# Supply Chain Excellence in the Pharmaceutical Industry: Novartis – A Case Study

by

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Submitted to the Zaragoza Logistics Center in Partial Fulfillment of the Requirements for the Degree of

MASTER OF ENGINEERING IN LOGISTICS AND SUPPLY CHAIN MANAGEMENT

in the

MIT-ZARAGOZA INTERNATIONAL LOGISTICS PROGRAM

at the

ZARAGOZA LOGISTICS CENTER,
A RESEARCH INSTITUTE ASSOCIATED WITH THE UNIVERSITY OF ZARAGOZA

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## ABSTRACT

This thesis is intended to research and explore key aspects of supply chains in the pharmaceutical industry. The research contained within was part of a larger research effort called the Supply Chain 2020 Project. The Supply Chain 2020 Project was intended to provide insight into major research questions about the future of supply chain excellence. Within the pharmaceutical industry there are many sources of operational efficiencies which contribute to excellence; operational efficiencies alone are not sufficient to deem a supply chain as excellent. The author chose to explore one particular company, Novartis AG, and examine the company's supply chain to determine if it fit the criterion of "excellence."

The author utilized existing sources of information about the pharmaceutical industry and the company in addition to personal, on site interviews of key management within Novartis. This report contains a detailed description of the supply chain strategy, framework, and operating model for Novartis. Within the operating model, the author describes key practices which support key company strategies and competencies.

Novartis utilizes unique approaches to managing its supply chain including: customized KPI metrics; logistics and financial hubs; asset and resource sharing; tax and revenue optimization strategies; collaborative forecasting, and parallel production development strategies.

The author describes the details of the internal supply chain management processes and illustrates how these processes support and fit the overall company strategy. Novartis has a clearly focused strategy that revolves around research and development of new, patent protected, chronic illness products and the ability to bring them to market quickly and efficiently.

## Acknowledgements

I would like to thank Tina, my fiancée, for her continued patience and support throughout this process.
I am grateful for my best friend Jonathan and his continued support of my academic career.
I would also like to thank my siblings, Gitali, Rajen, and Tuli, for challenging, loving, and supporting me unconditionally.
Many thanks to my thesis advisor, Prashant, for his motivation and wisdom.

## Dedication

I would like to dedicate this work to my parents with their unrelenting faith in my abilities and future.

## Biographical Note

On my quest for knowledge the bigger I become, the smaller I feel.

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# Chapter 1 – Introduction

The thesis is intended to contribute fundamentally to the research effort of the Supply Chain 2020 project (SC2020). The SC2020 research initiative is structured toward providing insight into major research questions about the future of supply chain excellence. There are several distinct areas of interest from the perspective of the SC2020 project: Aerospace, Apparel, Automotive, Communications Equipment, Computers, Consumer Products, Distribution, Pharmaceutical, Retail, and Steel are the industries that are included in the research sample. The SC 2020 project will attempt to accurately and concisely describe the structure and nature of how supply chains will have probably evolved by the year 2020. Additionally, the project will supply research which supports decisions about which risk management/mitigation strategies and indicators should be implemented to prepare for supply chains of the future.

In an effort to contribute to a specific portion of the SC2020 initiative, the following content will provide valuable insight into the current structure of pharmaceutical supply chains including the key components that make certain supply chains "excellent." Subsequently, an in depth look into a specific company, Novartis AG, will allow the reader to understand what key components illustrate supply chain excellence with respect to the current pharmaceutical industry.

## Supply Chain 2020 Phase 1: Project Scope Definition

| **Working Title** | Supply Chain 2020 Project: Excellent Supply Chain Studies |
|---|---|
| **Key Research Question / Hypothesis** | Uncover the elements of what constitutes an excellent supply chain within a broad range of industries including:<br>1. Aerospace<br>2. Apparel<br>3. Automotive<br>4. Communications Equipment<br>5. Computers |

| | |
|---|---|
| | 6. Consumer Products<br>7. Distribution<br>8. Pharmaceutical<br>9. Retail<br>10. Steel<br>Students can also propose additional industries that they may already know well or in which they have some contacts. |
| **Team Profile** | Two MLOG/ZLOG students or more per industry |
| **Project Description** | The Supply Chain 2020 Project intends to identify and analyze the factors that are critical to the success of future supply chains out to the year 2020. Phase 1 largely entails researching today's excellent supply chains to identify what is important to maintaining a competitive positioning, including the business strategies, operating models, goals, and best supply chain practices. In addition, the enablers of the best business practices will also be researched, as well as the cost-benefit rationale for these micro-based practices in the context of historical macro-based factors. |
| **Data Type & Sources** | • Company annual and SEC-related reports.<br>• Analyst reports and 3rd party syndicated company/industry reports.<br>• Supply chain and business publications<br>• Phone and on-site interviews with company executives and industry experts |
| **Potential Advisor** | Thesis advisors include:<br>• Prof Gabriel Bitran<br>• Dr. Kirk Bozdogan<br>• Prof. Charlie Fine<br>• Dr. Larry Lapide<br>• Prof Sharon Novak<br>• Prof. Yossi Sheffi |
| **Company Contact?** | Main company contacts are with the Supply Chain 2020 Project's Industry Advisory Council (IAC) and European Advisory Council (EAC). Council members from researched companies will provide input and access into their companies and industries, while other members will provide input on a broad range of industries and supply chain strategies. These members represent:<br><br>Accenture — Audi<br>BSH Spain — Borealis Group<br>C&S Wholesale Grocers — Cisco<br>CSC Consulting — Dell<br>DHL — Eli Lilly<br>ExxonMobil — General Motors<br>Gillette — Helix<br>Hewlett-Packard — i2 Technologies<br>IBM — Intel<br>Intervbrew/Imbev — Johnson & Johnson<br>Limited Brands — Lucent<br>Metro Group — Nike<br>Novartis — P&G<br>Roche — Scotts<br>SAP — Staples<br>Tata Steel — Texas Instruments<br>TPG — Unilever |

| | UPS |
|---|---|
| **Primary Methodology** | Literature review, phone interviews and on-site field visits to collect information according to an hypothesized excellent supply chain research framework. |
| **Is** | The scope is supply chain strategy. Focus will be on the elements of an excellent supply chain that deal with the critical success factors and linkages among competitive business strategies, competitive operating models, goals & objectives, and business practices. Analysis is comprised of synthesizing and analyzing largely qualitative and some quantitative data information. |
| **Is Not** | This is not a project involving modeling and extensive quantitative data analysis |

# Chapter 2 – Literature Review

In the process of developing this work several sources were used to obtain the research data contained within. Some of the sources include a large variety of print media, internet research, digital media, and books. In addition, the author used various personal sources for interviews and conversations with industry experts and company specific internal sources. The author also chose to enhance the work by including information from his personal industry experience.

Literature from authors such as Michael Porter, Michael Hammer, Chris Zook, and C.K. Prahalad created an understanding for the framework under which to evaluate the research, and in specific, Novartis AG. Corporate reporting and annual reports were also used to obtain specific information about the company's finances and operations.

Sources such as the PhRMA 2005 industry profile provided valuable insight into the current status of the pharmaceutical industry. The profile also provided accurate descriptions for the process by which new pharmaceutical products are researched, approved, and brought to market. In addition to the process definition, some of the problems which currently face the industry were depicted and illustrated using PhRMA member company data. The data was useful in evaluating the nature and trends within the industry regarding research and development, including specific trends toward biopharmaceutical research.

The author relied heavily on the Hoovers.com website for current company information and comparative charts and analysis. The Hoovers.com site provides an accurate financial picture for many of the top companies in the US and also provided information about organizational structure, product listings,

competitive categories and codes, and industry financial metrics compared to the respective companies which were researched.

The Novartis publicly filed documents including annual reports and 20f reports were used extensively for sources of information about the company mission, philosophy, resources, direction, and leadership. A large portion of this information overlapped with information provided by Hoovers.com. The 20f reports were also used for product category information and relevant research and development efforts and their applicable supply chain implications.

Industry research and development processes, procedures, and expenditures were carefully depicted through the tufts csdd.tufts.edu website. After thorough exploration, the author used several graphs and trend analysis from this source. This source is well regarded and highly referenced among other sources which the author included in this literature review. The Tufts CSDD documentation illustrated the declining trend of R&D effectiveness and some of the complications faced by the industry.

Finally, Novartis employees were also interviewed to acquire information about non-published information which was essential to the progress of this research document. Some of the employees provided information which was complimentary to PowerPoint presentations which the company graciously provided to the author. The employees interviewed created a very comprehensive cross-sectional view of the organization in the various functional support categories of the supply chain. The interviews supplied the author with accurate information and insight into the supply chain and business processes and the respective rationale behind each. The information provided in the interviews also allowed the author to examine certain processes and their future applicability within the changing landscape of the pharmaceutical industry.

# Chapter 3 – Pharmaceutical Industry Overview

## 3.1 Pharmaceutical Industry Definition

Hoovers defines the Pharmaceutical industry to include "Companies that research, develop, produce, and sell chemical or biological substances for medical or veterinary use, including prescription, generic and OTC drugs; vitamins and nutritional supplements; drug delivery systems and diagnostic substances; and related products, equipment, and services, including distribution and wholesale." (Hoovers.com 2005)

The Hoovers.com definition of the pharmaceutical industry quite broadly encompasses a large and varied number of logistic and supply chain activities that could be the basis of excellence. The industry, as a whole, relies on some standard benchmarking indicators such as months of on-hand inventory, and inventory turns; however, the existing metrics do not allow for idiosyncrasies of the industry or provide adequately detailed insight into the key factors that make a pharmaceutical supply chain excellent.

As defined by (Chopra – Meindl 2004):

> "a supply chain consists of all parties involved, directly or indirectly, in fulfilling a customer request. The supply chain not only includes the manufacturer and suppliers, but also transporters, warehouses, retailers, and customers themselves. Within each organization, such as a manufacturer, the supply chain includes all functions involved in receiving and filling a customer request. These functions include, but are not limited to new product development marketing, operations, distribution, finance, and customer service."

Marin Christopher defines a supply chain as:

"… is the network of organizations that are involved, through upstream and downstream linkages, in the different processes and activities that produce

value in the form of products and services in the hands of the ultimate consumer." (Christopher 2004)

The pharmaceutical industry, in recent years, underwent significant reshaping and restructuring via mergers and acquisitions. (Hoovers.com 2005) Today, pharmaceutical supply chains, although more mature, are subject to different constraints and restrictions than those of other industries. Generally, over 75% of the markup on pharmaceutical products takes place at the manufacturer. This causes inventory carrying costs to increase dramatically once the product is purchased by the distribution segments of the supply chain. Wholesalers and large pharmacy chains suffer high carrying costs on the final product and are inherently encouraged to carry less inventory. This conflict in interest between service level and holding cost is not new, however pharmaceutical manufacturers carry increased inventory levels to compensate for the cost and inventory reduction measures taken by large retail chains such as Wal-Mart and CVS. Subsequently, placement of inventory becomes perpetually more difficult and creates consumer shortages. These shortages which take place at the final consumer level of the supply chain are not representative of the actual product availability from the manufacturer. As managed health care increases pricing pressures, the cost of R&D is also increasing. The resulting profit margins at the retail level decrease with smaller reimbursements from insurance companies and the availability and placement of product increases even more in difficulty.

Inside pharmaceutical supply chains, companies must also face issues of product expiration and limited shelf lives. Seasonal and short shelf life products such as flu vaccines leave companies without the opportunity to redistribute or reallocate product in order to meet demand. In these instances the product placement must be accurate the first time; few second chances are available. With the increase in biopharmaceutical research, the importance of climate controlled supply chains and faster response times will continue to increase.

(PhRMA Industry Profile 2005) The evolution of pharmaceutical products to custom tailored or build to order products will create new challenges in the years to come. In addition to the proper placement of product to meet demand, the industry must continue to follow strict standards for the disposal of out of date or defective product. Although strict production standards are in place to reduce the chance of defective product; errors do occur. When defective product is discovered, immediate and complete action must be taken. Adequate systems for tracking product from the origin to the destination are necessary to enable reverse logistics in the event of a catastrophic recall. Regulatory agencies such as the FDA maintain high standards for the visibility of products and the ability for a company to retrieve substandard goods. Once defective products have been retrieved, they must be tested and/or disposed of properly. The disposal process and the controls in place to prevent tampering or intervention also raise concerns about the security measures within pharmaceutical supply chains. Certain anomalies also exist within the pharmaceutical industry. In recent years, with the threat of bioterrorism increasing, a number of products have become the source of large governmental or media induced variations in demand. Anti-infective products such as Cipro and Avelox were in short supply following the anthrax scares in the United States.

Many companies in the pharmaceutical industry are also exploring new methods of research and development which form collective collaboration agreements between two or more parties. These parties must later work out arrangements for the production, distribution, and sales channels through which the product will enter the market. Some of the cooperative arrangements can be quite complex and include cross organizational sales staff or third party production. Subsequently, tracking and monitoring of product and revenue flows can pose challenges.

Among the myriad of standard supply chain issues faced by most industries, pharmaceutical manufacturers tend to design their supply chains

around tax and revenue optimization strategies. The cost of transportation and inventory holding lack significance in comparison to the amount of money spent on taxes. Pharmaceutical companies pay higher taxes than other members of the supply chain since the cost of goods sold remains low without taking R&D expenses into consideration. The manufacturers try to locate their final production facilities where taxation of their operating income is the lowest. Until recently, US pharmaceutical companies located most of their manufacturing in Puerto Rico since it provided a tax haven for products entering the US market. Puerto Rico has since changed its taxation structure to reduce the tax benefits offered to major pharmaceutical companies. The affected companies have continued production in Puerto Rico for historical reasons, but other countries such as Ireland have recently created their taxation structures to attract these manufacturers. The nature of the margin structure on manufacturing causes pharmaceutical companies to pay more attention to the strategic level of manufacturing facility placement than to operational cost considerations with respect to transportation of goods.

The industry can be defined further by the products and markets which are served. Hoovers classifies the industry with SIC and NACIS codes and product descriptions. See the Appendix for a table.

## 3.2 Pharmaceutical Industry Revenues, Operating Margins, and Employees

Based on a detailed survey conducted by Tufts University, the average cost of developing a new drug in the United States is $802 million (csdd.tufts.edu 2005). This figure updates the last estimate by Tufts University from 1987 which estimated the average cost at $231 million.

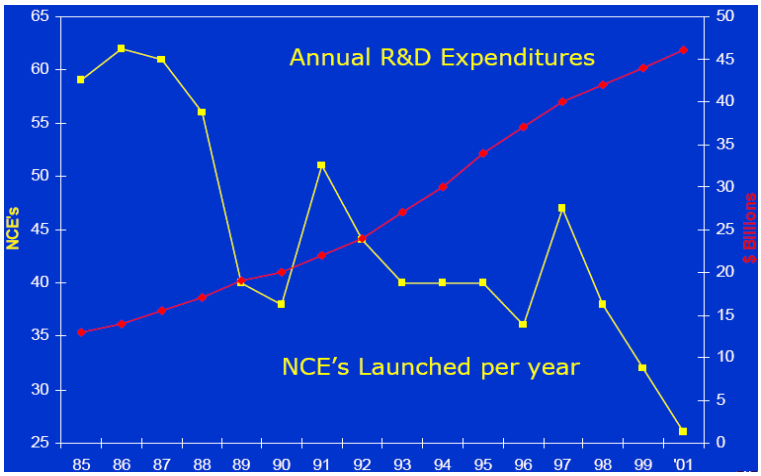



**Figure 1 NCE Decline with Increased R&D Spending**

(Singh 2004)

Dr. Kenneth I. Kaitin says “Bringing new drugs to market has always been an expensive, high-risk proposition, and our latest analysis indicates that costs have continued to skyrocket” “The single largest challenge facing drug developers — both pharmaceutical and biotechnology companies — is to contain R&D costs and reduce development times without compromising clinical test design. It’s a tall order.” (csdd.tufts.edu 2005)

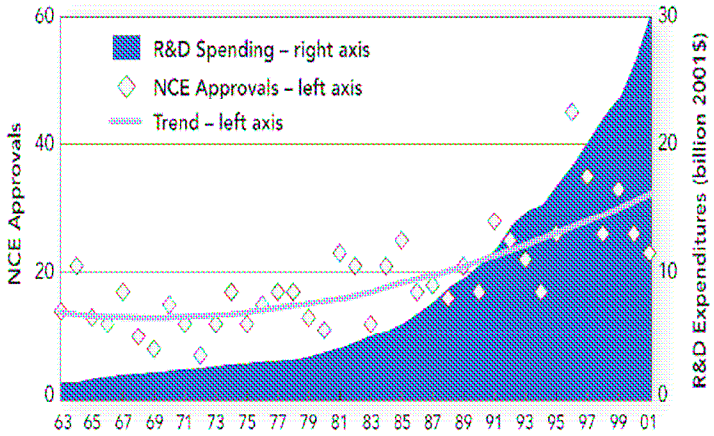



**Figure 2 NCE Approvals Trend**

(Singh 2004)

Definition: NCE (New Chemical Entity): “Any new molecular compound [excluding diagnostic agents, vaccines, and other biologic compounds] not

previously approved for human use by the CDER. Also excluded are new salts, esters, and dosage forms of previously approved compounds." (csdd.tufts.edu 2005)

Dr. Joseph A. DiMasi, director of economic analysis at the Tufts Center, believes that the increased cost of clinical trials contributes most significantly to the increased cost of new drug development. (csdd.tufts.edu 2005)
DiMasi also said, "The difficulty in recruiting patients into clinical trials in an era when drug development programs are expanding, and the increased focus on developing drugs to treat chronic and degenerative diseases, has added significantly to clinical costs,"

Cash Flows Throughout the Product Life Cycle

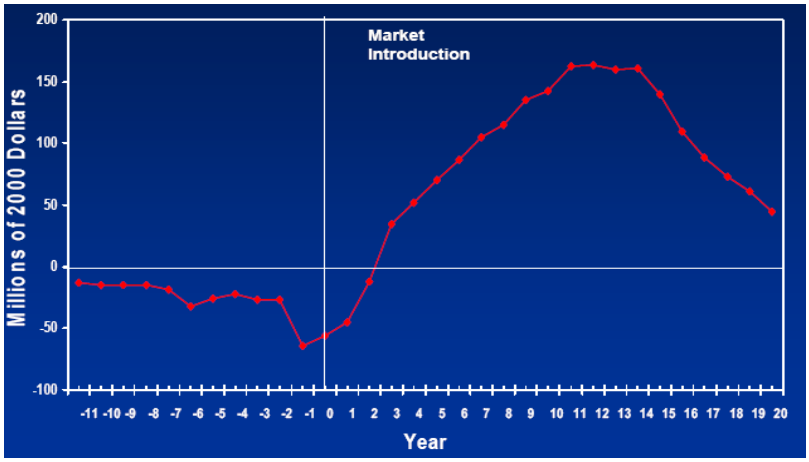



**Figure 3 R&D Spending**
(Singh 2004)

Currently the annual sales for pharmaceutical products, including prescription and over-the-counter products, exceed $300 billion dollars annually. (Hoovers.com 2005) This figure is expected to increase to over $350 billion by 2014. (Milkeninstitute.org 2005) Also, an estimated $49.3 billion was spent on Biopharmaceutical R&D in 2004 (PhRMA Industry Profile 2005) while the average revenue per company in the pharmaceutical industry is $10 billion. (Singh 2004) Presently, only 20% of industry companies' revenue is allocated to

R&D. The pharmaceutical industry is quite large and employs over 400,000 people in US biopharmaceutical companies alone. (Milkeninstitute.org 2005) Other segments of the industry, including generic product manufacturing, are also growing. Generic sales are expected to top the $50 billion mark within the next 3 years. Returns can also add significant expense and loss. Each year, over $2 billion worth of expense is absorbed by pharmaceutical companies for returns of recalled, overstocked, or out of date products. (Singh 2004)

According to Hoovers.com pharmaceutical companies currently operate with the following average financial statistics:

| | |
|---|---|
| Gross Profit Margin | 78.83% |
| Net Profit Margin | 16.55% |
| Inventory Turnover | 1.8 |

Companies' Revenues:

| | |
|---|---|
| Cost of goods sold | 100.0% |
| Selling and general administration | 25.3% |
| Research and development | 32.8% |
| Taxes | 7.3% |
| After-tax net profits | 20.6% |

(Health Affairs 2004)

## 3.3 Pharmaceutical Industry - Evolution of Top Companies

The US leads the worldwide pharmaceutical industry and is home to five of the ten largest pharmaceutical companies: Bristol-Myers Squibb, Johnson & Johnson, Merck & Co, Pfizer, and Abbott Laboratories. Pfizer is currently considered the market leader in terms of revenue and recently advanced its lead in the industry through the 2003 acquisition of Pharmacia. (Hoovers.com 2005) Behind the United States, the European Union also hosts five of the ten largest

pharmaceutical companies: AstraZeneca, Sanofi-Aventis, Novartis, Roche Group, and GlaxoSmithKline. (Hoovers.com 2005)

Japan falls into third place in terms of revenue in the pharmaceutical industry. Extremely high levels of regulation exist in the Japanese market. The Japanese market is currently recovering from an economic downturn that took place during the late 1990's and dropped it to third place behind the EU in sales. The top pharmaceutical companies in Japan are Sankyo Co., Takeda Chemical Industries, and Yamanouchi Pharmaceutical. Japan has remained unaffected by the industry wide consolidation which transpired in recent years. (Hoovers.com 2005)

The remainder of the world currently accounts for about 12% of the sales in the pharmaceutical market; however, this is rapidly increasing with advances in the living standards throughout the world. Subsequently, the demand for more advanced medical drugs and better overall health care will continue to increase outside of the three main pharmaceutical sales regions. (Hoovers.com 2005)

## 3.4 Pharmaceutical Industry Customer Segments and Sales Channels

The pharmaceutical industry primarily caters to large pharmacy retail chains and wholesalers of medical products. In addition to these primary customers, governmental agencies can also provide large quantity orders of prescription medications. With respect to prescription medication, the end consumer must purchase products from one of the above mentioned organizations, a few exceptions and anomalies withstanding. There has been an increasing trend in the number of consolidations amongst the wholesalers and pharmacy chains which is resulting in stronger customer purchasing power and in many cases this translates into lower margins for the pharmaceutical companies. The pharmaceutical industry also provides product directly to clinics and hospitals, however these are not the main market channels for prescription medications. The industry also encompasses the OTC (Over-The-Counter)

market for products. These products can be sold in less controlled and less stringent venues such as grocery stores and other retail outlets.

According to UPS consulting, “The increasing use of formularies, therapeutic interchange and step-care therapy by managed care means that sales and marketing efforts should cater to the root of these programs: cost management in treatment programs.” (UPS Consulting 2005) The trend of cost cutting and formulary use appears to be ongoing. As a result of formulary use, certain products’ revenues rely more on sales and marketing than on product effectiveness. The managed health care contracts often drive the market and changes in a formulary for one organization can often upset sales forecasts throughout an entire supply chain.

UPS consulting believes that, “2 marketing efforts must address the total cost management needs of both managed care and providers. Moreover, the time in which sales and marketing has to generate and influence demand is shrinking due to increased generics competition and shortening exclusivity periods. These shrinking timeframes and price pressures require that new product marketing and sales methods continuously address evolving sales channels. Pharmaceutical companies and their partners must also be able to quickly build differentiating capability in marketing to such sales channels.” (UPS Consulting 2005)

Companies in the US have started marketing directly to the end consumer instead of their customer. This marketing effort is designed to counter the pricing pressures which are amounting from increased buying power amongst pharmacy chains and wholesalers. Additionally, more consumers are purchasing both prescription and OTC medication via virtual stores such as mail order and Internet pharmacies. This change in the distribution channels can create an imbalance in sales forecasts. Subsequently, the manufacturers are not able to track demand on a geographic level. The migration of sales to non-

geographically specific forms of commerce will continue to grow and create parallel trade within markets. This parallel trade already exists in the EU because of regulated pricing. "The McKinsey Quarterly, 2002 second quarter, stated that direct-to-consumer (DTC) advertising produced mixed results, and while DTC budgets have significantly increased, efficacy has not." (UPS consulting 2005) This increasing trend in DTC marketing expenditures along with lower margins due to pricing pressures could lead to a shift in the market; pharmaceutical companies could start selling product directly to the end consumer through vertical integration.

In the event that new channels develop, pharmaceutical companies will need to adjust their distribution and logistics strategies to support the changing market needs. (UPS consulting 2005) "Drug makers can now sell direct to retailers and providers through e-marketplaces such as the Worldwide Retail Exchange and Global Healthcare Exchange" (UPS consulting 2005)

Companies must remain flexible in their strategy. Without flexibility new evolutions in sales channels could be detrimental to organizations. Parallel trade already poses problems within the EU; non-geographically specific retailers will continue to influence the shape of the distribution channels throughout the rest of the world.

Companies also face the increased threat of counterfeit drugs in the supply chain. It is estimated that, internationally, as much as 7% of drug products in supply chains are fake. (Singh 2004)

## 3.5 Pharmaceutical Industry - Supply Chain Structure

The pharmaceutical industry continues to exhibit some of the longest product pipelines and lead times. The process of drug development is becoming increasingly more complicated. The lead time for the development of a new product is exceptionally long; often times in excess of 10 - 15 years.

(csdd.tufts.edu 2005). Higher pressures from generic manufacturers force companies to seek recuperation of expenses in shorter time frames. Government agencies encourage generic manufacturers to enter the market once products' patents expire by providing market exclusivity for 180 days. (cms.hhs.gov 2005) CMS (Center for Medicare and Medicaid Services) encouraged the development of ANDAs (Abbreviated New Drug Applications) to assist generic manufacturers and expedite the approval process for new generic products.

The pharmaceutical industry has some of the highest research and development expenditures. R&D efforts often provide fruitless results and leave companies struggling to recuperate investments. Within the pharmaceutical industry it is not uncommon for over 5000 drug compounds to be tested for every 5 products that reach clinical trials. Once a product reaches clinical trials, only 1 out of every 5 will actually receive approval and enter the market. (PhRMA Industry Profile 2005) Once in the market, only 30% of the prescription drugs will ever provide a return on the initial R&D expenditure. (Singh 2004)

**Stages of Pharmaceutical Product Development:**

**Drug Discovery:**

Identify a target molecule or compound that scientists believe will affect certain medical conditions. Scientists then screen thousands of variations of this compound using computer screening or chemical testing. After testing, each compound that is identified as a potential medicine will then be further evaluated to determine its potential value with respect to existing products and its ability to be manufactured on a large scale. (PhRMA Industry Profile 2005)

**Pre-clinical Testing:**

The drugs which make it through the discovery process are then subjected to laboratory and animal testing for an additional 1 – 3 years. This testing assesses the safety of the compound and provides some insight into its activity against specific diseases. The purity, stability, and shelf life of the compound are also tested along with its manufacturability in different galenical forms. (PhRMA Industry Profile 2005)

**IND (Investigational New Drug) Review:**

In the US, a company must submit an application to the FDA (Food and Drug Administration) before it can begin clinical trials. (PhRMA Industry Profile 2005). The application process varies across regions and countries.

**Phase 1 Clinical Trial:**

In Phase 1, the drug compound undergoes testing regarding safety, dosage ranges, and action mechanisms. This phase of clinical trials involves between 20 and 100 healthy volunteers. (PhRMA Industry Profile 2005)

**Phase 2 Clinical Trial:**

Upon conclusion of Phase 1, the drug compound must undergo placebo-controlled trials on 100 to 500 volunteers who are afflicted with the target disease or condition. (PhRMA Industry Profile 2005)

**Phase 3 Clinical Trial:**

Phase 3 is the largest of the clinical trials and involves between 1000 and 5000 patients. The drug compound is tested on patients in clinics, hospitals, and other health care facilities. (PhRMA Industry Profile 2005)

**FDA or Other Agency Approval:**

FDA or agency scientists and committees review the application and decide the fate of the drug compound. Only 1 in 5 drugs that enters clinical trials are approved. (PhRMA Industry Profile 2005)

**Production:**

Once a drug compound receives regulatory approval it can still take upwards of 1 full year for the product to reach the market. The raw material for some pharmaceutical products takes over a year to traverse the supply chain and become a finished product. Processing and distribution comprises less than 25 days of the lead time (Singh 2004)

The industry needs more than ever to improve and expedite the process of launching new products. Forrester Research calculates that the per-day cost in lost sales for a $1 billion drug is $2.74 million. (McKinsey Quarterly 2002) "The location of [new drug] launches affects how quickly doctors and patients can access the most advanced treatments. One study shows that the U.S. averages a 4-month delay from initial drug launch to market. In Europe, this delay ranges from 7 to 19 months…. The reason: lengthy reimbursement negotiations that follow government approval of any new drug." (PhRMA Industry Profile 2005)

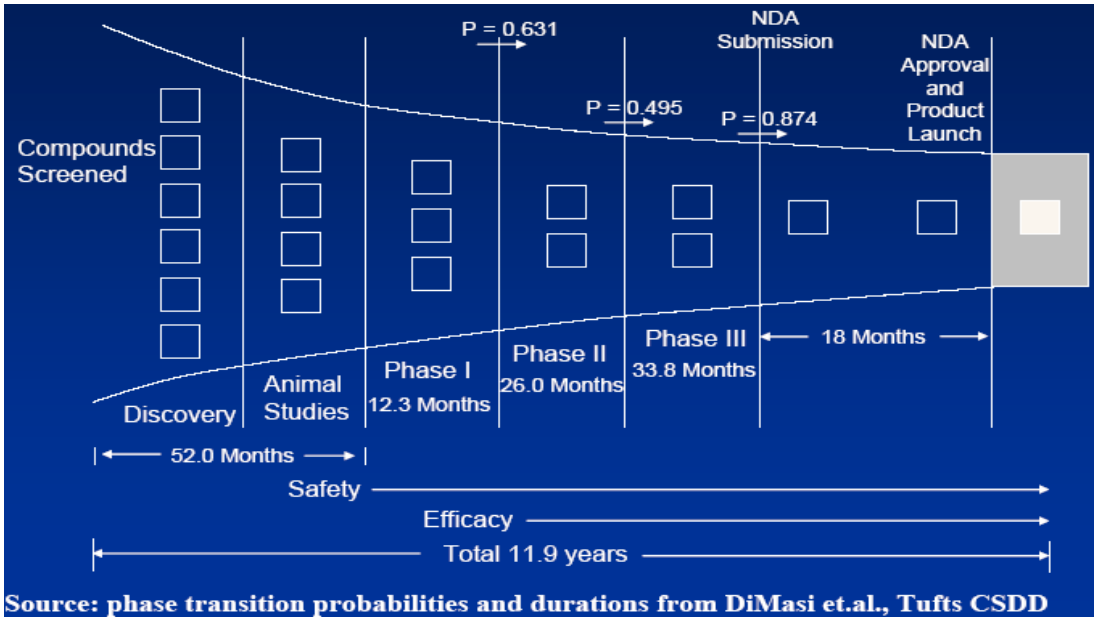



**Figure 4 NCE Phase Transition Probabilities**
(Tufts CSDD)

The pharmaceutical industry experiences a high level of scrap and rework in manufacturing processes. The industry average for rework and discarded product is 50%. Rework and scrap cost companies millions of dollars. Estimates place the cost of a scrapped batch of product around $3-$4 million. (Singh 2004) The industry is also notorious for maintaining high levels of WIP (work in progress) and finished good inventory. WIP inventories up to 100 days are not uncommon. (Singh 2004) Pharmaceutical inventories in the US have nearly doubled in the last decade and are approaching record high levels estimated around $18 billion. (Singh 2004)

Even amongst some of the highest recorded inventory levels, the industry still faces inevitable shortages. The American Society of Health System Pharmacists recognizes over 40 drug and vaccine products which experience unavailability and shortages. (Wall Street Journal, 2/15/2002) There is an escalation of the shortages throughout the supply chains of pharmaceutical companies. In the 5-6 years preceding 2002, the industry only experienced 8 –

10 shortages a year; as of 2002, the industry expected shortages of over 40 products annually. (Wall Street Journal, 2/15/2002) In the 1980's and 1990's backordered products were uncommon. (Associated Press, 12/8/2002)

**Reasons for drug shortages:**

Regulatory issues (7%)

Product discontinuation (20%)

Raw materials issues (8%)

Manufacturing problems (28%)

Supply and demand problems (10%)

Approximately 27% of shortages are unexplained.

(Singh 2004)

The capacity utilization in many companies' plants remains low causing lower contribution margins for products. Plant utilizations often fall around 50%. (Singh 2004)

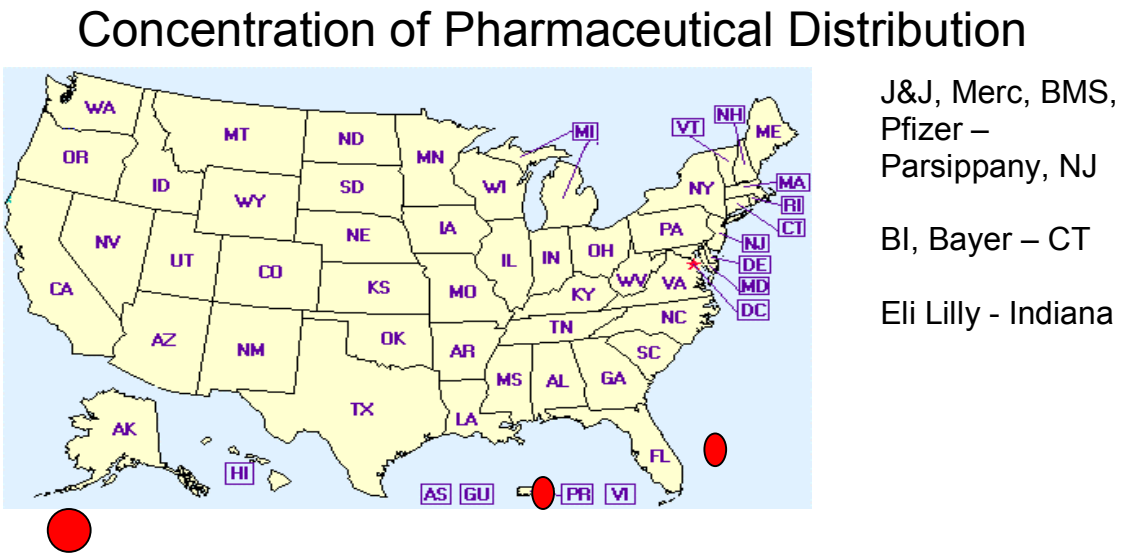



**Figure 5 Pharmaceutical Company Geographical Concentrations**

(US Department of Labor 2004)

## 3.6 Trends and industry drivers

PhRMA (Pharmaceutical Research and Manufacturers of America) member companies collectively invested over $38.8 billion in 2004 setting a record high for R&D expenditures. This represents a 12.6% increase over the previous year. (PhRMA Industry Profile 2005)

The global landscape of the pharmaceutical industry changed in the past few years as European pharmaceutical companies relocated a large number of researchers and facilities to the United States. The trend of relocation stems from the United States governmental attitude and policy that fosters new drug innovation and development. The European Union also imposes regulatory price and cost controls which make research and development unattractive. (Charles River Associates 2004) The European Union's policies and controls place undue downward pressure on research and innovation. In the last decade, the United States pharmaceutical industry has surpassed the European industry in the number of new products being introduced to the market. The incentive misalignment results in a shrinking market share for European pharmaceutical manufacturers. (Who.int 2005) From 1998 to 2002 the United States had almost twice as many new drug launches than the European Union. (PhRMA Industry Profile 2005)

According to the FDA, the number of new drug applications has declined significantly in the past few years. (Singh 2004) The rising cost of R&D has contributed to a more selective process for choosing new products. Companies are only interested in creating blockbuster drugs that will provide a positive net return on their investment and provide added shareholder equity. With the increased pressure of generic replacements for off patent products and less time to earn profits, drug companies often drop compounds which exhibit a marginal probability of success before they enter clinical trials.

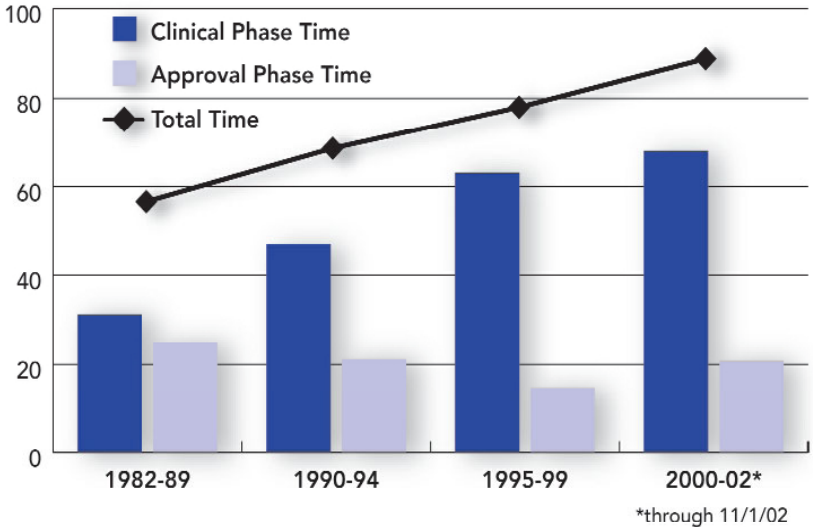



**Figure 6 Approval Time for New Products**

(Singh 2004)

"Demand directs drug development. With R&D costs climbing, drugmakers tend to focus on products for chronic rather than acute diseases with large patient populations (such as cancer, arthritis, cardiovascular conditions). Ulcer medications, cholesterol treatments, and antidepressants are the top three drug categories; the world's two best-selling drugs, Merck's Zocor and Pfizer's Lipitor, both treat high cholesterol. Advances in biotechnology are not only opening up new product opportunities but are also trimming the time and expense of development." (Hoovers.com 2005)

"Another factor driving the industry is the world's increasing elderly population. The over-65 set, which consumes three times as many drugs as younger populations, is expected to reach 690 million by 2025, and people are living longer thanks to drugs. Some 150 products for age-related conditions were brought to market in the 1990s, and some 600 more are in development. The aging population has also increased the demand for low-cost prescriptions. As drug prices continue to climb, many states are taking hard-line bargaining positions to reduce their Medicaid drug costs. The industry also faces the

possibility that the government will launch a Medicare prescription drug benefit." (Hoovers.com 2005)

"While the buyers may be living longer, monopoly profits from patents don't last forever. Patent expiration, in part, is fueling the M&A activity reshaping the industry. Although holders try to extend those precious patents with lawsuits and reformulations (such as Eli Lilly's failed move to extend its Prozac patent) or by simply paying generic rivals to keep generic versions of popular drugs off the market, such generic drugmakers as Barr Laboratories, Mylan Laboratories, Teva Pharmaceutical Industries, and Watson Pharmaceuticals will be adding big sellers to their product lists." (Hoovers.com 2005)

"Building a bigger, stronger drug pipeline can stave off losses when best sellers go off patent, and the push for new blockbusters is also driving industry consolidation. Pooling R&D potential has been part of the logic behind such megamergers as those between Pfizer and Pharmacia, Glaxo Welcome and SmithKline Beecham, and the companies that today are known as Sanofi-Aventis, Novartis, and AstraZeneca. Couplings with biotechnology companies provide another possible stream to fill emptying pipelines. As competition to create the next Viagra heats up, more companies will be merging and seeking collaborations to discover another blockbuster wonder drug." (Hoovers.com 2005)

## 3.7 Supply Chain Challenges and Opportunities

The practice of drug counterfeiting is escalating worldwide. Advances in technology, intermediary proliferation, high prices, excess demand, and a lack of regulatory intervention drive the escalation of counterfeiting in the pharmaceutical industry. (Wertheimer, Santella, Chaney, 2004). The counterfeit drugs continue to proliferate in existing pharmaceutical supply chains; the introduction of these counterfeit drugs taints the quality, effectiveness, and safety of the drug supply. Drug counterfeiting estimates range from "8% of the total drug supply in the

United States and other industrialized nations, and as high as 60% in poor countries" (Wertheimer, Santella, Chaney, 2004). Counterfeiting results in lost revenues, profits and lives.

The economic impact of counterfeit drugs extends and multiplies worldwide. Counterfeit drugs cause substantial losses in revenue and profit. The faux products also tarnish reputations; cause costly lawsuits from adverse drug reactions; and create expensive recalls and reverse logistics expenses. Indirectly, the counterfeit products can increase regulatory and political involvement in the industry which creates lengthened product approval times and costs. The end result: law suits, insurance costs and injuries, create higher prices for the end consumer and lower profit margins for pharmaceutical companies.

Industry wide profitability for pharmaceutical companies in 1996 was estimated conservatively at 18.8% (CEBR, 1998) this would translate into almost $95 billion for 2004. Subsequently, estimates for lost revenue due to counterfeiting in the pharmaceutical industry were approximately 5.8% or $29.3B in terms of 2004 industry profit (CEBR, 1998). This staggering figure represents the significant impact that counterfeit products impose on the pharmaceutical industry. Within the European Union the same comparison would represent an annual loss of profit equal to €292M (CEBR, 1998). In terms of GDP, the loss to the respective EU countries' GDPs exceeded €937M, and resulted in almost 2000 forfeited potential jobs (CEBR, 1998). The WHO (World Health Organization) estimated that the percentage of counterfeit drugs world wide could be as high as 10% (WHO, 1999).

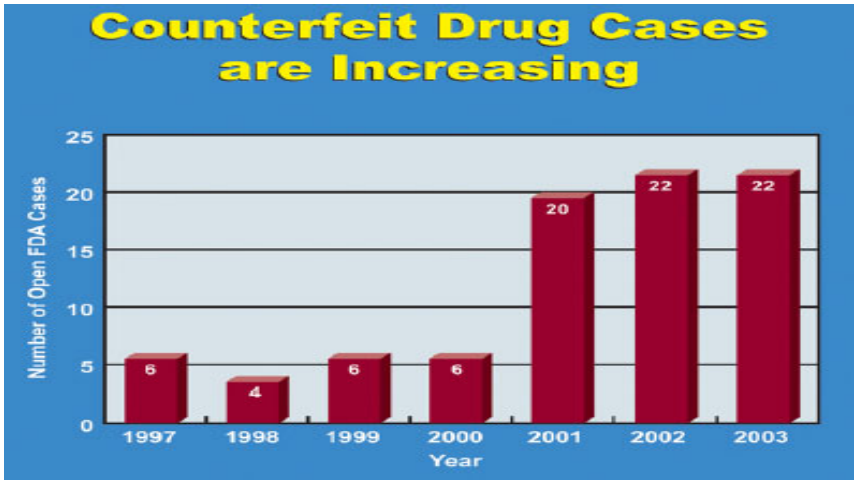



**Figure 7 Counterfeit Drug Proliferation**
(Singh 2004)

One of the future challenges for the pharmaceutical industry involves the combat of counterfeiting. The FDA has recognized that RFID (Radio Frequency Identification) technology possesses potential to reduce the treat of counterfeit drug introduction. The FDA believes, "Modern electronic technology is rapidly approaching the state at which it can reliably and affordably provide much greater assurances that a drug product was manufactured safely and distributed under conditions that did not compromise its potency" (Fda.gov 2004). As the FDA continues to examine alternatives to act against the counterfeiting pandemic, "Radiofrequency Identification (RFID) tagging of products by manufacturers, wholesalers, and retailers appears to be the most promising approach to reliable product tracking and tracing." (Fda.gov 2004) Additionally, "Authentication technologies for pharmaceuticals have been sufficiently perfected that they can now serve as a critical component of any strategy to protect products against counterfeiting." (Fda.gov 2004) If the FDA imposed mandatory implementation of RFID, the industry on a whole could experience vast changes in the cost basis for supply chains.

Although the pharmaceutical industry would take a significant cost hit to implement the new technology, the end result, if counterfeiting were reduced, would create substantial savings and additional profit. Presently, the average price of a bottle of prescription medication is estimated at around $53.10. It is estimated that 76% of that profit is received by the manufacturer ($7.60), the wholesaler receives 3% ($0.30), and the other 21% is retained by the retailer ($2.10) (Singh, 2004). According to the previous calculations and estimates, almost $3.10 of profit is lost per bottle due to counterfeiting.

The cost of the infrastructure to implement RFID would be a one time sunk cost; however the benefits would continue to contribute to the bottom line. Even if the cost of the RFID tags, which is where the main portion of the cost exists, remained high at $.20 /tag, the benefits would still show significant increases in profit from the reduction in counterfeit products. The benefits of RFID implementation far outweigh the costs (Lagasse 2003).

In addition to the quantitative losses suffered by the pharmaceutical industry, the world also experiences immeasurable humanitarian losses as a result of counterfeit drug introduction. In China over 192,000 lives were lost (cumulatively) throughout 2001 (Wertheimer, Santella, Chaney 2004).

| THE CALCULATION OF THE BENEFITS AND COSTS | | | | | | |
|---|---|---|---|---|---|---|
| COST | YEAR 0 | YEAR 1 | YEAR 2 | YEAR 3 | YEAR 4 | YEAR 5 |
| Shorter Trial | | $44,900,000 | $44,900,000 | $44,900,000 | $44,900,000 | $44,900,000 |
| Lower Development Costs | | $8,100,000 | $8,100,000 | $8,100,000 | $8,100,000 | $8,100,000 |
| Shorter Release Times | | $3,400,000 | $0 | $3,400,000 | $0 | $3,400,000 |
| Total Clinical Trial Benefits | | $56,400,000 | $53,000,000 | $56,400,000 | $53,000,000 | $56,400,000 |
| Installation & Integration | $8,746,000 | | | | | |
| Ongoing Maintenance, Training & Support | | $176,900 | $176,900 | $176,900 | $176,900 | $176,900 |
| Total Costs | $8,746,000 | $176,900 | $176,900 | $176,900 | $176,900 | $176,900 |
| Total Gross Benefit | ($8,746,000) | $56,223,100 | $52,823,100 | $56,223,100 | $52,823,100 | $56,223,100 |
| Taxes | ($2,600,000) | $16,900,000 | $15,800,000 | $16,900,000 | $15,800,000 | $16,900,000 |
| Net Benefit | ($8,746,000) | $39,323,100 | $37,023,100 | $39,323,100 | $37,023,100 | $39,323,100 |
| 5-Year NPV | $126,400,000 | | | | | |

**Figure 8 Financial Impact of RFID Implementation on Pharmaceuticals**
(CGE&Y 2003)

In a study performed by CGE&Y in 2003 (Illustrated above), the expected benefits of an RFID implementation in the pharmaceutical industry demonstrated an exceptionally strong 5-year NPV.

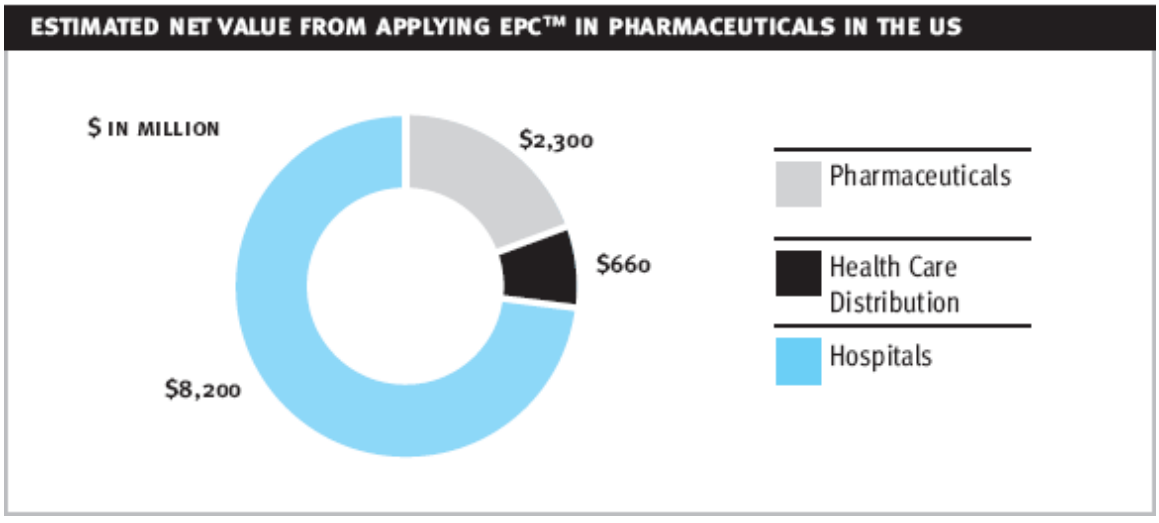



**Figure 9 Net Value of EPC for Pharmaceuticals**
(CGE&Y 2003)

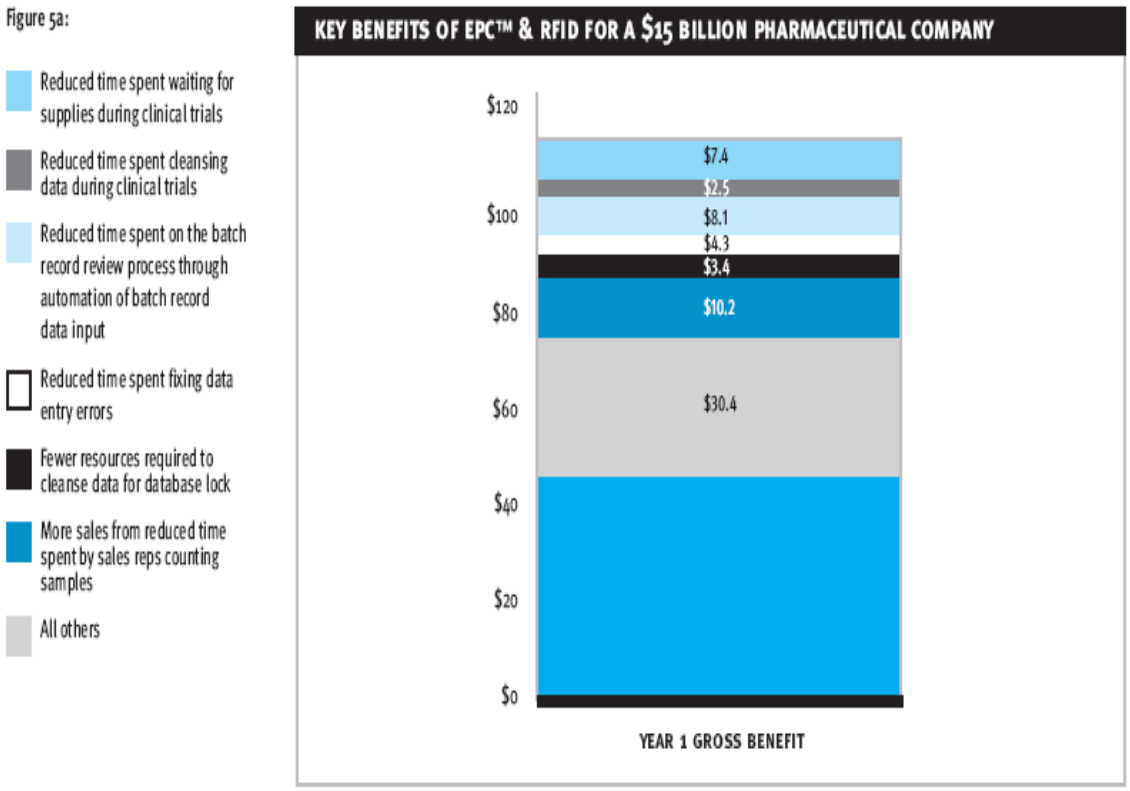



**Figure 10 Key Benefits of EPC for a Pharmaceutical Company**
(CGE&Y 2003)

The benefits of RFID seem promising in the pharmaceutical industry. The implementation may pose challenges, but with the backing and possible subsidy of regulatory agencies, these great giants of the pharmaceutical world may gracefully adopt the new technologies.

In addition to the already challenging issues within the pharmaceutical industry, there are also future concerns about the capacity sufficiency. As the pharmaceutical industry undergoes metamorphosis into a biopharmaceutical industry, the new therapies and products will be manufactured using new techniques including protein based manufacturing. Currently, laboratories are producing new research in product development; however the current

manufacturing equipment is not capable of manufacturing the newer more advanced drugs. According to Euractive.com, there are several factors which create a gap between research and production capabilities:

1. Large capital requirements for R&D with short patent protection and capital recovery time
2. Long build-out periods for new plants and facilities. Some of the new plants take in excess of 5 years to design and build.
3. Monoclonal antibodies are developing into a highly effective class of treatment, however manufacturing requires the use of mammalian cell cultures; the world capacity for this type of production is around 450,000 liters annually.
4. Biologics manufacturing facilities and plants can cost in excess of $500 million.
5. There is a vast shortage of talent in the fields of production and engineering for biopharmaceutical products

(Euractiv.com 2005)

# Chapter 4 – Novartis Industry Position

## 4.1 Novartis History

In 1758 a man by the name of Johann Geigy started selling natural dyes and spices in Basel, Switzerland. For almost a century the family business which he started continued under the Geigy family name and in the mid 1800's the business began producing synthetic dyes in addition to their existing products. During the time frame in which the family began synthetic dye production, another man in Basel by the name of Alexander Clavel also entered the presumably lucrative business of synthetic dye production. The company founded by Clavel was formally named "Gesellschaft fur Chemische Industrie Basel" (Ciba). Following in the success of the Giegy family and Ciba, another synthetic dye manufacturer, by the name of Sandoz, was established in 1886. By the turn of the century Ciba had become the most prominent chemical production company in Switzerland and continued to prosper through the beginning of the 20th century. (Hoovers.com 2005)

Around 1920, the 3 companies of Ciba, Geigy, and Sandoz allied with each other to form the Basel AG cartel in an effort to compete with the major German competitor at the time, I.G. Farben. The cartel generated greater profits which were reinvested into the diversification of its product line to include pharmaceuticals and other chemicals. The cartel grew throughout the 1920's and in 1929 merged with a German company. In the 1930's the Cartel merged further with French and British companies to form the Quadrapartite Cartel, but in 1939 the start of the Second World War caused the relationship to splinter. The only survivor of the dissolution was the Basel AG cartel. In 1948 one of the cartel's scientists received the Nobel Prize for the invention of DDT. Shortly after the award the Basel AG Cartel broke apart into its original component companies. (Hoovers.com 2005)

After the separation, Geigy once again took the title of market leader in sales and surpassed Ciba in 1967 through its diversification efforts in agricultural chemicals. 1967 proved exciting for the Switzerland based chemical producers; Sandoz purchased a group companies that produced Dietetic products. Three years following the Sandoz acquisition Ciba and Geigy joined once again. The post-merger company then proceeded to enter the US market. Ciba-Geigy, trying to gain additional market share and foothold in the United States, acquired Funk Seeds in 1974. Sandoz aggressively followed suit in 1976 by acquiring Northrup, King & Co. Four years later Sandoz also acquired the Zaadune, Dutch Seed Company. For the following decade, both companies pressured aggressively to gain market share and presence in the United States. Ciba-Geigy and Chiron entered a joint venture in 1986 which produced and marketed genetically engineered vaccines; less than 8 years later, Ciba-Geigy had acquired half of the ownership in Chiron. Sandoz continued voraciously to compete with Ciba-Geigy and invested heavily the Genetic Therapy and SyStemix US biotech companies. Ciba-Geigy also succeeded in making an out of character bid to acquire Gerber in 1994. (Hoovers.com 2005)

In 1996, the long awaited reunion of Ciba, Geigy, and Sandoz finally transpired. The product of the merger, Novartis, was a new company which had divested of some herbicide and animal health businesses. The year following the merger proved quite busy for Novartis; the company divested of its specialty chemicals unit and then purchased Merck's insecticide and fungicide divisions. The next year Novartis combined its OTC (Over-The-Counter) health division with its nutrition division to create a new consumer health division. The following year this division sold several smaller business units. The company remained quiet for two years and then acquired Wesley Jessen VisionCare in 2000. In 2001 Novartis separated its opthalmics division from its CIBA Vision division to create a new eye health care unit under the pharmaceutical division. Novartis continued to focus on its pharmaceutical core competencies by selling its food

divisions and acquiring several companies in 2002 including Grand Laboratories, Immtech Biologies, and Lek Pharmaceuticals. (Hoovers.com 2005)

## 4.2 Novartis Overview

**Mission Statement**

**Purpose**

"We want to discover, develop and successfully market innovative products to cure diseases, to ease suffering, and to enhance the quality of life. We also want to provide a shareholder return that reflects outstanding performance and to adequately reward those who invest ideas and work in our company." (Novartis.com 2005)

**Aspirations**

"We want to be recognized for having a positive impact on people's lives with our products, meeting needs and even surpassing external expectations. We strive to create sustainable earnings growth, ranking in the top quartile of the industry and securing long-term business success. We want to build a reputation for an exciting workplace in which people can realize their professional ambitions. We strive for a motivating environment where creativity and effectiveness are encouraged and where cutting-edge technologies are applied. In addition, we want to contribute to society through our economic contribution, through the positive environmental and social benefits of our products, and through open dialogue with our stakeholders." (Novartis.com 2005)

Although Novartis operates in over 140 countries worldwide, it's headquarters are centrally located in Basel Switzerland. The company provides a wide array of products from its different divisions. Some of these products include prescription drugs and other non prescription or OTC (Over-The-Counter) pharmaceutical products. The pharmaceutical products include treatments for

high blood pressure, cancer, nervous system disorders, ophthalmic conditions and other cardiovascular disorders. In addition to privately branded and produced products, the Sandoz generics division produces drug substances and active pharmaceutical ingredients for sale as intermediary products to other manufacturers or generic companies. The market demands for generic products will be met by the ever growing Sandoz division. To that accord, Novartis recently announced the purchase of controlling interest in Eon Labs, one of the top producers of generic products in the US. Novartis also has a consumer health unit which manufactures notable OTC products such as Ex-Lax, Theraflu, Maalox, and Gas –X. Novartis also manufactures products for an infant and baby business which includes the branded Gerber baby products. Gerber produces over 200 branded products in the US alone, and is regarded as the leading baby food brand in the US. (Novartis.com) Gerber products also include care and wellness products such as shampoos, lotions, and bottles. Novartis is also one of the top producers of contact lenses and solutions. The CIBA Vision division markets products worldwide and is a leader in the US and Europe. Novartis also owns an animal health unit which products pharmaceutical products for pet care. Of the list of pet care products, Sentinel is the most known and reputable brand. (Novartis.com)

Novartis is an industry leader!!! Since 2000, Novartis has led the industry with regulatory approvals, and has received approval for over 13 new products. Novartis also has over 75 drug compounds in development with 52 in Phase II, III, or Registration. (Novartis Annual Report 2004)

## 4.3 Novartis Historical Revenues, Operating Margins, and Employees

Novartis is one of the top ten pharmaceutical companies in the world and continues its trends of growth in all aspects of the industry. Novartis increased its sales by 14% to $28.2 billion in the 2004 fiscal year alone. These increased sales were attributed to strong growth in both the pharmaceuticals and consumer health divisions. The US market accounted for 40% of the company's sales

while Europe, the second largest market for Novartis, accounted for 36%. In part because of strong growth in Novartis' top selling pharmaceutical products like Diovan, the operating income grew by 11% in the 2004 fiscal year. In the 2004 fiscal year most "categories of function expenses had a positive impact on the operating margin." The Cost of Goods Sold (COGS) increased to 12% but remained comparatively the same with respect to percentage of net sales. For 2004 COGS was about 23.5% of net sales while marketing and sales accounted for 31.4%. Research and development fell slightly to 14.9% in proportion to net sales. The overall operating margin for Novartis was 23.1% for 2004. Novartis has maintained high profit margins above 20% since 1999. Figure 38 in the appendix illustrates the historical revenues and margins for Novartis. For the 2004 fiscal year, Novartis demonstrated strong organic growth and overall net income of 15% or $5.8 billion; historically, this represents the largest net income to date for the company. This growth increase resulted in higher earnings per share, up 16% from the pervious year, as well as an ending stock price increase of about $5 per share. Figure 39 in the appendix illustrates the historical stock prices and earnings for Novartis. Novartis also demonstrated better profit margins and per share revenues than the industry averages as illustrated in appendix figure 40 (Novartis 20F 2004)

## 4.4 Novartis Business Units

"Novartis is a world leader in both patent-protected and generic pharmaceuticals as well as consumer health products." (Novartis 20F 2004) At the end of 2004, Novartis was divided into three divisions: Pharmaceuticals, Consumer Heath, and Sandoz (generics).

### 4.4.1 The Consumer Heath Division

The consumer heath division of Novartis is organized in to 5 business units: OTC self-medication, animal health, medical nutrition, infant & baby, and CIBA Vision. (Novartis 20F 2004)

### 4.4.2 Sandoz Generics Division

The Sandoz generics division is structured as a retail generics manufacturer which also produces products for two other sub-businesses: industrial products and biopharmaceuticals. Within the retail generics core, Sandoz manufactures finished dosage galenical forms which are purchased by pharmacies, wholesalers, hospitals, and other non core customers. Sandoz manufactures active pharmaceutical ingredients and other ingredients for the pharmaceutical drug manufacturing process; these products are sold to other pharmaceutical companies. Additionally, Sandoz sells biopharmaceutical and biotech products to the open market. (Novartis 20F 2004)

### 4.4.3 The Pharmaceuticals Division

The pharmaceuticals division is further broken down into the two marketing organizations of primary care and specialty medicines. The pharmaceutical division markets pharmaceutical products in seven therapeutic concentration areas. The Novartis Institutes for Biomedical Research (NIBR), which focuses on “redefining drug discovery in a new era marketed by the completion of the human genome sequence,” also resides under the umbrella of the pharmaceuticals division. (Novartis 20F 2004) The pharmaceutical division is comprised of over 80 affiliated companies and employs over 47,000 people. Products from the different therapeutic areas are also sold in over 140 different countries worldwide.

## 4.5 Novartis Products

Below is a diagram that illustrates the therapeutic areas of concentrations for Novartis therapeutic categories:

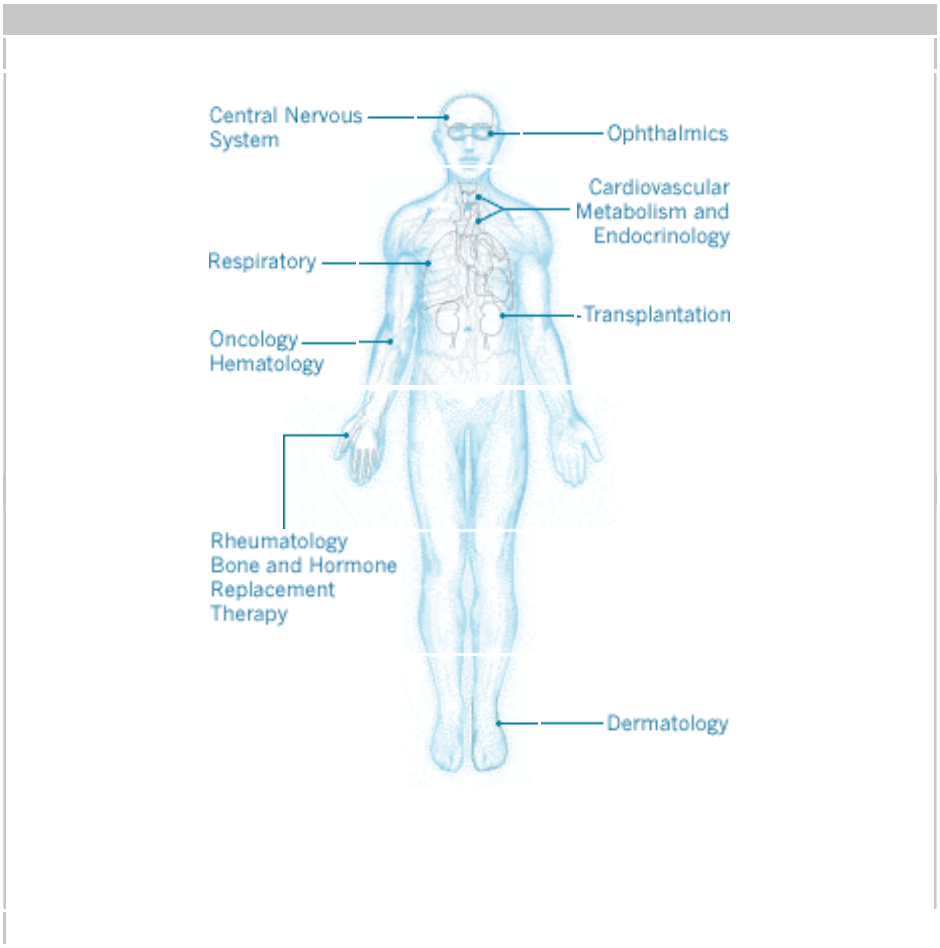



**Figure 11 Novartis Therapeutic Categories**
(Novartis.com 2005)

**Primary Care – Therapeutic Areas**

**• Cardiovascular & Metabolism**

Novartis remains one of the leading pharmaceutical companies in the plight against cardiovascular disease. The company specializes in providing products for the treatment of hypertension (high blood pressure), hyperlipidemia

(high cholesterol), and heart failure. Novartis also provides additional treatments for related prognoses including Type II diabetes. (Novartis 20F 2004)

**• Neuroscience**

Novartis was one of the first companies to create breakthrough treatments for neurological diseases and disorders. Some of the treatments for diseases such as Parkinson's Disease, Attention Deficit/Hyperactivity Disorder (AD/HD), schizophrenia, epilepsy, and Alzheimer's Disease date back more than 50 years in the history of Novartis. The company currently markets an anti-epileptic product, Trileptal, which is used by millions of people worldwide. It also provides a product, Erelon, which offers treatment for certain degrees of Alzheimer's disease. Ritalin LA is one of the division's most well know products because of its popular use in the United States to combat childhood AD/HD. (Novartis 20F 2004)

Novartis continues to make advances in the field of Neuroscience to enhance its portfolio of products. There are currently research efforts in the following fields: psychiatric diseases (bipolar disorder, psychosis, depression and anxiety), neurological disorders (Alzheimer's disease, multiple sclerosis, amyotrophic lateral sclerosis) and chronic pain. (Novartis 20F 2004)

**• Respiratory & Dermatology**

Novarts' "focus in dermatology is on the treatment of two very common diseases—the inflamed skin condition known as atopic dermatitis, or eczema, and fungal nail infections." The company's efforts in eczema are most recognized for the development of the product Elidel; Elidel was the first non-steriod cream to treat eczema. Novartis also offers, and is most famous for, its product Lamisil. Lamisil is used worldwide to treat fungal nail infection. In addition to the topical remedies, there are several advanced treatments for repiratory disorders including Foradil; this product provides "long-acting"

treatment for asthma and chronic obstructive pulmonary disease (COPD). (Novartis 20F 2004)

**• ABGHI (Arthritis, bone, gastrointestinal, hormone replacement therapy, infectious diseases)**

Novartis pays attention to "significant unmet medical needs, particularly in the areas of gastrointestinal (GI) disorders (including urinary incontinence), arthritis, osteoporosis, the treatment of pain and infectious diseases."
The company initially entered the GI market by launching Zelnorm/Zelmac; this product provides treatment for irritable bowel syndrome (IBS). This groundbreaking introduction makes Novartis the first company to receive regulatory approval for a treatment of IBS. The market for this product is anticipated to exceed 40 million consumers in the US alone, and should inevitably boost revenues and profitability in the ABGHI therapeutic area. In addition to the GI treatments, Novartis also offers treatments for bone disorders such as osteoporosis. The infectious disease area focuses on there main areas including anti-bacterial, tropical medicine, and anti-viral. The infectious disease research of this therapeutic area was acquired from Idenix Pharmaceuticals via acquisition in 2003. (Novartis 20F 2004)

**Specialty Medicines – Therapeutic Areas**

**• Oncology & Hematology**

Some of the most innovative drug substances arise out of research in the Oncology & Hematology therapeutic area. The products are geared toward the advancement of patient care and treatment with respect to cancer. Novartis is currently regarded as the No. 3 worldwide leader in the field of oncology and boasts an impressive market share in excess of 9%. Some of the most innovative and famous products in this therapeutic area include Gleevec/Glivec, Femara, and Zometa. (Novartis 20F 2004)

**• Transplantation & Immunology**

Novartis revolutionized the field of transplantation with the introduction of Neoral in 1982. This product is currently the "worlds most commonly used immunosuppressant." Novartis takes credit for the discovery of cyclosporine which is the active ingredient base for Neoral. The company continues its efforts to research and develop new and better compounds in this therapeutic area. Thanks to Novartis' contributions, transplantation success rates throughout the world have increased. (Novartis 20F 2004)

**• Ophthalmics**

Not to be confused with the contact lens business of CIBA vision, this therapeutic area develops and markets products for the treatment of eye diseases and disorders. Currently the product portfolio consists of treatments for "Back of the Eye" and "Dry Eye." Although colloquial sounding in name, these problem areas represent "significant unmet medical needs." Currently Novartis Opthalmics is best known for its product Visudyne which can successfully prevent or stop forms of age related vision loss. Currently there are not many product offerings in this area, however it seems to demonstrate significant potential for growth through R&D. (Novartis 20F 2004)

## 4.6 Novartis Sales Channels and Customer Segments

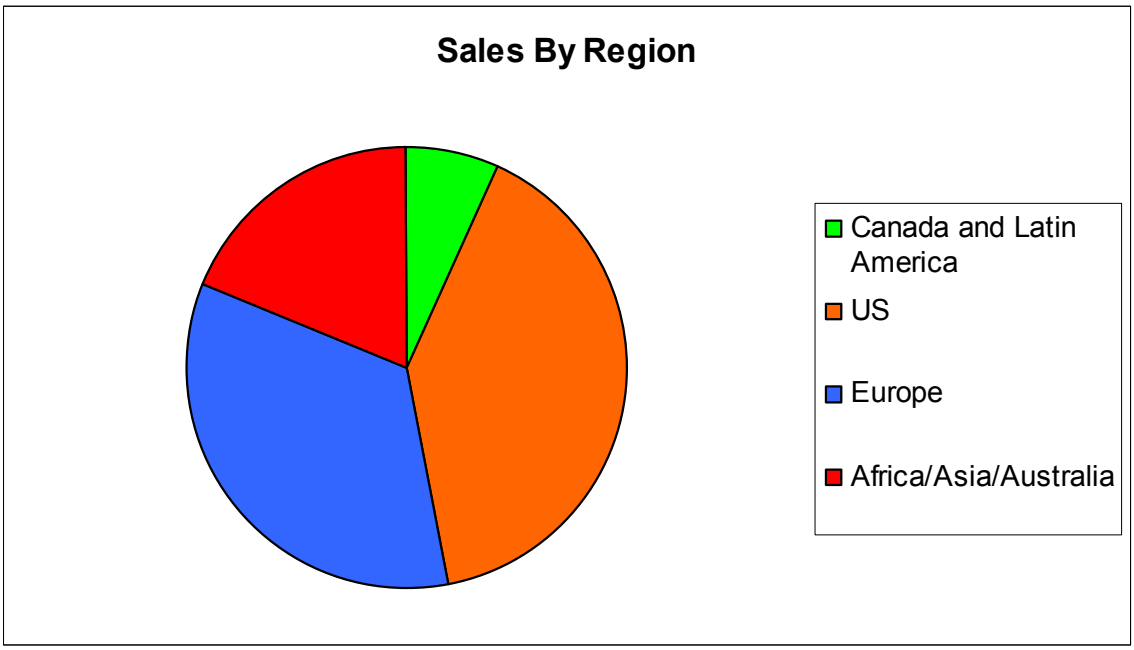



**Figure 12 Novartis Pharmaceutical Sales by Region**

Below is a list of the Particular area in which Novartis pharmaceuticals competes:

- SIC Codes
  - 2833Medicinals and botanicals
  - 2834Pharmaceutical preparations
  - 3851Ophthalmic goods
  - 5048Ophthalmic goods
- NAICS Codes
  - 32541Pharmaceutical and Medicine Manufacturing
  - 325411Medicinal and Botanical Manufacturing
  - 325412Pharmaceutical Preparation Manufacturing
  - 339115Ophthalmic Goods Manufacturing

(Hoovers.com 2004)

## 4.7 Top Competitors and Positioning

### Johnson & Johnson

Johnson & Johnson (J&J) is one of the world's largest pharmaceutical companies. J&J competes with Novartis in the pharmaceutical industry including prescription and OTC drug products. J&J also competes in the consumer health and baby products areas. One main differentiating factor is that J&J is one of the most diverse companies in the health care sector. Novartis demonstrates far more focus in its objectives and is able to compete in more specific product categories while J&J continues to diversify. In this respect, Novartis may actually produce better results with a focus on its core strategic competencies and brands. J&J continues, like many other pharmaceutical companies to grow through M&A. (Hoovers.com 2005)

### Merck

Unlike J&J, Merck is comparatively more like Novartis. Merck focuses on the pharmaceutical industry and the production of products within. Through the last couple of years Merck has proved to be a formidable competitor in several facets of the pharmaceutical industry. Merck is more comparable in size to Novartis with its annual revenue for the year ending in 2004 within the same range as that of Novartis. Additionally, Merck tends to focus on some particular areas of illness and treatment; some of those areas overlap with therapeutic areas which Novartis attacks. According to Hoovers.com, "Merck helps those who are hooked on hamburgers." Although financially well off, Merck has encountered a series of setbacks in recent months including premature loss of patent protection and lawsuits with respect to major revenue generating products. (Hoovers.com 2005)

**Pfizer**

Pfizer is recognized as the “world’s largest research-based pharmaceuticals firm.” Pfizer, like Novartis and Merck, focuses its effort solely in the pharmaceutical industry. Although very broad in pharmaceutical product category competition, Pfizer does not diversify its business like J&J. Pfizer also tends to focus its effort on the creation of Blockbuster drugs. This year Pfizer touted its size with 10 of its drug products each toping the $1 billion mark in sales. Pfizer competes extensively in the US and remains in the lead of the industry with respect to sales. Novartis realizes some of its stiffest competition from Pfizer. (Hoovers.com 2005)

# Chapter 5 – Novartis Supply Chain

## 5.1 Pharmaceutical Division Historical Revenues, Margins and Employees

| Pharmaceuticals | Net Sales 2004 | |
|---|---|---|
| | ($ millions) | (%) |
| United States | 7,368 | 40 |
| Americas (except the United States) | 1,244 | 7 |
| Europe | 6,370 | 34 |
| Japan | 2,081 | 11 |
| Rest of the World | 1,434 | 8 |
| Total | 18,497 | 100 |

**Figure 13 Pharmaceutical Division 2004 Sales**

(Novartis 20F 2004)

| Key figures (In USD millions unless indicated otherwise) | 2004 | 2003 |
|---|---|---|
| Net sales | **18 497** | 16 020 |
| Operating income | **5 253** | 4 423 |
| Research and development | **3 480** | 3 079 |
| Research and development as % of net sales | **18.8** | 19.2 |
| Free cash flow | **5 436** | 4 690 |
| Net operating assets | **9 496** | 8 969 |
| Investments in property, plant & equipment | **716** | 771 |
| Number of employees | **47 325** | 44 640 |

**Figure 14 Novartis Pharmaceutical Division Key Figures**

(Novartis Annual Report 2004)

**Top 20 Pharmaceuticals Division Product Net Sales—2003**

| Brands | Therapeutic Area | United States | % change in local currencies | Rest of the World | % change in local currencies | Total | % change in local currencies |
|---|---|---|---|---|---|---|---|
| | | ($ millions) | | ($ millions) | | ($ millions) | |
| *Diovan/Co-Diovan* | Hypertension | 1,107 | 42 | 1,318 | 34 | 2,425 | 38 |
| *Gleevec/Glivec* | Chronic myeloid leukemia/ Gastro-intestinal stromal tumors | 299 | 41 | 829 | 82 | 1,128 | 68 |
| *Neoral/Sandimmun* | Transplantation | 216 | (21) | 804 | (6) | 1,020 | (10) |
| *Lamisil* (group) | Fungal infections | 428 | 2 | 550 | 9 | 978 | 5 |
| *Zometa* | Cancer complications | 574 | 59 | 318 | 118 | 892 | 74 |
| *Lotrel* | Hypertension | 777 | 20 | | | 777 | 20 |
| *Lescol* | Cholesterol reduction | 309 | 19 | 425 | 18 | 734 | 18 |
| *Sandostatin* (group) | Acromegaly | 318 | 13 | 377 | 2 | 695 | 7 |
| *Voltaren* (group) | Inflammation/pain | 8 | (33) | 591 | (5) | 599 | (6) |
| *Cibacen/Lotensin/ Cibadrex* | Hypertension | 306 | (9) | 127 | (8) | 433 | (9) |
| **Top ten products** | | **4,342** | **21** | **5,339** | **20** | **9,681** | **20** |
| *Trileptal* | Epilepsy | 305 | 43 | 92 | 27 | 397 | 39 |
| *Miacalcic* | Osteoporosis | 239 | | 150 | (14) | 389 | (6) |
| *Tegretol (incl. CR/XR)* | Epilepsy | 122 | 1 | 262 | (1) | 384 | |
| *Exelon* | Alzheimer's disease | 181 | 8 | 186 | 19 | 367 | 13 |
| *Visudyne* | Wet form of age-related macular degeneration | 181 | 8 | 176 | 27 | 357 | 16 |
| *Leponex/Clozaril* | Schizophrenia | 86 | (28) | 223 | (2) | 309 | (12) |
| *Foradil* | Asthma | 9 | (61) | 280 | 2 | 289 | (4) |
| *Elidel* | Eczema | 205 | 125 | 30 | 575 | 235 | 144 |
| *Famvir* | Viral infections | 146 | (7) | 87 | 19 | 233 | |
| HRT Range | Hormone replacement | 125 | (9) | 106 | (24) | 231 | (16) |
| **Top twenty products** | | **5,941** | **18** | **6,931** | **16** | **12,872** | **17** |
| Rest of portfolio | | 643 | (9) | 2,505 | (9) | 3,148 | (9) |
| **Total** | | **6,584** | **15** | **9,436** | **8** | **16,020** | **11** |

**Figure 15 Top 20 Pharmaceutical Product Sales**

(Novartis 20F 2004)

"In 2004, group sales increased 14% to $28.2 billion. Pharmaceutical sales climbed 15% to $18.5 billion. The oncology and cardiovascular franchises grew 22% and 21% respectively and continued to be the main drivers throughout the year with market share expanding globally. At the consumer health division, full-year sales grew 10%." (Novartis 20F 2004)

"Novartis has launched 13 new medicines in the US since 2000. Our rich pipeline, with a total of 75 compounds and 52 projects in advanced development or registration, was rated as one of the industry's strongest by financial analysts." (Novartis 20F 2004)

## 5.2 Pharmaceutical Division Business Units

The nature of the Novartis supply chain subdivides responsibilities for the purpose of vertical integration. Historically, the Novartis supply chain is comprised of multiple locations throughout the world.

Subdivision of Supply Chain:

**Chemical Operations** (ChemOps): The ChemOps facilities are responsible for the transformation of raw materials or chemicals into the final drug substance. This process can take between 7 and 15 months and can involve as many as 8-9 chemical processing steps. The ChemOps facilities procure chemicals in a very basic form and transform them into a final concentrated drug substance.

**Pharmaceutical Operations** (PharmOps): The PharmOps facilites are responsible for taking the highly purified and concentrated drug substance and transforming it into the final galenical forms. This process involves the milling and blending of the drug substance. This process usually takes between 2-3 months. Once the final galenical form is produced, the product is then packaged and placed into finished product inventory in Basel, Switzerland.

**Country Pharmaceutical Office** (CPO): The CPO is responsible for the sales and distribution of products within a specific geographic region. Some of the CPOs are owned and operated by Novartis while others are operated by third parties or country specific agents. Novartis prefers to own and operate their own CPOs however some country regulations require partnerships or third party interactions.

## 5.3 Pharmaceutical Division Products (including #s, % new, % promoted)

Novartis adopted a new philosophy for bringing products to market. Once a product receives approval, TechOps (Technical operations) plans to "Launch in 1000 Days." (Novartis Interview 2005) Eventually, the TechOps group plans to implement an improved policy which will allow them to "Launch in 600 Days." By shortening the time which it takes to get a product to market, Novartis can capitalize on the additional time under patent protection. An extra year in the market without competition from generic drugs, for instance, could make a significant difference in the overall financial success of a new product with respect to its R&D cost basis. Novartis is reducing the time to launch by creating closer integration between the clinical trials production process and the final manufacturing process. By learning and improving on the manufacturing process while Novartis is still performing clinical trials, they can learn more about the efficiencies of manufacturing the final product and create a repository of information. Novartis is also beginning to start manufacturing the final product for market based on estimates of when the drug substance will receive approval. By anticipating the approval date in a given region, Novartis is able to go to market with the product much more quickly after approval is received. There are risks involved; Novartis could be refused approval and have additional sunk costs in a manufactured product which will never sell. This sunk manufacturing cost, however, is relatively insignificant in comparison to the loss of R&D funds for a failed product and is considered an acceptable financial risk.

Products coming off patent

- *Neoral 2009*
- *Sandostatin Expiring*
- *Cibacen/Lotensin/Cibadrex Expiring*
- *Lotrel 2017*
- *Lamisil 2006*
- *Miacalcin/Miacalcic 2015*
- *Voltaren Expired*

*(Novartis 20F 2003)*

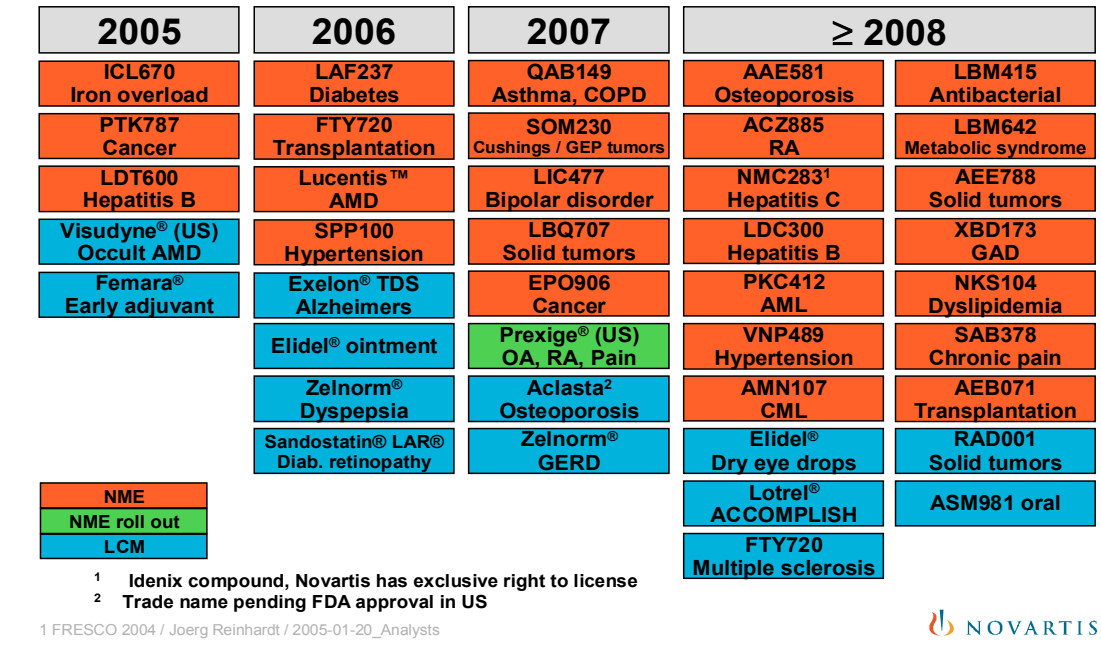



**Figure 16 Products Coming Off Patent**

(Novartis.com 2004)

## 5.4 Pharmaceutical Division Sales Channels and Customer Segments

The CPO in each country operates as the local sales organization for Novartis. Novartis employs over 13,000 people on its sales staff, with almost half of those employees located in the US. The sales staff must be trained and educated on the product as well as its uses and potential risks. The sales representatives must discuss the benefits and risks of the product with potential prescribers and customers including physicians, hospitals, pharmacists, hospitals, insurance companies, and other health care organizations.

The sales and distribution patterns vary slightly by geographic region, however Novartis sells its products directly to the customer; customers include hospitals, wholesalers, government agencies, and other health care providers.

Novartis does not segment its customers or sales channels. The nature of the pharmaceutical industry makes it very difficult for the organization to accurately track and measure the performance of sales staff and allocation of sales credits. For this reason, Novartis only segments its customers on a geographic basis. The geographical segmentation is attributed to the difference in regulations within the various respective geographic regions. (Novartis 20F 2004)

## 5.5 Pharmaceutical Division Competition and Positioning

Competition amongst drug manufacturers remains high. Novartis competes in both the branded pharmaceutical market as well as the generics market. Novartis regards the following companies as top competitors: Abbott, AstraZeneca, Bristol-Myers Squibb, Eli Lilly, GlaxoSmithKline, Johnson & Johnson, Merck, Pfizer, Sanofi-Aventis, Schering-Plough and Wyeth. (Novartis 20F 2004) The majority of competition in the pharmaceutical industry takes place at the R&D level. Once new products are created, companies usually receive exclusivity and patent protection for several years before a competitor can reproduce the product. Companies will, however try to create alternative products which address the same treatment area but provide better results. According to Novartis, once two companies have produced comparable products then the competition takes place in the following arenas: “commercial activities, including pricing, product characteristics, customer service, sales and marketing, and research and development.” (Novartis 20F 2004)

In addition to the branded pharmaceutical products, Novartis also encounters competition from generic players when products lose patent protection. Novartis notes, that even with patent protection, some markets do not honor intellectual property rights. (Novartis 20F 2004)

According to the author's interview sources, Novartis considers the following companies competition in the respective categories listed below:

1. Pfizer – Top competitor based on overall size.
2. Roche and BMS – Top competitors in the therapeutic category of oncology.
3. J & J – presents the heaviest competition in the US in the field of ophthalmics.
4. Pfizer, Glaxo, and Merck – all present heavy competition in the hypertension therapeutic category.

With respect to its own competencies and positioning, Novartis management considers the following areas as strengths within its own organization:

1. Transplantation - Novartis considers itself the market leader in transplantation
2. General Medicine - strongest therapeutic category in sales
3. Oncology - the strongest therapeutic category in terms of profitability
4. Ophthalmics - small comparatively, but very profitable
5. Antibiotics – Novartis does not currently compete in this market
6. Vaccines – Novartis owns licenses for vaccine products, however they do not product vaccines because of the high barriers to entry for vaccine production; it is more cost effective to license the products to a third party.

- **Johnson & Johnson**
- **Merck**
- **Pfizer**
- Abbott
- Astra Zeneca
- Aventis
- Bristo-Meyers Squibb
- Eli Lilly
- GlaxoSmithKline
- Schering-Plough
- Wyeth

Source: Novartis 20F 2003, (Hoovers.com 2004)

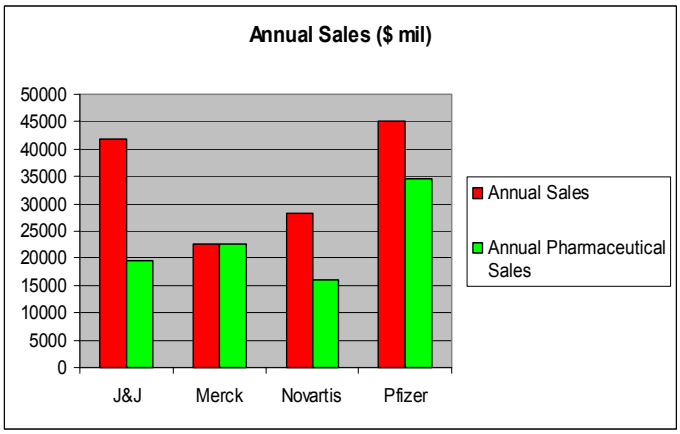



**Figure 17 Competitor Sales**

## 5.6 Pharmaceutical Division Competitive Business Strategy

Novartis emphasizes a focus on R&D as well as competitive generics production. The Sandoz generics division now includes a new acquisition of one of its top generic competitors. The primary focus of Novartis R&D with respect to its business strategy is geared toward the development and marketing of medicines that target specific conditions. The research efforts often produce innovative new prescriptive medications and breakthroughs that enable changes in medical practice techniques and strategy. Two examples of breakthrough medication are: Gleevec/Glivec - New treatment for Myeloid Leukemia, Neoral - organ transplantation medication.

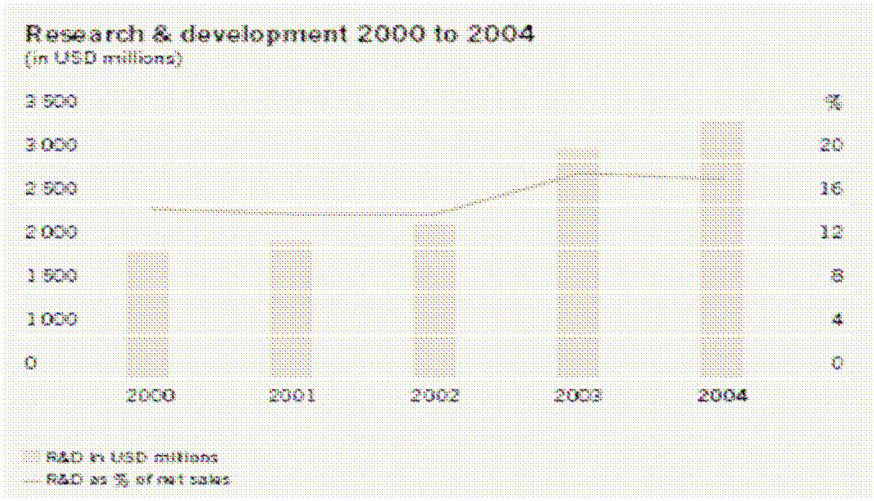



**Figure 18 R&D Expenditures 00 - 04**

(Novartis Annual Report 2004)

## 5.7 Pharmaceutical Division Operating Model

Because of the vast differences in regulations between the different markets (manufacturing process, language, warning labels, package/dosage size) as well as the wide variety of galenical forms, Novartis experiences a high degree of SKU proliferation as the following figure illustrates.


**One batch DS** **Multiple batches DP** **Multiple batches of packed Finished Products and Primary Packs**

**Figure 19 SKU Proliferation**

(Novartis Presentation 2005)

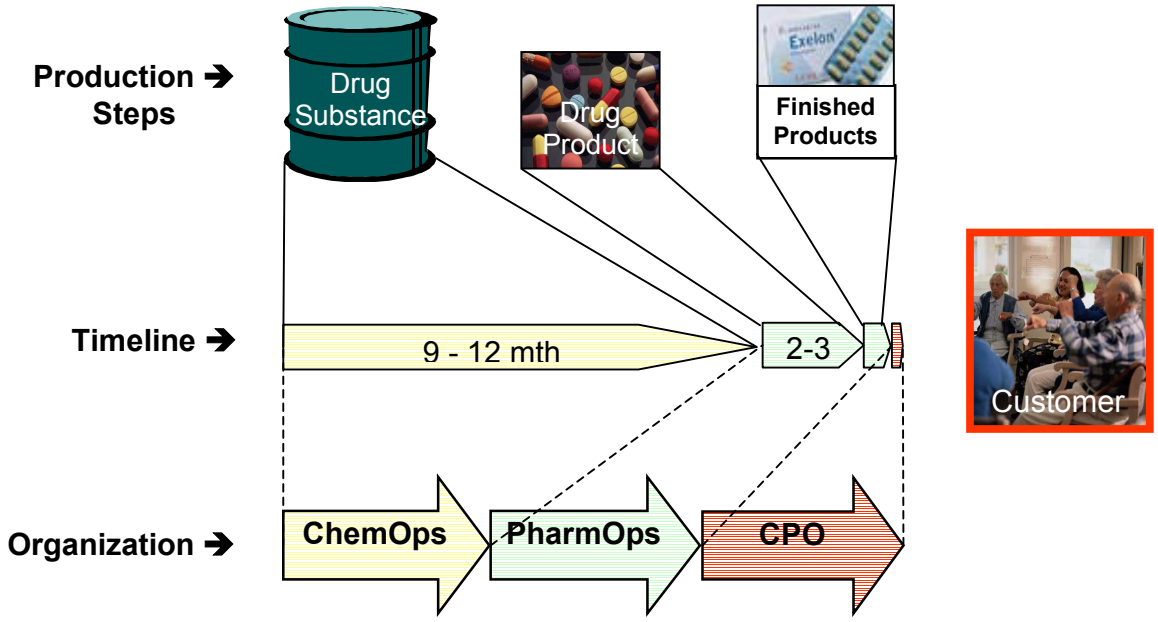



**Figure 20 Production Timeline**

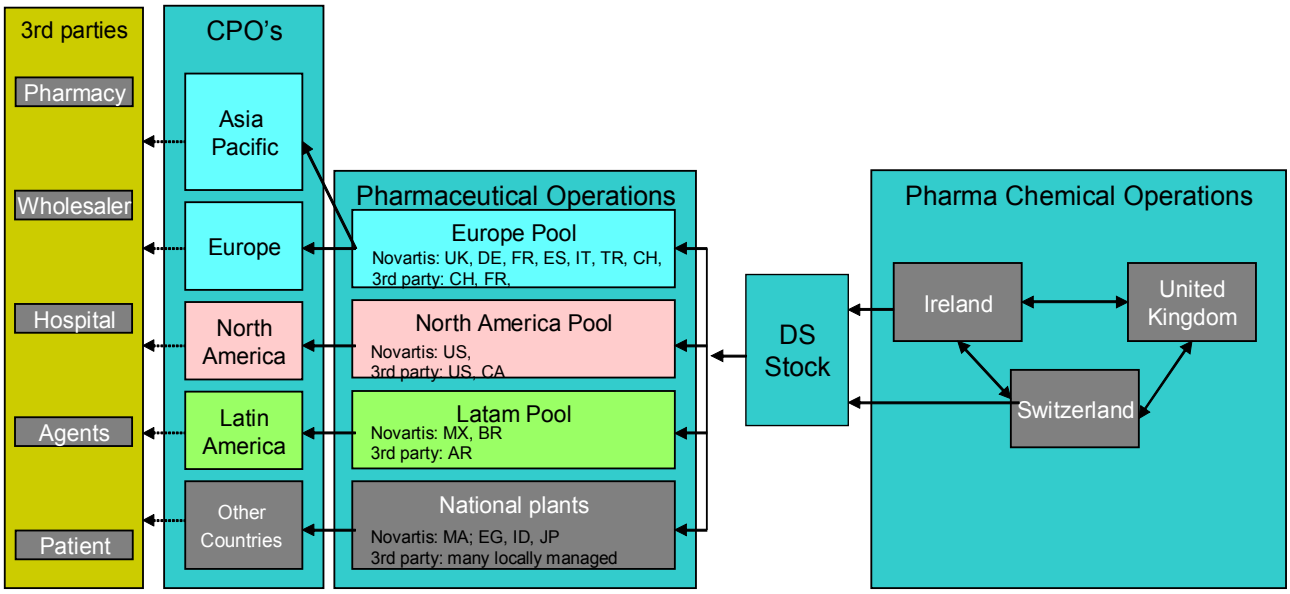
(Novartis Presentation 2005)

The drug substance manufacturing (or in some instances procurement) takes place under the chemical operations unit (ChemOps).

# Supply Chain Structure

## Novartis Pharma worldwide

Global
Integrated Supply Chain




9 February 2005/BSt Introduction program GSCM NOVARTIS

**Figure 21 Supply Chain Layout**

(Novartis Presentation 2005) DS is Drug Substance. This is stored in Basel and is made to stock. The remainder of the supply chain after the DS Stock is pulled

The generics business primarily focuses on the replication of other companies' products but there may be some future competitive advantage to having collaboration with their own pharmaceutical division for their own products coming off patent. As of now there is very little collaboration between the divisions; the divisions are managed and run like separate entities. Based on interview information, the generics manufacturing is primarily driven by the local markets, and there is not much production that is transferred from one region to another.

The pharmaceutical division purchases some active ingredients from the generics division but the relationship is similar to a supplier-customer relationship. Presently they do not share facilities between the generics and pharmaceutical division. Novartis recently completed a substantial acquisition for its Sandoz division and based on interview information, the supply chain management does not know what the post acquisition landscape will look like. Resource and facility sharing may be on the forefront.

Production -

The production process starts with the procurement of raw chemicals and the manufacturing of the active ingredients. After the active ingredient is manufactured, the product must be granulized for the manufacture of different galenical forms. There is very little fault tolerance and variability allowed in the granulation process. After the granulation process, the product is then compressed (tablet or capsule galenical forms) and then coated. Once the coating takes place the product is then labeled and packaged for distribution. It only takes 2-3 days for the finished product to arrive at the CPO (country pharmaceutical organization). The CPO's consist of corporate owned facilities as well as third party and agent owned organizations. The CPO in a specific country is responsible for the distribution and sale of product to Novartis' end customer. This end consumer is usually a pharmacy, wholesaler, hospital, or agent. Novartis operates their own CPO in 64 of the 140 countries in which they sell products. (Novartis Interview 2005)

The PharmOps (Pharmaceutical Operations) facilities perform the manufacturing of the final galenical forms. This manufacturing is performed as toll-manufacturing process in which the substance is moved to the PharmOps facility from Basel through a transfer price that is set by the funds flow committee. After the PharmOps facility finishes the manufacturing, the product is then

marked up and sent back to Basel with a new transfer price. (Novartis Interview 2005)

M&A - Since its inception and throughout the history of its component companies, Novartis has been the product of mergers and acquisitions. In recent years the acquisition of new firms has posed new organizational challenges as Novartis tries to consolidate supply chain activities. Each time the company acquires a new firm, they must rethink their existing infrastructure and reevaluate their SCM operations. Many of the company's facility locations are historically determined from M&A. This history also tends to be structured around the optimization (minimization) of the company's income taxes.

The active ingredients for the drug compounds are manufactured in a batch process. Batch production is necessary because of the nature of chemical manufacturing and the regulatory approval process. Batch production also facilitates a desire to maintain high standards of quality control. Batch sizes are generally determined by the availability of existing technology and equipment. With batch production quality control is easier to maintain. The product mix remains the same while the testing processes and manufacturing process are certified by the regulatory body. When a drug compound receives regulatory approval, the criterion for the manufacturing process and testing are very specifically and explicitly defined. Any deviation from the process will place the company at risk of having production suspended. It is possible to change the production process; however the new batch mixtures and formulas must also be re-approved by the agencies. These changes are sometimes necessary when newer and more efficient methods of production are discovered. The process of amending regulatory approval to include new or altered production techniques and batch sizes can take as little as 30 days and as long as 2 years depending on several factors including the nature of the particular product and the laws within a particular country. Changes in the manufacturing recipe can cost between $200k and $500k; changes to the galenical form of a product are much

more costly and for that reason galenical form decisions are made early in the new product development process. The manufacturer is also responsible for maintaining batch level production for tracking and tracing of recalls. Continuous production does not allow for the manufacturer to eliminate products containing faults, identify the failure in the production process, and recall all effected product. Technology primarily dictates batch formulation and sizing. (Interview 2005)

The manufacturing process can often be tedious. In an effort to maintain proper standards within each of the countries, the manufacturing process must adhere to all standards for all countries. If there are discrepancies, separate and specific manufacturing processes may be necessary for particular regions and countries. This causes additional complexity in the quality control and manufacturing processes.

Production scheduling remains a difficult process. Products which share a galenical form will often share the same equipment. It is necessary to determine how to best utilize the equipment which is available. There is also a corporate initiative to maximize asset utilization so down time on equipment is usually restricted to cleanings and changeovers between production campaigns. When material changes in demand occur, it is possible to shift production. Given the long lead/production times required for pharmaceutical products it is not feasible to adjust for small nonmaterial demand changes on a short term basis. Novartis also utilizes an inventory buffer of finished goods to compensate for small nonmaterial fluctuations in demand.

Manufacturing production quantities are primarily driven by aggregate demand forecasting. The demand forecasts are broken into three categories: optimistic, realistic, and pessimistic.

- Products are mostly developed for the treatment of chronic illness and therefore sales are not subject to material changes in seasonal demand (Novartis 20F 2003)
- Key Goal: "…ensure the uninterrupted, timely and cost-effective supply of products that meet all product specifications." (Novartis 20F 2003)


**Figure 22 Novartis Headquarters Location Map**
(SPG Media Limited a subsidiary of SPG Media Group PLC 2004)

Novartis chooses to utilize Basel Switzerland as its "Tax Haven"

### 5.7.1 Orders by channel

Novartis does not segment its orders by channel, but rather on a geographically specific distribution model. The orders in a particular country are taken by the local CPO in the respective country. All orders are treated the same and routed to the appropriate CPO for distribution. Once the product has arrived at the CPO, it is then forwarded to the final customer and payment is arranged. All transactional coordination of orders is managed at the country specific location. The CPO is responsible for the distribution of both prescription and

nonprescription products. In some instances where the CPO is owned and operated by an agent or third party, the CPO actually is the customer.

### 5.7.2 Order fulfillment

In a press release from SAP dated June 16th, 2003, Novartis AG announced that it had selected SAP to handle its information system software needs. This software is intended to support the global strategy by which Novartis intends to synchronize its global operations. The SAP solution is intended to replace legacy systems across the world and create new research and develop efficiencies in administration, production, HR, supplier relationships, and other supply chain functions. The company intends to reduce integration costs through the implementation of SAP. Peter Sany, Corporate CIO, said, "When faced with a choice between stand-alone systems or a suite solution, the added value, scalability, and flexibility of mySAP Business Suite made SAP the clear choice,

"Novartis needed a long-term strategic commitment and decided that SAP's industry experience and innovative solutions could best help them quickly reach their immediate aims while enabling them to carve an evolutionary path for deploying new solutions as future demands arise," said Henning Kagermann, chairman and CEO, SAP AG. "SAP solutions can streamline fragmented manufacturing, supply chain, and human capital management processes, enabling better collaboration with Novartis's worldwide supplier network and give Novartis the transparency and efficiency it needs across its global operations."

Novartis has chosen to implement mySAP™ Supply Chain Management. This adoption of new technology was driven in part by US FDA regulation compliance requirements.

The SAP solution will help to accelerate the procurement process for direct material acquisition by reducing communication errors. The system will also increase visibility of materials during the procurement process allowing more accurate tracking, tracing, and forecasting of product in the pipeline. SAP

promises to increase the reliability of delivery dates and quantities and provide more seamless integration with suppliers. The system will also standardize the platform for data interchange allowing management to eliminate the need for various proprietary interfaces and document interchanges, or “middleware”.

The system also provide a web-based supplier interface to support the deployment of the SAP® Advanced Planning & Optimization (SAP APO) component of mySAP SCM. These tools will assist in demand and supply network planning processes for drug substances, drug products, and finished goods. Novartis should gain shorter forecasting cycles and planning intervals overall reducing the costs of operating their global supply chain.

For the purpose of order fulfillment, Novartis has identified the decoupling point in their supply chain. Novartis must carefully manage the inventory level at the decoupling point in order to prevent stockouts and surplus.

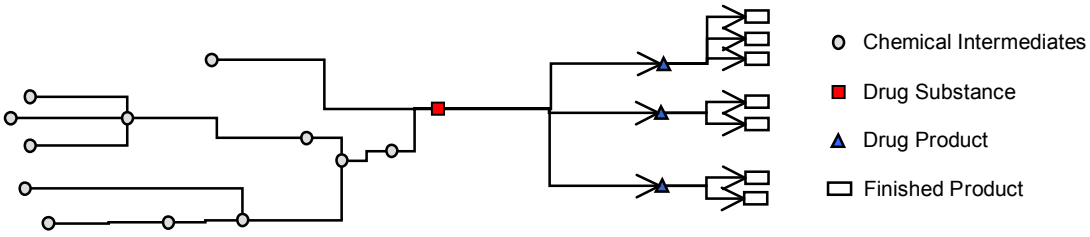



**Figure 23 Novartis Decoupling Point Illustration**
(Novartis Presentation 2005)

### 5.7.3 Facilities

Novartis maintains a policy of owning and operating its own facilities. The belief that this policy will add to shareholder value as well as ensure the ability to adequately control the operations within each facility remains an underlying concern of the organization. There are a few exceptions to this policy; however these agreements reflect idiosyncrasies in the particular locations which prevented ownership. Below, in Figure 24 you will see a map of the supply chain for the Pharmaceutical division and the dispersion of facilities across the world.

Additionally, Figure 25 provides a listing of the facilities which are depicted in Figure 24. Furthermore, figure 58 in the appendix describes the size, location, and primary functions of each of the Novartis facilities within their division. Please note that Novartis also maintains research facilities in addition to their production facilities. These facilities play an essential role in the R&D process which offers Novartis substantial competitive advantages as well as ensures future revenues. (Novartis 2004 20F)

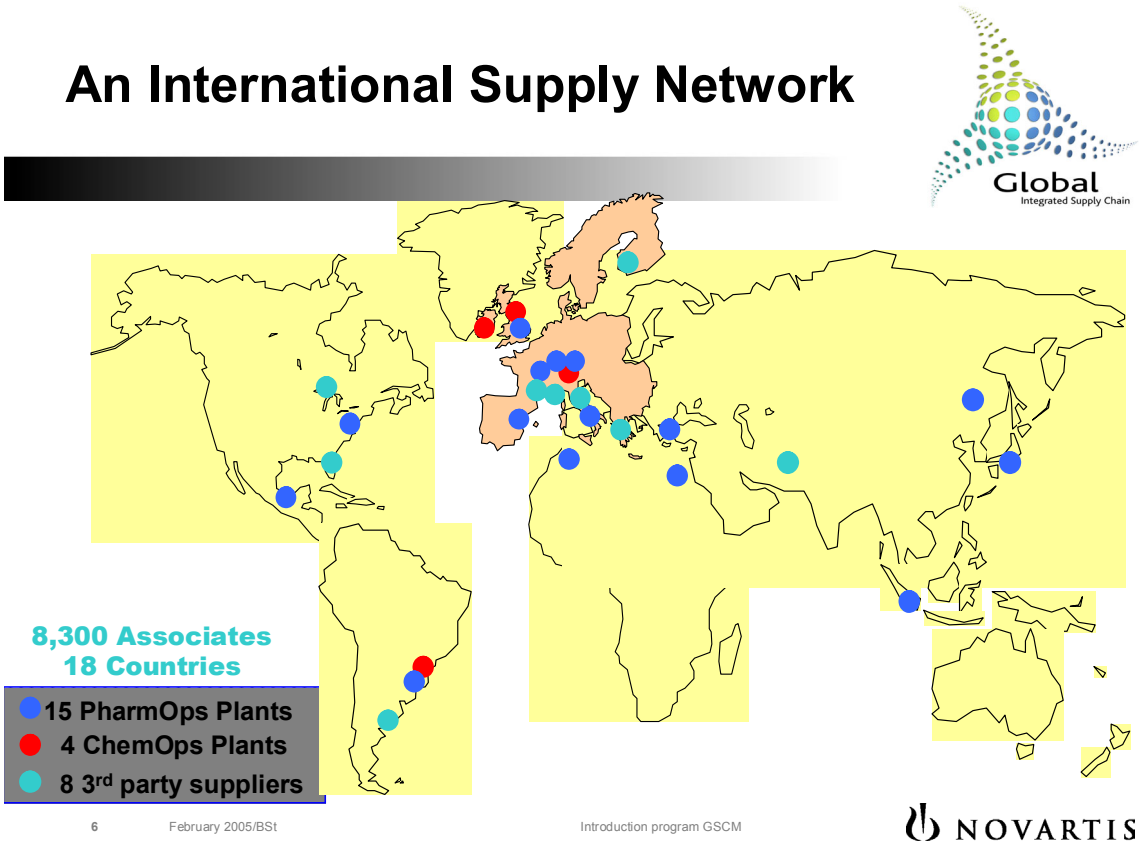



**Figure 24 Supply Chain Facility Map**

(Novartis Presentation 2005)

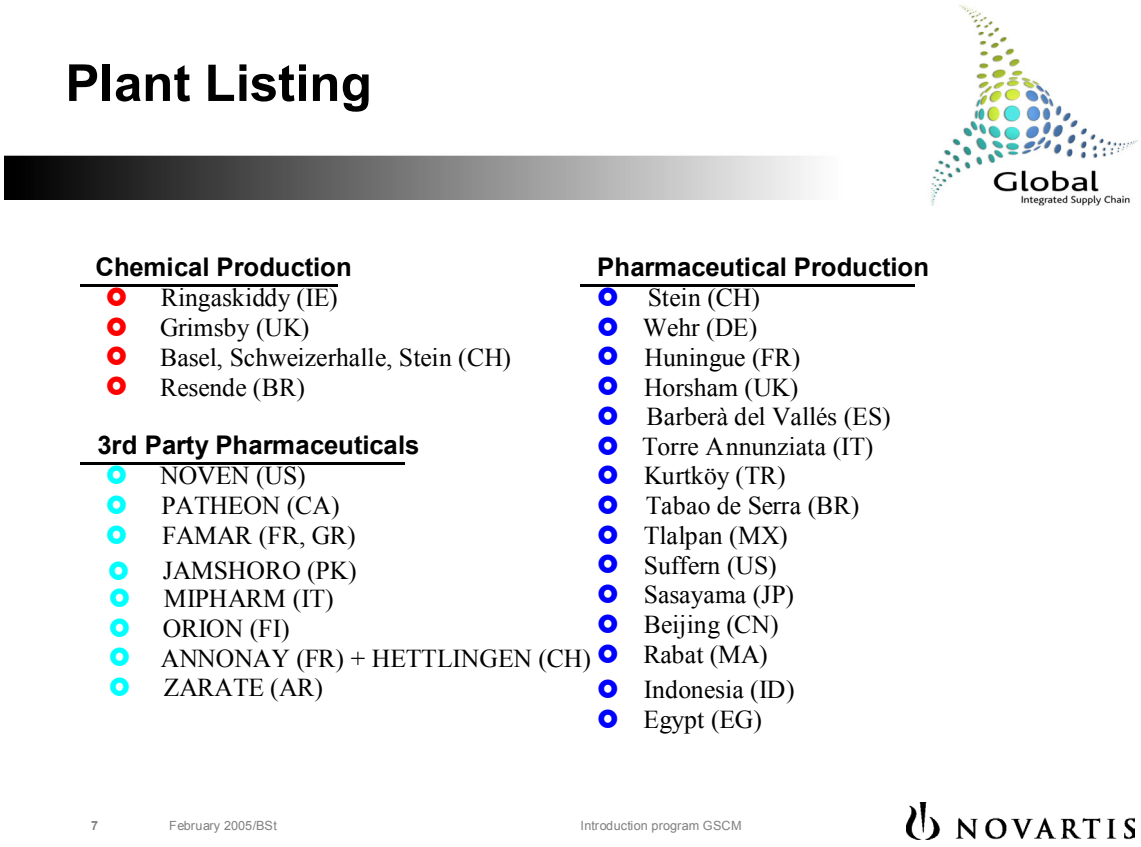



**Figure 25 Plant Listing**

(Novartis Presentation 2005)

### 5.7.4 Customers

Novartis primarily sells to wholesalers, pharmacies, hospitals, and agents. There are some medicines which are supplied directly to patients for the purpose of compassionate care; however providing products directly to patients is not a core business process. Compassionate care refers to providing patients with continuing medication for the treatment of their illness during the time between the end of clinical trials and the approval of the medication to enter the market. Novartis directly ships some orders for extremely high volume products such as Diovan, however this practice is uncommon.

### 5.7.5 Suppliers

Although global contracts exist for the purchase of raw materials, each location is responsible for its own procurement. For example, each PharmOps location will have access to some purchasing arrangements and benefits from the global organization; but the local organization is responsible for the procurement. They must sign an individual contract with their suppliers for the procurement of both active and exigent ingredients.

### 5.7.6 Products

The Novartis pharmaceutical division focuses primarily on prescription drug products. The products are segmented into various therapeutic categories for management and distribution. The products share resources including: production facilities and equipment; packaging and processing equipment; distribution facilities; and even sales staff. The higher revenue products are managed on a brand pipeline basis while the smaller products are managed in aggregation with others. Novartis does not usually dedicate any resources to a particular product; one exception however, is their largest product, Diovan, which receives some dedicated equipment that was purchased to accommodate demand.

## 5.8 Pharmaceutical Division Supply Chain Organizational Structure

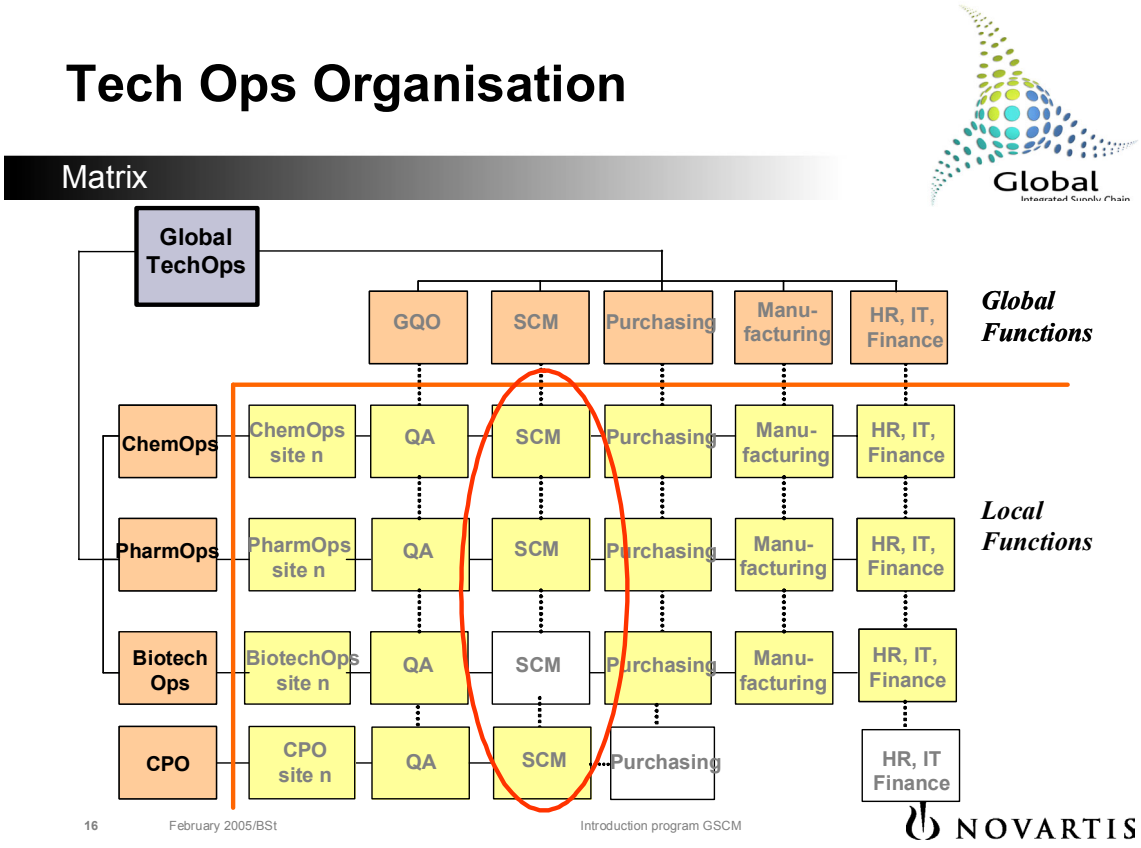



**Figure 26 TechOps Organizational Chart**

(Novartis Presentation 2005)

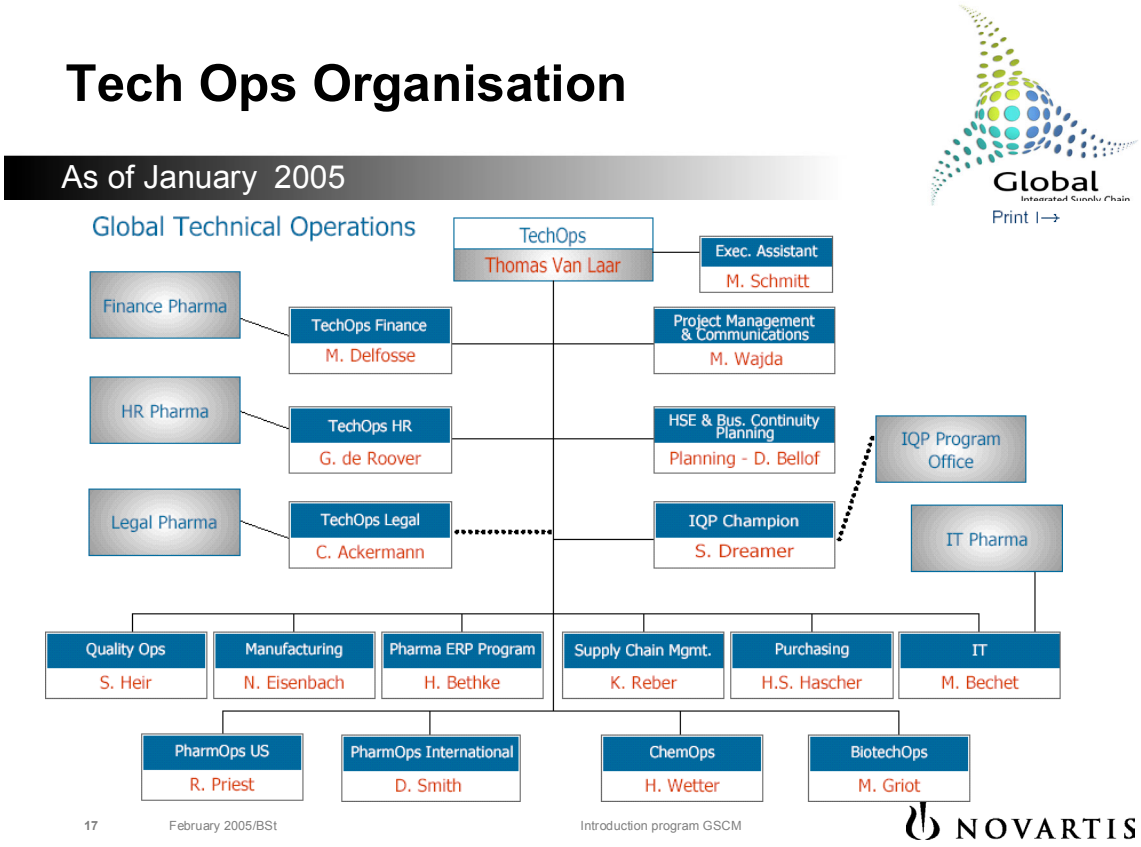



**Figure 27 TechOps Organizational Sub Chart**

(Novartis Presentation 2005)

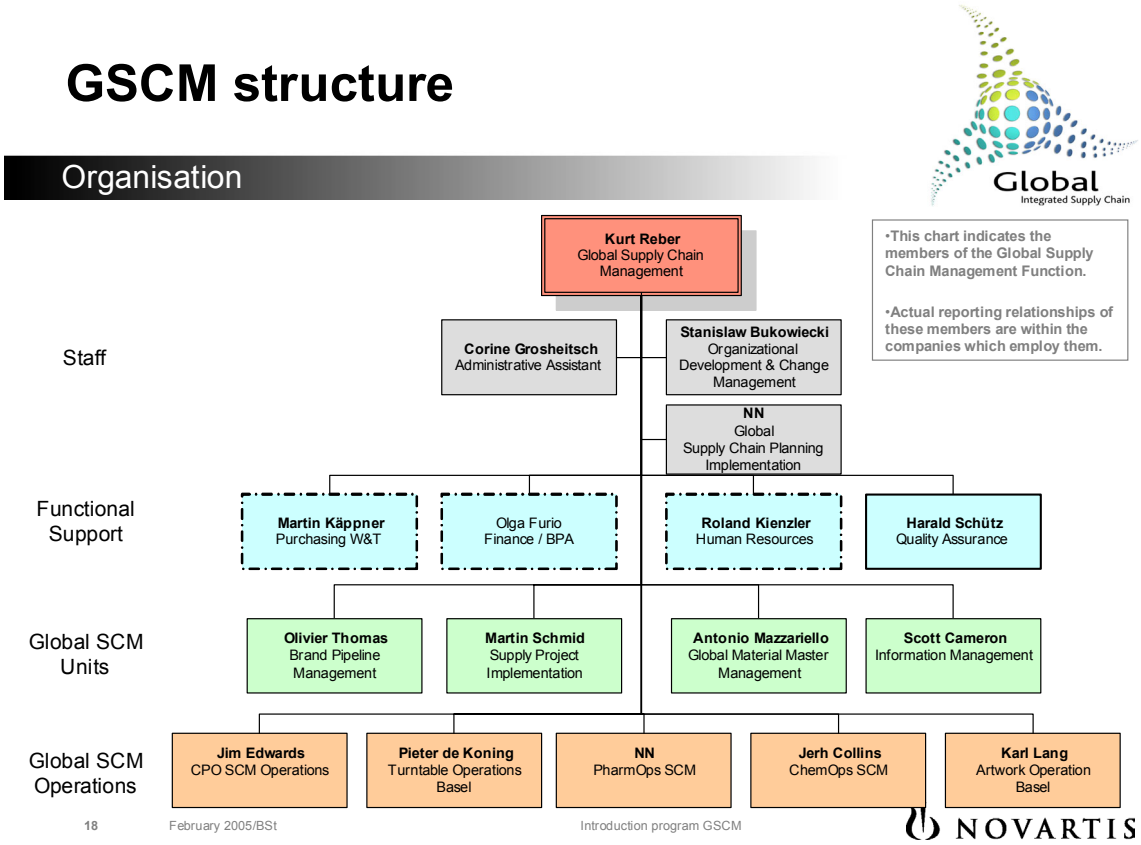



**Figure 28 Global Supply Chain Management Organizational Chart**
(Novartis Presentation 2005)

## 5.9 Pharmaceutical Division Supply – Side Business Processes

- **Source/Make Decision-Making**

Each ChemOps location is able to make its own decisions about where to source the chemical components for making drug substances. Some of the ChemOps locations rely on global sourcing agreements by which they receive competitive pricing. There is a global purchasing group within Novartis that manages the purchasing requirements for all the Novartis facilities. The purchasing group, however, does not purchase the product and then distribute it to the various production facilities. Each production facility has independent contracts with its suppliers and is able to seek the best prices on products.

Because of the differences in the pricing for raw chemical materials in the different regions, this allows each ChemOps location to receive the best pricing for its particular location by sourcing locally.

Novartis manufactures its own drug substances. It is possible to purchase active ingredients on the open market or to outsource the production of proprietary drug substances, however Novartis chooses to keep all of its production in-house to reduce costs and maximize asset utilization. The Sandoz division of Novartis also manufactures active ingredients and drug substances for other manufacturers.

All of the ChemOps locations are currently running SAP. In the next year, all the production locations should be on the SAP system which will allow the chemical production process for the various drug substances to better coordinate with the remainder of the supply chain.

- **Supplier selection and supply chain design**

In the past, Novartis has not experienced any major interruptions in the supply of raw materials. Although the supply of materials is expected to continue without interruption, Novartis has implemented a global manufacturing strategy to maximize their business continuity. In doing so, Novartis chooses to do business with suppliers who have high service levels; Novartis also does not depend on any one particular supplier. Management believes that, because of the highly regulated nature of the pharmaceutical business, at any point in time one of their suppliers could fail in their responsibilities for regulatory compliance. In the event that a third party supplier was to fail to meet requirements, the implications through the supply chain could be far reaching. Some of the implications could include a government mandated recall of products containing materials from a particular supplier. In addition, governmental agencies could suspend manufacturing facilities until costly inspections and recertification is performed.

Any major disruptions of this nature could result in shortages in the overall supply of products to the customers.

In addition to limiting the quality and number of external suppliers, Novartis also subscribes to a philosophy of producing as many of their materials in-house as possible; this assists in their goal for maximized asset utilization. When Novartis decides to source externally, policy dictates for the company "to maintain multiple supply sources so that the business is not dependant on a single or limited number of suppliers." Novartis takes business continuity seriously; they monitor market developments and the potential effects on the supply of materials. One benefit of the in-house manufacturing philosophy is that the materials that Novartis procures are quite basic in nature. As a result, the raw materials have both high pricing stability as well as good availability. As always, no supplier is chosen without rigorous attention to quality standards. (Novartis 2004 20F/Interview 2005)

- **Supplier segmentation**

Since the nature of the products which Novartis procures is fairly standard and readily available on the commodity market, Novartis makes other commitments to supplier segmentation. The company maintains strong objectives for creating and maintaining supplier diversity. By diversity Novartis means that prospective suppliers must adhere to the following four basic operating principles:

1. "Ensuring business opportunities for minority and women-owned suppliers and other diverse businesses."
2. "Leveraging multiple sources of talent wherever that talent is to be found."
3. "Developing and extending diverse supplier relationships."
4. "Communicating the value of supplier diversity, both internally and externally." (Novartis.com 2005)

Novartis believes that by abiding by the 4 stated principles their company will move into a “top tier of best-in class companies that are recognized for creating and maintaining such diverse partnerships.” In addition, Novartis subscribes to the philosophy that diverse suppliers will enhance the end customer and community experience. The diversity instilled in the supplier base is intended to more accurately reflect the diversity of their customer base. Novartis also encourages 1st tier suppliers to instill the same diversity requirements in their suppliers creating a diversified 2nd tier of suppliers. (Novartis.com 2005)

- **Supplier management**

The suppliers for the ChemOps facilities are contracted locally. The suppliers must meet requirements for production and regulatory standards. Generally, Novartis has individual contracts between suppliers and the local facilities. The facility management works directly with suppliers to create and manage these relationships. This local level of interaction allows the facility management the autonomy to make decisions and act quickly without the red tape of a large bureaucracy. There is not much collaboration between Novartis and its suppliers since the products are generally considered commodities and Novartis is vertically integrated; they only procure very basic chemicals. Novartis utilizes some SAP functions for supplier integration.

- **Collaborative new product development**

Novartis realizes the need to bring new pharmaceutical products to market as rapidly as possible. In the global pharmaceutical industry, other companies often produce similar or copycat products once a new product or treatment is released to market. The competitive landscape makes the rapid discovery and development of new products essential for success. Because of the need for expediency, Novartis tries to build on the success of other partner companies.

“Novartis has a long tradition of collaboration with partners with complimentary strengths.” (Novartis.com 2005) Through collaboration Novartis partners with companies who are often smaller in size and do not have the resources or capitol to bring new products to market rapidly. Novartis creates “…fair, effective, and mutually beneficial – winning – collaborations.” (Novartis.com 2005) Novartis believes that they are among the top companies in terms of their total number of collaborations. Additionally, the collaboration allows Novartis to acquire research and development in intermediate stages and shorten the time necessary to bring the product to market. These collaboration efforts are also useful when a product has multiple potential uses. In the even that a product may treat conditions which are not in one of Novartis’ core therapeutic categories, Novartis may choose only to market the product for a particular use. Another company, through a cooperative agreement, will market the same product produced by Novartis for other therapeutic categories in its respective core. These agreements also allow Novartis to share the risks associated with R&D expenditures as well as the marketing cost if the product receives regulatory approvals.

CEO and chairman, Dr. Daniel Vasella believes,

> “The importance that we place on building winning collaborations is evidenced by the early and substantial involvement of senior management. In this way, we achieve quick decision making and the allocation of necessary resources to achieve success. Thereafter, in the case of project and product commercialization collaborations, we aim to establish teams with representation from both partners. Both the NIBR Strategic Alliances and the Pharma Business Development and Licensing groups work hand-in-hand to seamlessly integrate the cooperation process.”

The following is a list of current licensing and collaboration opportunities with Novartis:

| Product | Indication | Mechanism | Phase |
|---|---|---|---|
| QAD171A | Male Erectile Dysfunction | Phosphodiesterase 5 (PDE5) Inhibitor | Phase II |
| MGR793 | Pain | MGluR5 antagonist | pre-clinical |
| MAR327 | Schizophrenia | Dopamine D2/ serotonin 5 HT1A partial antagonist | pre-clinical |
| KC0912 | Asthma | K Channel Activator | Phase IIa |

| Product | Description |
|---|---|
| **Biochip - Microarray Platform** | Significantly enhanced sensitivity as compared to commercial chips. To be applied for genetics, genomics, and proteomics |
| Cibacen® Cibadrex® | Product acquisition in Europe |

**Figure 29 Collaboration Opportunities Chart**
(Novartis.com 2005)

- **Purchasing/procurement**

Although there is a global purchasing and procurement group, they only provide guidance and assistance for the local facilities. The global purchasing group assists in the creation of contracts and the decision support for the sourcing, however the final decision for sourcing and procurement is made at the local facility level. The role of the global purchasing group is still being defined since it was only recently created in support of turntable operations. Previously, each facility had a purchasing department which handled its local decisions. Now the global purchasing group facilitates the procurement, however the procurement still takes place on a local level.

## 5.10 Pharmaceutical Division - Inside Business Processes

- **Product portfolio management**

The portfolio of products includes innovative medicines such as Neoral and Gleevec, as well as generic and self medication drug products. Generic production provides the company with the opportunity to capitalize on products, mostly those of competitors, which have lost patent protection. With heavy pressure from regulatory agencies and managed health care, the generic market allows the company to hedge its R&D investments against the R&D success of its competitors. The company also has the ability to compete in mature product markets which are not within the scope of its R&D core competency. The generics production unit of Novartis, Sandoz, provides generic low cost alternatives to the market. The Sandoz business unit experienced some delays in new product launches in recent years and requires additional focus on the expediting of product launches. Additionally, price competition in the generics business remains substantial; companies lack government protection and therefore must compete in a commodity market. Usually, this commodity style of competition is foreign to pharmaceutical companies who compete primarily on R&D differentiation. Time to market and cost will continue to drive the generics businesses profitability. Novartis also utilizes its consumer health, OTC, animal health, medical nutrition, and infant and baby business units to balance their portfolio of products; in 2004 these business units all outperformed their respective markets. (Novartis Annual Report 2004) Novartis created dedicated customer teams for key accounts including companies such as Wal-Mart to discover cross-functional capabilities and enhance future growth. (Novartis Annual Report 2004)

- **Facility and capacity planning**

Novartis tries to maximize the utilization of assets for production. They schedule for capacity planning on a 6 month production schedule basis. As they

plan batches of products, they decide what products and quantities should be allocated to which production equipment. There are overlaps in the utilization of resources which must be eliminated. On rare occasions, when material changes occur in the production requirements, changes can be made to the schedule. These changes can be costly, but usually do not require the disposal of product. In the event that a change is necessary and a product in production is delayed or postponed, the batch is processed until an appropriate stopping point where the production can be restarted without causing degradation of the drug substance.

- **Inventory segmentation**

The majority of the inventory in Novartis is held in the form of drug substances or finished products in Switzerland. It only takes 2-3 days for the inventory to reach the CPO and therefore inventory is pulled from the warehouses in Basel, Switzerland. The products which are packaged for a specific country are then shipped to the respective CPO; from there products are distributed further to the customer base in that country. (Novartis Interview 2005) Novartis experiences a high degree of SKU proliferation because of the country specific needs regarding labeling and languages. (Novartis Interview 2005)

- **Inventory management**

Novartis is making progress with reductions in its MOH (Month on hand) inventory. Currently Novartis' pharmaceutical division maintains a target of reducing its inventory to an average of 7 MOH. Since 80% of sales come from the top 25 brands, most inventory planning takes place at a brand pipeline level. (Novartis Interview 2005) The primary driver for the supply chain remains tax and revenue optimization; however the goals of inventory management and tax optimization are aligned. The reduction in inventory is complimentary to the cause of tax reduction. (Novartis Interview 2005)

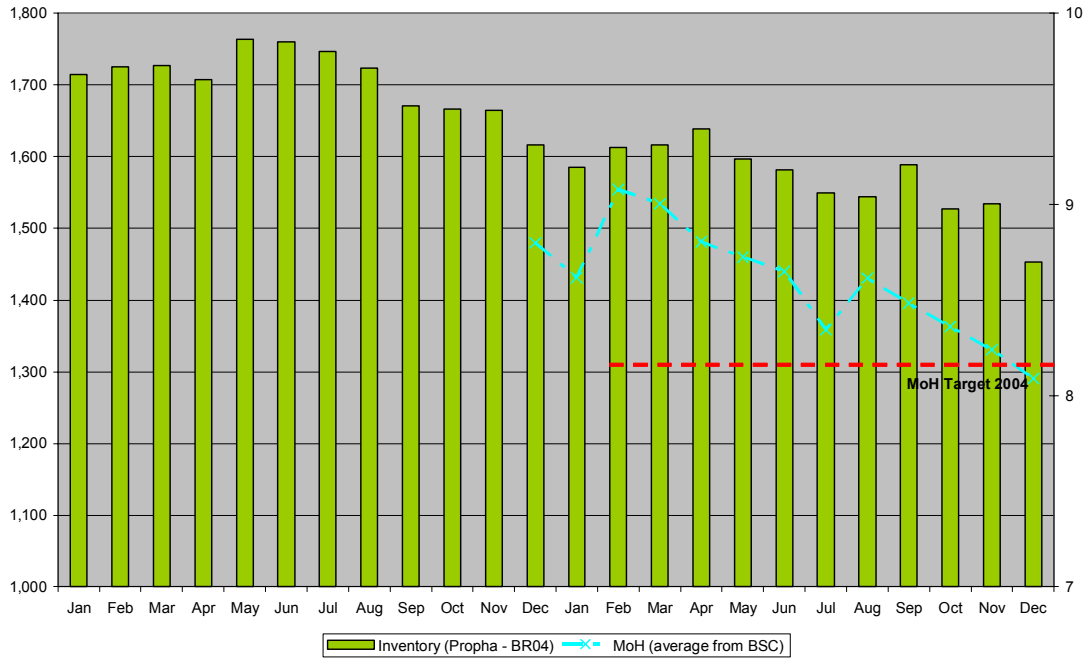



**Figure 30 Month On-Hand Inventory Graph**

(Novartis Presentation 2005)

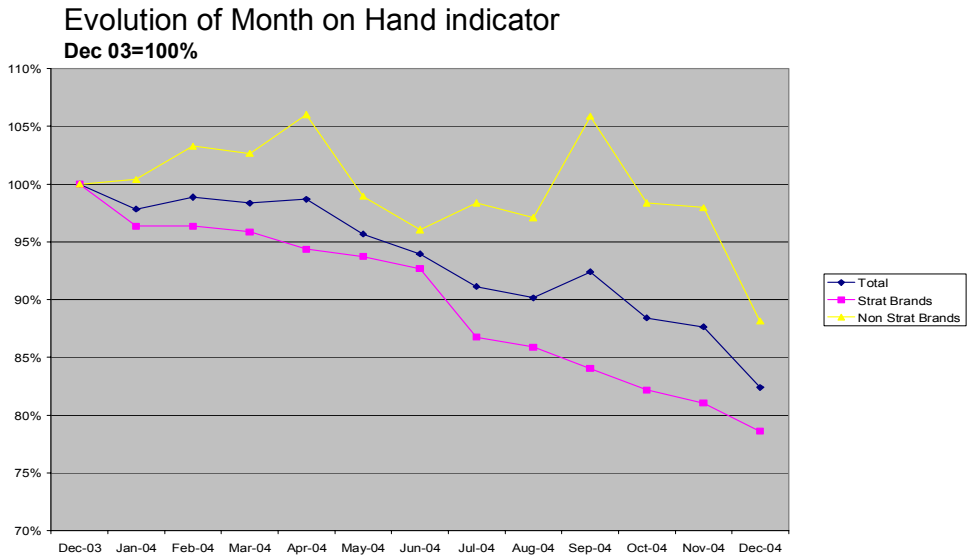



**Figure 31 Evolution of the Month on Hand Indicator**

(Novartis Presentation 2005)

- **Production management**

The production management for the top 25 strategic brands is handled on a brand pipeline level. Novartis looks at each new drug launch as a potential strategic brand. If the new product demonstrates high sales potential and revenue, then the brand will be managed separately on a pipeline basis.

The pipeline management starts with a comparison of actual information against previous projections. This can be done during the weekly management cycle in which previous forecasts are compared with the actual sales. If there are errors in the forecasting process or in demand fulfillment they are noted at the beginning of the cycle. If changes are necessary, the brand pipeline team will then propose changes to the overall market and brand strategy. Once the team reaches a consensus they proceed by changing the appropriate forecasts and assumptions.

The forecast changes will lead to demand planning and fulfillment changes. These changes, at a major level, could result in the reallocation of production assets and changes in production schedules. Demand changes are then used to adjust the supply needs for the particular brand. These changes will also affect the inventory levels and changes in the capacity planning throughout the production schedule. Finally, the necessary investments and changes in the financial plan are considered and the team must agree on the new projection figures for their brand. The team will then be accountable for their decisions since they will be used as a baseline during the next management cycle. Below is a figure that illustrates the steps in the pipeline management cycle.

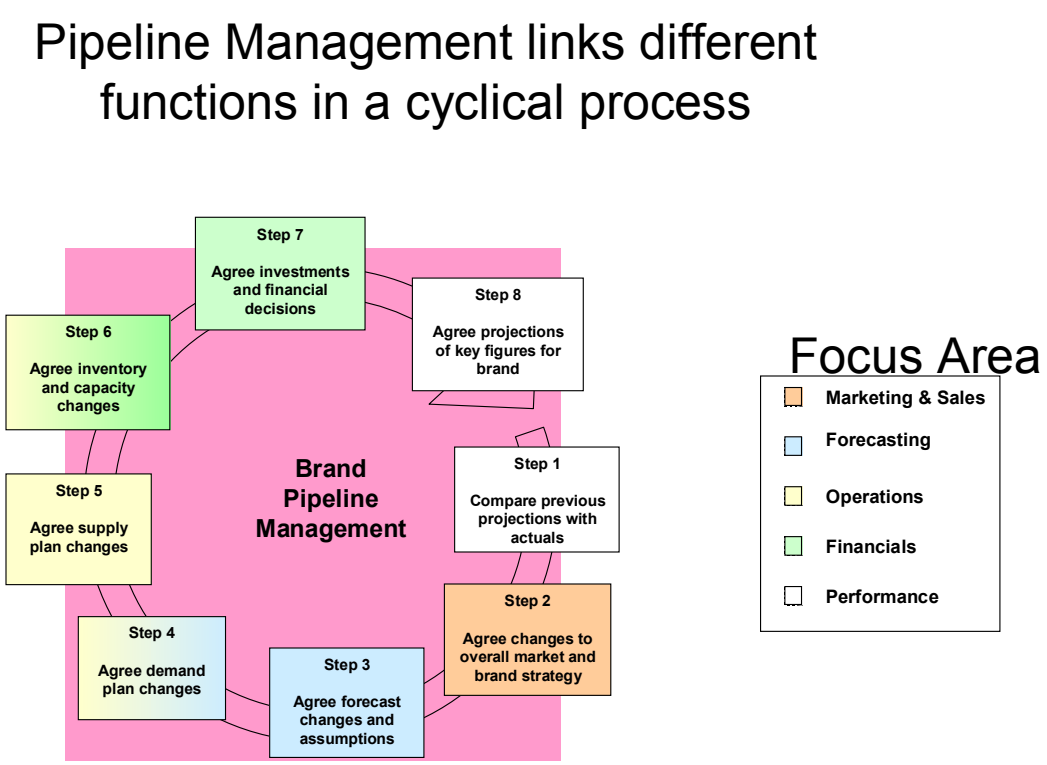



**Figure 32 Pipeline Management Cycle**

(Novartis Presentation 2005)

As a result of the pipeline management cycle, the team achieves better visibility and lower inventory throughout the entire brand pipeline. The same approach is used when determining the requirements throughout the supply chain for new product launches. Once the first galenical form is decided for a new product, the team assigned to the product launch will begin working on the forecasts for the product launch. (Novartis Interview 2005) The pipeline management approach yields better results on an organization wide level than the previous methods of resource management employed by Novartis. (Novartis Interview 2005)

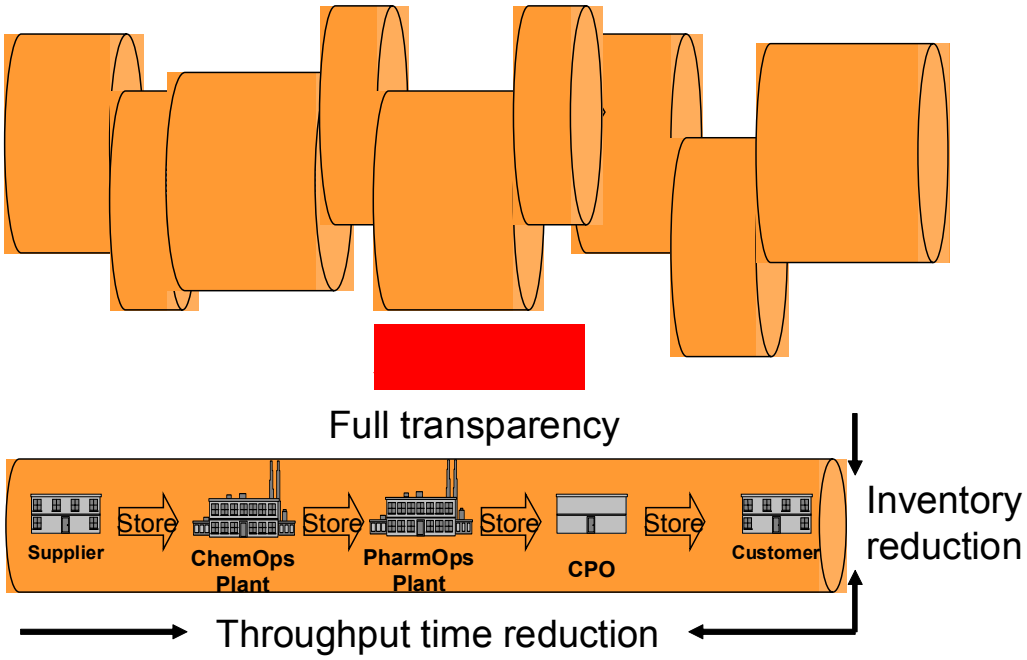



**Figure 33 Brand Pipeline Improvement Illustration**
(Novartis Presentation 2005)

- **Transportation management**

All transportation for products within the Novartis internal supply chain is handled by the turntable operations. Products will often travel in and out of Basel several times during the production process. Transportation within the supply chain represents less that 1% of the total COGS for a finished product. (Novartis Interview 2005) Because of the low significance of transportation costs, Novartis uses fast and reliable methods of moving product between locations; sometimes cheaper alternatives which may be available are not chosen. Generally Novartis uses air freight to move product between locations. Air freight shortens delivery time and provides additional security for products and WIP inventories.

- **Warehouse Management**

The final product warehouse management is performed at the CPO level. Each country's CPO or third party agency manages the internal operations of the local facility. The facilities will generate orders for finished product and the finished product is then shipped from the main warehouse in Basel.

## 5.11 Customer – Side Business Process

- **Distribution channel management**

The distribution to the final customer is handled at the CPO level. The CPO is responsible for maintaining the inventory levels at the country specific location. Once an end customer places an order, the company will then ship out product to the end customer. The shipments are usually sent via air freight. Transportation costs are not a significant portion of the product cost; importance is placed on the timeliness and accuracy of the distribution process. The reliability of air freight offers better customer service and responsiveness for the end customer. Almost half of the country specific distribution centers are operated by a third party or agency. The facilities which are operated by third parties will purchase product from Novartis directly; in these instances, Novartis considers the wholesaler to be the end customer.

50% of the CPO locations that are owned and operated by Novartis are now running SAP to assist in the management and distribution process. Novartis is trying to implement SAP across the entire supply chain, including third party facilities, in an effort to reduce inventories and increase order accuracy. The data provided by the SAP system will also assist in anticipating parallel trade and compensating in the supply chain.

- **Customer segmentation**

The majority of the products that Novartis produces are sold to wholesalers and large pharmacy chains. Some of the large wholesalers in the US are served directly from the distribution in Basel, however the majority of the customers are served from the CPO. Novartis does not typically segment customers on any basis other than geography. The customers in particular countries are served by their respective CPOs.

- **Customer management**

Customers that receive product from a CPO are managed by the CPO staff. Each country has its own sales staff which is responsible for customer relationships.

- **Demand planning and forecasting**

The demand planning for the end customer takes place at the CPO location. The CPO sales planning group reports back to the brand pipeline management group for the aggregation of forecasts. These forecasts are then used further, as described before, to initiate planning for the entire supply chain. The planning and forecasting for strategic brands is done through a brand pipeline management team. Previously, planning was performed annually and the planning horizons spanned 3 years. Today, for strategic brands, the planning is done on a weekly basis. The pipeline management team reviews the status of the entire pipeline and makes minor adjustments as needed.

Sales forecasting is done on a semi-annual basis. Each SKU, at each CPO, receives a 5 year forecast which is passed up to global sales forecasting for planning and aggregation. These forecasts are updated more frequently for the top 25 strategic brands.

- **Channel/sales management**

At the beginning of 2004, Novartis's pharmaceutical division continued to maintain a substantial US sales force including almost 6,000 representatives. Some of the sales staff includes contract field representatives from affiliated companies and third party sales organizations. In addition to the US sales force, which is the Novartis's largest sales force in a single country, Novartis also manages over 11,000 representatives throughout the rest of the world. In addition to the in house sales force, Novartis utilizes additional marketing strength provided through marketing partners, affiliates and distributors. (Novartis 20F 2003)

- **Order quoting and promising**

All the order quoting and promising takes place that the CPO. Each CPO is responsible for the distribution and sales of products to the end customer. Generally, longer term contracts are in place with the larger wholesalers and pharmacy chains. These longer term contracts allow Novartis to maintain the stability of demand.

- **Order fulfillment**

The order fulfillment for Novartis takes place at the CPO level. Each CPO has its own sales force and is responsible for the fulfillment of orders within their respective country. The CPO does not carry much inventory, but it is able to order and receive product from the finished product inventory in Basel in 2-3 days. This enables the CPO to manage incoming orders on a nearly JIT basis. The CPO is also a sales and marketing arm for the organization. The CPO manages the local sales force which is accountable to the global sales and marketing group. In the pharmaceutical industry and in Novartis in particular, the

sales representatives only provide information to the supplementary decision makers such as doctors and nurses. The representatives make calls to the wholesalers, but are measured based on the performance of product which is sold within their district. Some of the sales take place in the form of contract formularies. In these types of situations, a representative will market a product to a particular hospital or clinic and encourage them to add their product to the formulary, or list of approved medications for physician use. Even in these situations, the representatives do not market directly to the consumer or even in many cases not even directly to the customer. The sales representatives are also responsible for the distribution and tracking of samples to care givers. These samples encourage care givers to issue the first dosage directly to the consumer and then the consumer can later purchase the remaining needed supply from a retail location.

- **Returns and recycle management**

Drug manufacturers deal with the issues of returns and recycling. The products are rarely recycled unless there is an overstocking situation that is not pressured by product expiration. When products expire, the customer usually is responsible for the destruction of the product. There are certain regulatory requirements that must be met regarding the tracking and documentation for destroyed product after expiration. In addition to the instances where product expires, there are times, as with any industry, in which Novartis must recall defective product. In the event that a product is defective the company primarily destroys the product or issues an order for the destruction of product at the customer location. Novartis does however request the return of some product for testing and diagnosis purposes when applicable. In the event that the product is a controlled substance or a biological agent requiring a specific destruction procedure, Novartis will either have the product returned via courier, or contract for the destruction at the customer location.

- **After-market and post sales support**

Once sales take place, the sales representative is responsible for answering standard informational questions about products. If the questions exceed the scope or capacity of the sales representative, then the representative must put the customer in contact with the appropriate person within Novartis to answer the questions. This contact could include researchers or physicians who are on hand to answer questions. Novartis does also offer some consumer support, however most instances recommend that a consumer speak with his/her pharmacist or physician.

# Chapter 6 – Novartis Supply Chain Framework

## 6.1 Novartis Business Strategy

The pharmaceutical division for Novartis focuses on its core business strategy of adding new profitable and patent protected products to its broad portfolio of treatments for chronic illnesses; Novartis must employ the appropriate operational efficiencies which allow the production and marketing of new products both rapidly and efficiently after the receipt of regulatory approval. Through the use of a broad portfolio of products, Novartis also reduces the company's reliance on key blockbuster drug products. Unlike some of its key competitors, the company also has established a generics products division. The generics division allows the company to maintain market share after the expiration of patent protection for its key products and also its competitors' off-patent products.

Although there is significant market potential for many breakthrough products in a varied array of therapeutic categories, Novartis chooses to focus R&D efforts primarily on chronic illness products. Since chronic illness products are administered on a perpetual basis, these treatments are not subject to material variations in demand. Novartis focuses its R&D efforts in eight therapeutic categories which exhibit both market potential and social benefit.

Novartis strives for global market reach. It operates in over 140 countries worldwide and maintains a broad and geographically diverse asset base. This asset base allows Novartis to serve extremely diverse markets and was established in part through a history of successful M&A activities. The broad geography of facility locations also promotes a business continuity strategy. Novartis achieves global risk mitigation through a broad market base which reduces the company's reliance on any single geographic region.

## 6.2 Novartis Operating model

Novartis chooses an operating model that supports its strategy of creating a diversified product portfolio. The company seeks to produce a large variety of products in a highly vertically integrated supply chain. High vertical integration allows Novartis to retain more profits and increase control over production, however, this also increases complexity. The increased complexity is managed through a focused brand pipeline management structure. Each key product is evaluated throughout the production process from procurement to customer delivery.

The company operates production and sales facilities across a very broad geographical base. This broad base allows Novartis to employ customized sales practices in each country that it services. Country specific regulatory and language requirements are managed locally in their respective countries. Novartis also receives financial benefits from the broad array of facility locations. Taxation structures vary between countries and regions; Novartis is able to produce products in the regions which allow the company to retain the highest amount of profit.

The Novartis operating model is designed to support the high degree of complexity that occurs with a broad portfolio and vertical integration. The company maintains a globally and centrally managed approach to certain aspects of its supply chain. Throughout the production process, key products which are managed at a brand pipeline level remain visible to global management, while local facility decisions are managed locally. Novartis employs a matrix organization that allows both functional and process efficiency.

## 6.3 Novartis Operational Objectives

The Novartis SCM group places a focused emphasis on reducing both the cycle and lead times for the production. Novartis employs a strategy entitled "Launch in 1000 days" which is designed to limit the time it takes to bring a new product to market; in the past, it often took in excess of 5 years to bring new product launches to market. Once a product receives patent protection and regulatory approval, the clock starts ticking; Novartis has a limited time frame in which to recover R&D costs and produce a positive effective return on their investments.

While attempting to launch products more quickly, Novartis also tries to focus on higher asset utilization. One of the key goals in place for the SCM group is centered on maximizing production capacity utilization. The centralized operating model allows Novartis to accurately allocate production capacity amongst product production campaigns. Through the centralized brand pipeline management approach Novartis achieves superior information flows which lead to better physical flows of products. The centralized approach also allows Novartis to maintain end to end visibility of products in the production process. The global SCM group tries to achieve better traceability and control over material flows and asset utilization. Novartis SCM also tries to achieve global inventory reduction throughout the supply chain. Management utilizes benchmarking techniques to monitor overall inventory levels on both an aggregate and brand pipeline level.

## 6.4 Novartis Complementary Processes

### Parallel Development and Production of New Products

In an effort to facilitate shorter lead and cycle times, Novartis employs a parallel approach to the development and production of new products. While products are still in clinical development, Novartis removes boundaries and separation between their clinical and production supply chains. This allows better sharing of knowledge and information during the development process. Key aspects of the clinical production process are shared with production engineers. The early knowledge transfer allows Novartis to begin the certification process for their production techniques in sync with the product's regulatory approval.

### Turntable

Novartis utilizes a supply chain turntable to exercise control over production and to better manage the high degree of complexity resulting from a broad product portfolio, vertical integration, and broad geographical asset base. The turntable is located in Basel Switzerland, and often manages over 10,000 simultaneous open orders with over 50,000 order lines per year (Novartis Interview 2005). Even with over 20,000 inter-company shipments annually, Novartis spends less than $20 million annually on transportation. The turntable allows Novartis to centrally manage their vertically integrated supply chain and improve visibility and tracking of products and materials through the production process. Additionally, in support of the company's tax optimization strategy, the turntable serves as a financial hub for all inter-company transactions.

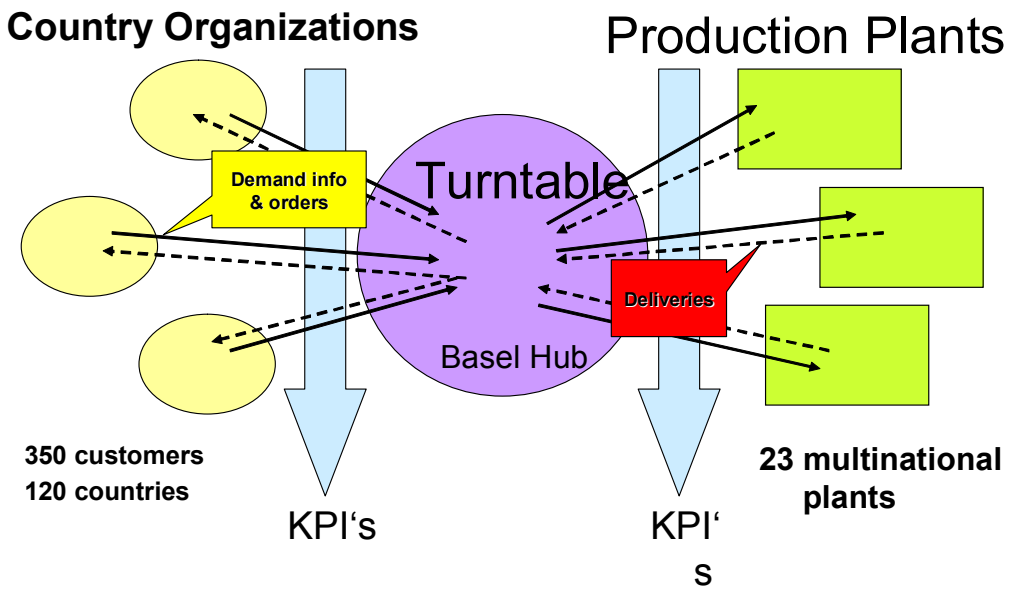



**Figure 34 Turntable KPI Illustration**

(Novartis Presentation 2005)

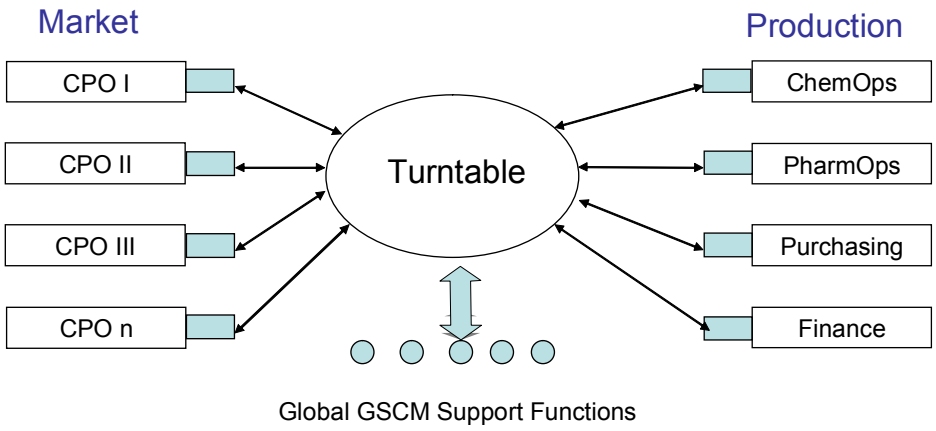


**Figure 35 Turntable Market/Production Illustration**
(Novartis Presentation 2005)

**Collaborative Forecasting Process**

Novartis employs a well developed collaborative process for sales forecasting. Each country or region specific sales organization develops its own sales forecast which is then passed up to the global sales and planning group. The supply chain process begins with a sales forecast. The forecasts will include information about the expected volume of sales as well as the projected financial impact of those sales. The sales staff must also produce accurate accounting of their assumptions about the forecast including explanations as to how and why each value was determined. The forecasting team must take into consideration each particular Brand Strategy, Historical Sales information, Market Intelligence, and other pertinent inputs to the forecasting process. Through better sharing of assumptions in the sales forecasting process, Novartis is able to achieve lower safety stock and inventory through the supply chain.

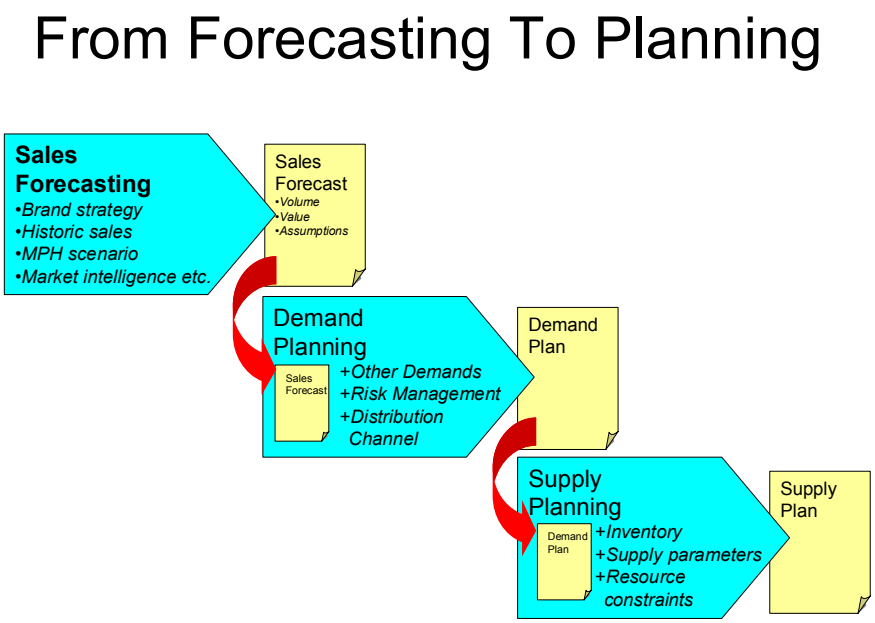


**Figure 36 Collaborative Forecasting**
(Novartis Presentation 2005)

**Planning and Scheduling**

To achieve high levels of asset utilization Novartis uses well founded planning and scheduling methods. Their broad product portfolio combined with a need for asset sharing requires more frequent setups and changeovers of production equipment. This added complexity requires Novartis to undergo a robust and formalized scheduling and planning process. The production planning process must be composed of both centralized and distributed decision making activities simultaneously. The brand pipeline management approach helps facilitate this process and reduce overlap in planning efforts. Novartis also utilizes their accurate sales forecasts to assist in producing better facility production plans. Novartis tries to operate approximately two production campaigns per product per year in order to keep changeovers and setup costs to a minimum. Improper planning could result in lowered efficiency throughout the supply chain.

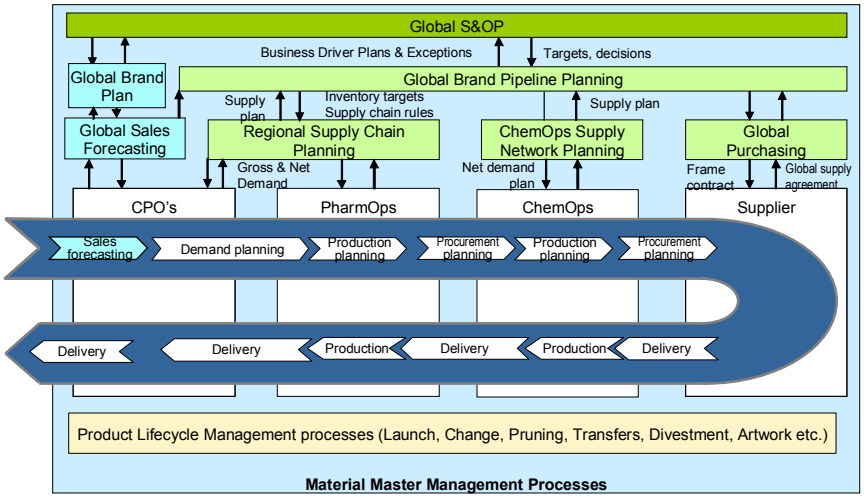



**Figure 37 Operating Model**

(Novartis Presentation 2005)

# Chapter 7 – The Future of Novartis

The overall supply chain and business strategy of Novartis focuses on supporting factors for their core competency of research and development for new pharmaceutical products. The supporting functions of their supply chain compliment the core strategy by which the company gains competitive advantage by discovering or creating new products which can reach market and provide a return on the R&D expenditures. In the current age of blockbuster drugs, companies disregard many of the potentially life altering or saving potential drug compounds in development because of lack of profit potential. During the process of drug compound selection, a company must consider the ability of the compound to provide a positive ROI which is in line with analysts' expectations for double digit growth. In order to meet expectations, especially in the US markets, pharmaceutical companies must aggressively develop the drugs which provide the highest margin potentials. Additionally, companies must bring products to market immediately following approval in order to maximize their time to recover investments. The market is changing.

**Changing Landscape**

The days in which blockbuster drugs provide double digit returns and account for substantial portions of companies' revenues are numbered. The latest studies indicate that R&D expenditures are increasing while the correlated decline in productivity is staggering. At present rates, the cost basis for the creation of new drug substances allows fewer drug compounds to reach the development stages, and even fewer to reach market. Pharmaceutical companies currently optimize their supply chains on a blockbuster drug basis, often times allocating substantial assets to dedicated production facilities for a particular blockbuster product. As products loose patent protection, many of the giants will lose high margin products, and subsequently decline in financial performance.

- **Blockbuster Drugs**

As the blockbuster era wanes, manufacturers will be forced to achieve the same margins and ROI as previously expected of the industry without the help of golden ticket products. Companies already find R&D and sales costs prohibitive, and collaborate on expenditures for risk pooling through cooperative agreements. The change in landscape will effect changes throughout the entire chain from the laboratory to sales, including end consumers and customers.

- **Regulation**

The changing landscape currently drives prices up for companies who still subscribe to the blockbuster drug strategy. The need to maintain margins with higher prices also produces higher drug pricing and resulting ethical pressures; governmental agencies and public discord promote pricing pressures and regulatory changes counter to the pharmaceutical companies' profit motivation. In particular the US continues to provide incentives for generic manufacturers while many countries in the EU create price ceilings for pharmaceutical products.

- **Research and Development**

Trends in medical research suggest that the future of treatments will include new and innovative therapies which include biologically or genetically developed pharmaceutical products. As these trends materialize, pharmaceutical companies will need to reevaluate the way they do business, including the structure of their R&D efforts as well as their supply chains. Pharmaceutical companies' quest for the next blockbuster drug lead to the development of landmark products and intense M&A for knowledge assimilation; but the new era will be driven by new motives and measured by different metrics.

- **Production and Technology**

New products will incorporate different production techniques, new controls and methods for distribution and administration, and even catch phrase logistics concepts such as mass customization and postponement. New biopharmaceutical and genetic products will require new facilities with new technologies. The products may be produced in part or entirely through the use of biological agents instead of traditional chemical synthesis. Most drastically, products may be one time use and customized for an individual who needs the product; the luxury of 7-15 month lead times for products will become extinct.

**Novartis Strategy for Adaptation to the New Landscape**

Novartis currently follows suit and subscribes to an industry wide revenue strategy based around the blockbuster drug, but they are prepared for the future. Novartis continues to increase spending on biopharmaceutical research and development and remains committed to gaining competitive advantage over other companies through its successful R&D ventures in both new and old products. Over the past several years Novartis has perpetually increased spending on R&D and is not at immediate risk of lost revenues with blockbuster patent protection for top products, such as Diovan, extending through 2012. However, the pharmaceutical industry operates at a relatively slow “clockspeed” (Charles Fine) and the seven years between now and then provides very little time for adaptation. Novartis also responds to the regulatory pressures from lower cost generics by competing in the generic product markets with its Sandoz division. Although generic production does not produce the analysts’ expected high margins for pharmaceuticals, it does allow Novartis to hedge against the loss of patent protection and declining R&D efficiency. The Sandoz business unit also sells intermediary products to other pharmaceutical companies who wish to shorten production times and carry less inventory within their supply chains.

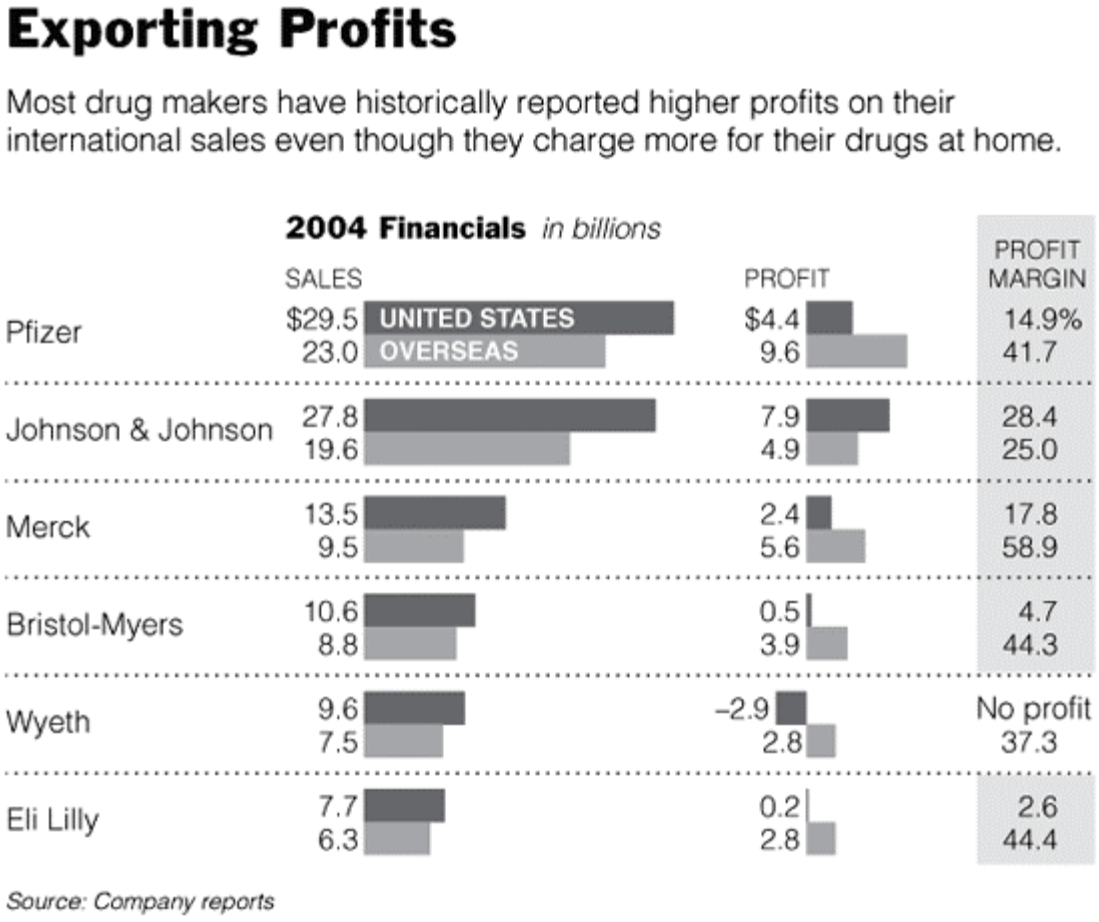
- **Counterintuitive Supply Chain Structure**

Novartis employs a unique system for the management of its supply chain. Unlike most companies whose supply chain design stems from the desire for transportation or materials flow optimization, the motivation and innovation for their supply chain came from both historical asset location and taxable revenue optimization. Through a substantial M&A history, Novartis continues to maintain a geographically diverse and vertically integrated asset base throughout many countries and regulatory regions. While this would normally create substantial logistical inefficiency, Novartis gains advantage from the different taxation structures across the various locations. The desire for revenue maximization and a need for control across the varied geography lead Novartis to develop a system of controls which may initially seem counterintuitive from a supply chain management perspective. Novartis surprisingly transports products through geographical regions using a hub; products may actually pass through the same geographic region, or even the same facility, more than once throughout the production process. Novartis performs optimization and achieves reasonably efficient logistics within the framework of necessary physical and financial flows.

- **Regulatory Adaptation**

Although Novartis benefits substantially from their tax optimization framework, the industry also is expected to experience some changes in tax structure. Many countries are now competing for the revenues of the pharmaceutical giants. In the past places like Ireland, Puerto Rico, and Benelux locations have created incentives through lower taxes to attract pharmaceutical manufactures. One of the latest developments in this trend is now sponsored by the US. Without pricing restraints like those in the EU, the US remains the largest single region for pharmaceutical sales and profits. Currently however, the US doesn't benefit from most of the revenues from pharmaceutical companies who produce in low tax regions. Future changes in the tax structure could

produce lower effective tax rates for pharmaceutical companies. By charging lower taxes, the US will gain more tax revenue while offering more retained operating income for the pharmaceutical companies.




Source: New York Times

- **Research and Development Direction**

The US already provides one of the best environments for R&D which has attracted a significant number of pharmaceutical research facilities. Novartis, already carefully chooses the locations for its research facilities; the locations must correspond with regions in which governmental regulation, funding, and policy supports and fosters their research. In recent years, Novartis has shifted many of its research projects to the US, in particular to its ever expanding facility in Cambridge, MA. (Novartis 20F 2004) This year alone, Novartis has hired an

additional 800 research scientists in their Boston MA facility and has increased R&D spending by an additional 12% to $4.2 billion. (Novartis Annual Report 2004).

# Appendix

## Chapter 4 Figures

### Novartis Historical Revenues and Margins

| Year | Revenue ($ mil.) | Net Income ($ mil.) | Net Profit Margin | Employees |
|---|---|---|---|---|
| Dec 04 | 28,247.0 | 5,767.0 | 20.4% | 81,392 |
| Dec 03 | 24,864.0 | 5,016.0 | 20.2% | 78,541 |
| Dec 02 | 23,151.0 | 5,224.0 | 22.6% | 72,877 |
| Dec 01 | 19,335.0 | 4,239.0 | 21.9% | 71,116 |
| Dec 00 | 21,832.0 | 4,395.0 | 20.1% | 68,000 |
| Dec 99 | 20,418.0 | 4,188.0 | 20.5% | 81,854 |
| Dec 98 | 22,990.3 | 4,397.6 | 19.1% | 82,449 |
| Dec 97 | 21,408.2 | 3,577.9 | 16.7% | 87,000 |
| Dec 96 | 27,009.3 | 1,717.5 | 6.4% | 116,178 |
| Dec 95 | 31,138.3 | 3,652.4 | 11.7% | 133,959 |

**Figure 38 Novartis Historical Revenues**

(Hoovers.com 2005)

### Novartis Historical Stock Prices and Earnings

| Year | Stock Price ($) | | | P/E | | Per Share ($) | | |
|---|---|---|---|---|---|---|---|---|
| | FY High | FY Low | FY Close | High | Low | Earns. | Div. | Book Value |
| Dec 04 | 50.77 | 41.30 | 50.54 | 22 | 18 | 2.34 | 0.69 | 13.92 |
| Dec 03 | 46.00 | 33.85 | 45.89 | 23 | 17 | 2.00 | 0.70 | 12.33 |
| Dec 02 | 44.10 | 33.96 | 36.73 | 22 | 17 | 2.03 | 0.52 | 11.45 |
| Dec 01 | 46.88 | 32.70 | 36.50 | 29 | 20 | 1.64 | 0.50 | 10.01 |
| Dec 00 | 44.94 | 34.63 | 44.75 | 27 | 21 | 1.68 | 0.00 | 344.91 |
| Dec 99 | -- | -- | -- | -- | -- | 1.58 | 0.00 | 356.70 |
| Dec 98 | -- | -- | -- | -- | -- | 64.54 | -- | -- |
| Dec 97 | -- | -- | -- | -- | -- | 52.18 | -- | -- |
| Dec 96 | -- | -- | -- | -- | -- | 1.25 | 0.75 | -- |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Dec 95 | -- | -- | -- | -- | -- | 2.64 | 0.65 | -- |

**Figure 39 Novartis Historical Stock Prices** (Hoovers.com 2005)

**Novartis vs. Industry vs. Market**

| Profitability | Novartis | Industry[1] | Market[2] |
|---|---|---|---|
| Gross Profit Margin | 81.46% | 80.10% | 48.32% |
| Pre-Tax Profit Margin | 24.46% | 23.95% | 9.69% |
| Net Profit Margin | 20.42% | 17.50% | 6.30% |
| Return on Equity | 17.1% | 22.1% | 11.9% |
| Return on Assets | 10.6% | 10.6% | 2.0% |
| Return on Invested Capital | 15.8% | 17.8% | 5.7% |
| **Valuation** | **Novartis** | **Industry[1]** | **Market[2]** |
| Price/Sales Ratio | 4.06 | 3.75 | 1.35 |
| Price/Earnings Ratio | 20.18 | 21.58 | 21.66 |
| Price/Book Ratio | 3.39 | 4.74 | 2.56 |
| Price/Cash Flow Ratio | 16.01 | 15.90 | 11.71 |
| **Operations** | **Novartis** | **Industry[1]** | **Market[2]** |
| Days of Sales Outstanding | 61.82 | 66.29 | 50.47 |
| Inventory Turnover | 1.5 | 1.7 | 7.9 |
| Days Cost of Goods Sold in Inventory | 237 | 209 | 45 |
| Asset Turnover | 0.5 | 0.6 | 0.3 |
| Net Receivables Turnover Flow | 6.1 | 5.6 | 7.4 |
| Effective Tax Rate | 16.3% | 25.7% | 32.6% |
| **Financial** | **Novartis** | **Industry[1]** | **Market[2]** |
| Current Ratio | 2.22 | 1.65 | 1.41 |
| Quick Ratio | 1.8 | 1.2 | 1.0 |
| Leverage Ratio | 1.61 | 2.09 | 5.96 |
| Total Debt/Equity | 0.20 | 0.36 | 1.41 |
| Interest Coverage | 27.40 | 34.70 | 2.90 |
| **Per Share Data ($)** | **Novartis** | **Industry[1]** | **Market[2]** |

| | | | |
|---|---|---|---|
| Revenue Per Share | 11.64 | 10.47 | 21.28 |
| Fully Diluted Earnings Per Share from Total Operations | 2.34 | 1.82 | 1.33 |
| Dividends Per Share | 0.69 | 0.95 | 0.48 |
| Cash Flow Per Share | 2.95 | 2.47 | 2.46 |
| Working Capital Per Share | 5.58 | 2.99 | 2.27 |
| Long-Term Debt Per Share | 1.13 | 1.97 | 12.03 |
| Book Value Per Share | 13.92 | 8.28 | 11.27 |
| Total Assets Per Share | 22.44 | 17.30 | 67.17 |
| Growth | **Novartis** | **Industry[1]** | **Market[2]** |
| 12-Month Revenue Growth | 13.6% | 7.0% | 11.3% |
| 12-Month Net Income Growth | 15.0% | 13.6% | 28.7% |
| 12-Month EPS Growth | 17.0% | 13.0% | 20.9% |
| 12-Month Dividend Growth | (1.4%) | 11.8% | 9.1% |
| 36-Month Revenue Growth | 12.8% | 1.3% | 7.3% |
| 36-Month Net Income Growth | 9.2% | (1.4%) | 69.2% |
| 36-Month EPS Growth | 11.1% | (1.7%) | 70.0% |
| 36-Month Dividend Growth | 13.1% | 7.5% | 4.9% |

**Figure 40 Novartis vs. Industry vs. Market**

(Hoovers.com 2005)

| **2004 Sales** | | |
|---|---|---|
| | **$ mil.** | **% of sales** |
| **Americas** | 13,285 | 47 |
| **Europe** | 10,289 | 36 |
| **Asia, Africa, & Australia** | 4,673 | 17 |
| **Total** | 28,247 | 100 |
| | | |
| **2004 Pharmaceutical Sales** | | |
| | **$ mil.** | **% of total** |
| **Americas** | | |
| **US** | 7,368 | 40 |
| **Other countries** | 1,244 | 7 |
| **Europe** | 6,370 | 34 |

| | | |
|---|---|---|
| **Japan** | 2,081 | 11 |
| **Other regions** | 1,434 | 8 |
| **Total** | 18,497 | 100 |
| | | |
| **2004 Sandoz Division Sales** | | |
| | **$ mil.** | **% of sales** |
| **Europe** | 1,448 | 48 |
| **Americas** | | |
| **US** | 981 | 32 |
| **Other countries** | 187 | 6 |
| **Other regions** | 429 | 14 |
| **Total** | 3,045 | 100 |
| | | |
| **2004 OTC Division Sales** | | |
| | **$ mil.** | **% of sales** |
| **Europe** | 1,056 | 53 |
| **Americas** | | |
| **US** | 521 | 26 |
| **Other countries** | 190 | 10 |
| **Other regions** | 208 | 11 |
| **Total** | 1,975 | 100 |
| | | |
| **2004 Infant & Baby Division Sales** | | |
| | **$ mil.** | **% of sales** |
| **North America** | 1,197 | 83 |
| **Latin America** | 194 | 14 |
| **Europe, Middle East,** | | |
| **& Africa** | 35 | 2 |
| **Other regions** | 15 | 1 |
| **Total** | 1,441 | 100 |
| | | |
| **2004 CIBA Vision Division Sales** | | |
| | **$ mil.** | **% of sales** |
| **Europe** | 572 | 41 |
| **Americas** | | |
| **US** | 481 | 34 |
| **Other countries** | 67 | 5 |
| **Japan** | 201 | 14 |
| **Other regions** | 91 | 6 |
| **Total** | 1,412 | 100 |
| | | |
| **2004 Medical Nutrition Sales** | | |
| | **$ mil.** | **% of sales** |
| **Europe** | 563 | 50 |

| | | |
|---|---|---|
| **Americas** | | |
| **US** | 413 | 37 |
| **Other countries** | 49 | 5 |
| **Other regions** | 94 | 8 |
| **Total** | 1,121 | 100 |
| | | |
| **2004 Animal Health Sales** | | |
| | **$ mil.** | **% of sales** |
| **Americas** | | |
| **US** | 308 | 41 |
| **Other countries** | 83 | 11 |
| **Europe** | 246 | 32 |
| **Other regions** | 119 | 16 |
| **Total** | 756 | 100 |
| | | |
| **2004 Sales** | | |
| | **$ mil.** | **% of total** |
| **Pharmaceuticals** | | |
| **Sandoz** | 3,045 | 11 |
| **OTC** | 1,975 | 7 |
| **Infant & Baby** | 1,441 | 5 |
| **CIBA Vision** | 1,412 | 5 |
| **Medical Nutrition** | 1,121 | 4 |
| **Animal Health** | 756 | 3 |
| **Other** | 8,747 | 31 |
| **Consumer Health** | 9,750 | 34 |
| **Total** | 28,247 | 100 |

**Figure 41 Novartis Division Sales Breakdown**

(Hoovers.com 2005)

**Business Unit Revenues as percentage by division**

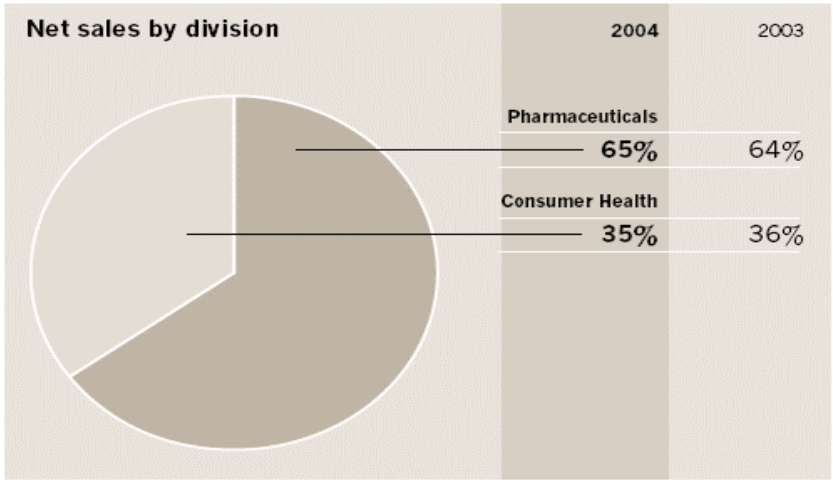



**Figure 42 Novartis Sales by Division**

(Novartis Annual Report 2004)

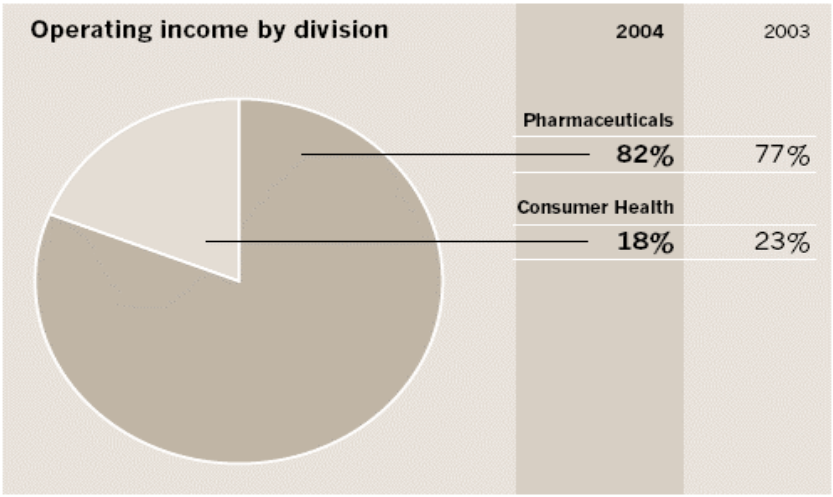



**Figure 43 Novartis Income by Division**

(Novartis Annual Report 2004)

| Key figures (in USD millions unless indicated otherwise) | 2004 | 2003 |
|---|---|---|
| Net sales | 28 247 | 24 864 |
| Operating income | 6 539 | 5 889 |
| Net income | 5 767 | 5 016 |
| Return on sales (%) | 23.1 | 23.7 |
| Research and development | 4 207 | 3 756 |
| Research and development as % of net sales | 14.9 | 15.1 |
| Free cash flow | 3 359 | 3 628 |
| Number of employees | 81 392 | 78 541 |

**Figure 44 Company Key Figures**

(Novartis Annual Report 2004)

| Share information | 2004 | 2003 |
|---|---|---|
| Return on average equity (%)* | 18.0 | 17.1 |
| Earnings per share (USD)* | 2.36 | 2.03 |
| Operating cash flow per share (USD) | 2.75 | 2.69 |
| ADS price at end of year (USD) | 50.54 | 45.89 |
| Share price at end of year (CHF) | 57.30 | 56.15 |
| Pay-out ratio based on outstanding shares (%) | 39 | 39 |

* Average number of shares outstanding in 2004: 2 447 954 737 (2003: 2 473 522 565)

**Figure 45 Share Information**

(Novartis Annual Report 2004)

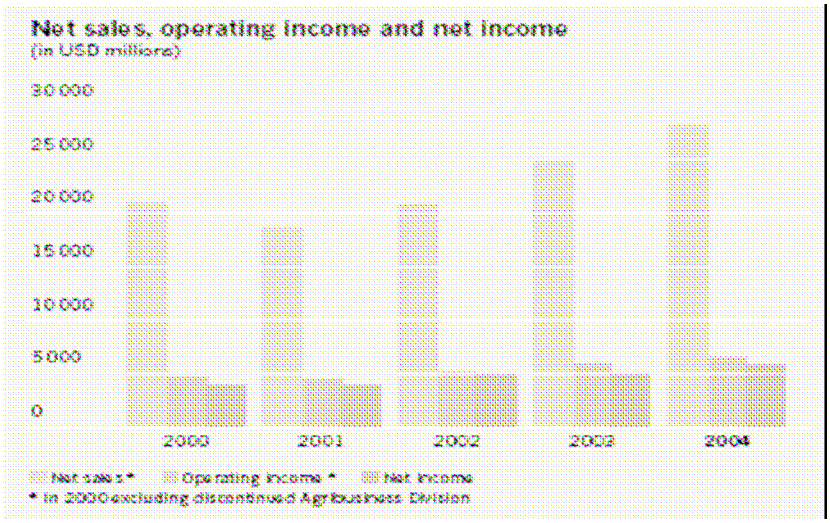



**Figure 46 Net Sales 2004**

(Novartis Annual Report 2004)

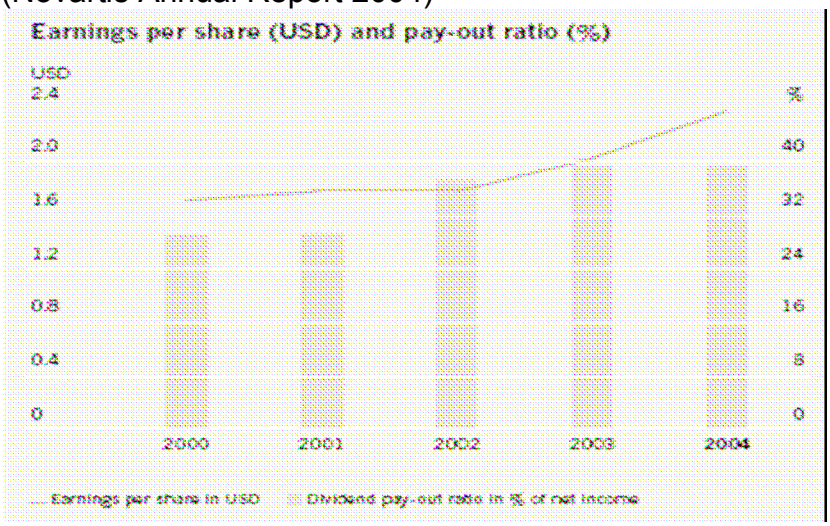



**Figure 47 Earnings Per Share**

(Novartis Annual Report 2004)

Product Portfolio:

| Therapeutic Area | Compound | Generic name | Indication | Formulation |
|---|---|---|---|---|
| **PRIMARY CARE** | | | | |
| **Cardiovascular & Metabolism** | *Diovan HCT/ Co-Diovan* | valsartan and hydrochlorothiazide | Hypertension | Film-coated tablet |
| | *Diovan* | valsartan | Hypertension<br>Heart failure in patients intolerant of ACE inhibitors<br>Post-myocardial infarction | Capsule<br>Coated tablet |
| | *Lescol/ Lescol XL* | fluvastatin sodium | Primary hypercholesterolemia and mixed dyslipidemia<br>Secondary prevention of coronary events<br>Slowing the progression of atherosclerosis<br>Increase of high-density lipoprotein cholesterol (HDL-C) | Capsule<br>Tablet |
| | *Lotensin/ Cibacen* | benazepril hydrochloride | Hypertension | Coated tablet |
| | *Lotensin HCT/ Cibadrex* | benazepril hydrochloride and hydrochlorothiazide | Hypertension<br>Adjunct therapy in heart failure<br>Progressive chronic renal insufficiency | Coated tablet |
| | *Lotrel* | amlodipine besylate and benazepril hydrochloride | Hypertension | Capsule |
| | *Starlix* | nateglinide | Type 2 diabetes | Coated tablet |

| Therapeutic Area | Compound | Generic name | Indication | Formulation |
|---|---|---|---|---|
| **Neuroscience** | *Comtan* | entacapone | Parkinson's disease | Coated tablet |
| | *Exelon* | rivastigmine tartrate | Alzheimer's disease | Capsule<br>Oral solution |
| | *Focalin* | dexmethylphenidate HCl | Attention-deficit hyperactivity disorder | Tablet |
| | *Clozaril/ Leponex* | clozapine | Treatment-resistant schizophrenia<br>Prevention and treatment of recurrent suicidal behavior in patients with schizophrenia and schizoaffective disorder | Tablet |
| | *Ritalin/ Ritalin LA* | methylphenidate HCl | Attention-deficit hyperactivity disorder | Tablet<br>Capsule |
| | *Stalevo* | carbidopa, levodopa and entacapone | Parkinson's disease | Coated tablet |
| | *Tegretol* | carbamazepine | Epilepsy<br>Acute mania and bipolar affective disorders<br>Treatment of pain associated with trigeminal neuralgia | Tablet<br>Chewable tablet<br>Syrup<br>Suppository |
| | *Trileptal* | oxcarbazepine | Epilepsy, including pediatric monotherapy | Tablet<br>Oral suspension |
| **Respiratory & Dermatology** | *Elidel* | pimecrolimus cream | Atopic dermatitis (eczema) | Cream |
| | *Foradil* | formoterol | Asthma<br>Chronic obstructive pulmonary disease | Aerolizer (capsules)<br>Aerosol |
| | *Lamisil* | terbinafine | Fungal infections of the skin and nails | Tablet<br>Cream<br>DermGel<br>Solution<br>Spray |
| | *Xolair* | omalizumab | Allergic asthma | Subcutaneous injection |

| Therapeutic Area | Compound | Generic name | Indication | Formulation |
|---|---|---|---|---|
| **ABGHI (Arthritis, Bone, Gastrointestinal disease, Hormone replacement therapy and Infectious diseases)** | *Enablex/ Emselex* | darifenacin hydrobromide | Overactive bladder | Tablet |
| | *Famvir* | famciclovir | Acute herpes zoster<br>Recurrent genital herpes in immunocompetent patients<br>Recurrent mucocutaneous herpes simplex infections in HIV-infected patients | Tablet |
| | *Zelnorm/ Zelmac* | tegaserod | Irritable bowel syndrome with constipation<br>Chronic constipation | Tablet |
| | *Coartem/ Riamet* | artemether and lumefantrine | Treatment of *Plasmodium falciparum* malaria or mixed infections that include *Plasmodium falciparum*<br>Standby emergency malaria treatment | Tablet |
| | *Combipatch/ Estalis* | estradiol norethisterone acetate | Symptoms of estrogen deficiency in post-menopausal women<br>Post-menopausal osteoporosis | Patch |
| | *Estraderm/ Estraderm MX* | estradiol | Symptoms of estrogen deficiency in post-menopausal women<br>Post-menopausal osteoporosis | Patch |
| | *Estragest TTS* | estradiol norethisterone acetate | Symptoms of estrogen deficiency in post-menopausal women<br>Post-menopausal osteoporosis | Patch |

| Therapeutic Area | Compound | Generic name | Indication | Formulation |
|---|---|---|---|---|
| | *Miacalcin/ Miacalcic* | salmon calcitonin | Osteoporosis<br>Paget's disease<br>Hypercalcemia | Nasal spray<br>Ampoule<br>Vial |
| | *Vivelle-Dot/ Estradot* | estradiol | Symptoms of estrogen deficiency in post-menopausal women<br>Post-menopausal osteoporosis | Patch |
| | *Voltaren* | diclofenac | Inflammatory forms of rheumatism<br>Pain management | Coated tablet<br>Drop<br>Ampoule<br>Suppository<br>Gel |
| **SPECIALTY MEDICINES**<br>**Oncology & Hematology** | *Femara* | letrozole tablets/ letrozole | Advanced post-menopausal breast cancer (worldwide)<br>Extended adjuvant use in early breast cancer following tamoxifen | Coated tablet |
| | *Gleevec/ Glivec* | imatinib mesylate/ imatinib | Certain forms of Chronic myeloid leukemia (CML)<br>Certain forms of gastrointestinal stromal tumors (GIST) | Tablet<br>Capsule |
| | *Sandostatin LAR/ Sandostatin SC* | octreotide acetate for injectable suspension/ octreotide acetate | Acromegaly<br>Symptoms associated with functional gastroenteropancreatic endocrine tumors | Vial<br>Ampoule<br>Pre-filled syringe |
| | *Zometa* | zoledronic acid for injection/zoledronic acid | Hypercalcemia of malignancy<br>Prevention of skeletal-related events in patients with bone metastases from solid tumors | Liquid concentrate<br>Vial |

| Therapeutic Area | Compound | Generic name | Indication | Formulation |
|---|---|---|---|---|
| **Transplantation & Immunology** | *Certican* | everolimus | Prevention of organ rejection following heart or kidney transplantation | Tablet<br>Tablet for oral suspension |
| | *Myfortic* | mycophenolic acid | Prevention of graft rejection following kidney transplantation | Enteric coated tablet |
| | *Neoral* | cyclosporine, USP modified | Prevention of graft rejection following organ and bone marrow transplantation<br>Severe psoriasis<br>Rheumatoid arthritis | Capsule<br>Oral solution |
| | *Simulect* | basiliximab | Acute organ rejection in de novo renal transplantation<br>Atopic dermatitis (eczema)<br>Uveitis<br>Nephrotic syndrome | Vial |
| **Ophthalmics** | *Visudyne* | verteporfin | Age-related macular degeneration (all forms of wet AMD) | Vial, activated by laser light |
| | *Zaditor/ Zaditen* | ketotifen | Allergic conjunctivitis | Eye drops |

**Figure 48 Product Offerings**

(Novartis 20F 2004)

**Associated SIC Codes**

| | |
|---|---|
| 2833 | Medicinals and botanicals |
| 2834 | Pharmaceutical preparations |
| 2835 | Diagnostic substances |
| 2836 | Biological products exc. Diagnostic |
| 2879 | Agricultural chemicals, nec |
| 2899 | Chemical preparations, nec |
| 3577 | Computer peripheral equipment, nec |
| 3821 | Laboratory apparatus and furniture |
| 3826 | Analytical instruments |
| 3841 | Surgical and medical instruments |
| 3845 | Electromedical equipment |
| 7372 | Prepackaged software |
| 7374 | Data processing and preparation |
| 8731 | Commercial physical research |
| 8733 | Noncommercial research organizations |
| 8734 | Testing laboratories |

**Associated NAICS Codes**

| | |
|---|---|
| 32541 | Pharmaceutical and Medicine Manufacturing |
| 325411 | Medicinal and Botanical Manufacturing |
| 325412 | Pharmaceutical Preparation Manufacturing |
| 325413 | In-Vitro Diagnostic Substance Manufacturing |
| 325414 | Biological Product (except Diagnostic) Manufacturing |
| 334516 | Analytical Laboratory Instrument Manufacturing |
| 339111 | Laboratory Apparatus and Furniture Manufacturing |
| 541710 | Research and Development in the Physical, Engineering, and Life Sciences |
| 621410 | Family Planning Centers |
| 62151 | Medical and Diagnostic Laboratories |
| 621511 | Medical Laboratories |
| 621512 | Diagnostic Imaging Centers |

**Figure 49 NAICS and SIC Product Categories**

(Hoovers.com 2005)

Comparison of Novartis and Competitors

| **Key Numbers** | **Novartis** | Johnson & Johnson | Merck | Pfizer | | |
|---|---|---|---|---|---|---|
| Annual Sales ($ mil.) | 28,247.0 | 47,348.0 | 22,938.6 | **52,516.0** | | |
| Employees | 81,392 | 109,900 | 63,000 | **115,000** | | |
| Market Cap ($ mil.) | 114,618.2 | **204,855.8** | 73,174.8 | 197,361.8 | | |
| **Profitability** | Novartis | Johnson & Johnson | Merck | Pfizer | Industry[2] | Market[3] |
| Gross Profit Margin | 81.46% | 76.14% | 84.70% | **90.27%** | 80.10% | 48.32% |
| Pre-Tax Profit Margin | 24.46% | 27.11% | **35.44%** | 26.67% | 23.95% | 9.69% |
| Net Profit Margin | 20.42% | 17.97% | **25.34%** | 21.63% | 17.50% | 6.30% |
| Return on Equity | 17.1% | 26.7% | **33.6%** | 16.7% | 22.1% | 11.9% |
| Return on Assets | 10.6% | **16.0%** | 13.7% | 9.2% | 10.6% | 2.0% |
| Return on Invested Capital | 15.8% | 24.8% | **26.4%** | 15.0% | 17.8% | 5.7% |
| **Valuation** | Novartis | Johnson & Johnson | Merck | Pfizer | Industry[2] | Market[3] |
| Price/Sales Ratio | 4.06 | 4.33 | **3.19** | 3.76 | 3.75 | 1.35 |
| Price/Earnings Ratio | 20.18 | 24.26 | **12.70** | 17.76 | 21.58 | 21.66 |
| Price/Book Ratio | 3.39 | 6.44 | 4.23 | **2.90** | 4.74 | 2.56 |
| Price/Cash Flow Ratio | 16.01 | 19.24 | **10.07** | 11.50 | 15.90 | 11.71 |
| **Operations** | Novartis | Johnson & Johnson | Merck | Pfizer | Industry[2] | Market[3] |
| Days of Sales Outstanding | 61.82 | **51.94** | 56.93 | 68.69 | 66.29 | 50.47 |
| Inventory | 1.5 | **3.1** | 1.6 | 0.8 | 1.7 | 7.9 |

| Turnover | | | | | | |
|---|---|---|---|---|---|---|
| Days Cost of Goods Sold in Inventory | 237 | **117** | 228 | 440 | 209 | 45 |
| Asset Turnover | 0.5 | **0.9** | 0.6 | 0.4 | 0.6 | 0.3 |
| Net Receivables Turnover Flow | 6.1 | **7.1** | 6.0 | 5.5 | 5.6 | 7.4 |
| Effective Tax Rate | **16.3%** | 33.7% | 26.6% | 19.0% | 25.7% | 32.6% |
| **Financial** | Novartis | Johnson & Johnson | Merck | Pfizer | Industry[2] | Market[3] |
| Current Ratio | **2.22** | 1.96 | 1.15 | 1.50 | 1.65 | 1.41 |
| Quick Ratio | **1.8** | 1.4 | 0.9 | 1.1 | 1.2 | 1.0 |
| Leverage Ratio | **1.61** | 1.68 | 2.46 | 1.82 | 2.09 | 5.96 |
| Total Debt/Equity | 0.20 | **0.09** | 0.40 | 0.27 | 0.36 | 1.41 |
| Interest Coverage | 27.40 | **69.70** | 28.20 | 41.30 | 34.70 | 2.90 |
| **Per Share Data ($)** | Novartis | Johnson & Johnson | Merck | Pfizer | Industry[2] | Market[3] |
| Revenue Per Share | 11.64 | **15.92** | 10.39 | 7.04 | 10.47 | 21.28 |
| Fully Diluted Earnings Per Share from Total Operations | 2.34 | **2.84** | 2.61 | 1.49 | 1.82 | 1.33 |
| Dividends Per Share | 0.69 | 1.10 | **1.49** | 0.68 | 0.95 | 0.48 |
| Cash Flow Per Share | 2.95 | **3.58** | 3.29 | 2.30 | 2.47 | 2.46 |
| Working Capital Per Share | **5.58** | 4.50 | 0.78 | 1.77 | 2.99 | 2.27 |
| Long-Term Debt Per Share | 1.13 | **0.86** | 2.12 | 0.98 | 1.97 | 12.03 |
| Book Value Per | **13.92** | 10.70 | 7.83 | 9.13 | 8.28 | 11.27 |

| Share | | | | | | |
|---|---|---|---|---|---|---|
| Total Assets Per Share | **22.44** | 17.93 | 19.28 | 16.58 | 17.30 | 67.17 |
| **Growth** | Novartis | Johnson & Johnson | Merck | Pfizer | Industry[2] | Market[3] |
| 12-Month Revenue Growth | 13.6% | 13.1% | 2.0% | **16.2%** | 7.0% | 11.3% |
| 12-Month Net Income Growth | 15.0% | 18.2% | (14.9%) | **188.4%** | 13.6% | 28.7% |
| 12-Month EPS Growth | 17.0% | 18.3% | (13.9%) | **175.9%** | 13.0% | 20.9% |
| 12-Month Dividend Growth | (1.4%) | **18.3%** | 2.8% | 13.3% | 11.8% | 9.1% |
| 36-Month Revenue Growth | 12.8% | 13.0% | (26.2%) | **19.7%** | 1.3% | 7.3% |
| 36-Month Net Income Growth | 9.2% | **13.9%** | (7.0%) | 2.5% | (1.4%) | 69.2% |
| 36-Month EPS Growth | 11.1% | **15.1%** | (5.7%) | (4.3%) | (1.7%) | 70.0% |
| 36-Month Dividend Growth | 13.1% | **16.1%** | 2.8% | 15.6% | 7.5% | 4.9% |

**Figure 50 Comparison of Novartis and Competitors**

(Hoovers.com 2005) Numbers in bold represent the best company's metric.

**Chapter 5 Figures & Tables**


**Figure 51 Global Quarterly Market Growth**

(Novartis Annual Report 2004)

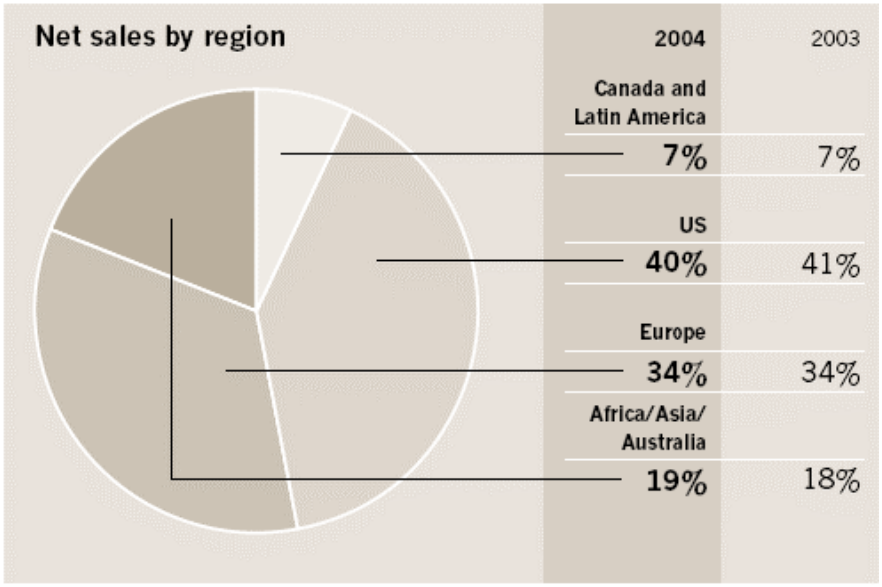



**Figure 52 Net Sales by Region**

(Novartis Annual Report 2004)

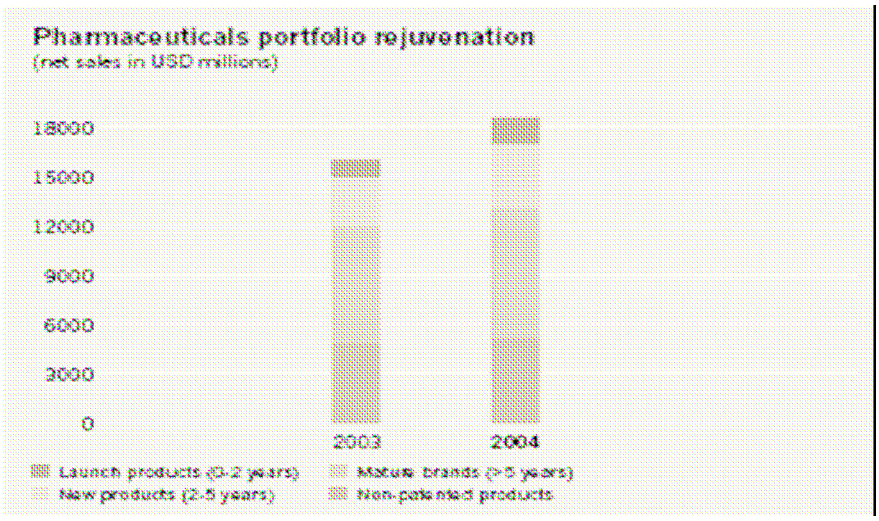



**Figure 53 Portfolio Rejuvenation**

(Novartis Annual Report 2004)

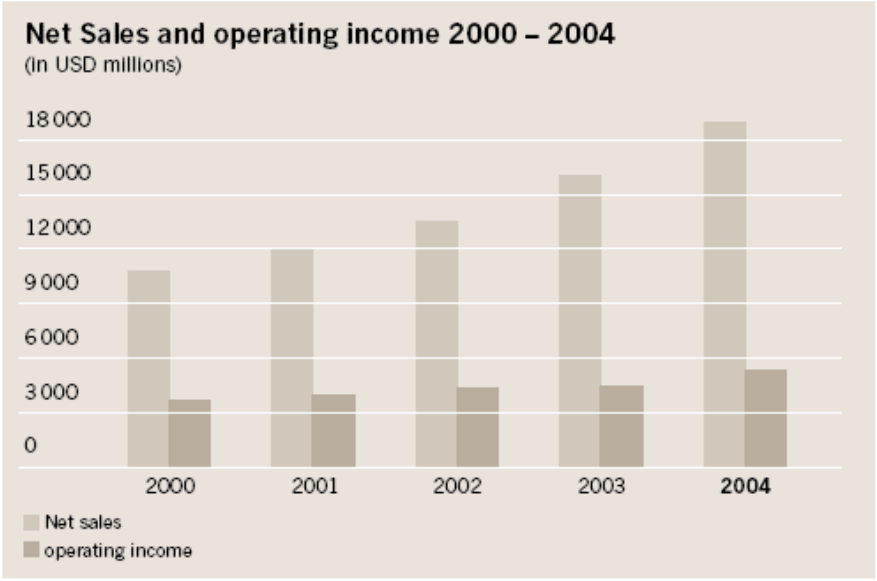



**Figure 54 Net Sales 00 - 04**

(Novartis Annual Report 2004)

## Compounds in Development:

| Therapeutic area | Project/ Compound | Generic name | Indication | Mechanism of action | Formulation | Planned filing dates/Current phase |
|---|---|---|---|---|---|---|
| **PRIMARY CARE Cardiovascular & Metabolism** | *Diovan* | valsartan | Heart failure in patients intolerant of ACE inhibitors (Val-HeFT) | Angiotensin-II receptor blocker | Oral | US (approved) EU (submitted) Approved in five markets |
| | | | Post-myocardial infarction (VALIANT) | | Oral | US/EU (submitted) Approved in 22 markets |
| | *Diovan and Starlix* | valsartan and nateglinide | Prevention of new onset type 2 diabetes, cardiovascular morbidity and mortality (NAVIGATOR) | | Oral | ≥2007/III |
| | *Lotrel* | amlodipine besylate and benazepril hydrochloride | Hypertension (5-40 and 10-40) | ACE inhibitor and calcium channel blocker | Oral | US (Submitted) |
| | | | High-risk hypertension (ACCOMPLISH) | | Oral | ≥2007/III |
| | LAF237 | vildagliptin | Type 2 diabetes | Dipeptidyl-pepidase (DPP-4) inhibitor | Oral | 2006/III |
| | SPP100 | aliskiren | Hypertension | Renin inhibitor | Oral | 2006/III |
| | NKS104 | pitavastatin | Dyslipidemia | HMG CoA reductase inhibitor | Oral | ≥2007/II |
| | LBM642 | TBD | Dyslipidemia | PPAR alpha and gamma dual agonist | TBD | ≥2007/I |
| | FAD286 | TBD | Congestive heart failure | | TBD | TBD/I |
| | VNP489 | TBD | Hypertension | NEP inhibitor | TBD | TBD/I |

| Therapeutic area | Project/ Compound | Generic name | Indication | Mechanism of action | Formulation | Planned filing dates/Current phase |
|---|---|---|---|---|---|---|
| Neuroscience | *Focalin XR* | methylphenidate | Attention-deficit hyperactivity disorder | Dopamine transport blocker | Oral | US (submitted) |
| | *Exelon TDS* | rivastigmine tartrate | Alzheimer's disease | Cholinesterase inhibitor | Transdermal patch | 2006/III |
| | *Exelon* | rivastigmine tartrate | Non Alzheimer's dementia | Cholinesterase inhibitor | Oral | 2005/III |
| | *Trileptal NP* | oxycarbazepine | Neuropathic pain | Voltage sensitive sodium channel blocker | Oral | 2007/III |
| | LIC477 | licarbazepine | Bipolar disorder | Voltage sensitive sodium channel blocker | Oral | 2007/III |
| | AMP397 | TBD | Epilepsy | AMPA receptor antagonist | Oral | ≥2007/II |
| | SAB378 | TBD | Neuropathic pain | Cannabinoid-1 receptor agonist | Oral | ≥2007/II |
| | FTY720 | TBD | Multiple sclerosis | Sphingosine-1-phosphate receptor agonist | Oral | ≥2007/II |
| | AEP924 | TBD | Depression | Somatostatin receptor antagonist | TBD | ≥2007/I |
| | XBD173 | TBD | Generalized anxiety disorder | Mitochondrial benzodiazepine receptor agonist | Oral | ≥2007/I |

| Therapeutic area | Project/ Compound | Generic name | Indication | Mechanism of action | Formulation | Planned filing dates/Current phase |
|---|---|---|---|---|---|---|
| **Respiratory & Dermatology** | *Foradil* | formoterol | Multi-dose dry powder inhaler in asthma | Long-acting beta-2 agonist | Dry powder for inhalation | US/EU (submitted) Approved in five European countries |
| | *Xolair* | omalizumab | Allergic asthma | Anti-IgE monoclonal antibody | Sub-cutaneous | US (approved) EU (submitted) |
| | | | Peanut allergy | Anti-IgE monoclonal antibody | Sub-cutaneous | 2007/I |
| | | | New formulations | Anti-IgE monoclonal antibody | Liquid formulation | 2007/I |
| | *Lamisil* | terbinafine | Fungal infection of the scalp in children | Fungal squalene epoxidase inhibitor | Oral | 2006 (US)/III |
| | | | Nail lacquer for fungal infection | Fungal squalene epoxidase inhibitor | Nail Lacquer | ≥2007/I |
| | *Elidel* | pimecrolimus | Seborrheic dermatitis | T-cell and mast cell inhibitor | Cream | 2006/II |
| | | | Atopic dermatitis in infants | | | 2006/III |
| | | | Chronic hand dermatitis | | | 2006/III |
| | *Elidel Ointment* | pimecrolimus | Inflammatory skin diseases | T-cell and mast cell inhibitor | Ointment | 2006/II |
| | ASM981 | pimecrolimus oral | Inflammatory skin diseases | T-cell and mast cell inhibitor | Oral | TBD/II |
| | QAB149 | TBD | Asthma Chronic obstructive pulmonary disease | Once-daily beta-2 agonist | Inhalation | 2007/II |
| | *Foradil/ mometasone* | Formoterol/ mometasone | Asthma Chronic obstructive pulmonary disease | Long-acting beta-2 agonist/inhaled corticosteroid | Inhalation | 2007/I |
| | ACZ885 | TBD | Asthma | Monoclonal antibody to IL-1 beta | TBD | 2007/I |
| | VAG624 | TBD | Acne | Steroid sulfatase inhibitor | TBD | TBD/I |
| | ABN912 | TBD | Asthma | Monoclonal antibody to monocyte chemoattractant protein-1 | TBD | ≥2007/I |
| | QAN747 | TBD | Asthma Chronic obstructive pulmonary disease | | TBD | ≥2007/I |
| | QAE397 | TBD | Asthma | | TBD | ≥2007/I |
| | QAK423 | TBD | Asthma Chronic obstructive pulmonary disease | | TBD | ≥2007/I |

| Therapeutic area | Project/ Compound | Generic name | Indication | Mechanism of action | Formulation | Planned filing dates/Current phase |
|---|---|---|---|---|---|---|
| **ABGHI (Arthritis, Bone, Gastrointestinal diseases, Hormone replacement therapy, Infectious diseases)** | *Prexige* | lumiracoxib | Osteoarthritis<br>Acute pain<br>Primary dysmenorrhea | Cyclo-oxygenase-2 inhibitor | Oral | UK (approved)<br>EU (2005/III)<br>US 2007/III |
| | | | Rheumatoid arthritis | Cyclo-oxygenase-2 inhibitor | Oral | EU 2006/III |
| | | | New formulations (oral suspension; parenteral) | Cyclo-oxygenase-2 inhibitor | Oral | TBD/I |
| | *Zelnorm/ Zelmac* | tegaserod | Irritable bowel syndrome with constipation<br>Dyspepsia<br>Gastroesophageal reflux disease<br>Chronic constipation in certain countries | 5HT4-receptor agonist | Oral Solution | US (approved)<br>EU (submitted)<br>2006/II<br>2007/II |
| | *Aclasta* | zoledronic acid | Paget's disease<br>Osteoporosis<br>Rheumatoid arthritis | Bisphosphonate, osteoclast inhibitor | Intravenous | US/EU (submitted)<br>2007/III<br>≥2007/II |
| | LTD600 | telbivudine | Hepatitis B | Viral polymerase inhibitor | Oral | 2005/III |
| | LDC300 | valtorcitabine | Hepatitis B | Viral polymerase inhibitor | Oral | ≥2007/II |
| | AAE581 | balicatib | Osteoporosis | Cathepsin K inhibitor | Oral | ≥2007/II |
| | SMC021 | calcitonin | Osteoporosis | Regulator of calcium homeostasis | Oral | ≥2007/II |
| | ACZ885 | TBD | Rheumatoid arthritis | Monoclonal antibody to IL-1 beta | TBD | ≥2007/I |
| | AKU517 | TBD | Gastroesophageal reflux disease | Reversible acid pump antagonist | TBD | ≥2007/I |
| | LBM415 | TBD | Anti-bacterial | Peptide deformylase inhibitor | TBD | ≥2007/I |
| | AFG495 | TBD | Osteoporosis | | TBD | TBD/I |

| Therapeutic area | Project/ Compound | Generic name | Indication | Mechanism of action | Formulation | Planned filing dates/Current phase |
|---|---|---|---|---|---|---|
| **SPECIALTY MEDICINES** | | | | | | |
| **Oncology & Hematolgy** | *Zometa* | zoledronic acid | Treatment of bone metastases | Bisphosphonate | Intravenous | Japan (submitted) |
| | *Femara* | letrozole | Breast cancer (extended adjuvant therapy) | Aromatase inhibitor | Oral | US (approved) EU (submitted) |
| | | | Breast cancer (early adjuvant therapy) | Aromatase inhibitor | Oral | 2005/III |
| | ICL670 | deferasirox | Chronic iron overload | Iron chelator | Oral | 2005/III |
| | PTK787 | vatalanib | Colorectal cancer Solid tumors | Angiogenesis inhibitor | Oral | 2005/III TBD/I |
| | EPO906 | patupilone | Solid tumors | Microtubule depolymerization inhibitor | Oral | 2007/II |
| | *OctreoTher* | edotreotide | Somatostatin receptor-positive tumors | Radioactive labeled peptide | Intravenous | TBD/II |
| | PKC412 | midostaurin | Acute myeloid leukemia (AML) | Signal transduction inhibitor | Oral | TBD/II |
| | SOM230 | pasireotide | Acromegaly GEP neuroendocrine tumors | Somatostatin (sst) 1/2/3/5 binder and hormone inhibitor | Intramuscular injection Sub cutaneous injection | 2006/II |
| | *Gleevec/ Glivec* | imatinib mesylate/ imatinib | Solid tumors | Signal transduction inhibitor | Oral | 2007/II |
| | LBQ707 | gimatecan | Solid tumors | Topoisomerase-I inhibitor (cytotoxic) | Oral | 2007/II |
| | RAD001 | everolimus | Solid tumors | Growth-factor-induced cell proliferation signal transduction inhibitor | Oral | ≥2007/II |
| | AMN107 | TBD | Chronic myeloid leukemia (CML) | Signal transduction inhibitor | Oral | 2007/I |
| | LBH589 | TBD | Solid and liquid tumors | Histone deacetylase inhibitor | Oral | 2007/I |
| | AEE788 | TBD | Solid tumors | Tyrosine kinase inhibitor | Oral | ≥2007/I |
| | ABJ879 | TBD | Solid tumors | Microtubule stabilizer | Intravenous injection | ≥2007/I |

| Therapeutic area | Project/ Compound | Generic name | Indication | Mechanism of action | Formulation | Planned filing dates/Current phase |
|---|---|---|---|---|---|---|
| **Transplantation & Immunology** | *Certican* | everolimus | Prevention of organ rejection | Growth-factor-induced cell proliferation inhibitor | Oral | EU (approved) US (submitted) |
| | FTY720 | TBD | Prevention of organ rejection | Sphingosine-1 -phosphate receptor agonist | Oral | 2006/III |
| | AEB071 | TBD | Prevention of organ rejection | T-cell activation Ophthalmics | TBD | TBD/I |
| **Ophthalmics** | *Visudyne* | verteporfin | Age-related macular degeneration (AMD)(occult) | Photosensitizer for photodynamic therapy | Intravenous | 2005/III |
| | *Sandostatin LAR* | octreotide acetate | Diabetic retinopathy Other indications | Growth hormone and IGF-1 inhibitor | Intra muscular | 2005/III |
| | *Lucentis™* | ranibizumab | Age-related macular degeneration (AMD) | VEGF blocker | Intra-vitreal | 2005 (EU)/III |
| | *Elidel* | pimecrolimus | Dry eye<br>Blepharitis | T-cell and mast cell inhibitor | Eye drops<br>Eye ointment | ≥2007/II<br>≥2007/II |

**Phase I:** First clinical trial of a new compound, generally performed in a small number of human volunteers, to assess clinical safety, tolerability as well as metabolic and pharmacologic properties.

**Phase II:** Clinical studies that test the safety and efficacy of the compound in patients with the targeted disease with the goal of determining the appropriate doses for further testing and evaluating study design as well as identifying common side effects and risks. (Cancer drugs, as well as those for other life-threatening diseases, can sometimes be submitted for approval based on only Phase II data).

**Phase III:** Large-scale clinical studies with several hundred or several thousand patients to establish safety and effectiveness for regulatory approval for indicated uses and to evaluate the overall benefit-risk relationship.

**Figure 55 Compounds in Development**

(Novartis 20F 2004)

# Industry Comparison

| NAICS Codes | Novartis | J&J | Merck | Pfizer |
|---|---|---|---|---|
| 322291 Sanitary Paper Product Manufacturing | | x | | |
| 32541 Pharmaceutical and Medicine Manufacturing | x | x | x | x |
| 325411 Medicinal and Botanical Manufacturing | x | x | x | x |
| 325412 Pharmaceutical Preparation Manufacturing | x | x | x | x |
| 325413 In−Vitro Diagnostic Substance Manufacturing | | x | | |
| 325414 Biological Product (except Diagnostic) Manufacturing | | x | | |
| 32562 Toilet Preparation Manufacturing | | x | | |
| 325620 Toilet Preparation Manufacturing | | x | | x |
| 334516 Analytical Laboratory Instrument Manufacturing | | x | | |
| 339111 Laboratory Apparatus and Furniture Manufacturing | | x | | |
| 339113 Surgical Appliance and Supplies Manufacturing | | x | | |
| 339115 Ophthalmic Goods Manufacturing | x | x | | |
| 54138 Testing Laboratories | | x | | |
| 54171 Research and Development in the Physical, Engineering, and Life Sciences | | x | | |
| 54194 Veterinary Services | | x | | |

**Figure 56 Company Comparison by NAICS Codes**

# Industry Comparison

J&J Is Very Diversified with over 200 Subidiaries

| SIC Codes | Novartis | J&J | Merck | Pfizer |
|---|---|---|---|---|
| | | | | |
| 2833 Medicinals and botanicals | x | x | x | x |
| 2834 Pharmaceutical preparations | x | x | x | x |
| 2835 Diagnostic substances | | x | | |
| 2836 Biological products exc. diagnostic | | x | | |
| 2844 Toilet preparations | | x | | x |
| 3821 Laboratory apparatus and furniture | | x | | |
| 3826 Analytical instruments | | x | | |
| 3841 Surgical and medical instruments | | x | | |
| 3842 Surgical appliances and supplies | | x | | |
| 3851 Ophthalmic goods | x | x | | |
| 5048 Ophthalmic goods | x | | | |
| 5122 Drugs, proprietaries, and sundries | | | x | |
| 8731 Commercial physical research | | x | | |
| 8734 Testing laboratories | | x | | |

**Figure 57 Company Comparison by SIC Codes**

The following table sets forth our major production and research facilities.

| Location/Division or Business Unit | Size of Site (in square meters) | Major Activity |
|---|---|---|
| **Major Production facilities:** | | |
| **Pharmaceuticals** | | |
| Taboão da Serra, Brazil | 539,000 square meters | Capsules, tablets, syrups, suppositories, suspensions, creams, drop solutions, powders |
| Ringaskiddy, Ireland | 532,000 square meters | Drug substances, intermediates |
| Basel, Switzerland—Klybeck | 254,000 square meters | Drug substances, intermediates |
| Basel, Switzerland—St. Johann | 219,000 square meters | Drug substances, intermediates, biotechnology |
| Basel, Switzerland—Schweizerhalle | 237,000 square meters | Drug substances, intermediates |
| Stein, Switzerland | 460,000 square meters | Steriles, tablets, capsules, transdermals |
| Grimsby, UK | 929,000 square meters | Drug substances, intermediates |
| Suffern, NY | 656,000 square meters | Tablets, capsules, transdermals |
| Horsham, UK | 112,000 square meters | Tablets, capsules |
| Wehr, Germany | 165,000 square meters | Tablets, creams, ointments |
| Torre, Italy | 210,000 square meters | Tablets, biotechnology |
| Barbera, Spain | 51,000 square meters | Tablets, capsules |
| Huningue, France | 250,000 square meters (includes Animal Health facilities) | Suppositories, liquids, solutions, suspensions, biotechnology |
| Kurtkoy, Turkey | 109,000 square meters | Tablets, capsules, effervescents |
| Sasayama, Japan | 104,000 square meters | Capsules, tablets, syrups, suppositories, creams, drop solutions, powders |
| **Consumer Health** | | |
| **Sandoz** | | |
| Kundl and Schaftenau, Austria | 320,000 square meters (production and R&D facilities) | Biotech products, intermediates, active drug substances, final steps (finished pharmaceuticals) |

| Location/Division or Business Unit | Size of Site (in square meters) | Major Activity |
|---|---|---|
| Mengeš, Slovenia | 131,000 square meters (production and R&D facilities) | Biotech products and active drug substances |
| Ljubljana, Slovenia | 83,000 square meters (production and R&D facilities) | Broad range of finished dosage forms |
| Broomfield, CO | 60,000 square meters | Broad range of finished dosage forms |
| Stryków, Poland | 20,000 square meters | Broad range of finished dosage forms |
| Palafolls, Spain | 13,000 square meters | Injectable products |
| Kalwe, India | 10,000 square meters | Broad range of finished dosage forms |
| Boucherville, Canada | 4,600 square meters | Injectable products |
| OTC | | |
| Lincoln, NE | 44,870 square meters | Liquids, creams and tablets |
| Nyon, Switzerland | 14,700 square meters (production and R&D facilities) | Liquids and creams |
| Humacao, Puerto Rico | 8,000 square meters | Sugar coated tablets, small chocolate tablets, packaging of softgels |
| **OTC** | | |
| Lincoln, NE | 44,870 square meters | Liquids, creams and tablets |
| Nyon, Switzerland | 14,700 square meters (production and R&D facilities) | Liquids and creams |
| Humacao, Puerto Rico | 8,000 square meters | Sugar coated tablets, small chocolate tablets, packaging of softgels |
| **Animal Health** | | |
| Wusi Farm, China | 42,000 square meters | Insecticides, antibacterials, acaricides, powders |
| Dundee, UK | 34,000 square meters | Packaging, formulation liquids, solids, creams, sterile filling |
| Larchwood, IA | 29,700 square meters (production and R&D facilities) | Veterinary immunologicals |
| Braintree, UK | 10,000 square meters | Veterinary immunologicals |
| Huningue, France | 6,000 square meters | Formulation and packaging of tablets, creams, ointments, suspensions and liquids |

| | | |
|---|---|---|
| **Medical Nutrition** | | |
| Minneapolis, MN | 33,500 square meters (production and R&D facilities) | Medical nutrition products |
| Osthofen, Germany | 17,000 square meters (production and R&D facilities) | Medical nutrition and Nutrition & Santé products |
| **Infant & Baby** | | |
| Fremont, MI | 107,000 square meters (production and R&D facilities) | *Gerber* jarred baby food, fruit and vegetable juices, dry boxed cereal |
| Fort Smith, AR | 80,451 square meters | *Gerber* jarred baby food, dry cereal |
| Querétaro, Mexico | 205,000 square meters | *Gerber* jarred baby food, fruit and vegetable juices, dry canned and bagged cereal |
| Reedsburg, WI | 30,000 square meters | Baby Care products; spill-proof cups, bottles, nipples, breast pads, pacifiers, overcaps |
| Campo Grande, Brazil | 89,000 square meters | Baby Care products; spill-proof cups, bottles, nipples, breast pads, pacifiers, overcaps |
| Rzeszow, Poland | 45,000 square meters | Gerber baby food, fruit juice |
| **CIBA Vision** | | |
| Pulau Batam, Indonesia | 19,000 square meters | Contact lenses |
| Duluth, GA | 34,000 square meters | Contact lenses |
| Des Plaines, IL | 27,400 square meters | *Freshlook* product line |
| Grosswallstadt, Germany | 23,000 square meters | Contact lenses |
| Cidra, Puerto Rico | 6,100 square meters | Contact lenses |
| Toronto, Canada | 14,500 square meters | Lens care products |
| **Major Research and Development Facilities:** | | |
| **Pharmaceuticals** | | |
| East Hanover, NJ | 177,398 square meters | General pharmaceutical products |
| Cambridge, MA | 75,300 square meters | General pharmaceutical products |
| Basel, Switzerland—Klybeck | 140,000 square meters | General pharmaceutical products |

| | | |
|---|---|---|
| Basel, Switzerland—St. Johann | 150,000 square meters | General pharmaceutical products |
| Vienna, Austria | 39,000 square meters | Dermatology |
| Tsukuba, Japan | 20,600 square meters | General pharmaceutical products |
| Horsham and London, UK | 37,700 square meters | Respiratory and nervous system diseases |
| **Consumer Health** | | |
| **Sandoz** | | |
| Kundl and Schaftenau, Austria | 320,000 square meters total area (production and R&D facilities) | Biotech processes, innovations in antibiotic technologies |
| Mengeš, Slovenia | 131,000 square meters (production and R&D facilities) | Biotech products and active drug substances |
| Ljubljana, Slovenia | 83,000 square meters (production and R&D facilities) | Broad range of finished dosage forms |
| Kolshet, India | 5,000 square meters | Generic pharmaceuticals |
| Dayton, NJ | 29,000 square meters | Broad range of finished dosage forms |
| Boucherville, Canada | 4,377 square meters | Injectable products |
| **OTC** | | |
| Lincoln, NE | 44,870 square meters | Liquids, creams and tablets |
| Nyon, Switzerland | 14,700 square meters (production and R&D facilities) | Over-the-counter medicine products |
| **Animal Health** | | |
| St. Aubin, Switzerland | 26,000 square meters | Parasiticides |
| Larchwood, IA | 29,700 square meters (production and R&D facilities) | Veterinary immunologicals development |
| Yarandoo, Australia | 3,250 square meters | Animal Health products |
| **Medical Nutrition** | | |
| Minneapolis, MN | 33,500 square meters (production and R&D facilities) | Medical nutrition products |

| | | |
|---|---|---|
| Osthofen, Germany | 17,000 square meters (production and R&D facilities) | Medical nutrition and Nutrition & Santé products |
| Infant & Baby | | |
| Fremont, MI | 107,000 square meters (production and R&D facilities) | Baby food products |
| CIBA Vision | | |
| Duluth, GA | 9,000 square meters | Vision-related medical devices |

**Figure 58 Facility Listing**

(Novartis 20F 2004)


**Figure 59 Global Inventory by Product**

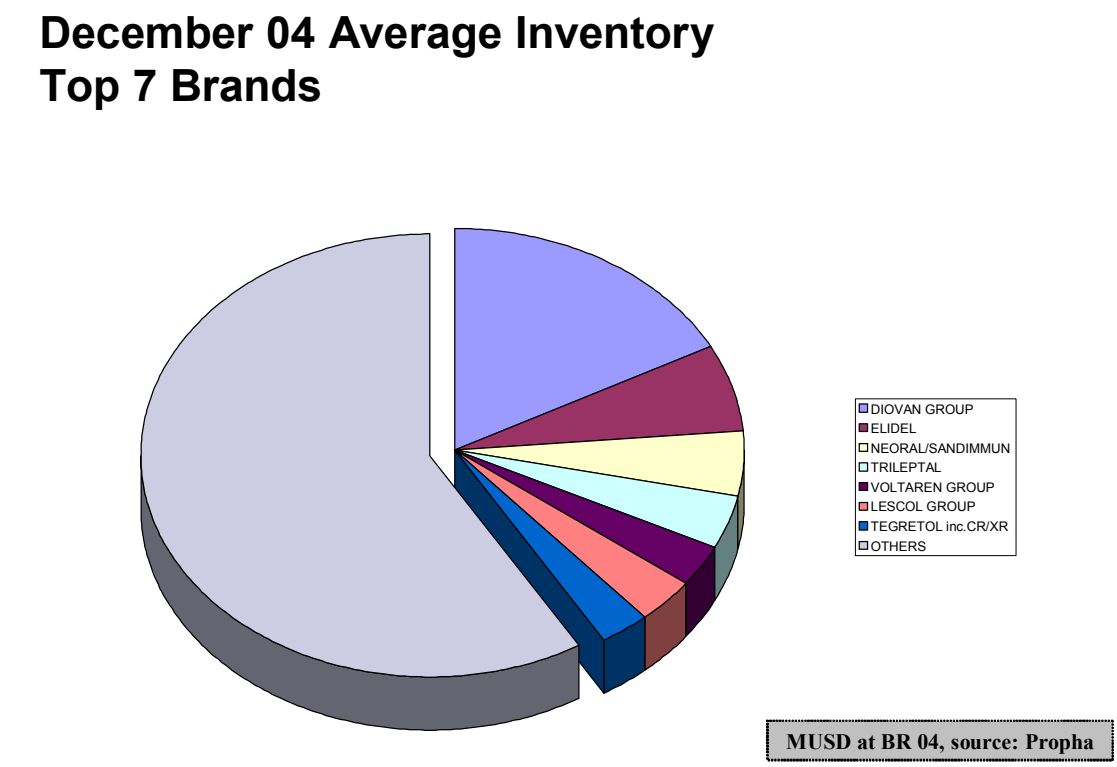



**Figure 60 Average Inventory by Top Brands**

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