global market.
- Generics penetration has been extremely low until now in Japan.
- The Japanese government has initiated a string of pro-generics legislation reforms to increase the penetration up to 40 per cent from the present 16 per cent.

Key pro-generic reforms in Japan

- Generics substitution is allowed.
- Physicians are incentivised to prescribe generic medications over branded ones.
- The regulatory body expedites the drug approval process.
- Obligations to manufacture locally have been removed with these reforms.

Focus of Indian companies shifting from the US

Key initiatives of Indian companies in Japan
Zydus Cadila acquired Nippon Universal Pharmaceutical Ltd
Lupin acquired a majority stake in Japanese generic drug maker Kyowa Pharmaceutical.
Dishman established a joint venture with (JV) Azzuro Corporation in 2007
Strides entered into a JV with Sorm Corporation Ltd

Indian companies preferring the inorganic growth route

Announcement date	Announced total value US$ (mn)	Target name	Target country	Acquirer name
March 27, 2009	N/A	MUTLICARE PHARMACEUTICALS	THE PHILIPPINES	LUPIN LTD
January 28, 2009	4.2	RxELITE HOLDINGS INC	UNITED STATES	PIRAMAL HEALTHCARE LTD
December 23, 2008	44.8	MINRAD INTERNATIONAL INC	UNITED STATES	PIRAMAL HEALTHCARE LTD
December 17, 2008	NA	ZYDUS PHARMACEUTICALS INC	UNITED STATES	CADILA HEALTHCARE LTD
November 28, 2008	20.0	CIS RETAIL PHARMACY CHAIN CO	HONG KONG	PLETHICO PHARMACEUTICALS LTD
September 18, 2008	N/A	PHARMA DYNAMICS	SOUTH AFRICA	LUPIN LTD
September 16, 2008	N/A	DIASPA SPA	ITALY	PI DRUGS & PHARMACEUTICALS LTD
August 21, 2008	N/A	GENERIC HEALTH PTY LTD	AUSTRALIA	LUPIN LTD
July 30, 2008	NA	HORMOSAN PHARMA GMBH	GERMANY	LUPIN LTD
July 21, 2008	NA	INTERNATIONAL LABS INC	UNITED STATES	BILCARE, ALONG WITH US-BASED MEADWESTVACO CORP
June 18, 2008	18.5	SYNOVICS PHARMACEUTICALS INC	UNITED STATES	MANEESH PHARMACEUTICALS PVT

Indian companies preferring the inorganic growth route

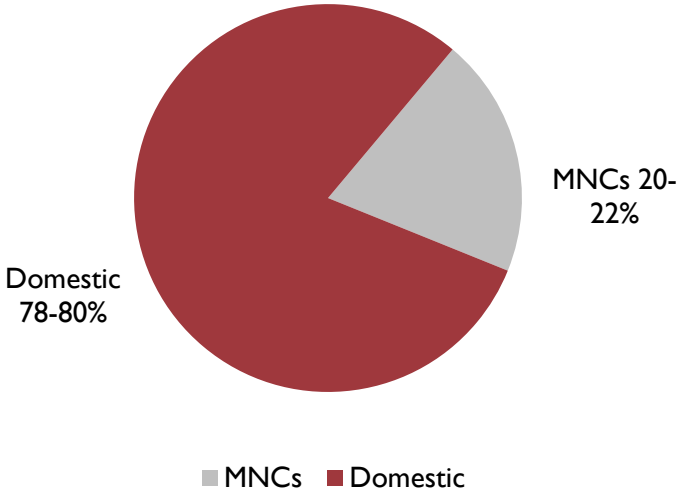
- M&A has been the key strategy adopted by Indian companies to gain a foothold in export markets, although a significant slowdown was seen in outbound activity in 2009.
- Large Indian companies have increased their foothold in regulated markets worldwide.
- Small- and medium-sized players are focussing on semi-regulated markets such as Latin America.
- Increased penetration, access to established distribution networks and increase in buyer confidence due to localised presence have been the key factors driving acquisition-led growth.

Rising confidence of global pharma companies in the Indian market

Patented molecule launches in India after enactment of Product Patent Regime in 2005

Product	Company	Therapeutic category	Launch date
VFend	Pfizer	Systemic anti-fungal	Feb 2005
Viagra	Pfizer	Erectile dysfunction	Dec 2005
Lyrica	Pfizer	Neuropathic	Jan 2006
Caduet	Pfizer	Cardiovascular	Feb 2006
Carvedilol	GSK	Cardiovascular	Mar 2006
Avastin	Roche	Various cancers	Apr 2006
Tarceva	Roche	Lung cancer	Apr 2006
Tamiflu	Roche	Bird flu	Apr 2006

Split of Indian pharmaceutical market



Source: Ernst & Young research

Rising confidence of global pharma companies in the Indian market

Patented molecule launches in India after enactment of Product Patent Regime in 2005

Pegasys	Roche	Hepatitis C	May 2006
Macugen	Pfizer	Wet age-related macular degeneration	Jun 2006
Avalide	Sanofi Aventis	Cardiovascular	Jul 2006
Lucentis	Novartis	Wet age-related macular degeneration	Nov 2006
Ambien	Sanofi Aventis	Insomnia	Jan 2007
Champix	Pfizer	Smoke cessation	Feb 2008
Tykerb	GSK	Breast cancer	May 2008
Abraxane	Abraxis	Breast cancer	Jul 2008
Januvia	Merck	Diabetes	Jul 2008

- The enactment of product patent in 2005 has reposed the confidence of innovator pharmaceutical companies in the Indian market.
- Since January 2005, about 15 patented products have been launched in the country (until March 2008).
- Innovators are treading a cautious path and are awaiting further clarity on several issues such as data protection, patenting of derivatives and pre- and post-grant opposition.

Source: Pharmaceuticals: industry profile, Dec 2008, CRIS INFAC

Global pharmaceutical companies establishing local presence

Recent global players to enter the Indian market

Company	Area of focus in India	Investment (US$ million)
Allergan Inc.	Inflammatory, infection, urological indications	3–5
Eisai Pharmaceuticals	API processes	120
Dupont	Molecular biology, bio-informatics and polymer synthesis	23
Ratiopharm GmbH	Basic processes	36
Teva	Basic processes	3–4
AstraZeneca	TB and NCE** research, process and development	15
BMS-Syngene	Basic drug discovery	N/A
Pliva	Basic studies for generics	1
Nektar Therapeutics	Pre-clinical and bio-analytical development	10
Daiichi Sankyo Company Ltd	Strengthening generic presence through acquisition of Ranbaxy	3,400–4,600
Actavis Group	60 per cent of Grandix Pharmaceuticals and API division of Sanmar Specialty Chemicals	N/A
Merieux Alliance	60 per cent of Shantha Biotechnics Ltd	N/A
Mylan Laboratories Inc.	Strengthening generic presence through acquisition of Matrix Laboratories	736

Source: Business Standard: August 27, 2007

** *NCE = New chemical entities*

Global pharmaceutical companies establishing local presence

Case Study: AMRI extends its R&D centre at Hyderabad, India*

Albany Molecular Research, Inc. (AMRI), a global drug discovery company that provides chemistry services to pharmaceutical and biotechnology companies, has completed the construction of a new 50,000 sq.ft. R&D centre at the Shapoorji Pallonji Biotech Park at Hyderabad, India. Completed in the latter part of 2007, the R&D centre conducts contract projects in early stage drug discovery research, including custom chemical synthesis and medicinal chemistry. In addition, a scale-up laboratory will be used to develop efficient methods for producing larger quantities of APIs and intermediates. When fully staffed, the new facility would add over 100 employees to the company's existing Hyderabad operations.

* *Source:* EY USAIC Position Paper "Pharma-Biotech Research: Decoding the Indian link"

Increasing quest for NCEs

Indian pharmaceutical R&D expenditure			
Specifics	2001	2008	Comments
R&D expenditure as a percentage of sales	1.4%	9.9%	7 times
R&D expenditure in absolute terms (US$ mn)	55	660	22 times

Source: Taking wings, Ernst & Young, 2009

No. of molecules in various stages of drug development pipeline of key Indian companies				
	Discovery/ pre-clinical phase	Phases		
		I	II	III
Ranbaxy	6	0	1	0
Dr. Reddy's	1	1	0	1
Glenmark	6	2	3	0
Zydus Cadila	4	3	2	0
Piramal Healthcare	10	3	4	0
Lupin	4	1	2	1
Sun	3	0	1	0

Source: "Taking wings," Ernst & Young, 2009

- Indian pharmaceutical companies are looking to move up the value chain and make place for themselves in the innovator league.
- The level of investments in R&D capabilities and infrastructure have been enhanced by both the industry and the government.
- Dr. Reddy's Laboratories' NCE Balaglitazone is India's first indigenously developed molecule to enter the Phase III trial.
- Growing R&D pipeline of Indian companies presents significant in-licensing opportunities for global companies.

Strategic partnerships on the rise, 2007–08

Indian company	Overseas company	Description
Biocon	Bayer Healthcare	Register and market insulin in China
	Invitrogen	Develop and market pharmaceutical-grade insulin
	BMS	Establish a research facility in Bangalore with more than 400 scientists
Dr. Reddy's	Clin Tech	Development of an anti-cancer compound
	7TM Pharma	Identification of drugs to treat metabolic disorders
	Albemarle Corp	Dr. Reddy's to distribute Ibuprofen, a drug used for relief from pain and fever, globally
	The Medical House	Create a new self-injectable disposable injector
	Ceragenix Pharmaceuticals, Inc.	Distribute and market EpiCeram, a cream used to treat atopic dermatitis

Strategic partnerships on the rise, 2007–08

Indian company	Overseas company	Description
GVK Biosciences	Wyeth	Develop drug candidates for Wyeth
Jubilant	Forest Laboratories	Develop drug candidate to treat a novel metabolic disorders
	Amgen	Novel drugs in new target areas of interest across multiple therapeutic areas
	Eli Lilly	Collaboration in the area of discovery research
Ranbaxy	GlaxoSmithKline	Ranbaxy will advance leads beyond candidate selection to completion of clinical proof of concept. GSK thereafter will conduct further clinical development
	Merck & Co.	Develop new products in the field of anti-infectives
	Cipher Pharmaceuticals	Develop and market Cipher's Cip-Isotretinoin in the US market
	Pharma (Yemen)	Marketing alliance
Suven Life Sciences Ltd	Eli Lilly	NCE research for nervous system disorders
Zydus Cadila	Karo Bio AB	Develop glucocorticoid receptor modulators used in the treatment of rheumatoid arthritis
	Prolong Pharma	Development of PEG-EPO, therapeutic protein used for the treatment of anaemia

Source: Ernst & Young research

In and out licensing deals, 2007–08

Indian company	Partner	Deal value (US$ mn)	Nature of deal	Year	Molecule/technology
Alembic	UCB, Belgium	Milestone payment of US$11 million and royalties on sales	Out licensing	2007	Novel drug delivery systems (NDDS) for Keppra XR
Glenmark	Eli Lilly	350	Out licensing	2007	GRC 6211, pain treatment molecule
Lupin Labs	Laboratories Servier	26.7	Out licensing	2007	Sale of patent applications and other intellectual property for Perindopril, a drug used to treat hypertension and cardiac diseases
Piramal Healthcare	Eli Lilly	Milestone payments of up to US$100 million and royalties on sales	In licensing	2007	Pre-clinical drug candidate for metabolic disorder
	Merck & Co.	Milestone payments of up to US$ 175 million and royalties on sales	In licensing	2007	Two oncology targets
Ranbaxy	PPD Inc.	44	Out licensing	2007	RBx 10558 (dyslipidemia)
Venus Remedies	Jiangsu Provincial Institute of Microbiology	N/A	In licensing	2007	Amino-glycoside

Source: Ernst & Young research

Private equity (PE) deals in pharmaceuticals and healthcare, 2008–09

Target Name	Amount (US$ mn)	Deal Stake %	Announcement Date	Investor(s)
Anjan Drugs Pvt Ltd	5.3	-	June 2009	3 Logi Capital (United Arab Emirates)
Sphaera Pharma Pvt Ltd	10.0	-	November 2008	Baring Private Equity Partners India Pvt Ltd (United Kingdom)
Hikal Ltd	15.0	-	September 2008	International Finance Corporation (IFC) (United States)
Marck Biosciences Ltd	4.7	-	August 2008	IFCI Venture Capital Funds Ltd (India)
Nectar Lifesciences Ltd	2.5	1.3	August 2008	Citigroup Venture Capital International–India (United States)
Rubicon Research Pvt Ltd	-	-	August 2008	Kotak Investment Advisors Ltd (India)
Themis Laboratories Pvt Ltd	21.0	-	July 2008	Jacob Ballas Capital India Pvt Ltd (India)

Private equity (PE) deals in pharmaceuticals and healthcare, 2008–09

Target Name	Amount (US$ mn)	Deal Stake %	Announcement Date	Investor(s)
AgilityBio Pvt Ltd India	-	-	June 2008	3 Logi Capital (United Arab Emirates); BioImagene India Pvt Ltd (India); The Halo Funds Management Company (United States)
BioPlus Life Sciences Pvt Ltd	31.0	-	June 2008	AIF Capital (India) Pvt Ltd (Hong Kong)
Centaur Group	7.0	-	May 2008	SIDBI Venture Capital Ltd (India)
Sai Advantium Pharma Ltd	20.0	12.0	May 2008	MPM Capital L.P (United States)
Parabolic Drugs Ltd	7.0	-	May 2008	BTS Investment Advisors Private Ltd (India)
Century Pharmaceuticals Ltd (India)	-	-	January 2008	GVFL Ltd (India)
Gland Pharma Ltd	30.4	-	January 2008	3 Logi Capital (United Arab Emirates)

Source: Ernst & Young research

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The focus of this presentation is to discuss…

- Market overview
- Policy
- Key trends and drivers
- Key players
- Key opportunities

Key players

Leading players by annual sales

Company name	Year end	Sales (US$ mn)
Cipla	200903	1,091.33
Ranbaxy Laboratories Ltd	200812	1,004.29
Dr. Reddy's Laboratories Ltd	200903	914.96
Sun Pharmaceutical Industries Ltd	200903	850.62
Lupin	200903	637.81
Piramal Health	200903	510.16
Cadila Health	200903	373.85
GlaxoSmithKline	200812	366.36
Wockhardt	200812	327.86
Torrent Pharmaceuticals Ltd	200903	256.80
Alembic	200903	238.75
Aventis Pharma	200812	218.98
Intas Pharmaceuticals Ltd	200803	208.30
Alkem Lab	200703	196.90
USV	200903	184.17

Source: Capitaline

Key players

Leading players by annual sales

Company name	Year end	Sales (US$ mn)
Aristo Pharmaceuticals	200903	170.07
Pfizer	200811	155.56
Abbott India	200811	152.97
Unichem Laboratories Ltd	200903	143.26
Novartis India	200903	132.11
FDC Ltd	200903	126.83

Source: Capitaline

Key MNC companies in India

Select domestic players

Ranbaxy	Dr. Reddy's Labs
• Incorporated in 1961 • Ranked among the top 10 generics companies in the world • Ground operations in 49 countries and manufacturing operations in 11 nations • Sales in India during first quarter of 2008–09 reached US$ 7.3 million, a 5 per cent over the first quarter of the previous year • Aspires to become a research-based pharmaceutical company with revenues of US$ 5 billion by 2012 • Envisions being among the top five global generics players by 2012 • TC presence; anti-infectives, cardio-vascular system (CVS) and diabetes, dermatological, neuro-psychiatry, pain management, gastro-intestinal (GI) and nutritional	• Established in 1984 • Ranks among the top 15 generics players in the world. • First pharmaceutical company in Asia-Pacific (outside Japan) to be listed on NYSE • Presence in 35 countries with operations in over 115 countries • Overall revenues at US$ 381 million in first quarter of 2009–10, as against US$ 315 million the corresponding period of the previous year • TC presence; anti-infectives, CVS, diabetes, dermatological, pain management, GI, nutritional, dental, urological and oncology

Select domestic players

Cipla	Nicholas Piramal India Ltd (NPIL)
• Set up in 1935 • World's largest manufacturer of cost-effective anti-retroviral drugs • Products sold in over 170 countries • Partnerships with nine companies for over 125 products • Registered an 18 per cent year-on-year (y-o-y) rise in net profit during the first quarter of 2008–09 • Over 100 DMF registrations in the US and over 85 in Europe • Presence across most therapeutic categories	• Came into existence in 1988 • Fourth-largest pharmaceutical company and leader in CVS segment • Has grown primarily on acquisitions, mergers and alliances in last 15 years • Operating income for the year ended March 31, 2008, was US$ 558 millon, a 16.2 per cent increase compared to the previous year. • Profit-after-tax rose by 53.1 per cent to US$ 65 million • TC presence; anti-infectives, CVS, diabetes, dermatological, pain management, GI, respiratory, nutritional, central nervous system (CNS) and urological

Select foreign players

GlaxoSmithKline	Pfizer India
• Two manufacturing units in India at Nashik and Thane • 2,000-strong field worker strength and a country-wide network of over 4,000 stockists • Indian subsidiary looking to touch US$ 1 billion in sales by 2015 • Two R&D centres, which are approved by the Department of Scientific and Industrial Research, Government of India. • TC presence: anti-infectives, CVS, diabetes, dermatological, pain management, CNS, GI, nutritional, gynaecological, respiratory, sera and immunoglobulin, hormones	• Entered the Indian market in 1950 • Manufacturing facility at Thane, Maharashtra • Launched five patented products since 2005 — Vfend, Viagra, Lyrica, Caduet and Macugen • Clinical research investments of US $ 15.75 million in India • TC presence: anti-infectives, CVS, dermatological, sera and immunoglobulin, pain management, diabetes, CNS, GI, nutritional, gynaecological and respiratory

Select foreign players

AstraZeneca	Sanofi Aventis
• R&D, manufacturing and marketing offices at Bangalore • R&D centre is dedicated to the 'Discovery of Novel Therapies for the Developing World'; the centre has more than 90 scientists • Added a state-of-the-art process R&D facility, which employs more than 50 scientists • TC presence: focus on respiratory, maternal health, oncology infection, pain control and anaesthesia	• Incorporated in1956 under the name Hoechst Fedco Pharma Pvt Ltd • 1,840 employees • Manufacturing facilities in Ankleshwar and Goa • TC presence: CVS, thrombosis, oncology, metabolic disorders, CNS, internal medicine and vaccines

Key contract research organisations in India

Company	Services portfolio	Clients
Advinus Therapeutic	Drug discovery, medicinal chemistry, toxicology studies	Development projects for Merck
Avra Labs	Product chemistry, organic synthesis, chiral synthesis and technology	Top 20 big pharmaceutical and biotech companies
BioArc Research Solutions	Medicinal chemistry, custom synthesis and formulations, pre-clinical pharmabiology, BA/BE, CRAMS	N/A
Aurigene	Lead generation and optimisation and early computational chemistry aided ligand design, mining and screening of novel chemical entities. Early animal work involving ADME and toxicity	Collaborative discovery programmes with Novo Nordisk on diabetes and discovery services with Rheosciences, Denmark
GVK Biosciences	Medicinal chemistry, bioinformatics, clinical trials, custom synthesis and drug discovery	Pharma/biotech companies across US, UK, Germany and Japan; Wyeth, Biogen, Merck & Co. (50 projects)
Hikal Ltd	Medicinal chemistry, custom synthesis, CRAMS	Five pharmaceutical companies also work in agrochemical
Innovasynth	Medicinal chemistry, custom synthesis, CRAMS	Work for big pharmaceuticals
Jubilant Organosys	Bioinformatics, clinical trials, CRAMS, medicinal chemistry services, custom synthesis and drug discovery services	60 clients/20 projects at any time

Source: Ernst & Young research

Key contract research organisations in India

Company	Services portfolio	Clients
Matrix	CRAMS, medicinal chemistry, custom synthesis and dossier development.	Rigen Inc., GSK India, Merck KGaA
Procitius Research	Medicinal chemistry, custom synthesis, biology services, clinical trials and CRAMS	N/A
Sai Life Sciences	Medicinal chemistry services, scale-up services	200 projects for almost 30 MNC pharmaceutical and biotech companies
Shasun Chemicals and Drugs	CRAMS, organic chemistry, medicinal chemistry, custom synthesis and biology services like protein purification, microbial fermentation and process optimisation	N/A
Suven Life Sciences	CRAMS, medicinal chemistry services, custom synthesis and clinical trials (ACT and Sipra), drug discovery services	About 18 to 20 international clients from across US and Europe
Syngene	Medicinal chemistry, custom synthesis and drug discovery, affiliate clinigene	Novartis, Merck & Co.
TCG	Silicogene, medicinal chemistry, drug discovery services	N/A
Bharavi Labs	Medicinal chemistry services, custom synthesis and drug discovery services	20 to 25 ongoing projects. Works on FTE and ongoing contracts

Source: Ernst & Young research

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Contract research — India an emerging hotspot

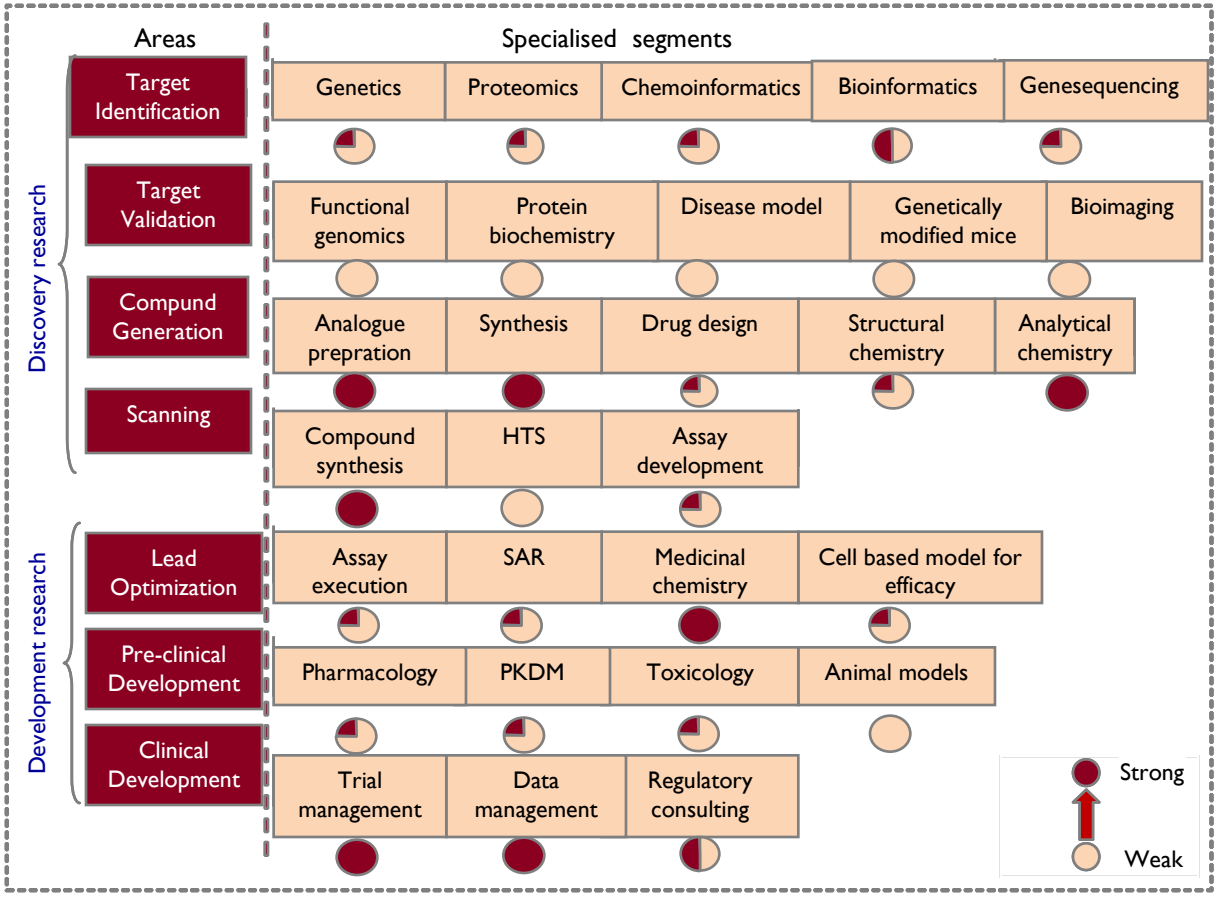
- Indian drug discovery and development outsourcing market is projected to grow at a rate of 50 per cent to reach US$ 900 million in 2009.

- Presently, a major portion of the services are limited to chemistry-based lead identification/optimisation, pre-clinical and clinical research stages.

- Select companies provide biology-based services for target validation; notable examples are Avesthagen, Ocimum Biosolutions and TCG Life Sciences.

- Bioinformatics companies that offer research-enabling software technologies are also emerging as a valuable segment.

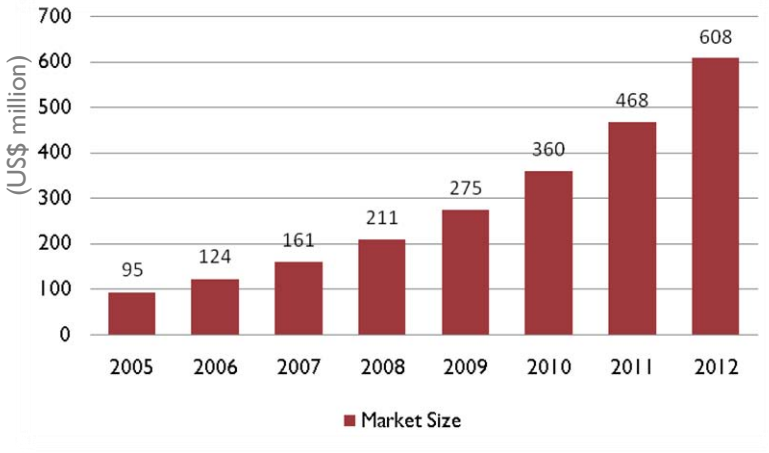
Contract research — India an emerging hotspot



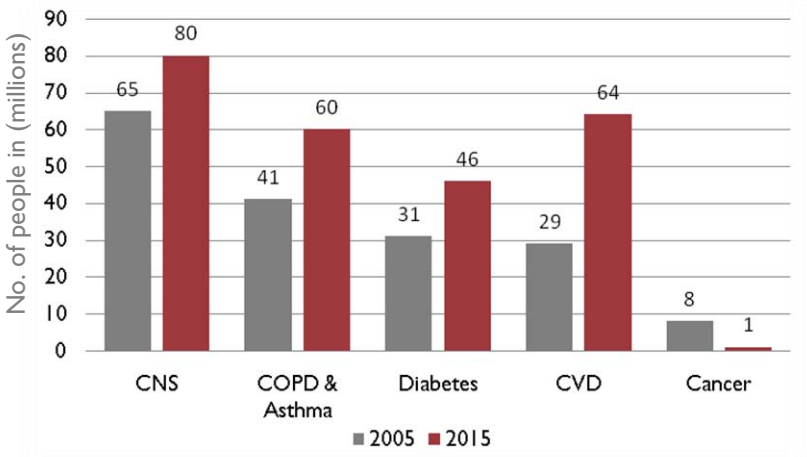
Source: "Offshoring in the Pharmaceutical Industry," Mridula Pore, Yu Pu, Charles Cooney, MIT, Ernst & Young analysis

Clinical research — leveraging India's advantage

Forecasted clinical research market



Key disease populations



- The clinical trials market in India is currently sized at approximately US$ 250 million to US$ 275 million and is expected to grow at a robust CAGR of 30 per cent over the next few years, at almost double the global average.

- Clinical trials for NCEs constitute around 60 per cent of the total revenue mix, while 40 per cent is accounted for by bioavailabilty/bioequivalence (BA/BE) studies for generics development. However, by volume, around 70 per cent of the work is directed towards generic research.

- The market for BA/BE studies in India was estimated to be around US$ 60 million to US$ 70 million in 2006. It is estimated to reach US$ 150 million to US$ 200 million by 2010–11 growing at a CAGR of 18 to 20 per cent.

Source: "The glorious metamorphosis," Ernst & Young 2009

Contract manufacturing (CM)

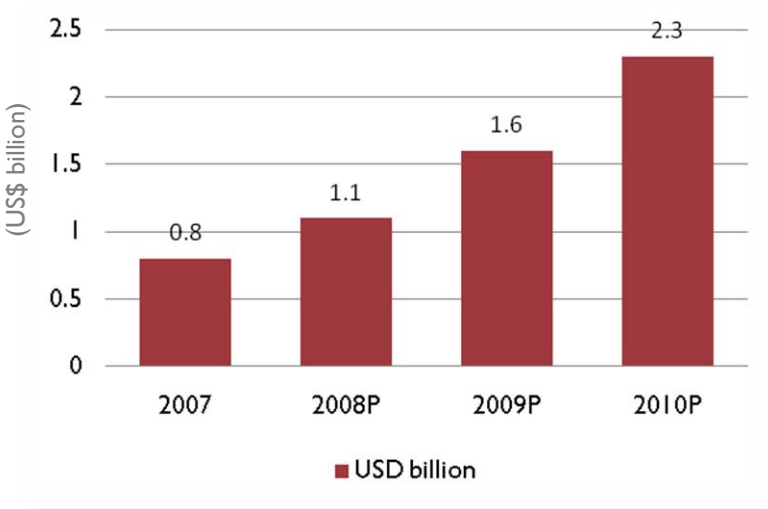
- The Indian pharmaceutical manufacturing outsourcing market is valued at US$ 1.1 billion and the segment is growing at thrice the global market rate.
- India's share of the outsourcing market is estimated to increase from 2.8 per cent in 2007 to 5.5 per cent in 2010.
- APIs /intermediate outsourcing is more prevalent in India than formulation outsourcing; around 64 per cent of total outsourcing is in the area of APIs/intermediates.
- The market is estimated to increase to US$ 1 billion by 2010.
- By 2010, the demand for contract manufacturing of formulations is likely to be around US$ 210 million to US$ 300 million. APIs and intermediate demand is likely to be in the range of US$ 600 million to US$ 700 million by 2010.

Contract manufacturing (CM)

Key growth drivers

- Closure of assets: As majority of big pharma is operating at only 20 to 30 per cent of their capacity as companies are looking at divesting these plants and outsourcing manufacturing.
- Biologics: As a high percentage of the current pipeline globally is biologics, the cost of investing in a new facility is high.

Indian custom manufacturing outsourcing market



Source: "Taking wings," Ernst & Young, 2009

Oncology — Indian players eyeing the global opportunity

- Cancer accounts for an estimated 7.6 million annual deaths globally.
- Treatment for cancer is estimated to become the largest therapeutic segment by sales at US$ 55 billion by 2009, from the current US$ 45 billion.
- The oncology pipeline is the richest in number, with a large number of pharmaceutical and biotech companies focussing on oncology drugs.
- Over 50 new oncology products are expected to be launched in the next five years with new players entering the market.
- About 30 per cent of all launches by 2010 will be in oncology.
- The global oncology drug market is growing at 17 per cent annually.
- Presently, the Indian oncology market stands at US$ 18.6 million and it is expected to treble by 2010.

Oncology — Indian players eyeing the global opportunity

Biocon recently launched its monoclonal antibody-based drug BIOMAb-EGFR for treating solid tumors. The company is looking at introducing products in the US and Europe.

Dabur Pharmaceuticals introduced a nano technology-based chemotherapy agent, Nanoxel, in the country and plans to take it to the US and the European markets, and has already planned clinical trials there.

Ranbaxy Laboratories Ltd has entered into a strategic alliance with Zenotech Laboratories Ltd Ranbaxy will market Zenotech's oncology cytotoxic injectible products under the Ranbaxy label, leveraging its global marketing and distribution network in the key markets of Latin America, including Brazil and Mexico, Russia and other CIS markets.

Pharmaceutical retail-emerging growth segment

- With revenues of US$ 200 million in 2009, organised pharmaceutical retail constitutes just 2 per cent of the pharmaceutical retail market in India.
- It is expected to grow at a high y-o-y growth of 30 to 40 per cent and is likely to become a US$ 400 million to US$ 530 million market by 2010.
- The government is contemplating the increase of FDI cap to up to 51 per cent in the case of retail of single-brand products.
- New entrants include Emami Group (Frank Ross Pharmacies), Dabur (Health and Wellness chain by the name of NewU), Reliance Wellness (in a joint venture with Alliance Boots of the UK) and Manipal Cure & Care.

* Religare Wellness acquired CRS Health and LifeKen (formerly owned by Lifetime Heathcare Pvt Ltd)

Source: Neha Jain and Shailendra Gupta, "Pharma retail in India," EY CBK, August 2009, via IRAD

Pharmaceutical retail-emerging growth segment

Brand	Ownership	Year of starting operations	Number of outlets	Company owned or franchised
Apollo Pharmacy	Apollo Hospitals Enterprises Ltd	1983	740	Company owned
Medplus	Medplus Health Services Pvt Ltd	2006	600	570 – company owned 30 – franchised
Himalaya	Himalaya Drug Co	1930	150 (200 shop-in-shop)	N/A
Guardian	The Guardian Lifecare Pvt Ltd	2003	180	Franchised
Health & Glow	Dairy Farm International	N/A	59	N/A
Medicine Shoppe	Medicine Shoppe (India)	1999	140	Franchised
98.4	The Global Healthline Pvt Ltd	2002	30	N/A
Religare Wellness*	Formerly Fortis Healthworld	1996	200	Franchised
Trust	Trust Chemists And Druggists Ltd	2003	41	N/A
Frank Ross	Emami Group	1906	30	N/A
* Religare Wellness acquired CRS Health and LifeKen (formerly owned by Lifetime Heathcare Pvt Ltd)				

Source: Neha Jain and Shailendra Gupta, "Pharma retail in India," EY CBK, August 2009, via IRAD

Indian pharmaceutical players-retail plans

Case study: Reliance Retail

The Mukesh Dhirubhai Ambani Group is planning a foray into the pharma retail segment. This is part of an overall strategy for building super-malls in 21 zones across India. Through its biopharmaceutical venture, Reliance Life Sciences, the firm is looking to increase investments, targeting US$ 33 billion of the local market by 2012.

The company has allocated US$ 2.2 billion for setting up production facilities. The firm is also keen on acquiring small, local drug-producing units and companies to offer low-margin drugs at the retail level.

Case study: AIOCD

The All India Organisation of Chemists and Druggists (AIOCD) is a leading industry association with a membership of around 600,000 pharma retailers and wholesalers in the country. It has taken steps to facilitate the creation of a centralised procurement system and a special purpose vehicle (SPV) network in each state.

A centralised procurement system is part of the general push by AIOCD towards a network of small pharma retailers, who have dominated the Indian market for decades. This initiative was test-piloted last year in Maharashtra, where the largest network of small pharma retailers exists.

Indian pharmaceutical players-retail plans

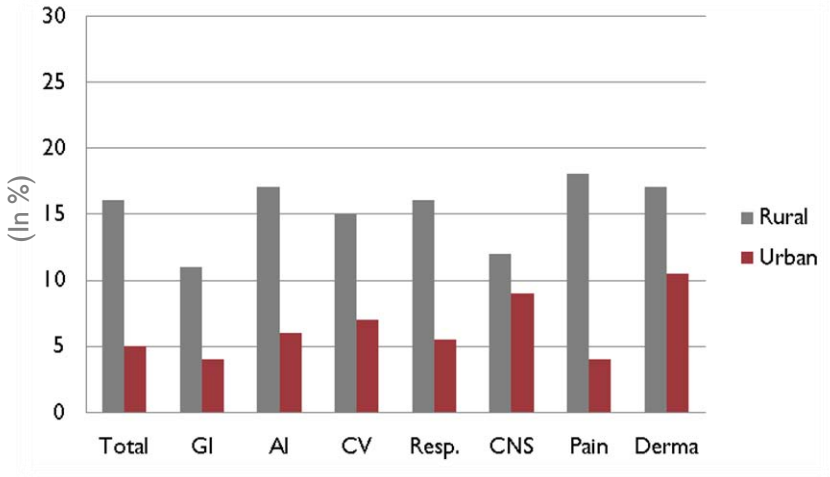
Case study: Zydus Cadila

Zydus Cadila plans to create a separate company from its health product lines. The first outlet of this new company was commissioned in 2007. The company expects to enhance its product range by launching a smoking-cessation product and hopes to improve its revenues by close to 300 per cent to US$ 1 billion from the current US$ 266 million.

Rural market-opportunities at the bottom of the pyramid

- 65 per cent of the population resides in rural areas with limited or absolutely no access to medicines and other healthcare facilities.
- With a growth rate of 39 per cent in 2006, the rural market has outstripped the growth in the urban region across most of the therapeutic categories in both value and volume terms.
- General physician-driven segments such as anti-infectives, analgesics, etc., have registered high growth compared to specialist-driven segments such as CNS.
- Non-communicable diseases such as cancer, blindness, mental illness, hypertension, diabetes, HIV/AIDS, accidents and injuries are also on the rise.

Volume Growth (2005-06)



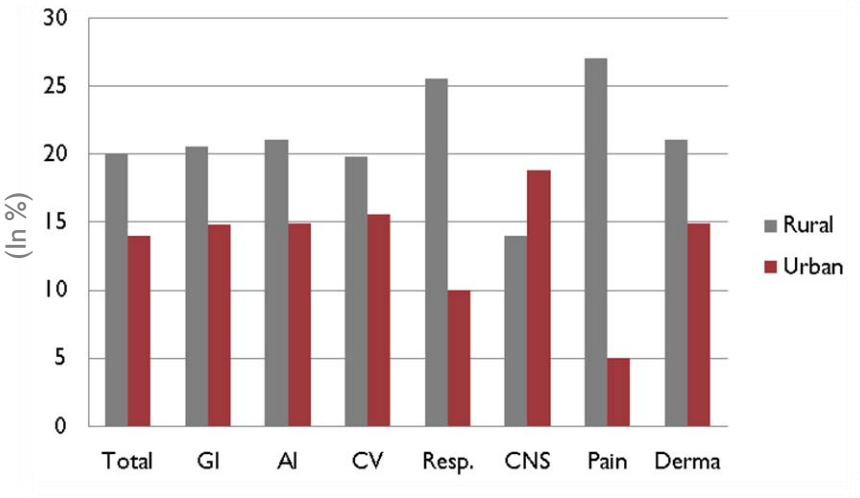
Source: Enam

Rural market-opportunities at the bottom of the pyramid

Lifestyle diseases on the rise in rural areas

According to a 2007 study conducted by the George Institute for International Health in 45 villages in the east and west Godavari districts of Andhra Pradesh, diseases of the cardiovascular system, such as heart attacks and stroke, caused 32 per cent of the deaths in the region.

Value Growth (2005-06)



Source: Enam

Biopharma-domestic players eying the global biosimilar market

- Globally, sales of biological drugs are estimated to reach US$ 52 billion by 2010.
- Leading Indian companies are intensifying their focus on the biotech segment.
- Moreover, Indian players are also eyeing the huge opportunity presented by biosimilars across the globe.
- Biosimilars are expected to be a US$10 billion market in the US and the EU by 2015.
- Further, biologics as a drug class is itself growing rapidly and estimates suggest that by 2014 seven of the top 10 drugs by sales globally would be biologics.
- Leading Indian pharmaceutical companies such as Biocon, Dr. Reddy's, Wockhardt, Intas and Zenotech, etc., have invested in manufacturing facilities for biosimilars..
- A legal framework for biosimilars has been established in the EU.
- Further, the US is expected to set up an approval framework for biosimilars soon.

Biopharma-domestic players eying the global bio-similar market

Key initiatives of Indian companies
Ranbaxy Laboratories has signed a development and marketing agreement with generic injectables company Zenotech Laboratories to produce its first biosimilar G-CSF.
Reliance Life Sciences has bought 74 per cent stake in GeneMedix. The joint entity will develop biosimilar drugs and offer full service in CRAMS.
Dr. Reddy's has created a copy of Roche's Rituximab, which is used to treat non-Hodgkin's lymphoma. Marketed by Genentech Inc. and Biogen Idec Inc. as Rituxan in the US, the drug generated a global revenue of more than US$ 2 billion in 2007.
Dr. Reddy's sells Grafeel, or filgrastim, in India. The drug is used to boost white blood cell production and is marketed by Amgen in the US.
Glenmark has set up a biologics research facility in Switzerland with more than 25 scientists. It expects the first biological lead to enter into clinics in 2009 and two more by 2010.
Glenmark has tied up with US-based Dyax to expedite biologics research. Dyax will perform funded research for three of Glenmark's targets in the areas of inflammation and oncology.
Biocon has started clinical trials on Insugen, BIOMab-EGFR trials in regulated markets.

Source: "Biosimilars 101," Credit Suisse, September 16, 2009, via Thomson Research

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