

INDIAN PHARMACEUTICALS



Industry Insight **Indian Pharmaceuticals**

Cygnus

Business Consulting & Research

Knowledge Partner for Profitable Growth

CONTENTS

1. EXECUTIVE SUMMARY	5
2. HIGHLIGHTS.....	8
3. INDUSTRY OVERVIEW.....	10
3.1 Indian Pharmaceutical Industry	10
3.2 Pharmaceutical Market Size.....	10
3.3 Industry Segmentation	11
3.4 Major Players	12
3.5 Major Exporters	15
3.6 Demand-supply analysis.....	17
3.7 Foreign Direct Investments in Indian Pharma.....	17
4. GROWTH DRIVERS.....	19
4.1 Global Growth Drivers.....	19
4.1.1 Innovation of Biotechnology.....	19
4.1.2 Demographic Transition	19
4.1.3 Rising real incomes	20
4.1.4 Medical technology	21
4.1.5 Generic and niche segments.....	21
4.1.6 Unmet medical needs.....	21
4.2 Indian Pharma	22
4.2.1 Ageing Population.....	22
4.2.2 Life Style Drugs	22
4.2.3 Healthcare Expenditure.....	23
4.2.4 Upgradation of Medical Devices & Equipment.....	23
4.2.5 Export	23
4.2.6 Generic Drugs	24
4.2.7 Research & Development.....	24
4.2.8 Contract Manufacturing Opportunities	24
5. ISSUES & CHALLENGES.....	26
5.1 Sustaining exports	26
5.2 IPR issues	27
5.2.1 Pricing	28
5.2.2 Central excise on MRP of medicines.....	28
5.2.3 Data protection.....	28
5.3 R&D focus.....	29
5.3.1 Looming shortage of trained manpower	30
5.3.2 Animal trials	30
5.3.3 Regulatory Infrastructure	30
5.3.4 Managing productivity.....	31
5.4 Exploiting generic opportunities	31
5.5 Price control.....	31
5.6 Infrastructure	32
5.6.1 R&D Infrastructure	32
5.6.2 Quality of marketing infrastructure	32

5.7 Fragmentation	32
5.8 Spurious drugs	33
6. MAJOR PLAYERS	34
6.1 Ranbaxy Laboratories Ltd.	35
6.2 Cipla Ltd.	40
6.3 Dr. Reddy's Laboratories Ltd.	44
6.4 Glaxo SmithKline Pharmaceuticals Ltd.	49
6.5 Nicholas Piramal India Ltd.	53
6.6 Lupin Ltd.	57
6.7 Sun Pharmaceutical Industries Ltd.	62
6.8 Cadila Healthcare Ltd.	67
6.9 Aurobindo Pharma Ltd.	71
6.10 Wockhardt Ltd.	76
6.11 Aventis Pharma Ltd.	80
6.12 Ipca Laboratoaries Ltd.	84
6.13 Pfizer Ltd.	88
6.14 Biocon Ltd.	92
6.15 Orchid Chemicals and Pharmaceuticals Ltd.	96
6.16 Matrix Laboratories Ltd.	100
6.17 Alkem Laboratories Ltd.	104
6.18 Alembic Ltd.	107
6.19 Morepen Laboratories Ltd.	111
6.20 Torrent Pharmaceuticals Ltd.	116
7. MAJOR SEGMENTS	120
7.1 Bulk drugs	120
7.2 Formulations	121
8. OUTSOURCING OPPORTUNITIES	124
8.1 Factors driving outsourcing	125
8.1.1 Weaker pipelines and rising approval times	125
8.1.2 Pressure to cut prices	127
8.1.3 Declining market exclusivity period	127
8.1.4 Boosting marketing productivity	128
8.2 Outsourcing Market	129
8.2.1 Contract Manufacturing	130
8.2.2 Contract Research	132
9. REGULATORY ISSUES	138
9.1 Overview	138
9.2 Regulatory environment	138
9.2.1 General regulations	139
9.3 Entry strategies	140
9.3.1 Importing pharmaceuticals	141
9.3.2 Manufacturing under license	141
9.3.3 Entry through joint venture/subsidiary	141
9.3.4 Foreign Investment promotion board	141
9.3.5 Approvals for foreign companies with prior Indian exposure	142
9.3.6 Additional options	142
9.4 Key legislations	143

9.4.1 The drugs and cosmetics act, 1940.....	143
9.4.2 The medicinal & toilet preparations act, 1955 with rules, 1956.....	143
9.4.3 The drug policy, 1986.....	144
9.4.4 The essential commodities act, 1955.....	144
9.4.5 Indian patents act, 1970.....	144
9.4.6 The drugs price control order (DPCO), 1995.....	144
9.4.7 Good manufacturing practices.....	145
9.4.8 The pharmacy act, 1948.....	145
9.5 Regulatory bodies.....	145
9.5.1 The drugs controller of India (DCI).....	145
9.5.2 State food and drug administrations (FDAS).....	145
9.5.3 National pharmaceutical pricing authority (NPPA).....	145
9.5.4 Department of chemicals and petrochemicals.....	146
9.6 Price controls.....	146
9.6.1 Pricing of scheduled bulk drugs.....	147
9.6.2 Pricing of scheduled formulations imported into India.....	147
9.6.3 Pricing regulations.....	147
9.7 Intellectual property rights.....	148
9.7.1 Legal procedure.....	149
9.7.2 Compulsory licensing and revocation of EMR.....	149
9.7.3 Permission for residents to apply for patents outside India.....	150
9.7.4 Trademarks.....	150
9.8 Manufacturing.....	151
9.8.1 Industrial licensing.....	151
9.8.2 Additional approvals/registration.....	152
9.8.3 Reservation for public sector.....	152
9.9 Imports.....	152
9.9.1 Imports of capital goods and raw materials.....	153
9.9.2 Pharmaceutical Imports.....	153
9.10 New drug approval process.....	153
9.10.1 Drug approval procedure.....	154
9.11 Product standards.....	155
9.11.1 Labeling.....	156
9.12 Tariff structure.....	156
9.12.1 Local manufacturing duty.....	157
9.12.2 Sales tax.....	157
9.13 Marketing and distribution.....	158
9.13.1 Licensing of sales outlets and stock holding.....	158
9.13.2 Prescription drugs.....	158
9.13.3 Advertisement and Promotion.....	159
9.13.4 Regulations of advertising.....	159
9.13.5 Packing and labeling.....	159
9.13.6 Distribution.....	159
9.13.7 Brands.....	160
9.13.8 Restrictive trade practices.....	160
9.12.9 Consumer protection.....	160
10. CRITICAL SUCCESS FACTORS.....	161
10.1 Research & Development.....	161
10.2 New product development.....	162

10.3 Therapeutic coverage	164
10.4 Marketing	165
10.5 Exports	165
10.6 Critical mass	166
10.7 Low cost production through scale.....	166
10.8 World class practices	167
10.9 Conclusion	167
11. OUTLOOK.....	168