A Failure of Regulatory Diligence: A Case Study of Ranbaxy Laboratories Ltd

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Ranbaxy Laboratories Ltd., based in India, with sales both in India and abroad, yet ironically was pulled up for violations from GMP only by the United States Federal Drug Administration (USFDA). Records of any active regulatory diligence by Indian pharma regulators that may have prevented the slide of this once internationally reputed company seems unavailable. International investigations on Ranbaxy has inevitably led to questions also being raised on the safety and manufacturing processes and practices of the entire Indian pharmaceutical industry. While the case study dwell on lapses by Ranbaxy Laboratories, it is in parallel a critique on regulatory lapses of Indian pharmaceutical regulators.

1. Introduction

*I*n 2014, when Sun Pharma acquired 64% of Ranbaxy Laboratories from Daiichi Sankyo for$3.2 billion, it would be the second time the company has changed hands in 6 years (Malhotra, 2014). The earlier acquisition of Ranbaxy by Daichi Sankyo in June 2008 from the original promoter family, had got mired in a series of controversies regarding diligence disclosures by the promoters. This has led to an arbitration court in Singapore levying a fine of $525 million on former shareholders of India's Ranbaxy Laboratories for concealing the severity of its regulatory issues with United States Federal Drug Administration (USFDA)

The first wave of serious trouble hit Ranbaxy in the year 2008 when the FDA suspended importation of more than 30 products from Ranbaxy Laboratories Ltd after discovering manufacturing and quality violations that were revealed by a whistle blower in 2007(Associated Press, 2013). Consequently in 2011, FDA struck a deal with Ranbaxy that required the company to ensure that data on its products was accurate. It was also required to undergo extra oversight from a third-party and improve its drug making procedures. From then onwards, the company went rapidly downhill, so much so that even a visit to the website of the Sun Pharma will show no milestones listed against Ranbaxy post 2012. Finally in 2013, Ranbaxy Laboratories Limited agreed to plead guilty to criminal charges and admitted as part of the deal that it sold impure drugs developed at two manufacturing sites in India. A once admired company had fallen into disrepute. But the signs of misdemeanor were evident from the year 2002 onwards itself.

Ironically before the highlighting of quality lapses in 2008 onwards, Ranbaxy was regarded as one of the leading pharmaceutical companies in the world. With a revenue of US $ 260 million in 2006 and a share of 5.1% in the domestic market, Ranbaxy Laboratories Ltd. was India's largest pharmaceutical company. It's international sales at that time was $ 1.3 billion and was one of the largest ANDA (Abbreviated New Drug Application) filers with US FDA (United States Food and Drug Administration). The company's offices were spread over 49 countries with approximate employment strength of 12,000. (Bhatt P. R.) Not only was it one of the ten largest generic drug manufactures in the country, it also had a strongly international focus with three-fourth of Ranbaxy's revenue coming from international sales, with the US alone accounting for almost one third(Bhatt P. R.).

The transition from a leading company to one that is mired in controversy has entirely come about through investigations by USFDA into Ranbaxy's operations initiated largely through Dinesh Thakur, an employee of Ranbaxy later turned whistleblower. He found that the generic drugs that were made by Ranbaxy used bioequivalence data that either did not exist or was made up. The Indian regulators virtually sat through the entire process with no independent investigations into Ranbaxy's manufacturing processes. Given that Ranbaxy had a huge domestic market, this constituted a serious dereliction of regulatory oversight by Indian pharma regulators. Very recently, Dinesh Thakur has filed a Public Interest Litigation (PIL) against Indian drug regulators accusing them of failure to enforce safety standards in the $ 15 billion domestic drug industry.

In his filing, Thakur has also cited the case of CDSCO allowing UCB to sell Buclizine (later marketed by Mankind Pharma) as an appetite stimulant in 2006 even though it was not approved for that purpose in Belgium and moreover banned in several other countries. Neither UCB nor later Mankind Pharma was asked to conduct clinical studies on the efficacy of the drug even though the drug was still being sold in the market. Apparently, despite a demand for an enquiry into the same by a parliamentary committee in 2013, Reuters at the time of going into print has not received any intimation of any initiation of any enquiry.

The fall from grace of a once reputed company might primarily be blamed on management of the company but it somewhat also puts Indian drug regulators in the dock for turning a blind eye to violations by the company. It also brings into question why regulators in India did not move fast enough to take matters into their hand once violations were discovered. Throughout the USFDA investigations into the affairs of Ranbaxy, there was virtually no parallel inquiry that was conducted at the end of Indian regulators even though the process was long drawn out and was in the public domain. Only as late as 2014, when Ranbaxy was final banned, did Indian regulators sit up and take notice, but hid under the excuse that they neither had the resources & infrastructure nor the standards commensurate with the USFDA to do a similar level of stringent vetting. (Dey, 2014)

1. HISTORY OF RANBAXY

1937-1968: Origins

Ranbaxy, was founded in Amritsar in 1937 as a distributor company distributing vitamins and anti-tuberculosis drugs for a Japanese pharmaceutical company by Ranjit Singh and Dr Gurbax Singh. The company was bought by Bhai Mohan Singh from his cousins thereafter. It ventured into a distribution alliance with an Italian company Lapetit in 1951. It's manufacturing venture began with technical assistance from Lapet it for some limited local manufacture in 1961. The association with Lapetit ended in 1966, with Ranbaxy making a decision to get into more local formulations and also into reverse engineering of drugs (Sundar). Ranbaxy tasted success for the first time in the 1960s with a drug marketed under the name of 'Calmpose', a tranquilizer made from diazepam imported from a supplier in Soviet Bloc. Incidentally, diazepam, was owned by Roche but it hadn't sought patent protection for it in India. Calm pose went on to become India's first pharmaceutical super-brand (Bhandari, 2014).

1969-2006: Growth and Consolidation

With the new patent regime initiated in India in 1970 being based on process rather than product, Ranbaxy got an opportunity to make any drug in India provided they could follow a different process. The new patent regime coupled with price controls on drug pricing, and restrictions on quantum of equity holding in Indian local companies by multinational companies gave a fillip to local manufacture that Ranbaxy was also able to take advantage of. It established its bulk drugs facility at Mohali, Punjab, in 1971 primarily to manufacture antibiotics. It went on to make it first public issue in 1973 which though meant to mobilize INR 70 lakh, was oversubscribed 14 times**Error! Bookmark not defined.**(Bhandari, 2014).

It's first foray into antibiotics was with "Roscillin" with imported ampicillin since Beecham had not taken a patent on the ampicillin. Owing to high landed cost of ampicillin, Ranbaxy started manufacturing it in its own factory at Mohali. It followed it up with more semi-synthetic penicillin drugs, a whole new category of antibiotics from the cephalosporin family and over-the-counter products that could be sold without a doctor's prescription.

In 1975, the recommendations of the Hathi Committee gave more advantage to local companies by allowing increase of the ratio of bulk drugs to formulations to 1:4 for Indian companies as against 1:2 for multinational companies. This ratio was later increased to 1:10 subsequently. This, the low cost of labour and capital cost to set up a pharmaceutical drug company in India gave a huge advantage to Ranbaxy which then started exporting generic products, which were off- patent, or "copies" of patented drugs to countries which were prepared to accept them. After a family split in 1980, and ouster of Bhai Mohan Singh, the control of the company passed on to Parvinder Singh, son of Bhai Mohan Singh who converted it into an international company. In 1992, Ranbaxy expanded its operations via a joint venture with Eli Lilly to manufacture Lilly products in India and market them throughout South Asia. In 1994, Eli Lilly also contracted Ranbaxy to make generics for it. Ranbaxy continued to engage in alliances and acquisitions to gain scale though post 2004, its international activities had considerably accelerated.

In 2001 Ranbaxy entered the consumer healthcare market through the launch of 4 brands Revital, Pepfiz, Gesdyp & Garlic Pearls. In 2004, it launched its first herbal range of products through New Age Herbals (NAH), with products offering remedies in categories of Cough & Cold (Olesan Oil & Cough Syrups) and Appetite Stimulant (Eat Ease).In 2005, another popular brand, Chericof – The complete cough formula was introduced. During 2006, the business registered sales of $19 Million registering a growth of 19%. Revital, the flagship brand continues to maintain leadership in its segment (NDTV Profit).

2006-2014: Declining Fortunes and Leadership Changes

In June 2008, Japan's third-largest drug maker Daiichi Sankyo paid $ 4.6 billion to buy a 64% state with the third generation of the promoter family, Malvinder and Shivinder Singh ceding control. This was done through acquisition of the entire 34.82 per cent stake of the promoter holding, an open offer for an additional 20 per cent stake in Ranbaxy and9 per cent through issue of preferential allotment of shares and some warrants which could be later converted into another 4.5 per cent holding. This valued the company at about $8.5 billion or INR Rs 36,000 crore in 2008(Lee, 2008).

In September 2008. barely three months after Daiichi took control of Ranbaxy, the US FDA banned 30 generic drugs manufactured from three of Ranbaxy's units in India – Dewas (Madhya Pradesh), Paonta Sahib and Batamandi unit in Himachal Pradesh – citing gross violation of approved manufacturing norms. Later, the US department of justice moved a motion against the company in a local court alleging forgery of documents and fraudulent practice.

The decision by the US Food and Drug Administration (FDA) to put Ranbaxy Laboratories on the Application Integrity Policy (AIP) list on February 24, 2009 meant stepping down of Malvinder from the company in May 2009. Putting Ranbaxy

on the AIP meant it was now the onus of the company to prove that its drugs were of quality and that it was no longer the FDA that had to look at Ranbaxy's data to prove the drugs didn't make the grade. The AIP covered all products manufactured at Ranbaxy's facility at Paonta Sahib, Himachal Pradesh. In August 2011, Ranbaxy also closed the unit located at Gloversville, NY, USA.

With FDA putting Ranbaxy on watch, Daiichi Sankyo also proceeded to initiate legal proceedings against the the former promoters of India's biggest drug maker Ranbaxy Laboratories Limited — Malvinder Singh and family for concealing and misrepresenting critical information.

This turbulence in Ranbaxy was also reflected in its leadership changes. The CEO of the firm, Mr. D.S. Brar stepped down in June 2004 following differences with the family. This was followed by a series of leadership changes beginning from Mr. Brian Tempest (July 2004-December 2005), Malvinder Singh (January 2006-May 2009), Atul Sobti (June 2009- August 2010) and finally Mr. Arun Sawhney (September 2010-October 2015). Finally, in April 2014, Sun Pharmaceutical Industries Ltd announced the acquisition of Ranbaxy Laboratories Ltd in an all–stock transaction.

The Sun Pharmaceutical Industries' $3.2-billion all-share acquisition of Ranbaxy created not only India's largest pharmaceutical company but also a significant global supplier of generic medicine. The biggest question however was turning around Ranbaxy which had already been under financial stress for several quarters. Its four plants had been barred from selling in the United States. It has already admitted that it had falsified data while seeking approval of the United States Food & Drug Administration, for its generic medicines and also paid a penalty of $500 million to settle the matter (Dey, Sun Pharma draws up plan to fix ailing Ranbaxy, 2014).

2. The Brush with the Food and Drug Administration, USA

Since 2002, Ranbaxy has seemed to actively court the wrath of FDA regarding its compliances with the United States Current Good Manufacturing Practices (CGMP). The degree of seriousness intensified from the year 2006 with 4 of its manufacturing facilities declared as being under a consent decree by 2014.

A first letter of warning was issued to Ranbaxy Laboratories in 2002 regarding the safety and effectiveness in relation to Guafenesin LA Tablets 600 mg. The second warning issued in 2006 was in relation to the pharmaceutical manufacturing facility in Paonta Sahib detailing significant deviations from U.S. Current Good Manufacturing Practice (CGMP) Regulations in the manufacture of drug products as per FDA 483 form. The deviations among others referred to failure in retaining [redacted] analytical raw data, undocumented stability sample test intervals, the unclear purpose of "standby samples, the FDA lab results for Isotretinoin capsules, and the inadequate staffing and resources in the stability laboratory.

The 3rd warning letter detailing significant violations from the Current Good Manufacturing Practice (CGMP) regulations for finished pharmaceuticals was issued in 2009 with regard to its pharmaceutical manufacturing facility, Ohm Laboratories, Inc., located at New York, USA. The inspection revealed drug product(s) to be adulterated in that the methods used in; or the facilities or controls used for, their manufacture, processing, packing, or holding did not conform to or were not operated or administered in conformity with CGMP regulations. It also charged the company with manufacturing and distributing a prescription drug without approved application.

In, 2008 the FDA issued two warning letters and an import alert for generic drugs produced by Ranbaxy's Dewas and Paonta Sahib plants in India which covered 30 generic drugs produced by Ranbaxy for deviations from U.S. Current Good Manufacturing Practice (cGMP). The deviations identified included:-

- The facility's beta-lactam containment program (measures taken to control cross-contamination), appeared inadequate to prevent the potential for cross-contamination of pharmaceuticals;
- Inadequate batch production and control records;
- Inadequate failure investigations to address any manufacturing control or product rejection to determine the root cause and prevent recurrence);
- Inadequate aseptic (sterile) processing operations;
- The lack of assurance that responsible individuals were present to determine whether the firm was taking necessary steps under cGMP;
- Inaccurate written records of the cleaning and use of major equipment;
- Incomplete batch production and control records

In 2009, the FDA halted review of drug applications from the Paonta Sahib plant due to evidence of falsified data and invoked the Application Integrity Policy(AIP). It announced that the facility falsified data and test results in approved and pending drug applications and that it had submitted stability information in numerous approved and pending applications that contain untrue statements of material fact. This led the Department of Justice, on behalf of the U.S. Food and Drug Administration, to file a consent decree of permanent injunction against Ranbaxy Laboratories, Ltd., an Indian corporation and its subsidiary Ranbaxy Inc., headquartered in Princeton, N.J. The consent decree required that Ranbaxy comply with detailed data integrity provisions before FDA would resume reviewing drug applications containing data or other information from the Paonta Sahib, Batamandi, and Dewas facilities. Specifically, Ranbaxy was required to:-

1. Hire a third-party expert to conduct a thorough internal review at the facilities and audit applications containing data from the affected facilities;
2. Implement procedures and controls sufficient to ensure data integrity in the company's drug applications; and

3. Withdraw any applications found to contain untrue statements of material fact and/or a pattern or practice of data irregularities that could affect approval of the application.

In addition, the consent decree prevented Ranbaxy from manufacturing drugs for introduction to the U.S. market and for the President's Emergency Plan for AIDS Relief (PEPFAR) Program at the Paonta Sahib, Batamandi, Dewas, and Gloversville facilities until drugs can be manufactured at such facilities in compliance with U.S. manufacturing quality standards.

In 2013, Ranbaxy USA Inc., a subsidiary of Ranbaxy Laboratories Limited, pleaded guilty to three felony FDCA counts, and four felony counts of knowingly making material false statements to the FDA regarding generic drugs made at two of Ranbaxy's manufacturing facilities in India. It agreed to pay a criminal fine and forfeiture totaling $150 million and to settle civil claims under the False Claims Act and related State laws for $350 million. This happened to be USA's largest financial penalty paid by a generic pharmaceutical company for FDCA violations Specifically, Ranbaxy USA admitted to introducing certain batches of adulterated drugs that included Sotret (branded generic form of isotretinoin, a drug used to treat severe recalcitrant nodular acne), Gabapent in (used to treat epilepsy and nerve pain), and Ciprofloxacin (broad-spectrum antibiotic)

The FDA also followed up the above order with an import alert under which U.S. officials could detain at the U.S. border drug products manufactured at Ranbaxy Laboratories, Ltd.'s facility in Mohali, India. It's Mohali plant was prohibited from manufacturing FDA regulated drugs until the firm's methods, facilities, and controls used to manufacture drugs at the Mohali facility are established, operated, and administered in compliance with CGMP.

In 2014, the FDA prohibited the Toansa facility of Ranbaxy to manufacture and distribute active pharmaceutical ingredients (APIs) for FDA-regulated drug products. Among others the FDA's form 483 listed numerous violations from CGMP which included flies in the sample storage room, inadequate control over sample and non-adherence of procedures in sample analysis. The report especially came strongly on the deliberate falsification of data by Ranbaxy through methods of retesting suspect API results until acceptable results were obtained, or in failing that not reporting suspect results. Some other lapses that were discovered during inspection included- samples not being analysed according to established laboratory test method procedures, non-reporting of numerous test results, lack of written procedures and documentation of test results, inadequate controls over computerized systems, backdating testing records and log books, and non-control of laboratory samples to prevent mixing of samples. There were also inadequacies in laboratory facilities, maintenance of manufacturing equipment, and calibration of analytical instruments.

3. Drug Regulation in India

The Centre for Drug Standard and Control Organization (CDSCO) is the Indian equivalent of the USFDA. It functions under the Central Government and owes its existence to the Drugs and Cosmetics Act. The CDSCO has Regulatory control over the import of drugs, approval of new drugs and clinical trials. It lists its mission as *"To safeguard and enhance the public health by assuring the safety, efficacy and quality of drugs, cosmetics and medical devices."*

In the context of export of drugs, all drug manufacturers are required to get a NOC for the export of drugs against a valid export order. Along with requirements, the applicant is required to identify the premises where the drug will be manufactured for export, and also whether the batch has undergone quality control testing. The last condition also expressly mentions that the drug for which NOC has been given shall cease to be manufactured or exported if the drug is prohibited in future in the country or in the importing country.

Given the large number of instances of adulterous drugs flooding the market or flaws in the clinical trial processes, it is evident that Indian drug manufactures have serious quality issues (Khan & Khar, 2015). Ranbaxy laboratories may have been one of the large cases that have been pulled up by the FDA, but is only reflective of the weak regulatory regime in the country on drug manufacturing (Chowdhary, et al., September 2015). Very recently, CDSCO initiated a detailed survey involving 50,000 samples to judge the extent of counterfeit drugs that are available in the market. (Ghosh, 2015) In fact, with more and more cases of spurious drugs hitting the market, the Government has been forced to sit up and take cognizance of the functioning of CSDCO. The Parliamentary Standing Committee on Health and Family Welfare Sixty-Sixth report on action taken by the Government on the recommendations/observations contained in the 59th report on the functioning of Central Drugs Standards Control Organization (CDSCO) pointed out serious weaknesses in the functioning of CDSCO along with glaring inconsistencies and illegalities in its drug approval process. The government's inability to discipline CSDCO was also highlighted in light of the lax action taken on earlier recommendations related to CSDCO. (Parliamentary Standing Committee on Health and Family Welfare, 2013)

"In the instant case, it is clearly apparent from the analysis of the action taken by the Government on the Recommendations of Committee that out of 69 Recommendations that were actionable, only 19 have been implemented by the Government in varying degrees. In case of 46 Recommendations the action taken by Government is only with the intent to delay, obfuscate, stagger implementation or not implement at all with a view to delay/negate action in proven cases of wrong doing."

This is a sharp contrast to the seriousness with which countries like United States approach the issue of drug safety. In 2012, a report on how FDA Approves Drugs and Regulates Their Safety and Effectiveness was submitted before US Congress. A similar elaborate process with detailed standard operating procedures needs to be also explored for CDSCO for their approval and safety process for drugs that are manufactured in the country or allowed to be used in India.

4. Conclusion

The FDA lays down the toughest regulations in relation to drug discovery, manufacturing and distribution to ensure that the American public gets access to quality drugs. Any manufacturer aiming to enter the U.S. market must comply with the strictest standards of quality and safety. Given the huge anomalies that were discovered in Ranbaxy's manufacturing facilities, it leads one to suggest that the same quality standards are not enforced by Indian drug regulators for drugs that are manufactured, and sold to the Indian consumer. A very detailed investigative report on the regulatory and safety process of the Indian drug industry has been compiled by Dinesh Thakur and Prashant Reddy T.(Thakur & Reddy, 2016) It outlines the *"fragmented federal drug regulatory framework, the weak investigation and enforcement mechanism under the Drugs and Cosmetics Act, 1940, and the absence of fundamental quality testing and recall norms in Indian law"* as responsible for the extremely lax standards that prevent Indian consumers from consuming adulterated drugs. If in fact, the weakness of the drug regulatory system did not exist, Ranbaxy Laboratories perhaps would never have been exposed to this kind of intense scrutiny by the USFDA. This situation also does not portend well for Indian companies that would like explore international markets especially the Western developed ones. If this situation is allowed to persist, quality and safety concerns will continue to plague the reputation of Indian drug manufacturers. This will have long not only term public health implications but also competitiveness concerns for Indian drug manufacturers both within and outside India.

Table I *Ranbaxy's Fall from Fame: A Chronological Timeline*

October 2003	A consulting firm reported to Ranbaxy's Director of regulatory affairs, that *"formalised training as required by cGMPs (current good manufacturing practices)...was essentially non-existent"* and that investigations into product complaints were 'incomplete and poorly documented' and that numerous discrepancies were found in the 'source data'. Ranbaxy's senior management overlooked the matter.
February-March 2005	An independent consulting firm that audited Dewas and Paonta Sahib facilities warned Ranbaxy that the existing level of GMP (good manufacturing practices) compliance wouldn't meet US FDA's expectation. It had also red-flagged the data documentation of the company, claiming that 'batch records from all sites were found to be deficient' and that the firm needs to completely overhaul the batch records to ensure consistency in manufacture of batches. The auditor alerted Ranbaxy that staffing was inadequate in the stability department of the Paonta Sahib facility and that the stability programme needed 'enhancement' to be aligned to US industry practices. It also asked "Ranbaxy personnel to acquire a better understanding of principles of validation to meet current US regulatory requirement and expectation and to be in alignment with the accepted US industry practices".
April 2005	A consulting firm asked the pharma company to run a training programme for its employees to 'create a culture of trust, ethical behaviour, and quality first mindset'.
April-March 2005	Dinesh Thakur, the then director of research information & project management at Ranbaxy and his boss Rajinder Kumar, who headed R&D, quit the firm in April and March 2005 respectively. Dinesh Thakur who later turned whistle blower informed the US court that Mr Rajinder Kumar had alerted the top brass of the dubious practices of falsification of data and other malpractices between September to December 2004
December 2005	A US court ruled against Ranbaxy in its case for non-infringement and invalidation of two patents of its competitor Pfizer on cholesterol-lowering drug Atorvastatin, prompting the Indian pharma major to announce that it would appeal against the decision. The drug is marketed by Pfizer under brand name Lipitor and is the largest selling drug in the world
June 2006	The FDA issues a warning letter to Ranbaxy for deviations from standard good manufacturing practices at its Paonta Sahib manufacturing facility in Himachal Pradesh. The letter came after the US regulator inspected both the facilities around February and March 2006.
July 2008	A second US government agency - the department of justice - reprimanded the firm and dragged it to a US district court, levelling serious charges of adulteration and submission of false data to the FDA
September 2008	The Food and Drug Administration (FDA) today issued two Warning Letters and an Import Alert for generic drugs produced by Ranbaxy's Dewas and Paonta Sahib plants in India. FDA also informed Ranbaxy that until it resolves the deficiencies at each of these two facilities and the plants come into compliance with U.S. cGMP requirements, FDA's drug compliance office will recommend denial of approval of any New Drug Applications (NDAs) and Abbreviated New Drug Applications (ANDAs) that list the Paonta Sahib or Dewas plants respectively as the manufacturer of APIs or finished drug products
October 2008	The company posted a third-quarter loss on foreign-exchange fluctuations and a write-down of inventories because of a US import ban. The company made a loss of Rs395 crore in the three months ended 30 September compared with a profit of Rs 235 crore a year earlier, the company said. That compares with the Rs 19.75 crore median profit estimate of 10 analysts surveyed by Bloomberg. Ranbaxy's profit was crimped by a one-time write-down of the value of its foreign-currency convertible bonds as the Indian currency had its biggest quarterly decline in 16 years. Ranbaxy posted a $73 million translation loss on its foreign currency debt because of the adverse movement of the rupee and wrote down the value of its inventories by $59 million after the U.S. import ban.
February 2009	The US Food and Drug Administration (FDA) decides to put Ranbaxy Laboratories on the Application Integrity Policy (AIP) list on February 24, 2009. The FDA's February 25, 2009, letter said it had "determined that Ranbaxy Laboratories Limited submitted untrue statements of material fact in abbreviated and new drug applications filed with the Agency".. It also wrote a letter to Malvinder Singh citing several examples to support its conclusion that Ranbaxy was falsifying data on a regular basis.
March 2010	Ranbaxy lost an opportunity to launch the generic version of the urinary drug Flomax due to lack of requisite approval from the US drug regulator. An unimpeded launch would have helped the company earn up to $50 million in the sale of generic Flomax alone in the next two months, according to industry analysts. The rejection of Ranbaxy's application happened after the US FDA said it was not confident of the good manufacturing practices (GMP) being followed in Ranbaxy in its US manufacturing facility. Ranbaxy's US manufacturing facility "Ohm Laboratories" was seen as an alternative production base

	by the company, until the USFDA pulled up Ohm also for GMP lapses in December 2009.
March 2010	Bentley A. Hollander filed a case in a district court in Pennsylvania, complaining that Ranbaxy's US arm "Ranbaxy Laboratories Inc." is marketing some products with false patent claims. The petitioner wanted Ranbaxy to be fined for falsely marking articles with expired patents, as well as using these expired patents in advertising in connection with such articles, all for the purpose of deceiving the public into believing that such articles are covered by these expired patents. The complaint rose from Ranbaxy's use of a patent (number 4,619,921) on the label of Ultra ate, a skin care brand, which the company acquired from Bristol Myers Squibb along with 12 other dermatology products three years ago. The petitioner argued that the patent rights over that product had expired about five years ago, much before the brand was acquired by Ranbaxy and the company had no right to continue its mention on the product labels.
February 2012	Ranbaxy Laboratories posted a consolidated net loss of Rs.2,982.70 crore in the fourth quarter ended December 31, 2011, on account of provisions made in connection with the consent decree it signed with the U.S. authorities. The company had posted a net loss (after tax and minority interest) of Rs.97.40 crore in the same period previous year.
November 2012	It recalled some generic Lipitor, known as atorvastatin, in the United States after certain batches were found to contain glass particles.
September 2013	The U.S. Food and Drug Administration today issued an import alert under which U.S. officials may detain at the U.S. border drug products manufactured at Ranbaxy Laboratories, Ltd.'s facility in Mohali, India. The firm will remain on the import alert until the company complies with
December 2013	A cardiologist from Cleveland, Ohio questioned the effectiveness of drugs made by Ranbaxy to seven felonies in a case brought by the U.S Department of Justice by citing several cases of health issues faced by patients of his who used Ranbaxy drugs, He claimed that those whose symptoms were either worsening or not improving with these drugs saw significant improvement after he switched them to drugs made by other manufacturers
January 2014	The U.S. Food and Drug Administration today notified Ranbaxy Laboratories, Ltd., that it is prohibited from manufacturing and distributing active pharmaceutical ingredients (APIs) from its facility in Toansa, India, for FDA-regulated drug products.
January 2014	Ranbaxy shares fell as much as 20 per cent on Friday after the US Food and Drug Administration banned products from the company's Toansa plant in Punjab. The stock breached long-term support levels and most analysts turned bearish on Ranbaxy post the FDA move. The Toansa unit accounts for 70-75 per cent of APIs (active pharmaceutical ingredient) used in Ranbaxy formulations and is the fourth Ranbaxy plant to be barred from making products for the US, which accounts for over 40 per cent of the company's sales.

Table II *Ranbaxy Laboratories: A Chronology of Achievement Milestones*

1938	Ranbaxy & Co.was established.
1952	RC was the sole distributer of Lepet it Sp A
1959	RCstarted a joint venture with Lept it Sp A
1961	Ajoint venture with Lepet it Sp A ended. RL incorporated.
1961	Company Incorporated
1973	Ranbaxy goes public. A multipurpose chemical plant is setup for the manufacture of APIs at Mohali in India
1977	Ranbaxy's first joint venture in Lagos (Nigeria) is setup
1983	A modern dosage forms facility at Dewas (MP) in India goes on stream
1985	Ranbaxy Research Foundation is established. Stan care, Ranbaxy's second pharmaceutical marketing division, starts functioning
1987	Production start-up at the modern APIs plant at Toansa (Punjab), makes Ranbaxy the country's largest manufacturer of antibiotics/antibacterials
1988	Ranbaxy's Toansa plant gets US FDA approval
1990	Ranbaxy is granted US patent for Doxycyline
1991	New state-of-the-art facility for Cephalosporins set up at Mohali. US patent granted for Cephalosporins
1992	Company enters into an agreement with Eli Lilly & Co of USA for setting up a joint venture in India to market select Lilly products
1993	• Company enters into an agreement to setup a joint venture in China, Ranbaxy (Guangzhou China) Limited. • Ranbaxy enunciates its corporate mission 'to become a Research based International Pharmaceutical Company
1994	• The new Research Centre at Gurgaon,(near Delhi), becomes fully operational • Established Regional Headquarters in London (UK) and Raleigh (USA) • The Fermentation pilot plant at Paonte Sahib is commissioned • Ranbaxy's GDR listed in Luxembourg Stock Exchange
1995	• Acquisition of Ohm Laboratories, a manufacturing facility in the US. • Inauguration of FDA approved, state-of-the-art new manufacturing wing, at Ranbaxy's US subsidiary Ohm Laboratories Inc.
1997	Ranbaxy Laboratories Limited crosses a sales turnover of Rs. 10,000 million, with its exports reaching an all- time high of Rs. 5,000 million
1998	• Ranbaxy enters USA, world's largest pharmaceutical market, with products under its own name. • Ranbaxy filed its first Investigational New Drug (IND) application with the Drugs Controller General of India (DCGI) for approval to conduct Phase I clinical trials
1999	• DCGI grants approval to conduct phase I clinical trials for RBx-2258 • Bayer AG, Germany and Ranbaxy sign an agreement where Bayer obtains exclusive development and worldwide marketing

	rights to an oral once daily formulation of Ciprofloxacin, originally developed by Ranbaxy.
2000	• Ranbaxy files IND application for Asthma Molecule RBx-7796 after successful completion of preclinical studies. • Ranbaxy acquires Bayer's Generics business (trading under the name of Basics) in Germany • Ranbaxy forays into Brazil, the largest pharmaceutical market in South America and achieves global sales of US $ 2.5 million in this market
2001	• Ranbaxy took a significant step forward in Vietnam by initiating the setting up of a new manufacturing facility with an investment of US $ 10 million • Ranbaxy achieved a turnover of US $ 600 million for the year 2001 and moved closer to achieving the target of 1 billion dollar by 2004. • Ranbaxy USA crosses sales of US $ 100 million, fastest growing company in the US
2002	• Ranbaxy files IND for an Anti-bacterial Oxazolidine-RBx-7644 • Ranbaxy launched Cefuroxime Axetil post approval from USFDA for 125mg, 250mg, 500mg Tablet, a first approval granted to any generic company for this product • Ranbaxy receives permission from DCGI to conduct Phase-I clinical trials for RBx 7796 (Anti-Asthma)
2003	• Ranbaxy receives The Economic Times Award for Corporate Excellence for 'The company of the year 2002-03' • Ranbaxy and Glaxo SmithKline Plc (GSK) accelerate their discovery programmes through a global alliance for drug discovery and development. • RBx 7796, Ranbaxy's first NCE in the respiratory segment successfully completes Phase I clinical trials and steps into Phase II. • Ranbaxy files an IND application for RBx 9001, its second NCE for the treatment of Benign Prostatic Hyperplasia (BPH) • Cipro XR 500mg and 1g, based on the technology developed by Ranbaxy, were launched in USA by Bayer AG • Ranbaxy launched the first branded product Sotret (isotretinoin) for 10mg, 20mg and 40mg capsules in USA
2004	• Ranbaxy acquired the generics business of RPG Aventis Life Sciences in France to enter European • Joins the elite club of Billion Dollar Companies, achieving global sales of US$ 1 billion (on MAT basis) • RBx 11160, an Anti-malarial molecule in collaboration with Medicines for Malaria Venture (MMV), successfully completes Phase I studies subsequent to the filing of an Investigational New Drug (IND) application in the UK and in India Made the first Anti-retroviral (ARV) filing with the U.S. Food and Drug Administration (FDA) under the U.S. President's Emergency Plan for AIDS Relief (PEPFAR)
2005	• Ranbaxy acquired 18 generic drugs from Spain's Eframes for sale in the local market • The joint venture with Nippon Chemiphar in Japan (Nihon Pharmaceutical Industry Limited) launches its first product, Vogseal • Received India's first approval from the U.S. Food and Drug Administration (FDA) for an Anti-retroviral (ARV) drug under the U.S. President's Emergency Plan for AIDS Relief (PEPFAR)
2006	• Ranbaxy's US arm buys patents, trademarks, and automated manufacturing equipment from Senetek for its disposable auto injector for self-administration of parental drugs for anaphylactic shock • Ranbaxy's Italian subsidiary acquires the unbranded generic business of Allen, a division of GlaxoSmithKline, to complement its own pipeline for the Italian Market. • Buys 96.7% of Romanian drug maker Terapia from Advent International for $324 million. Combined with Ranbaxy's own operation in Romania, the Terapia acquisition creates Romania's largest generic firm • Placed US$ 440 million Foreign Currency Convertible Bonds (FCCB) issue, the largest in the healthcare segment in India • Enters into a strategic alliance with Zenotech for its basket of oncology products to be marketed under the Ranbaxy brand in various global markets • Acquires generics company, Ethimed in Belgium. Provided Ranbaxy a base from where to manage and expand its operations in the Benelux countries • Ranbaxy's Spanish subsidiary purchases the Mundogen generics business of GlaxoSmithKline in Spain. The acquisition beefs up Ranbaxy's product portfolio in the country. • Launches the First to File (FTF) product Simvastatin 80 mg tablets in US with the 180 -day market exclusivity • Acquires Be Tabs Pharmaceuticals, the 5th largest generic company in South Africa, for US$ 70 million • Acquired the unbranded generic business of GSK in Italy and Spain
2007	Signs a new R&D agreement with GSK and get expanded drug development responsibilities, identify candidate for Respiratory Inflammation Enters into independent settlements with GSK (Valacyclovir) and Boehringer Ingelheim/Astellas Pharma (Tamsulosin) Launched First-to-File (FTF) product Pravastatin sodium tablets 80 mg with 180-day market exclusivity in the US Healthcare System
2008	Reached settlement on the world's two highest selling drugs - Lipitor (with Pfizer) and Nexium (with Astra Zeneca)
2009	Launched First-to-File (FTF) product Valacyclovir hydrochloride tablets 500 mg and 1 g with 180-day market exclusivity in the US Healthcare System
2010	Launched First-to-File (FTF) product Donepezil hydrochloride tablets 5 mg and 10 mg with 180-day market exclusivity in the US Healthcare System Deliver quarterly sales of over US$ 500 million for the first time
2011	Launched Atorvastatin, a generic version of the world's largest selling cholesterol lowering drug, in the US with 180-day market exclusivity Cross global revenues of US$ 2 billion, becoming the first pharmaceutical company of Indian origin to do so
2012	Launched India's first New Chemical Entity (NCE), Synriam™, a new age cure for Malaria. It also launches Absorica (isotretinoin) in the US market

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Table III *Ranbaxy's Portfolio*

Anti-Infective Drugs
• Leadership position in key markets in Penicillin, Cephalosporin, Macrolides, Flouroquinolone, Anti-fungal, Anti-viral, Anti-retroviral and critical care. • Leading molecules in this segment are Valacyclovir, Amoxicillin + Clavulanic Acid, Ciprofloxacin, Imipenem + Cilasatin and Amoxicillin. • Penems form an important part of portfolio sold as Imipenem + Cilastatin in more than 50 countries. • On April 25, 2012, India's first New Chemical Entity (NCE), Synriam, was launched for the treatment of uncomplicated falciparum malaria.
Cardiovascular Drugs
• Developers of quality drugs for various CVS ailments like Hyperlipidemia, Hypertension and Diabetes. • Launched the generic version of the world's largest selling drug (Atorvastatin) in the US as a First-to-File (FTF) product. • Among the leading companies selling Simvastatin, Rosuvastatin, Aspirin, Losartan and Acarbose formulations in markets like India, Romania, Russia, South Africa and Malaysia.
Pain And Musculoskeletal Drugs
• Best-selling molecules in the Pain and Musculoskeletal segment are Ketorolac, Diclofenac, Paracetamol and Ibuprofen combinations. • Launched specialized products like Cox 2 inhibitors for Osteoarthritis in several markets
Gastrointestinal Drugs
• Proton pump inhibitor (PPI) drugs like Pantoprazole, Rabeprazole, Lansoprazole and Omeprazole for the treatment of ulcers are the leading drug class for the company. • Strong presence in Ranitidine, H Pylori kits, Papain and digestive enzyme formulations
Respiratory Drugs
• Leaders in this segment, especially in the US, India, Eastern Europe, South Africa and Latin America. Leading products are Ambazone, Loratadine combinations, Triamcinolone, Montelukast and Fexofenadine
Central Nervous System Drugs
• Drugs for ailments like Schizophrenia, Epilepsy, Depression, Neuropathic Pain, Alzheimer's disease and Parkinson's. • Leading molecules in CNS are Donepezil, Sertraline, Gabapentin, Pentazocine and Olanzapine
Anti-Retroviral Drugs
• Wide range of World Health Organisation prequalified (WHO PQ) Anti-retroviral (ARV) products that are supplied in more than 100 countries in Africa, Latin America, CIS and Asia. • ARV portfolio comprises Bio-equivalent Anti-retroviral products and Anti-infectives.
Dermatology Drugs
• Major presence across markets of US, India and Brazil with a robust franchise in the Corticosteroids, Anti-infectives and Anti-acne segments. • Ultravate, Kenalog and Lac Hydrin are the major brands inconsumer driven Over-the-Counter (OTC) markets. • Global licensing rights to market Luliconazole (a novel Anti-fungal) in 16 markets, including India, Malaysia, Singapore and South Africa.
Over the Counter (Otc) Drugs
• Ranbaxy Global Consumer Healthcare (RGCH) is a separate business division through which Over-the-Counter (OTC) products are developed and marketed in more than 20 countries. • The division offers 15 products including some top-selling brands. • Some of key OTC brands are Revital, Volini, Faringosept, Aspenter and Chericof. • RGCH commenced its operations in 2002 with the launch of Pepfiz, Gesdyp and Garlic Pearls in the Indian market and was strengthened with the addition of Revital (India's largest selling Vitamins and Minerals supplement). • In 2005, Chericof was added to the offering and, in 2007, Volini, a topical analgesic brand, which is also the fastest growing pain relievers, was introduced. • RGCH division follows an aggressive sales and distribution strategy that involves penetrating Class II towns directly and smaller towns through the 'hub and spoke' model.

Source: Retrieved from www.ranbaxy.com: http://www.ranbaxy.com/products/

Table IV *Drug Regulations*

The Pharmacy Act 1948
• A law enacted to control and regulate the profession of pharmacy in India. • Proposed to establish a Central Council of Pharmacy, which will prescribe the minimum standards of education and approve courses of study and examinations for pharmacists • Setup of Provincial Pharmacy Councils, responsible for the maintenance of provincial registers of qualified pharmacists was also proposed.
Drug Policy 1986
• Contains measures for Rationalisation, Quality Control and Growth of Drugs & Pharmaceutical Industry in India • Ensures abundant availability, at reasonable prices, of essential lifesaving and prophylactic medicines of good quality; strengthening

the system of quality control over drug production and promoting the rational use of drugs in the country • Creates an environment conducive to channelizing new investment into the pharmaceutical industry, to encouraging cost-effective production with economic sizes and to introducing new technologies and new drugs, • Strengthens the indigenous capability for production of drugs.
Modifications In Drug Policy 1986
• Modified in 1994 to make the domestic industry more internationally competitive. • The modifications were made on areas of licensing, basic stage production, review of items reserved for the public sector, foreign investment, and foreign technology agreements. • Research and development was encouraged and pricing, span of control, ceiling prices, coordination between ministries etc.
Drugs (Prices Control) Policy 1995
• Issued by the Government of India under Section 3 of the Essential Commodities Act, 1955 to regulate the prices of drugs. • Provides the list of price controlled drugs, procedures for fixation of prices of drugs, method of implementation of prices fixed by Government and penalties for contravention of provisions among other things. • 74 bulk drugs were put under price control and there was no price control on 70-75% of the retail pharmaceutical market. • Facilitates Win –Win situation for the government, but not for the industries.
Drugs (Prices Control) Policy 2013
• Governed by national pharmaceutical pricing authority, based on national list of essential medicines. • Prices of 652 drugs are regulated by this act. • Ceiling and non-ceiling prices of drugs are specified. • Prices of the drugs are fixed by the mutual agreement of government and industries for the welfare of the public.
Pharmaceutical Policy 2002
• Evolved to make the domestic industry more internationally competitive and directing it towards new initiatives. • Apart from the objectives of The Drug Policy 1986, its main objective was to encourage R&D in the pharmaceutical sector in a manner compatible with the country's needs with particular focus on diseases endemic or relevant to India. • Aims at creating an incentive framework for the pharmaceutical industry which promotes new investment into the knowledge based sector.
The Patents Act
• The present Patents Act, 1970 came into force in the year 1972, amending and incorporating the existing laws relating to Patents and Designs act 1911 in India. • The Patent (amendment) Act 2005 came into force from 1st January 2005, which brought changes in the previous patent system of India wherein product patent was extended to all subjects of technology consisting of food, drugs, chemicals and microorganisms. • Section 3(d) introduced in to the said amendment act 2005 and introduces pharmaceutical product patents in India for the first time. • The Patent (amendment) Act 2005 defines what invention is and makes it clear that any existing knowledge or thing cannot be patented.
National Pharmaceutical Pricing Policy 2012
• It was notified on 07.12.2012. • Aims at bringing 652 commonly used drugs under the ambit of price control. • Seeks to limit itself to the central objective of promulgating the principles for pricing of Essential Drugs as laid down in the "National List of Essential Medicines – 2011. • The objective was to put in place a regulatory framework for pricing of drugs so as to ensure availability of required medicines – "essential medicines" – at reasonable prices even while providing sufficient opportunity for innovation and competition to support the growth of industry, thereby meeting the goals of employment and shared economic well-being for all.

Ranbaxy's Vision and Mission Achieving customer satisfaction is fundamental to our business

- *Provide products and services of the highest quality*
- *Practice dignity and equity in relationships and provide opportunities for our people to realise their full potential*
- *Ensure profitable growth and enhance wealth of the shareholders*
- *Foster mutually beneficial relations with all our business partners*
- *Manage our operations with high concern for safety and environment*
- *Be a responsible corporate citizen*

Table V *Indian Regulators, Regulations and Guidelines*

CDSCO	**Central Drugs Standard Control Organization (CDSCO),** Ministry of Health & Family Welfare, Government of India provides general information about drug regulatory requirements in India.
NPPA	**Drugs (Price Control) Order 1995** and other orders enforced by **National Pharmaceutical Pricing Authority (NPPA),** Government of India.
D & C Act, 1940	**The Drugs & Cosmetics Act, 1940** regulates the import, manufacture, distribution and sale of drugs in India.
Schedule M	**Schedule M**of the D&C Act specifies the general and specific requirements for factory premises and materials, plant and equipment and minimum recommended areas for basic installation for certain categories of drugs.

Schedule T	**Schedule T** of the D&C Act prescribes GMP specifications for manufacture of Ayurvedic, Siddha and Unani medicines.
Schedule Y	The clinical trials legislative requirements are guided by specifications of **Schedule Y**of The D&C Act.
GCP guidelines	**The Ministry of Health,** along with **Drugs Controller General of India (DCGI) and Indian Council for Medical Research (ICMR)** has come out with draft guidelines for research in human subjects. These **GCP guidelines** are essentially based on Declaration of Helsinki, WHO guidelines and ICH requirements for good clinical practice.
The Pharmacy Act,1948	**The Pharmacy Act, 1948** is meant to regulate the profession of Pharmacy in India.
The Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954	**The Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954** provides to control the advertisements regarding drugs; it prohibits the advertising of remedies alleged to possess magic qualities.
The Narcotic Drugs and Psychotropic Substances Act, 1985	**The Narcotic Drugs and Psychotropic Substances Act, 1985** is an act concerned with control and regulation of operations relating to Narcotic Drugs and Psychotropic Substances.

5. References

1. Malhotra, Girish, Ranbaxy: Lesson and Opportunities, Contract Pharma, April 9. 2014, http://www.contractpharma.com/contents/view_experts-opinion/2014-04-09/ranbaxy-lessons-and-opportunities, (accessed October 21, 2016)
2. Tremblay, J.-F. (2016, May 16). Court awards $525 million to Daiichi Sankyo for Ranbaxy deal gone wrong. Retrieved October 25, 2016, from Chemical and Engineering News: http://cen.acs.org/articles/94/i20/Court-awards-525-million-Daiichi.html
3. Associate Press. (2013, May 14). Ranbaxy case: Whistleblower to get $49 m of penalty money. Retrieved October 18, 2016, from Hindustan Times Website: http://www.hindustantimes.com/business/ranbaxy-case-whistleblower-to-get-49-m-of-penalty-money/story-qSIEAWJwdaXDnFf1rFC3eM.html.
4. Sun Pharma. (n.d.). Milestones. Retrieved October 16, 2016, from Sun Pharma Milestones: http://www.sunpharma.com/about-us/milestones
5. Bhatt, P. R. (n.d.). Global Strategy for Growth: A Case of Ranbaxy Laboratories. Journal of Case Research , II(01). Retrieved October 2, 2016, from http://home.ximb.ac.in/~jcr/Global_Strategy.pdf
6. CBS News. (2013, November 13). Ranbaxy whistleblower reveals how he exposed massive pharmaceutical fraud. Retrieved October 18, 2016, from Website of CBS News: http://www.cbsnews.com/news/ranbaxy-whistleblower-reveals-how-he-exposed-massive-pharmaceutical-fraud/
7. Siddiqui, Z. (2016, March 7). Pharma crusader Dinesh Thakur takes India's drug regulators to court. Retrieved October 19, 2016, from website of Reuters.com: http://www.reuters.com/article/india-pharma-whistleblower-idUSKCN0W90C8
8. Dey, S. (2014, January 30). If I follow US standards, I will have to shut almost all drug facilities: G N Singh- Interview with Drug Controller General of India. Retrieved March 28, 2017, from Business Standard: http://www.business-standard.com/article/economy-policy/if-i-follow-us-standards-i-will-have-to-shut-almost-all-drug-facilities-g-n-singh-114013000034_1.html
9. Sundar, M. (n.d.). The History of Ranbaxy. Retrieved February 15, 2017, from Welcome- maheshsundar.com: http://www.maheshsundar.com/Home/maheshsundarcom---pharma-updates/the-history-of-ranbaxy.
10. Bhandari, B. (2014, October 22). 40 Years Ago... And now: Ranbaxy grew with liberal regimes, moving out of family control. Business Standard. Retrieved October 5, 2016, from http://www.business-standard.com/article/companies/40-years-ago-and-now-ranbaxy-grew-with-liberal-regimes-moving-out-of-family-control-114102101500_1.html
11. Sundar, M. (n.d.). The History of Ranbaxy. Retrieved February 15, 2017, from Welcome- maheshsundar.com: http://www.maheshsundar.com/Home/maheshsundarcom---pharma-updates/the-history-of-ranbaxy.
12. NDTV Profit. (n.d.). Ranbaxy Laboratories Ltd.- (Amalgamation). Retrieved November 10, 2016, from NDTV Profit Website: http://profit.ndtv.com/stock/ranbaxy-laboratories-ltd-_ranbaxy/reports
13. Lee, A. (2008, June 12). Daiichi Sankyo takes control of Ranbaxy. Retrieved December 8, 2016, from Financial Times: https://www.ft.com/content/25a46440-3780-11dd-aabb-0000779fd2ac.
14. USFDA(2009, February 25). FDA Takes New Regulatory Action Against Ranbaxy's Paonta Sahib Plant in India. Retrieved from FDA website: http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2009/ucm149532.htm
15. Bureau, E. (2013, May 23). Ranbaxy's $500 mn US fine: Daiichi may sue ex-promoters Malvinder, Shivinder. Retrieved October 8, 2016, from Economic Times: http://articles.economictimes.indiatimes.com/2013-05-23/news/39475737_1_daiichi-sankyo-ranbaxy-laboratories-drug-maker.
16. Dey, S. (2014, September 16). Sun Pharma draws up plan to fix ailing Ranbaxy. Business Standard. Retrieved October 13, 2016, from http://www.business-standard.com/article/companies/sun-pharma-draws-up-plan-to-fix-ailing-ranbaxy-114091101300_1.html.
17. Inspections, Compliance, Enforcement, and Criminal Investigations, WL: 320-06-03 (June 15, 2006). Retrieved from FDA website: http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2006/ucm075947.htm

18. Inspections, Compliance, Enforcement, and Criminal Investigations-Ohm Laboratories Inc, NYK 2010-07 (December 21, 2009). Retrieved from http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2009/ucm204903.htm.
19. USFDA. (2008, September 16). FDA Issues Warning Letters to Ranbaxy Laboratories Ltd., and an Import Alert for Drugs from Two Ranbaxy Plants in India. Retrieved from FDA Website: http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2008/ucm116949.htm
20. USFDA. (2009, February 25). FDA Takes New Regulatory Action Against Ranbaxy's Paonta Sahib Plant in India. Retrieved from FDA website: http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2009/ucm149532.htm
21. USFDA. (2012, January 25). Department of Justice files consent decree of permanent injunction against Ranbaxy. Retrieved from FDA website: http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm289224.htm.
22. Department of Justice. (2013, May 13). Generic Drug Manufacturer Ranbaxy Pleads Guilty and Agrees to Pay $500 Million to Resolve False Claims Allegations, cGMP Violations and False Statements to the FDA. Retrieved from The United States Department of Justice website: https://www.justice.gov/opa/pr/generic-drug-manufacturer-ranbaxy-pleads-guilty-and-agrees-pay-500-million-resolve-false.
23. USFDA. (2013, September 16). FDA prohibits manufacture of FDA-regulated drugs from Ranbaxy's Mohali, India, plant and issues import alert. Retrieved from FDA Website: http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm368445.htm
24. USFDA. (2014, January 23). FDA prohibits Ranbaxy's Toansa, India facility from producing and distributing drugs for the U.S. market. Retrieved from FDA Website: http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm382736.htm
25. Lakshman, N. (2014, January 29). Decoding FDA's Ranbaxy inspections. Retrieved October 7, 2016, from The Hindu Website: http://www.thehindu.com/business/Industry/decoding-fdas-ranbaxy-inspections/article5629557.ece.
26. Central Drugs Standard Control Organization (n.d.). Guidance Document. Retrieved October 12, 2016, from http://www.cdsco.nic.in/writereaddata/guidane_documents_export_noc.pdf
27. Khan, A., & Khar, R. (2015, Jan-Feb). Current Scenario of Spurious and Substandard Medicines in India: A Systematic Review. Indian Journal of Pharmaceutical Sciences, 77(1), 2–7. Retrieved March 29, 2017, from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4355878/
28. Chowdhary, N., Joshi, P., Patnaik, A., & Saraswathy, B. (September 2015). Administrative Structure and Functions of Drug Regulatory Authorities in India. New Delhi: ICRIER. Retrieved March 29, 2017, from http://icrier.org/pdf/Working_Paper_309.pdf
29. Ghosh, A. (2015, June 19). Central drug controller unveils 'world's biggest' quality check. Retrieved March 27, 2017, from The Indian Express: http://indianexpress.com/article/india/india-others/central-drug-controller-unveils-worlds-biggest-quality-check/
30. Parliamentary Standing Committee on Health and Family Welfare. (2013). Action Taken by the Government on the Recommendations/Observations contained in the Fifty Ninth Report on Functioning of CDSCO. New Delhi: Government of India. Retrieved March 27, 2017, from http://www.searchingforsafety.net/uploads/2/6/2/1/26218021/rajya_sabha_april_2013.pdf
31. Thaul, S. (2012). How FDA Approves Drugs and Regulates their Safety and Effectiveness. Congressional Research Service.
32. Thakur, D., & Reddy, T. (2016). A report on fixing India's broken drug regulatory system. New Delhi: Self Published. Retrieved March 28, 2017, from http://dineshthakur.com/wp-content/uploads/2016/06/CDSCO-Reform.pdf
33. Ranbaxy loses Lipitor patent case in US. (2005, December 17). The Economic TImes.
34. FDA Issues Warning Letters to Ranbaxy Laboratories Ltd., and an Import Alert for Drugs from Two Ranbaxy Plants in India. (n.d.). FierceBiotech.
35. USFDA(2008). FDA Issues Warning Letters to Ranbaxy Laboratories Ltd., and an Import Alert for Drugs from Two Ranbaxy Plants in India. US FDA.
36. Chatterjee, S. (2008, October 31). Ranbaxy loses Rs395 crore; Daiichi cuts profit forecast. Livemint.
37. Ghose, J. (2013, May 29). FDA's 2009 Ranbaxy Laboratories letter sealed Malvinder Singhs fate. The Financial Express.
38. Mathew, J. C. (2010, March 4). Ranbaxy faces more trouble in US. Business Standard.
39. Ranbaxy posts Rs.2,900-crore net loss in 2011. (2012, February 23). The Hindu.
40. Lakshman, N. (2013, December 6). U.S. doctor questions effectiveness of Ranbaxy drugs. The Hindu.
41. USFDA (2014, January 23), FDA prohibits Ranbaxy's Toansa, India facility from producing and distributing drugs for the U.S. market. .
42. Ranbaxy loses investment grade on FDA ban, sinks 20%. (2014, January 24). NDTV Profit.
43. Pharmacy_act_1948. (n.d.). Retrieved from http://www.ipapharma.org/: http://www.ipapharma.org/pdf/Pharmacy_act_1948.pdf
44. index. (n.d.). Retrieved from http://www.nppaindia.nic.in/: http://www.nppaindia.nic.in/index1.html
45. (n.d.). Drugs Price Control Order (DPCO). Pharmaceutical Drug Manufacturers.
46. Kumar, V., Gupta, N. V., & Kumar, K. A. (2014). A comparision between old and latest systems in DPCO. International Journal of Pharmacy and Pharmaceutical Sciences.
47. (n.d.). Pharmaceutical Policy 2002. Pharmaceutical Drug Manufacturers.
48. Sharma, A. (2014, Februrary 26). Section 3(D) Of Indian Patents Act 1970: Significance And Interpretation. Mondaq.

49. (2012). National Pharmaceuticals Pricing Policy, 2012 (NPPP-2012). The Gazette of India, 7 December 2012. (Hindi and English Version). Essential Medicines and Health Products Information Portal)