## Contents

<table>
<thead>
<tr>
<th>Section</th>
<th>Page No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.1 Ranbaxy Laboratories Limited</td>
<td>35</td>
</tr>
<tr>
<td>2.2 Dr. Reddy's Laboratories Ltd.</td>
<td>38</td>
</tr>
<tr>
<td>2.3 Cipla Limited</td>
<td>54</td>
</tr>
<tr>
<td>2.4 Sun Pharmaceutical</td>
<td>61</td>
</tr>
<tr>
<td>2.5 Lupin Ltd.</td>
<td>66</td>
</tr>
<tr>
<td>2.6 Aurobindo Pharma</td>
<td>68</td>
</tr>
<tr>
<td>2.7 GlaxoSmithKline Pharmaceuticals Ltd.</td>
<td>69</td>
</tr>
<tr>
<td>2.8 Cadila Healthcare</td>
<td>70</td>
</tr>
<tr>
<td>2.9 Aventis Pharma Limited</td>
<td>78</td>
</tr>
<tr>
<td>2.10 Ipca Laboratories</td>
<td>79</td>
</tr>
</tbody>
</table>
2.1 Ranbaxy Laboratories Limited

Ranbaxy Laboratories Limited is India's largest pharmaceutical company. Incorporated in 1961, Ranbaxy exports its products to 125 countries with ground operations in 46 and manufacturing facilities in seven countries. The company went public in 1973 and Japanese pharmaceutical company Daiichi Sankyo gained majority control in 2008.\textsuperscript{11} CEO and Managing Director Atul Sobti resigned from Ranbaxy in late 2010.

**Formation : -**

Ranbaxy was started by Ranbir Singh and Gurbax Singh in 1937 as a distributor for a Japanese company Shionogi. The name Ranbaxy is a combination of the names of its first owners Ranbir and Gurbax. Bhai Mohan Singh bought the company in 1952 from his cousins Ranbir and Gurbax. After Bhai Mohan Singh's son Parvinder Singh joined the company in 1967, the company saw a significant transformation in its business and scale. His sons Malvinder Mohan Singh and Shivinder Mohan Singh sold the company to the Japanese company Daiichi Sankyo in June 2008.

\textsuperscript{11} Bloomberg - Daiichi to Take Control of Ranbaxy for $4.6 Billion - June 11 2008

Trading:

In 1998, Ranbaxy entered the United States, the world's largest pharmaceuticals market and now the biggest market for Ranbaxy, accounting for 28% of Ranbaxy's sales in 2005.

For the twelve months ending on 31 December 2005, the company's global sales were at US $1,178 million with overseas markets accounting for 75% of global sales (USA: 28%, Europe: 17%, Brazil, Russia, and China: 29%). For the twelve months ending on December 31, 2006, the company's global sales were at US $1,300 million.

Most of Ranbaxy's products are manufactured by license from foreign pharmaceutical developers, though a significant percentage of their products are off-patent drugs that are manufactured and distributed without licensing from the original manufacturer because the patents on such drugs have expired.

In December 2005, Ranbaxy's shares were hit hard by a patent ruling disallowing production of its own version of Pfizer's cholesterol-cutting drug Lipitor, which has annual sales of more than $10 billion. In June 2008, Ranbaxy settled the patent dispute with Pfizer allowing them to sell Atorvastatin Calcium, the generic version

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12 BBC News - Patent ruling hits Ranbaxy shares - 19 December 2005
of Lipitor(R) and Atorvastatin Calcium-Amyloidipe Besylate, the
generic version of Pfizer's Caduet(R) in the US starting November 30,
2011. The settlement also resolved several other disputes in other
countries.

On 23 June 2006, Ranbaxy received from the United States Food & Drug Administration a 180-day exclusivity period to
sell simvastatin (Zocor) in the U.S. as a generic drug at 80 mg
strength. Ranbaxy presently competes with the maker of brand-name
Zocor, Merck & Co.; IVAX Corporation (which was acquired by and
merged into Teva Pharmaceutical Industries Ltd.), which has 180-day
exclusivity at strengths other than 80 mg; and Dr. Reddy's
Laboratories, also from India, whose authorized generic version
(licensed by Merck) is exempt from exclusivity.

On 10 June 2008, Japan's Daiichi Sankyo Co. agreed
to take a majority (50.1%) stake in Ranbaxy, with a deal valued at
about $4.6 billion. Ranbaxy's Malvinder Singh will remain CEO after
the transaction. Malvinder Singh also said that this was a strategical
deal and not a sell out.\(^\text{13}\)

On 16 September 2008, the Food and Drug
Administration issued two Warning Letters to Ranbaxy Laboratories

\(^{13}\) Bloomberg - Daiichi to Take Control of Ranbaxy for $4.6 Billion - June 11, 2008
LTD. and an Import Alert for generic drugs produced by two manufacturing plants in India.\textsuperscript{14}

On February 25, 2009 the U.S. Food and Drug Administration said it has halted reviews of all drug applications including data developed at Ranbaxy's Paonta Sahib plant in India because of a practice of falsified data and test results in approved and pending drug applications. "Investigations revealed a pattern of questionable data," the FDA said.

**Acquisition:**

On June 11, 2008, Daiichi-Sankyo acquired a 34.8% stake in Ranbaxy, for a value $2.4 billion. In November 2008, Daiichi-Sankyo completed the takeover of the company from the founding Singh family in a deal worth $4.6 billion by acquiring a 63.92% stake in Ranbaxy.

The addition of Ranbaxy Laboratories extends Daiichi-Sankyo's operations - already comprising businesses in 22 countries. The combined company is worth about $30 billion.

2.2 Dr. Reddy's Laboratories Ltd.

\textsuperscript{14} FDA.gov - FDA Issues Warning Letters to Ranbaxy Laboratories Ltd. - September 16, 2008 http://www.fda.gov/bbs/topics/NEWS/2008/NEW01886.html

Dr. Reddy's Laboratories Ltd. founded in 1984 by Dr. K. Anji Reddy, has become India's second biggest pharmaceutical company. Dr. Anji Reddy had worked in the publicly-owned Indian Drugs and Pharmaceuticals Ltd. Reddy's manufactures and markets a wide range of pharmaceuticals in India and overseas. The company has over 190 medications, 60 active pharmaceutical ingredients for drug manufacture, diagnostic kits, critical care, and biotechnology products.

Dr. Reddy's began as a supplier to Indian drug manufacturers, but it soon started exporting to other less-regulated markets that had the advantage of not having to spend time and money on a manufacturing plant that would gain approval from a drug licensing body such as the U.S. Food and Drug Administration (FDA). By the early 1990s, the expanded scale and profitability from these unregulated markets enabled the company to begin focusing on getting approval from drug regulators for their formulations and bulk drug manufacturing plants in more-developed economies. This allowed their movement into regulated markets such as the US and Europe.

By 2007, Dr. Reddy's had six FDA-plants producing active pharmaceutical ingredients in India and seven FDA-inspected and ISO 9001 (quality) and ISO 14001 (environmental management)
certified plants making patient-ready medications – five of them in India and two in the UK.\textsuperscript{15}

In 2010, the family-controlled Dr Reddy’s denied that it was in talks to sell its generics business in India to US pharmaceutical giant Pfizer, which had been suing the company for alleged patent infringement after Dr Reddy’s announced that it intended to produce a generic version of Atorvastatin, marketed by Pfizer as Lipitor, an anti-cholesterol medication.\textsuperscript{16} Reddy’s was already linked to UK pharmaceuticals multinational Glaxo Smithkline.

\textbf{Generics goldmine : -}

With drug prices high in most OECD member states, health services came to rely on generic versions of drugs rather than the branded ‘originals’ – in the UK this was made the result of advice to National Health Service doctors from the country’s health department and in the US by the 1984 Hatch-Waxman Act or Drug


Price Competition and Patent Term Restoration Act and the financial liberalization of the mid 1990s gave what had been 'third world' pharmaceuticals firms a chance of getting into more lucrative markets, using their ability to reverse-engineer.\textsuperscript{17} In 1997, the U.S. FDA created an incentive for generics companies to engage branded drug makers in court, with the introduction of the Para 4 filing law, in a bid to generate competition. The law rewarded generic manufacturers for challenging existing patents instead of waiting for them to expire.

\textbf{India: patents and profits:} 

In the 60 years since India's independence, the domestic pharmaceutical industry has been shaped primarily by regulation. Initially, multinationals had a near monopoly on pharmaceuticals. They imported and marketed complete formulations in India, mainly low-cost generics along with a few highly priced specialty drugs. When the government increased pressure to deter the import of finished products, multinationals set up formulating units and continued importing bulk drugs.

In the 1960s, the Indian government laid the foundation for a domestic pharmaceuticals industry by promoting the state-owned Hindustan Antibiotics Ltd. and Indian Drugs and Pharmaceuticals Ltd. for the manufacture of bulk drugs. However, the multinationals maintained their lead because of their technical expertise, financial muscle, and ability to move innovations from one market to another. The high cost of original research, the sophisticated scientific knowledge needed and a lack of financing options worked against the private-sector Indian companies.

This state of affairs changed with the 1970 Indian Patent Act, whereby substances used in foods and pharmaceuticals were not granted product patents. Process patents were granted for a period of five years from the date of grant or seven years from the date of filing, whichever was earlier. Process modifications were easier to accomplish, and there was a rapid influx of domestic manufacturers. These companies generally started with bulk drugs and gradually progressed into complete medications. The multinationals were constrained by their parent companies' product ranges but the Indian producers could make almost anything. Not paying product patent royalties cut the cost of local manufacture and helped Indian producers thrive.

Shortly thereafter, the Drugs Price Control Order put a ceiling on prices of certain mass-usage formulations. Since selling at such low prices could cause discontent in their home markets,
multinationals dramatically curtailed new product launches, further boosting India's domestic players.

Under the Foreign Exchange Regulations Act in the late 1970s, the multinationals had to reduce their stakes in Indian ventures to 40%, or comply with certain export obligations and keep their equity stake at 51%. Many multinationals preferred not to do business in that climate – another shot in the arm for India's pharmaceutical industry.

In 1986, Reddy's started operations on branded formulations. Within a year Reddy's had launched Norilet, Reddy's first recognized brand in India. But, thanks to its superior process technology, Reddy's scored a big success with Omez, its branded omeprazole – ulcer and reflux oesophagitis medication – launched at half the price of other brands on the Indian market at that time.

Within a year, Reddy's became the first Indian company to export the active ingredients for pharmaceuticals to Europe. In 1987, Reddy's started to transform itself from a supplier of pharmaceutical ingredients to other manufacturers into a manufacturer of pharmaceutical products.

**The passage from India : -**

First it moved into Russia, forming a joint venture with the country's biggest pharmaceuticals producer Biomed in 1992, pulling out in 1995 amid accusations of scandal, involving 'a
significant material loss due to the activities of Moscow's branch of Reddy's Labs with the help of Biomed's chief executive selling the joint venture to the Kremlin-friendly Sistema group and buying the whole company in 2002.18

In 1993, Reddy's entered into a joint venture in the Middle East and created two formulation units there and in Russia. Reddy's exported bulk drugs to these formulation units, which then converted them into finished products. In 1994, Reddy's started targeting the US generic market by building state of art manufacturing facility.

Reddy's path into new drug discovery involved targeting speciality generics products in western markets to gain drug discovery abilities. The reason why development of speciality drugs was an important link to the development of new chemical entities is that all the elements that are involved in an NCE effort, such as innovation in the laboratory, developing the compound, sending the sales team to the market etc. are also stages in the development of a specialty drug. Reddy's also invested heavily in building R&D labs and is the only Indian company to have significant R&D being undertaken overseas. Dr. Reddy's Research Foundation was established in 1992 and dedicated to research in area of new drug

discovery. At first, the foundation's drug research strategy revolved around searching for analogues but its changed focus to innovative R&D, hiring new scientists – especially Indian students studying abroad on doctoral and post-doctoral courses. In 2000, foundation set up a US lab in Atlanta, dedicated to discovery and design of novel therapeutics. The lab is called Reddy US Therapeutics Inc (RUSTI) and its main aim is the discovery of next-generation drugs using genomics and proteomics. Reddy's research thrust focused on large niche areas in western markets – anti-cancer, anti-diabetes, cardiovascular and anti-infection drugs.

Reddy's international marketing successes were built on a strong manufacturing base which itself was a result of inorganic growth through acquisition of international and national facilities. Reddy's merged Cheminor Drug Limited (CDL) with primary aim of supplying APIs to the technically demanding markets of North America and Europe. This merger also gave Reddy's entry into value added generics business in the regulated markets of APIs.

By 1997, Reddy's was ready for the next major step. From being an API and bulk drug supplier to regulated markets like the USA and the UK, and a branded formulations supplier in unregulated markets like India and Russia, Reddy's made the transition into generics by filing an Abbreviated New Drug Application (ANDA) in the USA. The same year, Reddy's out-
licensed a molecule for clinical trials to Novo Nordisk, a Danish pharmaceutical company.

It strengthened its Indian manufacturing operations by acquiring American Remedies Ltd. in 1999. This acquisition made Reddy’s the third largest pharmaceutical company in India, after Ranbaxy and Glaxo (I) Ltd., with a full spectrum of pharmaceutical products, which included bulk drugs, intermediates, finished dosages, chemical synthesis, diagnostics and biotechnology.

Reddy’s started exploiting Para 4 filing as a strategy in bringing new drugs to the market at a faster pace. In 1999 it submitted a Para 4 application for Omeprazole- the drug it had so successfully marketed in India. In December 2000, Reddy’s had undertaken its first commercial launch of a generic product in the USA., and its first product with market exclusivity was launched there in August 2001. The same year, it also became the first non-Japanese pharmaceutical company from the Asia-Pacific region to obtain a New York Stock Exchange listing. Each of these achievements was path breaking for the Indian pharmaceutical industry.

In 2001 when Reddy’s became the first Indian company to launch the generic drug, fluoxetine (a generic version of Eli Lilly and Company’s Prozac) with 180 day market exclusivity in the USA. Eli Lilly's antidepressant drug Prozac had sales in excess of
$1 billion per year in the late nineties. Barr Laboratories of the U.S. obtained exclusivity for all of the approved dosage forms (10 mg, 20 mg) except one (40 mg), which was obtained by Reddy’s. Lilly had numerous other patents surrounding the drug compound and had already enjoyed a long period of patent protection. The case was heard twice by the Federal Circuit court, and Reddy’s won both hearings. The importance of market exclusivity is illustrated by the fact that Reddy’s generated nearly $70 million in revenue during the six-month period. With such phenomenal returns at stake, Reddy’s was beginning to gamble on litigation that could cost millions of dollars, depending on the length of the trial.

The fluoxetine marketing success was followed by the launch of ibuprofen tablets 400, 600 and 800 mg in the US under its own brand name, in January 2003. Direct marketing under the Reddy’s brand name represented a significant step in the company’s efforts to build a strong and sustainable US generic business. It was the first step in building Reddy’s fully fledged distribution network in the US market. This was much on the lines of the Indian software majors who have marketing professionals in the US.

In 2001 Reddy’s completed its US initial public offering of $132.8 million American Depositary Receipts issue and also listed on the New York Stock exchange. Funds raised from the US initial public offering helped Reddy’s move into international production – and take over technology-based companies.
In 2002, Reddy’s started its European operations by acquiring two pharmaceutical firms in the UK. The acquisition of BMS Laboratories and its wholly owned subsidiary, Meridian UK allowed Reddy’s to expand geographically and gave company an opportunity to enter the European market. In 2003 Reddy’s also invested US$. 5.25 million in equity capital of Bio Sciences ltd.

Auriegene Discovery Technologies, a contract research company was established as a fully owned subsidiary of Reddy’s in 2002, to gain experience of drug discovery through contract research for other pharma companies. Reddy’s entered into a venture investment type of agreement with the Indian bank, ICICI. Under the terms of the agreement, ICICI Venture funds the development, registration and legal costs related to the commercialization of ANDAs on a pre-determined basis. On commercialization of these products, Dr. Reddy's pays ICICI Venture royalty on net sales for a period of 5 years. Reddy’s successful growth into a fully integrated pharmaceutical company in less than a decade was founded on a successful and targeted program of inorganic growth and investments in process R&D. It had chosen a high risk-high gain strategy to growth by going into direct competition with existing patent holders. A major challenge for Reddy’s is to find ways to de-risk its overall strategy. One way may lie in managing the cash flows from the ‘safer’ API and formulations businesses. Another way may be to seek out more experienced
partners for the R&D business or use acquisitions to boost R&D resources and revenues. It has chosen the global route and went on an acquiring spree.

In March 2002, Dr. Reddy’s acquired BMS Laboratories, Beverley, and its wholly owned subsidiary Meridian Healthcare, for EUR 14.81 million. These companies deal in oral solids, liquids and packaging, with manufacturing facilities in London and Beverley in the UK. Recently, Dr. Reddy’s entered into an R&D and commercialization agreement with Argenta Discovery Ltd., a private drug development company based in the UK, for the treatment of COPD.

With growing success in the generics market, Reddy’s also came to realize the need for developing marketing and distribution capabilities in the USA. Reddy’s was considering several options for marketing the hypertension product in 2003. The company already had one tie-up with Pharmaceutical Resources, Inc. to market Fluoxetine 40 mg tablets. It also had a tie-up with Par Pharmaceuticals Inc., to produce and market over-the-counter drugs in the U.S. In addition to the United States, Reddy’s generics business had established a presence in the UK, is a platform for expansion into other countries in Europe. Reddy’s also plans to expand its presence in Canada and South Africa. Its API business had sales in over 60 countries, with the US and India being the most significant revenue contributors. The branded formulations business
was active in over 30 countries and Reddy’s was a significant player in the Indian and Russian markets. The business planned to significantly increase its presence in China, Brazil and Mexico in the near future.

Dr. Reddy’s entered into a 10-year agreement with Rheoscience A/S of Denmark for the joint development and commercialization of Balaglitazone (DRF-2593), a molecule for the treatment of type-2 diabetes. Rheoscience holds this product’s marketing rights for the European Union and China, while the rights for the US and the rest of the world will be held by Dr. Reddy’s. Dr. Reddy’s conducted clinical trials of its cardiovascular drug RUS 3108 in Belfast, Northern Ireland, in 2005. The trials were conducted to study the safety and the pharmacokinetic profiles of the drug, which is intended for the treatment of atherosclerosis, a major cause of cardiovascular disorders.

Dr. Reddy’s entered into a marketing agreement with Eurodrug Laboratories, a pharmaceutical company based in Netherlands, for improving its product portfolio for respiratory diseases. It introduced a second-generation xanthine bronchodilator, Doxofylline, which is used for the treatment of asthma and chronic obstructive pulmonary disease (COPD) patients.

In 2004, Reddy’s acquired Trigenesis Therapeutics Inc; the US based private dermatology company. This acquisition
gave Reddy’s access to certain products and proprietary technologies in dermatology segment. Dr. Reddy’s Para 4 application strategy for generic business received a severe set back when Reddy’s lost the patent challenge in case of Pfizer’s drug Norvasc (amlodipine maleate). Amlodipine maleate, the generic version of Pfizer’s Norvasc, is indicated for the treatment of hypertension and angina. The cost involved in patent litigation as well as the strategic reversal affected Reddy’s plans to start speciality business in the US generic markets.

In March 2006, Dr. Reddy’s acquired Betapharm Arzneimittel GmbH from 3i for EUR 480 million. This is one of the largest-ever foreign acquisitions by an Indian pharmaceutical company. Betapharm is Germany’s fourth-largest generics pharmaceuticals covering 3.5% market share including 150 active pharmaceutical ingredients.

Reddy’s has promoted India’s first integrated drug development company Perlecan Pharma Pvt Ltd together with ICICI ventures capital fund management company Ltd and Citigroup Venture Capital International growth partnership Mauritius Ltd. The combined entity will undertake clinical development and out-licensing of New Chemical Entity Assets.

Dr. Reddy's is presently licensed by Merck & Co. to sell an authorized generic version of the popular drug simvastatin
(Zocor) in the USA. Since Dr. Reddy's has a license from Merck, it is not subject to the exclusivity period on generic simvastatin of 180 days from June 23, 2006, which is split between Ranbaxy Laboratories (also from India) and Teva Pharmaceutical Industries.

As on 2006, Dr. Reddy’s Labs crossed US $500 M in revenues flowing from segments such as APIs, Branded Formulations and Generics with the former two segments accounting for almost 75% of revenues. It deals in and manages all the processes, from the development of the API to the submission of finished dosage dossiers to the regulatory agencies.

**Drug discovery troubles : -**

Dr. Reddy's spun off its drug discovery and research wing into a separate company called Perlecan Pharma Private Limited in September 2005 which was hailed as an innovative move at that time but it had to be wound down in 2008 due to funding constraints. Dr. Reddy's was the first Indian pharma company to attempt such an effort to de-couple risk of drug discovery from the parent company by creating a separate company with external source of funding. Perlecan Pharma was part funded by ICICI Venture Capital and Citigroup Venture International, both of which held a 43% stake in Perlecan for an estimated $22.5 million. However, the company had to buy back the Perlecan shares from ICICI and Citigroup as the venture capitalists wanted out because of their doubts in the commercial viability of the drugs candidates that were
in Perlecan's pipeline. Dr. Reddy's bought back the shares in July and Perlecan became a wholly owned subsidiary, however in the board meeting set for 23 October, the company is set to amalgamate/absorb Perlecan, thereby making it an inhouse research facility, like before 2005.19

In 2009, the company did a U-turn and has handed over discovery research and related Intellectual property to its Bangalore based subsidiary, with the possibility of spinning it off as a different entity altogether. "The company may be hoping to find a strategic partner in the future to share the risks and research funding."

**Diabetes drug in Phase III trial : -**

The Phase III testing of the company's diabetes drug candidate, Balaglitazone, was delayed reportedly due to the Danish research partner conducting the clinical trials facing financial problems Rheoscience's parent company Nordic Bioscience is believed to have undertaken to provide funds to Rheoscience to continue the trials and thus live up to the contractual obligations to Dr. Reddy's.

In January 2010, Dr. Reddy's Laboratories announced that its first late-stage trial of the experimental diabetes drug

Balaglitazone hit its primary endpoint for the reduction of blood glucose levels. Dr Reddy's claims the data "leaves the program on track to an eventual regulatory approval".  

2.3 Cipla Limited

Cipla Limited is a prominent Indian pharmaceutical company, best-known outside its home country for manufacturing low-cost anti-AIDS drugs for HIV-positive patients in developing countries. Founded by Khwaja Abdul Hamied as The Chemical, Industrial & Pharmaceutical Laboratories in 1935, Cipla makes drugs to treat cardiovascular disease, arthritis, diabetes, weight control, depression and many other health conditions, and its products are distributed in more than 180 countries worldwide.  

Technology services: -

Cipla offers services like consulting, commissioning, engineering, project appraisal, quality control, know-how transfer, support, and plant supply.

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Apart from its presence in the Indian market, Cipla also has an export market and regularly exports to more than 185 countries in regions such as North America, South America, Asia, Europe, Middle East, Australia, and Africa. For the year ended 31 March 2007 Cipla’s exports were worth approximately Rs. 17,500 million. Cipla is also considerably well-known for its technological innovation and processes for which the company received know-how royalties to the tune of Rs. 750 million during 2006-0. Cipla has been approved by regulatory bodies such as:

- World Health Organization
- Food and Drug Administration (FDA), USA
- Therapeutic Goods Administration (TGA), Australia
- Pharmaceutical Inspection Convention (PIC), Germany
- National Institute of Pharmacy (NIP), Hungary
- The Medicines and Healthcare products Regulatory Agency (MHRA) is the UK government agency

Cipla has recently launched i-Pill which is a single dose emergency contraceptive and has acquired a great deal of popularity in a short span of time. Other latest launches of Cipla include products such as Nova, Moxicip, Flomex, Fullform, Montair LC, and Imicrit, Starpill and dytor Plus.

**HIV/AIDS in the developing world : -**

Today (2007), Cipla is the world's largest manufacturer of antiretroviral drugs (ARVs) to fight HIV/AIDS, as
measured by units produced and distributed (multinational brand-name drugs are much more expensive, so in money terms Cipla medicines are probably somewhere down the list). Roughly 40 percent of HIV/AIDS patients undergoing antiretroviral therapy worldwide take Cipla drugs.

Indian law from 1972 until 2005 allowed no (end-product) patents on drugs, and provided for compulsory licensing, Cipla was able to manufacture medicines which enjoyed patent monopoly in certain other countries (particularly those where large, multinational pharmaceutical companies are based). By doing so, as well as by making an executive decision not to make profits on AIDS medication, Cipla reduced the cost of providing antiretrovirals to AIDS patients from $12,000 and beyond (monopoly prices charged by international pharma conglomerates) down to around $300 per year. Today they are able to do so for under $150 per patient per year.

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While this sum remains out of reach for many millions of people in Third World countries, government and charitable sources often are in a position to make up the difference for destitute patients. However, in producing generic versions of drugs which are patent-protected, the company has provoked the ire of the pharmaceutical companies which own the patents.\textsuperscript{25} \textsuperscript{26} Whilst Cipla has argued that the ethics of humanitarian relief should outweigh Intellectual property considerations, brand-name pharmaceutical companies have countered that high prices are vital to offset high Research and development costs (though typically such companies spend far more on marketing and administration than they do on research).\textsuperscript{27}

Cipla developed a three-in-one tablet called \textit{Triomune} containing a fixed-dose combination (FDC) of three ARVs (Lamivudine, stavudine and Nevirapine), something difficult


elsewhere because the three patents were held by different companies. Another popular fixed-dose combination is produced under the name Duovir-N. This contains Lamivudine, Zidovudine and Nevirapine. Cipla manufactures generic versions of many of the most commonly prescribed anti-retroviral medication in the market, and is a highly capable manufacturer in its own right. This innovation made ARVs far more accessible and easy-to-take for patients everywhere, but particularly in poor- and middle-income countries, where the vast majority of people on anti-retroviral therapy (ART) now take such combination pills.

Cipla is one of the first companies to register AIDS drugs under the US program PEPFAR.

**2007 AHF campaign : -**

In August 2007 Cipla was confronted by a US-based group known as AIDS Healthcare Foundation (AHF) with a well-funded campaign of full-page ads in various Indian newspapers suggesting Cipla was pricing an AIDS drug called Viraday higher in India than in Africa.

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29 [FDA](http://www.fda.gov/internationalprograms/fdbeyondbordersforeignoffices/asiaandafrica/ucm119231.htm)  

30 AIDS Healthcare Foundation's official release on Cipla's overpricing in India, 8
It soon emerged that AHF was closely associated with American pharma conglomerate Gilead Sciences, maker of a competing drug. On September 1, 2007, The Economic Times of Delhi wrote that:

It has now emerged that Aids Healthcare Foundation (AHF), the US-based NGO that accused Cipla of over pricing anti-AIDS drug, Viraday, in India is part funded by American anti-AIDS drug maker Gilead and the NGO's treasurer is a senior Gilead executive. This is largely the reason why foreign and Indian NGOs such as Medicins Sans Frontieres (MSF), Delhi Network of Positive People (DNP+), Indian Network of Positive People (INP+), Sahara and others refused to be part of AHF's anti-Cipla campaign.”

Antiflu and Virenza :

In December 2008, Cipla won a court case in India allowing it to manufacture a cheaper generic version of oseltamivir, marketed by Hoffmann-La Roche (Roche) under the trade name Tamiflu, under the Cipla tradename Antiflu. In May 2009, Cipla won


approval from the World Health Organization certifying that its drug Antiflu was as effective as Tamiflu, and Antiflu is included in the World Health Organization list of prequalified medicinal products.32

Cipla announced that Oseltamivir 75 mg capsules marketed as `Antiflu` by the company has been included in the World Health Organization (WHO) list of prequalified medicinal products (PMP).

Oseltamivir is indicated for use in the treatment of influenza A (H1N1) infection commonly known as swine flu.

Cipla also produces a generic version of zanamivir, marketed by Glaxo under the trade name Relenza, under the Cipla tradename Virenza.

The Saudi government has recently purchased stockpiles of Antiflu in preparation for the upcoming Hajj.33

The firm announced the launch of the drug under brand name: "antiflu" on November 11, 2009 to be sold as a category

32 "Ciplas anti-flu drug gets nod", Times of India.

33 New York Times
X drug, strictly under prescription. The firm has already sold 2 lakh (200,000) doses to the Indian Government.\textsuperscript{34}

**Other drugs : -**

Cipla also has a product range comprising antibiotics, anti-bacterials, anti-asthmatics, anthelmintics, anti-ulcerants, oncology, corticosteroids, nutritional supplements and cardiovascular drugs. The company has at least nine different prescription drugs registered with the US FDA. Cipla is into anti-bacterial and anti-asthmatic segments and is the first player in Asia to launch non-CFC metered dose inhaler.

2.4 Sun Pharmaceutical

Sun Pharmaceutical (or Sun Pharmaceutical Industries Limited) is an international pharmaceutical company based in Mumbai, India. It should not be confused with Sun Pharmaceuticals Corp, which is a manufacturer of sun care products, owned by the Playtex branch of Energizer Holdings.

Sun Pharmaceutical, often known just as Sun Pharma, makes many generic and brand name drugs that are distributed in the United States, Europe, Asia and worldwide.\textsuperscript{35} Sun manufactures both


\textsuperscript{35} Sun Pharmaceutical Industries Ltd. (SUN.BO): Stock Quote & Company Profile –
pharmaceuticals and active pharmaceutical ingredients (API), in essence, ingredients to be used in finished pharmaceutical products. Its products are in several therapeutic areas, including psychiatry, neurology, cardiology, diabetology, gastroenterology, respiratory, and orthopedics.

**History:**

Established in 1983, Sun Pharma was a start-up company with five products. Since 1996, Sun has grown largely through a combination of internal growth, and acquisition of other pharmaceutical companies. For example, it bought US-based Caraco Pharm Labs, and ICN Hungary.

A planned acquisition of Israeli *Taro Pharmaceuticals* initiated in March 2007 was terminated by the Taro board in May 2008;\(^{36}\)\(^{37}\) this was subsequently followed by an unsolicited tender offer in June 2008, the outcome of which remains to be determined.\(^{38}\)

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As of 2008, it has grown to become an international speciality pharma company with more than 8000 employees, 19 manufacturing locations worldwide, two research centers, and a presence in 30 countries. It is one of the leading Indian-based pharma companies in India.  

**Corporate structure:**

The company's overall management is the responsibility of its board, whose members are

Dilip S. Shanghvi, Chairman and Managing Director. Mr. Shanghvi founded the company in 1982.

Sudhir V. Valia Executive Director

Sailesh T. Desai Executive Director

S. Kalyansundaram Chief Executive Officer and Director.

Hasmukh S. Shah Non-Executive Independent Director

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Mergers and acquisitions:

Acquisitions formed a major part of the company's growth, starting with the purchase of Knoll Pharma's bulk actives manufacturing business based in Ahmednagar in 1996. It was upgraded for approvals from regulated markets, with substantial capacity addition over the years. In that year, Sun also took a step to break into the important U.S. healthcare market, with its purchase of stake in Detroit-based Caraco Pharmaceutical Laboratories, which specialized in the manufacture of generic dosage form medications and gave Sun its first production plant approved by the U.S. Food and Drug Administration (USFDA). Also in 1996, Sun purchased a shareholding in Gujarat Lyka Organics, which brought Sun a USFDA-approved manufacturing facility.

The acquisition drive continued and in the same year it purchased a stake in MJ Pharmaceuticals Ltd., based in Halol. MJ Pharma brought Sun its strong insulin production, as well as a springboard for entry into the European market. In 1997, TDPL, a company with an extensive product offering (oncology, fertility, anesthesiology, pain management) got merged with Sun. TDPL's
products offer a ready entry with known brands and customer equity into new high growth therapy areas like oncology and gynecology.

In 1998, the company expanded its line with the purchase of a number of brands from Natco Pharma, adding some Rs 500 million to its sales. The Natco brands gave the company new products in the gastroenterology, orthopedics, pediatrics, and other categories, as well as access to Natco's time-release technology. Sun bought Milmet Labs, enabling the company to enter the ophthalmology products market for the first time. At the end of 2001, the company merged its MJ Pharmaceuticals subsidiary into its core operation at the beginning of 2002.

manufacturer with established subsidiaries, manufacturing and products across the U.S., Israel, and Canada for $454 million.\textsuperscript{40}

### 2.1 Key Acquisitions & Rationale:

<table>
<thead>
<tr>
<th>Year</th>
<th>Country</th>
<th>Acquisition</th>
</tr>
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<tbody>
<tr>
<td>2008</td>
<td>U.S.</td>
<td>Caraco acquired some products of Forest’s Inwood business</td>
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<tr>
<td>2005</td>
<td>New Jersey, US</td>
<td>Assets of Able labs</td>
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<tr>
<td>2005</td>
<td>Ohio, US</td>
<td>Formulation plant in Bryan</td>
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<tr>
<td>2005</td>
<td>Hungary</td>
<td>Acquired ICN Hungary</td>
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<tr>
<td>2004</td>
<td>US</td>
<td>Women’s Health Brands</td>
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<tr>
<td>2004</td>
<td>Baroda, India</td>
<td>Merged Phlox Pharma</td>
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<tr>
<td>2000</td>
<td>Chennai, India</td>
<td>Merged Pradeep Drug Company Ltd (PDCL)</td>
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<tr>
<td>1999</td>
<td>India</td>
<td>Merged Milmet Labs</td>
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<tr>
<td>1998</td>
<td>India</td>
<td>Brands from Natco</td>
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<tr>
<td>1997</td>
<td>Detroit, US</td>
<td>Acquired Caraco</td>
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<tr>
<td>1997</td>
<td>Chennai, India</td>
<td>Merged Tamil Nadu Dadha Pharmaceuticals Ltd (TDPL)</td>
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<tr>
<td>1996</td>
<td>Halol, India</td>
<td>Acquired MJ Pharma</td>
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<tr>
<td>1996</td>
<td>Ankleshwar, India</td>
<td>Acquired Gujarat Lyka</td>
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<tr>
<td>1996</td>
<td>Ahmednagar, India</td>
<td>Bulk Drug plant from Knoll Pharma</td>
</tr>
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### 2.5 Lupin Ltd.

Lupin Ltd. is world's largest manufacturer of the anti-TB drugs based in Mumbai, Maharashtra, India.\textsuperscript{41} The company

\textsuperscript{40} http://www.sunpharma.com/sunpharma-aboutus/acquisitions.php Accessed:

26 March 2011 4:46 P.m.
production contains the Cardiovascular (prils and statins), Diabetology, Asthma, Pediatrics, CNS, GI, Anti-Infectives and NSAIDs therapy and world largest manufacturer of Anti-TB and Cephalosporins segments.\textsuperscript{42} It is also India' fifth largest drug maker by revenue. India is the first Asian country where the company has launched the new prescription drug after launching first anti TB drugs in single tablet.\textsuperscript{43}

History :

It was founded by Desh Bandhu Gupta in 1968. It became the first in India to manufacture Anti-TB APIs. for the recruitment lupin goes jhantu college invertis institute of engineering&mgmt.bareilly which is now named as invertis university.


2.6 Aurobindo Pharma

**History : -**

Aurobindo Pharma was born of a vision. Founded in 1986 by Mr. P.V.Ramaprasad Reddy, Mr. K.Nityananda Reddy and a small, highly committed group of professionals, the company became a public venture in 1992. It commenced operations in 1988-89 with a single unit manufacturing semi synthetic penicillins (SSPs) at Pondicherry.

Aurobindo Pharma had gone public in 1995 by listing its shares in various stock exchanges in the country. The company is the market leader in semi-synthetic penicillin drugs. It has a presence in key therapeutic segments like SSPs, cephalosporins, antivirals, CNS, cardio-vascular, gastroenterology, etc.

Over the years, the Aurobindo Pharma has evolved into a knowledge driven company. It is R&D focused, has a multi-product portfolio with multi-country manufacturing facilities, and is becoming a marketing conglomerate across the world.

Aurobindo Pharma created a name for itself in the manufacture of bulk actives, its area of core competence. After ensuring a firm foundation of cost effective production capabilities and a clutch of loyal customers, the company has entered the high
margin speciality generic formulations segment, with a global marketing network.

The formulation business is systematically organised with a divisional structure, and has a focused team for each key international market. Aurobindo believes in gaining volume and market share in every business/segment it enters.

Aurobindo has invested significant resources in building a mega infrastructure for APIs and formulations to emerge as a vertically integrated pharmaceutical company. Aurobindo’s five units for APIs and four units for formulations are designed for the regulated markets.  

2.7 GlaxoSmithKline Pharmaceuticals Ltd.

GlaxoSmithKline Pharmaceuticals Ltd. is an Indian subsidiary of GlaxoSmithKline plc, one of the world’s leading research based pharmaceutical and healthcare companies. It is one of the oldest pharmaceuticals company in India. It product portfolio includes prescription medicines and vaccines. Its prescription medicines range across therapeutic areas such as anti-infectives, dermatology, gynaecology, diabetes, oncology, cardiovascular disease and respiratory diseases. It also offers a range of vaccines, for the prevention of hepatitis A, hepatitis B, invasive disease caused by

H. influenzae, chickenpox, diphtheria, pertussis, tetanus, rotavirus, cervical cancer and others.45

**History:**

It was founded 13th November 1924 in India under the name of H.J.Foster & Co. Limited as an Agency House for distributing Baby Food Glaxo, Joseph Nathan & Co. In 1950 it changed its name to Glaxo Laboratories (I) Ltd.46

2.8 Cadila Healthcare

'Cadila Healthcare' is an Indian pharmaceutical company head quartered at Ahmedabad in Gujarat state of western India. The company is the fifth largest pharmaceutical company in India,47 with US$290m in turnover in 2004. It is a significant

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manufacturer of generic drugs. Cadila Pharma have developed a drug named Roserin which has reduced the cost of curing TB by 33%.

**History : -**

Cadila Laboratories was founded in 1952 by Ramanbhai Patel (1925–2001), formerly a lecturer in the L.M. College of Pharmacy, and his business partner Shri Indravadan Modi. The company evolved over the next four decades into one of India's established pharmaceutical companies.

In 1995 the Patel and Modi families split, with the Modi family's share being moved into a new company called Cadila Pharmaceuticals Ltd. and Cadila Healthcare became the Patel family's holding company. Cadila Healthcare did its IPO on the Bombay Stock Exchange in 2000. Its stock code on the Bombay exchange is 532321.

In 2001 the company acquired another Indian pharmaceutical company called German Remedies. On June 25, 2007, the company signed an agreement to acquire 100 per cent stake in Brazil's Quimica e Farmaceutica Nikkho do Brasil Ltda (Nikkho) for around 26 million dollars.

**Products : -**
From nine pharmaceutical production operations in India as well as a major R&D operation Zydus Cadila develops and manufactures a large range of pharmaceuticals as well as diagnostics, herbal products, skin care products and other OTC products. The company also makes EverYuth Naturals Walnut Scrub & Ultra Mild Scrub - India’s leading scrub brand, EverYuth Naturals Golden Glow Peel-Off - the no. 1 in the peel-off category and a face wash range. It is also the maker of Sugar Free, India's most popular artificial sweetener, and Nutralite, India's most popular cholesterol-free margarine.48

**Active pharmaceutical ingredient plants :-**

The company makes active pharmaceutical ingredients at three sites in India:

**Ankleshwar plants :-**

Zydus Cadila’s plant complex at Ankleshwar in Bharuch District of Gujarat, has been producing drug material since 1972. There are around 10 plants in the complex, which is ISO 9002 and ISO 14001 certified as well as FDA Approved. Total plant capacity at Ankleshwar is around 180 million tonnes.

**Vadodara plant : -**

Zydus Cadila's plant at Dhabhasa, in Vadodara District's Padra taluka (in the eastern part of the district) in Gujarat, was commissioned in 1997 by a company called Banyan Chemicals, and acquired by Zydus Cadila in 2002. The plant has a 90 million tonne capacity. It is an FDA-approved facility that is also approved to WHO GMP guidelines.

**Patalganga plant : -**

Zydus Cadila acquired an API plant at Patalganga in Maharashtra state, 700 km from Mumbai, about 200 km from Nagpur, in the 2001 German Remedies deal. This plant operates to WHO GMP standards.

**Formulation plants : -**

The company operates from multiple locations:

**Zydus Tower : -**

Zydus Tower is the multi-story corporate office of the Group and Seat of the Chairman. All strategic functions and department are located here. It is situated in the Western Ahmedabad at Satellite Road.

**Moraiya plant : -**
Zydus Cadila’s formulation plant at Moraiya in Sanand taluka on the outskirts of Ahmedabad is the largest formulation plant in India. It plant became Food and Drug Administration (FDA)- approved in 2004/2005. The plant makes tablets, capsules, and soft gel capsules as well as injectable drugs in both sterile liquid and lyophilized form. Zydus Cadila also runs a large R&D operation at Moraiya; This Plant manufactures Regulated, Semi-Regulated and LATAM market products.

**Ankleshwar plant :** -

Zydus Cadila’s API/Bulk Drug Plant in Ankleshwar is the oldest manufacturing facility of the Company. This plant too has received approvals from various FDA agencies including USFDA.

**Dabhasa plant :** -

Zydus Cadila’s API/Bulk Drug Plant in a village about 20 kilometers South from Vadodara houses one of the largest process research (API) centers in the country. This plant belonged to Banyan Chemicals which was acquired by Zydus in 2003.

**Vatwa plant :** -
Zydus Cadila's plant at Vatwa, an industrial suburb of Ahmedabad, makes products for Animal Health care division of the company.

**Zyfine plant (Changodar) : -**

Zydus Cadila’s plant at Changodar, 20 kilometres from Ahmedabad on the city's outskirts, manufactures fine chemicals. Zydus is current constructing a facility at Changodar to make vaccines for hepatitis B and rabies.

**Zydus Research Centre (Changodar) : -**

Zydus's NCE, NME, MBE research facility is the largest of its kind in Indian, with more than 500 post graduate scientists it is working towards the prosperous future of the company and Indian Pharmaceutical Industry.

**Zydus Hospira Oncology Pvt. Ltd. (SEZ, Matoda) : -**

Zydus's JV venture with Hospira Inc. of US manufactures Anti Cancer Injectables at this plant. This plant is also USFDA approved and situated in Special Economy Zone, about 25 kilometers from Ahmedabad. This SEZ is developed by Zydus Infrastructure Pvt. Ltd., another group company of Zydus.

**Zydus - BSV(SEZ, Matoda) : -**
Zydus’s JV with Bharat Serum and Vaccine Ltd.’s Plant is another facility located in the same SEZ.

**Zydus Technologies Ltd.(SEZ, Matoda) : -**

Zydus's JV with Noveltech Inc.Plant is another world class facility located in the same SEZ for Novel Drug Delivery Systems.

**Nutralite Manufacturing Fascility (Changodar) : -**

Zydus manufactures and sells, Nutralite - a health, butter substitute. This plant comes under the banner of Zydus Wellness Ltd. This company also manufactures and sales, popular brands as SugraFree, Everyouth, Everyouth Men’z and D’lite.

**Navi Mumbai plant : -**

This operation, at Navi Mumbai in Maharashtra, is a 50/50 joint venture with Nycomed Pharma of US, makes intermediates of the drug pantoprazole.

**Mumbai Business Office : -**

This office houses Business Unit India - 2 or German Remedies. This office belonged to German Remedies (I) Ltd. This company was acquired in 2000. This was the biggest takeover in the
History of Indian Pharmacological Industry. German Remedies is now a Registered Trademark of Cadila Healthcare Ltd.

**Goa plants** :

The company's plants at Ponda in the southern Indian state of Goa do formulation work as well as manufacture oncology drugs and a herbal laxative branded *Agiolax* based on Psyllium seeds. These Plants belonged to German Remedies (I) Ltd. too and now are part of Business Unit - Manufacturing of the Company.

**Baddi plant** :

In 2004 Zydus commissioned at formulation plant at Baddi, in Himachal Pradesh state of northern India. The Baddi plant makes solid oral pharmaceuticals.

**Sikkim plant** :

In 2008 Zydus commissioned at formulation plant at Majhitar, in Sikkim state of eastern India. The Sikkim plant makes solid oral pharmaceuticals and hormones. This plant now caters almost all Domestic Formulation needs of the Company.

**Corporate control** :

Zydus Cadila's major shareholder remains the Patel family. Pankaj Patel (born 1951), son of the founder, is CEO. In 2004 Pankaj Patel was included by *Forbes* magazine in its annual List of
India's richest people. *Forbes* estimated Patel's net worth at US$510m, making him India's 26th richest person. However in 2005 Patel dropped off the *Forbes* list due to a fall in the stock price of Cadila Healthcare. Moreover, there is a team of nine senior level executives, known as the Executive Committee, who are heads of different operations look after the overall management processes. None of the members except Pankaj Patel are on the Board of Directors. In September 2007 Cadila in a joint venture opened a pharmaceutical plant in Ethiopia.

2.9 Aventis Pharma Limited

Aventis Pharma Limited headquartered in Mumbai, is a part of Sanofi-Aventis group. Sanofi-Aventis and its 100% subsidiary Hoechst AG, are the major shareholders of Aventis Pharma Limited. Its manufacturing portfolio contains medicines for several therapeutic areas including cardiovascular, thrombotic, metabolic disorders, oncology, disorders of the central nervous system.

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system, internal medicine.\textsuperscript{51} Its primarily business is medicines in the dosage forms of liquid injectibles, tablets, capsules, ointments, drops and syrup.\textsuperscript{52} In July 2003, company launched Lantus, the world’s first and only once a day insulin.\textsuperscript{53}

**History : -**

Aventis Pharma Limited was incorporated in May 1956 under the name Hoechst Fedco Pharma Private Limited.\textsuperscript{54} Over the years, its name was changed to Hoechst Pharmaceuticals Private Limited, Hoechst India Limited and Hoechst Marion Roussel Limited.

2.10 Ipca Laboratories

\textsuperscript{51} "BUSINESS OPPORTUNITIES Maharashtra Page 51"

\textsuperscript{52} "Top 500 Companies 2009"

\textsuperscript{53} "Aventis Pharma Ltd Background details about Company Profile"

\textsuperscript{54} "Sanofi Aventis plans rural push under Hoechst brand"
Ipca Laboratories is an international pharmaceutical company based in Mumbai, India. It is also one of the largest suppliers of these APIs and their intermediates world over. It produces more than 150 formulations that include oral liquids, tablets, dry powders, and capsules. The various kinds of drug intermediates that the company manufactures include Theo bromine, Acetylthiophene, and P-Bromo Toluene and promotes over 36 countries of Asia, Africa, CIS, and South America, including Cambodia, Kazakhstan, Kenya, Mauritius, Myanmar, Nigeria, Oman, Russia, Sri Lanka, Sudan, Tanzania, Ukraine, Vietnam and Yemen. The main activities of company are to produce and market pharmaceuticals and drugs. The various products of the company include formulations, drug intermediates, and active pharmaceutical ingredients (API). In 2004, Forbes selected Ipca, for the second consecutive year as one among the first 200 'Best under a Billion Company' in Asia.


It also got certification from US Food and Drug Administration (FDA), UK-Medicines and Healthcare products Regulatory Agency (MHRA), South Africa-Medicines Control Council (MCC), Brazil-Brazilian National Health Vigilance Agency (ANVISA) and Australia-Therapeutic Goods Administration (TGA).

**History:**

It was founded by group of businessmen and medical professionals in 1949. In 1975, the management of the company was taken over by Amitabh Bachchan, Ajitabh Bachchan, Jaya Bachchan, M.R. Chandurkar, P.C. Godha.