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Vellore Institute of Technology

(Deemed to be University under section 3 of UGC Act, 1956)

Retail Marketing – CCA1033

Department of Commerce

FINAL REVIEW DOCUMENT

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APRIL-2019

1. Introduction:

The **pharmaceutical industry** discovers, develops, produces, and markets drugs or pharmaceutical drugs for use as medications to be administered (or self-administered) to patients to cure them, vaccinate them, or alleviate a symptom. Pharmaceutical companies may deal in generic or brand medications and medical devices. They are subject to a variety of laws and regulations that govern the patenting, testing, safety, efficacy and marketing of drugs.

Drug discovery is the process by which potential drugs are discovered or designed. In the past most drugs have been discovered either by isolating the active ingredient from traditional remedies or by serendipitous discovery. Modern biotechnology often focuses on understanding the metabolic pathways related to a disease state or pathogen, and manipulating these pathways using molecular biology or biochemistry. A great deal of early-stage drug discovery has traditionally been carried out by universities and research institutions.

Drug development refers to activities undertaken after a compound is identified as a potential drug in order to establish its suitability as a medication. Objectives of drug development are to determine appropriate formulation and dosing, as well as to establish safety. Research in these areas generally includes a combination of *in vitro* studies, *in vivo* studies, and clinical trials. The cost of late stage development has meant it is usually done by the larger pharmaceutical companies.

Often, large multinational corporations exhibit vertical integration, participating in a broad range of drug discovery and development, manufacturing and quality control, marketing, sales, and distribution. Smaller organizations, on the other hand, often focus on a specific aspect such as discovering drug candidates or developing formulations. Often, collaborative agreements between research organizations and large pharmaceutical companies are formed to explore the potential of new drug substances. More recently, multi-nationals are increasingly relying on contract research organizations to manage drug development.

1. The cost of innovation

Drug discovery and development is very expensive; of all compounds investigated for use in humans only a small fraction are eventually approved in most nations by government appointed medical institutions or boards, who have to approve new drugs before they can be marketed in those countries. In 2010 18 NMEs (New Molecular Entities) were approved and three biologics by the FDA, or 21 in total, which is down from 26 in 2009 and 24 in 2008. On the other hand, there were only 18 approvals in total in 2007 and 22 back in 2006. Since 2001, the Center for Drug Evaluation and Research has averaged 22.9 approvals a year. This approval comes only after heavy investment in pre-clinical development and clinical trials, as well as a commitment to ongoing safety monitoring. Drugs which fail part-way through this process often incur large costs, while generating no revenue in return. If the cost of these failed drugs is taken into account, the cost of developing a successful new drug (new chemical entity, or NCE), has been estimated at about US\$1.3 billion (not including marketing expenses). Professors Light and Lexchin reported in 2012, however, that the rate of approval for new drugs has been a relatively stable average rate of 15 to 25 for decades.

Industry-wide research and investment reached a record \$65.3 billion in 2009. While the cost of research in the U.S. was about \$34.2 billion between 1995 and 2010, revenues rose faster (revenues rose by \$200.4 billion in that time).

A study by the consulting firm Bain & Company reported that the cost for discovering, developing and launching (which factored in marketing and other business expenses) a new drug (along with the prospective drugs that fail) rose over a five-year period to nearly \$1.7 billion in 2003. According to Forbes, by 2010 development costs were between \$4 billion to \$11 billion per drug.

2. Controversies

Due to repeated accusations and findings that some clinical trials conducted or funded by pharmaceutical companies may report only positive results for the preferred medication, the industry has been looked at much more closely by independent groups and government agencies.

In response to specific cases in which unfavorable data from pharmaceutical company-sponsored research was not published, the Pharmaceutical Research and Manufacturers of America have published new guidelines urging companies to report all findings and limit the financial involvement in drug companies of researchers. US congress signed into law a bill which requires phase II and phase III clinical trials to be registered by the sponsor on the clinicaltrials.gov website run by the NIH.

Drug researchers not directly employed by pharmaceutical companies often look to companies for grants, and companies often look to researchers for studies that will make their products look favorable. Sponsored researchers are rewarded by drug companies, for example with support for their conference/symposium costs. Lecture scripts and even journal articles presented by academic researchers may actually be "ghost-written" by pharmaceutical companies.

An investigation by ProPublica found that at least 21 doctors have been paid more than \$500,000 for speeches and consulting by drugs manufacturers since 2009, with half of the top earners working in psychiatry, and about \$2 billion in total paid to doctors for such services. AstraZeneca, Johnson & Johnson and Eli Lilly have paid billions of dollars in federal settlements over allegations that they paid doctors to promote drugs for unapproved uses. Some prominent medical schools have since tightened rules on faculty acceptance of such payments by drug companies.

3. Product Approval

In the United States, new pharmaceutical products must be approved by the Food and Drug Administration (FDA) as being both safe and effective. This process generally involves submission of an Investigational New Drug filing with sufficient pre-clinical data to support proceeding with human trials. Following IND approval, three phases of progressively larger human clinical trials may be conducted. Phase I generally studies toxicity using healthy volunteers. Phase II can include pharmacokinetics and dosing in patients, and Phase III is a very large study of efficacy in the intended patient population. Following the successful completion of phase III testing, a New Drug Application is submitted to the FDA. The FDA review the data and if the product is seen as having a positive benefit-risk assessment, approval to market the product in the US is granted.

A fourth phase of post-approval surveillance is also often required due to the fact that even the largest clinical trials cannot effectively predict the prevalence of rare side-effects. Postmarketing surveillance ensures that after marketing the safety of a drug is monitored closely. In certain instances, its indication may need to be limited to particular patient groups, and in others the substance is withdrawn from the market completely.

The FDA provides information about approved drugs at the Orange Book site.^[90]

In the UK, the Medicines and Healthcare Products Regulatory Agency approves drugs for use, though the evaluation is done by the European Medicines Agency, an agency of the European Union based in London. Normally an approval in the UK and other European countries comes later than one in the USA. Then it is the National Institute for Health and Care Excellence (NICE), for England and Wales, who decides if and how the National Health Service (NHS) will allow (in the sense of paying for) their use. The British National Formulary is the core guide for pharmacists and clinicians.

In many non-US western countries a 'fourth hurdle' of cost effectiveness analysis has developed before new technologies can be provided. This focuses on the efficiency (in terms of the cost per QALY) of the technologies in question rather than their efficacy. In England and Wales NICE decides whether and in what circumstances drugs and technologies will be made available by the NHS, whilst similar arrangements exist with the Scottish Medicines Consortium in Scotland, and the Pharmaceutical Benefits Advisory Committee in Australia. A product must pass the threshold for cost-effectiveness if it is to be approved. Treatments must represent 'value for money' and a net benefit to society.

Top 25 Drug Companies by Sales

Company	Pharma Sales (\$ billion)
Abbott Laboratories	30,40
Amgen	23,32
Astellas	7,390
AstraZeneca	21,45
Baxter International	6,461
Bayer	10,162
Boehringer Ingelheim	13,860
Bristol-Myers Squibb	22,04

Top 25 Drug Companies by Sales

Company	Pharma Sales (\$ billion)
Daiichi Sankyo	6,790
Eisai	4,703
Genentech	7,640
GlaxoSmithKline	38,30
Johnson & Johnson	81,38
Lilly	24,28
Merck & Co	41,37
Merck KGaA	5,643
Novartis	52,67
Novo Nordisk	7,087
Pfizer	53,370
Roche	27,290

Top 25 Drug Companies by Sales

Company	Pharma Sales (\$ billion)
Sanofi-Aventis	40,14
Schering-Plough	8,561
Takeda	8,716
Teva	19,75
Wyeth	1,68

4. Marketing:

Advertising is common in healthcare journals as well as through more mainstream media routes. In some countries, notably the US, they are allowed to advertise directly to the general public. Pharmaceutical companies generally employ sales people (often called 'drug reps' or, an older term, 'detail men') to market directly and personally to physicians and other healthcare providers. In some countries, notably the US, pharmaceutical companies also employ lobbyists to influence politicians. Marketing of prescription drugs in the US is regulated by the federal Prescription Drug Marketing Act of 1987.

a) To healthcare professionals

The book Bad Pharma also discusses the influence of drug representatives, how ghostwriters are employed by the drug companies to write papers for academics to publish, how independent the academic journals really are, how the drug companies finance doctors' continuing education, and how patients' groups are often funded by industry.

b) Direct to consumer advertising

Since the 1980s new methods of marketing for prescription drugs to consumers have become important. Direct-to-consumer media advertising was legalised in the FDA Guidance for Industry on Consumer-Directed Broadcast Advertisements.

5. Controversy about drug marketing and lobbying

There has been increasing controversy surrounding pharmaceutical marketing and influence. There have been accusations and findings of influence on doctors and other health professionals through drug reps including the constant provision of marketing 'gifts' and biased information to health professionals;^[105] highly prevalent advertising in journals and conferences; funding independent healthcare organizations and health promotion campaigns; lobbying physicians and politicians (more than any other industry in the US); sponsorship of medical schools or nurse training; sponsorship of continuing educational events, with influence on the curriculum; and hiring physicians as paid consultants on medical advisory boards.

Some advocacy groups, such as No Free Lunch and All Trials, have criticized the effect of drug marketing to physicians because they say it biases physicians to prescribe the marketed drugs even when others might be cheaper or better for the patient.

6. Regulatory issues

Ben Goldacre has argued that regulators – such as the Medicines and Healthcare products Regulatory Agency (MHRA) in the UK, or the Food and Drug Administration (FDA) in the United States – advance the interests of the drug companies rather than the interests of the public due to revolving door exchange of employees between the regulator and the companies and friendships develop between regulator and company employees. He argues that regulators do not require that new drugs offer an improvement over what is already available, or even that they be particularly effective.

Others have argued that excessive regulation suppresses therapeutic innovation, and that the current cost of regulator-required clinical trials prevents the full exploitation of new genetic and biological knowledge for the treatment of human disease. A 2012 report by the President's Council of Advisors on Science and Technology made several key recommendations to reduce regulatory burdens to new drug development, including

- 1) expanding the FDA's use of accelerated approval processes,
- 2) creating an expedited approval pathway for drugs intended for use in narrowly defined populations, and
- 3) undertaking pilot projects designed to evaluate the feasibility of a new, adaptive drug approval process.^[121]

Pharmaceutical fraud involves deceptions which bring financial gain to a pharmaceutical company. It affects individuals and public and private insurers. There are several different schemes used to defraud the health care system which are particular to the pharmaceutical industry. These include: Good Manufacturing Practice (GMP) Violations, Off Label Marketing, Best Price Fraud, CME Fraud, Medicaid Price Reporting, and Manufactured Compound Drugs. Of this amount \$2.5 billion was recovered through *False Claims Act* cases in FY 2010. Examples of fraud cases include the GlaxoSmithKline \$3 billion settlement, Pfizer \$2.3 billion settlement and Merck & Co. \$650 million settlement. Damages from fraud can be recovered by use of the False Claims Act, most commonly under the qui tam provisions which rewards an individual for being a "whistleblower", or relator (law).

Every major company selling the antipsychotics — Bristol-Myers Squibb, Eli Lilly, Pfizer, AstraZeneca and Johnson & Johnson — has either settled recent government cases, under the False Claims Act, for hundreds of millions of dollars or is currently under investigation for possible health care fraud.

S.No	Product Name	Disease	Price for 10 capsules
1	Allobeta	Urology	100
2	Amantadin Beta	Central Nervous System	120
3	Captobeta	Cardiovascular	100
4	Cefadroxil Beta	Anti-Infective	90
5	Cetirizin Beta	Respiratory	80
6	Glibenbeta	Diabetology	100
7	Ibubeta (M01A1)	Pain Management	90
8	Jod Beta	Hormone	135
9	Loperhoe	Gastro-Intestinal	98

Visited some of the pharmacies around vellore and collected some information about their marketing strategies. The pictures of Pharmacies which I had visited are furnished below

1. Visited MedPlus in vellore and interacted with seller.







7. Business Strategies

The days when the Indian pharmaceutical industry was synonymous with cheap generic drug production are passing. While generics continue to play a major part in the industry's success, many companies have started down the long road of drug discovery, novel product development and pharma services.

With high-quality research, low-cost manufacturing facilities and educated personnel, the Indian pharmaceutical industry presents both a competitive threat and partnering opportunities.

As a significant international industry India is the world's fourth largest producer of pharmaceuticals by volume, accounting for around 8.5% of global production. In value terms, production accounts for around 1.7% of the world total. The Indian pharmaceutical industry directly employs around 600,000 people and is highly fragmented. While there are around 280 large R&D based pharmaceutical companies in India, including multinationals, government-owned and private companies, there are also around 6000 smaller licensed generics manufacturers, and although in reality only around 3500 companies are involved in pharmaceutical production. Most small firms do not have their own production facilities, but operate using the spare capacity of other drug manufacturers.

Pharmaceutical Marketing Strategies: An assortment of limited time methodologies has been utilized to fortify offers of pharmaceutical medications. Customarily, push methods have been the transcendent means used to urge doctors to endorse medications and along these lines increment deals. As of late, the customary push procedure has been supplemented by a drawing technique.

India is developing as the worldwide center for contract research and assembling administrations because of its ease leverage and world class quality norms. The presentation of item patent got some major changes techniques of pcd pharma companies, with the center moving more towards Research and Development. The significant income to the pharmaceutical industry has been increased through fares. Pharmaceutical items are trading to more than 200 nations around the globe.

In this manner Pharmaceutical Marketing Strategies makes a difference:

- To have a sound rivalry
- To expand the client learning
- To have a superior client relationship
- To lessen the underlying advancement costs.

8. TYPES OF PHARMACEUTICAL MARKETING STRATEGIES

Diverse sort of business sectors and distinctive sorts of methods for work is trailed by pcd pharma companies. Indeed, even there is a contrast in considering – essential clients.

1. GENERIC MARKETING

Stockiest or retail counter is an essential client. There is almost no focus toward Doctors and Patients in their promoting system or method. Low edge advertising sort, however, the exchange is done in mass. Mass obtaining repay edges.

2. BRANDED MARKETING

Specialists are the matter of prime concern. Pharma organizations the main target is to recommend its image from specialists. There is little fixation require for patients and merchants. Scientific expert is the additional matter of concern since they can substitute your image with a comparable item. That is the fundamental purpose of substantial cost for marked items since they don't consider the patient's viewpoint in it.

3. PCD OR FRANCHISE MARKETING

In pcd/establishment showcasing, Pharma Franchise gatherings or merchants are prime focused on groups of onlookers. Organizations showcase system move around franchisee. PCD Pharma Franchises costs depend on generation cost of medication.

4. OTC (OVER THE COUNTER PRODUCTS) MARKETING

Each other sort of advertising pcd pharma Companies take after is OTC i.e. over the counter items. Not all pharma items can't be advanced by along these lines, yet beautifiers or torment or skin arrangements – basically be advanced as OTC items by organizations. Showcasing methodology, for the most part, includes notice and advancements – as different divisions organization does.

CONCLUSION

As rivalry is expanding better approaches for promoting Marketing Strategies are evolving. New ways and ideas of showcasing will be created in not so distant future moreover. Each organization and individual ought to change its methodology according to market patterns other insightful he will be out from the market. Then who will accompany diverse approach and with various methods will win.

9. SWOT ANALYSIS

i) Indian pharmaceutical companies – CIPLA

Cipla Limited manufactures and markets prescription drugs, active pharmaceutical ingredients (API) and veterinary products. Cipla generated an increase of 20 percent year-on-year in revenue in the FY 2016. The company is headquartered in Mumbai, India and has strong R&D and manufacturing facilities in India.

a) Strengths in the SWOT Analysis of Cipla:

Strong R&D: Cipla has focused on developing new products as well As improving drug delivery systems and expanding product applications. Cipla has set up strong Research and Development department for the same. The strong R&D facilities are well supported by many manufacturing plants across the cities.

The wide range of Products: Cipla has a broad product portfolio includes APIs and formulations for humans and animal healthcare products. Cipla has over 2000 products in over 65 categories and is constantly looking for expansion of its product portfolio.

Social and technological initiatives: Cipla provides and supports to cancer patients by providing them low-cost medicines and it also initiated a “No touch Breast Scan” which is a step forward to screening technology in India.

Well recognised by various regulatory authorities: Cipla’s products are well recognised by regulatory authorities of India, USA, Germany and the UK etc. this provides credibility to the products of Cipla.

b) Weaknesses in the SWOT Analysis of Cipla :

Lack of significant presence in developed countries: India is Cipla’s major market for revenue generation. Although, Cipla has the presence in over 100 other countries but it has low significance in other developed markets and hence is highly dependent on the Indian market.

Negative campaigning: AIDS healthcare foundation had challenged Cipla over pricing of its drug for AIDS, which keep the drugs out of reach of many in need. This brought a negative publicity for Cipla.

Limited market share: High competition from local as well as multinational pharmaceutical companies limits market share for Cipla and doesn’t allow rapid growth.

c) Opportunities in the SWOT Analysis of Cipla :

Strategic Expansion: In the recent past, Cipla has been expanding its business through initiatives such as investments, partnerships and acquisitions in India as well as in the international market. For instance, Cipla invested in a biotech manufacturing facility in South Africa. It also acquired InvaGen pharmaceuticals in the USA etc.

Treatment of HIV: Cipla offers a wide range of ARV products through C-GA for the treatment of HIV/AIDS in both children and adults. The growing number of patients can be provided cure by Cipla's medicines.

Grow in Emerging markets: Cipla should look forward to growing in emerging markets, especially places where medical infrastructure is improving and hence pharmaceutical is also expected to grow.

d) Threat in the SWOT Analysis of Cipla :

Drug Pricing control methods in India: Governments have influence over pricing of a drug through national health organisations. In India, a new pricing policy under Drug price control has been proposed which can have a negative impact on the industry. Changes in pricing policy affect pharmaceutical companies.

Intense competition in generics industry: There is intense competition in the Indian generics industry from major competitors such as Lupin, Sun Pharma etc. This affects growth potential as well as limits the market share for Cipla.

Fluctuation in Exchange rates: Any changes in the exchange rates affect the company's financial agreement with other countries and thus can affect profitability.

ii) SWOT ANALYSIS OF FOREIGN COMPANY – JOHNSON AND JOHNSON

Johnson & Johnson has always been synonymous with products that gently care for babies. The company has a product that caters to even the minutest needs of a baby and their products range from newborns to toddlers. The company has positioned their baby care product line as gentle and safe and they ensure that they follow the most stringent quality norms in ensuring that the products are safe on delicate skin.

The products under Johnson Baby care line include baby oil, Soaps, shampoos, body scrubs, hair oil, powder, cream, lotion, toothbrush, toothpaste, nappy pads, diaper creams, wet wipes and hair brushes amongst others. Their products are rigorously tested in the most advanced laboratories to ensure that they do not cause any sort of harm to the baby skin and their

formulations have achieved proven success over the years. Johnson & Johnson through a highly sensitive marketing campaign has been able to create a leadership position in the domain of baby care globally.

a) Strengths in the SWOT analysis of Johnson & Johnson

The following are the strengths of Johnson's Baby Products are:

- **Successful diversification:** Johnson & Johnson identified a market in baby care and through a successful set of products diversified into that market. Today the company has products that cater to all needs of babies right from powder to diaper cream.
- **Customer trust:** Babycare is a product line where the primary factor that triggers purchase behavior will be the level of trust that the mother holds for the brand. Johnson & Johnson has been highly successful in winning the trust of their target segment through a series of successful advertisement campaigns and also products that keep up with the promise of the brand.
- **Focus on research:** Johnsons Baby Care products are not just based on customer research. Once the need is determined through customer research, there is a lot of laboratory research as well as testing of products for dermatological safety in the background and these processes ensure that the products that are developed by the company are safe on the skin and also cater to the very need that they promise.
- **Focus on features:** Besides just offering cleanliness and hygiene through their baby care products, Johnson & Johnson also focuses on ensuring that their products create an everlasting bond between the mother and the child. The products are also designed to create multi-sensory experiences in infants which ensures their emotional and cognitive development.
- **Testimonial advertising:** Johnsons Baby care products have always relied on a two-pronged approach to advertising. The first is to showcase the bond between the mother and the child and the second on testimonials from experts like doctors or medical practitioners. This strategy has helped in increasing the trust that customers have on the brand.
- Worldwide sales continue to grow with ongoing plans for further geographic and market solution expansion to sustain sales growth.

- Johnson and Johnson uses a flexible business model that allows to adapt quickly to market changes and trends, focusing on entrepreneurship, problem solving techniques, and innovation.
- This business model has led to numerous innovative medical devices, pharmaceuticals, and other consumer healthcare product releases, further differentiating the company from its competitors.
- Many of its portfolio brands are admired by a wide range of customers who regularly return to these products for reliability, quality, and value.
- The company has enhanced its brand equity through accolades like most reputable company and one of the best companies to work for around the world.

b) Weaknesses in the SWOT analysis of Johnson & Johnson

Weaknesses are used to refer to areas where the business or the brand needs improvement. Some of the key weaknesses of Johnson & Johnson are :

Reduced scope for innovation: In baby care the scope for innovation is limited. Initially, the company focused on creating new kinds of products which were based on needs that were created by the business themselves. However, once those were exhausted the business has been struggling to create new variants and innovation in the products is limited to just new fragrances or flavors.

- **Change of preference to organic products:** Millennial parents are overly concerned about the usage of chemicals in baby care products and with more exposure online these fears are getting worse. This has resulted in many of them choosing to use natural products than purchased ones or they also prefer to use organic products. Johnson & Johnson currently do not have an organic product line in their portfolio.
- **Reduced ability to break into local brands:** In most countries across the world baby care markets are dominated by local players. In India, for example, Johnson & Johnson faces severe heat from Himalaya Baby care line which also has a host of natural products. This is proving to be a huge challenge for the company.
- Pharmaceutical companies have been criticised for their high prices, which many consumers have trouble paying so this has led to concerns over corporate greed.
- There have been recent protests against some of Johnson and Johnson's products, including its pelvic mesh implants, which have led to a damaged reputation.

- The company is dependent on certain products and small niche drugs for the pharmaceutical industry.
- Recent reports that employees of the company have stolen company secrets and information, which has undermined its efforts to create an ethical and responsible workplace.

c) Opportunities in the SWOT analysis of Johnson & Johnson

Some of the opportunities include :

- **Diversification into organic baby care products:** With growing negative publicity on the usage of chemicals in baby care products and their side effects companies like Johnson & Johnson which have established the presence in this market should look at diversifying into organic products or include more natural ingredients in their products in order to survive in the long run.
- With a diverse portfolio of solutions, there are many untapped opportunities for cross-selling products. This includes cross-selling between medical devices, pharmaceuticals, and diagnostics related to care-giving and specific therapies for oncology, diabetes, and other health issues.
- There are opportunities for further acquisitions to strengthen its position, further diversify its product portfolio, expand its territories, add to its resource and research capabilities and grow revenue streams.
- There are new medical therapies and findings that align with some of the company's core capabilities, providing new opportunities for additional market share and leadership.
- The diagnostic market appears to be growing, which positions Johnson and Johnson as a first mover in many applications.
- Some countries are now banning generic medicine, which gives Johnson and Johnson an advantage.

d) Threats in the SWOT analysis of Johnson & Johnson

Threats are those factors in the environment which can be detrimental to the growth of the business. Some of the threats include:

- **Competition:** Johnson's Baby Care Products face a lot of competition from Himalaya Baby Care.
- The company's success with any product release, including medical devices, pharmaceuticals, and healthcare products are often tied to regulatory approval more so than market acceptance. This can also vary from country to country, which further complicates the potential for success with new products.
- There have been many product recalls, which can threaten the company's credibility.
- Generic pharmaceutical products at a much reduced price are a significant threat to Johnson and Johnson.
- U.S. competition has the perception of being more reliable than Johnson and Johnson with many products, especially in light of product recalls and protests about the adverse side effects of some of its products.

Suggestions & Recommendations

- First and foremost sun Pharma should take proper action in order to
- Improve promotion and marketing because only 19% of the doctors prescribe the drugs of sun Pharma.
- Majority of the doctors and pharmacist were able to recall only the two drugs, while sun Pharma comes up with 25- 30 drugs every year, so it needs to promote the other brands too.
- As the majority of the drugs are prescribed by specialist, the specialist should be targeted for the marketing of drugs for certain disease.
- Majority of the doctors have the internet access they should be send information about new drugs through mails.
- Majority of the doctors read "Times Of India" and "Mumbai mirror "
- So these news papers should be used for advertising
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*****THANK YOU*****