Dissertation Proposal

Title:

Does the Pharmaceutical Blockbuster Model Reach Its Bottom-Line? - The Case of Vioxx

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Word count: **2958 words**

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- The Case of VIOXX

Introduction

For the last decade Pharmaceutical Blockbuster product development has driven the pharmaceutical industry. Big pharmaceutical companies have been concentrating on blockbuster medicines production and sales revenue boosting in order to cover their enormous investment on Research & Development. The Blockbuster Model did prove its success by generating tremendous return and pushing the Pharmaceutical industry to a golden age. Until recent years, some blockbuster drugs went busted and Blockbuster Model has revealed its weaknesses. Is the Blockbuster Model still a successful structure to bring investors favourable return or is it running to the end of its bottom-line?

Objectives

It was said that the world largest pharmaceutical companies are now struggling to compensate drug revenue due to blockbuster drug patent expiry and later stage pipeline empty. The experience of working with Eli Lilly Company gave me an opportunity to look into pharmaceutical industry. As it said that top companies might no longer be able to continue appreciating its blockbuster drugs long term benefits.

In 2004, Eli Lilly's blockbuster drug Zyprexa was facing patent challenges. Responding to the trial case Lilly's stock Price was dropping 29 percent to $54.40 in 2004. Following that, Eli Lilly started facing its critical time year 2011 to 2015, by then Zyperxa, Symbyax, Evista, Gemzar and Humalog, these major marketed products' patent will be expired. There would be an estimate loss of 50 percent of 2010 revenue. Another blockbuster drug Prozac would also loss up to 20 percent of revenue.

However, Lilly never lose the faith of Blockbuster Model. It is still trying to maintain the scale of drug researching and development to expand its pipeline. It also adjusted the strategy to improve earning profile by launching more than five products in 2004 in order to prevent the gap between new drug launching and blockbuster drug dying out and hoping that the new launched drug will become another blockbuster success.

In December, a journal article published in McKinsey Quarterly (2004) described the Pharmaceutical Blockbuster Model with the title 'Riding the pharma Rollercoaster' to imply the risk of this model structure. On 30th September 2004, the headline of Merck's global withdrawn of its blockbuster drug VIOXX, due to its side effect of heart attack and strokes, hits pharmaceutical industry. Merck's blockbuster product VIOXX, arthritis and pain medication, which was marketed in more than 80 countries, generated up to $2.5billion worldwide sales in 2003. The moment Merck released this announcement, its stock price dropped from $45.07 to $33, a large 22 percent. This is a perfect example to illustrate the risk that's threatening the big pharmaceutical companies under this blockbuster model.

On one side, some pharmaceutical companies are still holding the faith over Blockbuster Model by adjusting business strategies to survive; while the other side, there still are blockbuster drugs going busted. Evidently there is a huge risk over investing in the Blockbuster Model. However, what is the bottom line of this blockbuster model? Is it running to the end of its golden age or is

it still strongly committable to investors? It is the time to review this Blockbuster Model. To answer these questions, I started looking into related literatures and researches hoping to find the final answer.

Comment 1: The objective is effectively the last sentence of the Introduction paragraph. This is amplified in the 2 questions in the paragraph above. The paragraph below is simply a list of tasks to try and resolve that objective.

My initial approach is: to define Blockbuster Model Structure and to find out its historical successful reasoning and essential requirements; secondly, to define its weaknesses by focusing on top global pharmaceutical companies' common difficulties and pressures; thirdly, to analysis Blockbuster Model by dissecting its structure and to analysis its critical success factor, risks, current threats and future opportunities; Fourthly, to analysis and evaluate current strategies pharmaceutical companies are carried out; Finally, to combine those factors with drug portfolio analysis to define the bottom line of this Blockbuster Model.

Literature Research

Due to the nature of my research objective and the pace of change in the pharmaceutical industry, there is not much information widely availed in textbooks. Therefore my research is mainly based on websites and library databases to obtain online academic journal articles, magazines related to pharmaceutical industry.

Bain Company is a business consultant company, within its publication section, there are a wide range of journal articles across variety of industries including Healthcare Industry. This source was recommended by my previous manager in Eli Lilly Company.

Business Source Premier and Econlit databases are very useful. By typing "Blockbuster"with the following: model, pharma, big pharma, market share, failure or success, combination provided me up to 20 related articles. Using the same searching approach on Google Scholar, I obtained another 17 related articles. Other available internet sources also including Pharmaceutical Executive, McKinsey Quarterly, Economics, Drug discovery today and Wall Street Journals (require internal loan).

Literature Review

Gilbert, Henske & Singh (2003) Rebuilding Big Pharma's Business Model (The Business & Medicine Report, November 2003), briefly defined the blockbuster model as an "approach focuses the majority of a company's investment on creating blockbuster product franchises – that is, brands that achieve global sales of more than $1 billion."

NOTE: The citation to Gilbert … above does not need the title, journal and full date. However, it may be appropriate to include the title if this is particularly relevant in the context – which it is in this case. The journal and full date are not needed.

Previously, "blockbuster model has served the pharmaceutical industry well; generating over 13% annual growth in market capitalization between 1992 and 2002"; building up a large infrastructure around the blockbuster model within in pharmaceutical industry. Moreover, Gilbert, Henske & Singh (2003) added, a successful blockbuster can yield returns 10 -20 times as large as average drug which only can deliver 5% return on investment.

However, blockbuster model contains high uncertainties, requires long term investment and huge cost with enormous risks.

As Rasmussen (2002) pointed out in his paper - Implications of the Business Strategies of Pharmaceutical Companies for Industry Developments in Australia (Centre for Strategic

Economic Studies, March 2002, Pharmaceutical Industry Project, Working Paper No.1) that, "the uncertainty of the discovery process and the potentially huge returns from the discovery of a single drug means that success in the industry depends on a high measure of luck." Therefore, "returns from pharmaceuticals are highly volatile."

He also briefly mentioned blockbuster model's current urgent issues: "existing blockbuster patents expire and expected blockbusters fail to materialize".

Franco & Kaitin (2002) listed several pressures that are threatening current business model: "Uncertainty over pipeline sufficiency"; "Genomics and the promise of personalized medicine"; "increased speed of 'fast follower'"; "reimbursement and cost pressures"; and "tightening of regulatory pressures".

Further more, Gilbert, Henske & Singh (2003) carried out a systematic research and study on current blockbuster model's issues and performance, pointed out that, "the blockbuster business model that underpinned big pharma's success is now irreparably broken, the industry needs a new approach." According to their study, cost of new drug launching has increased to $1.7 billion, while return on investment reduced to 5% only and possibility of achieving 12 percent ROI is reduced from 30% to 15%. There is also a decline on R&D productivities, "Only one compound now reaches the market for every 13 discovered and placed in the pre-clinical trials, compared to one for every eight between 1995 and 2000."

Therefore, they defined four business building blocks which they believe could replace existing business model: "shift from opportunistic to focus"; "Shift from a fully integrated pharma company model (FIPCO) to using partnerships to manage risk and return"; "Shift from science-driven provision of specific drugs to providing customer solutions; shift from a functional to an integrated business organization model".

Evidently, Singh & Gilbert's blockbuster model broken-down theory caused a range of reactions. Thayer (2004) wrote "Blockbuster Model Breaking Down and Pharma industry reaches new sales peak, despite rising costs and bigger challenges for drug R&D." Clough (2004) wrote for the 8th Annual Pharmaceuticals Conference, "Rethinking the Formula [and she questioned]… new business model- the end of an era?" Krauss (2003) questioned, "Has the Pharmaceutical Blockbuster Model Gone Bust?" Clarke (2004) also questioned "Is big pharma's golden era over?" Malek (2004) also stated "the blockbuster is dead, Long living the blockbuster!" and suggested three alternatives approaches: diagnostic-led; single-pill and treatment-platform.

There is still substantial amount of discussions around blockbuster model, its issues and company strategies and so on.

Evidence suggests that blockbuster model has strong dependency on patent protection. Gillin (2002) also mentioned that blockbuster drugs strongly rely on patent protection therefore, "Pharmaceutical companies go to protect patents because even a single day of sales reaps major profits." A direct consequence for those drugs losing patent protection would be the generic issue. "The patent on 47 blockbuster drugs with combined sales of $31 billion will expire before 2005".

Hirschler (2004) reported that companies would use acquisitions and other strategies to build up a significant presence in generic or off-patent medicines.

Venture Capital Journal (2004) suggested that "big pharmaceutical companies are starting to seek more investment deals and partnership opportunities with emerging companies. [The large pharmaceuticals]…are more prone to enter into a deal with a small company to access new products with strong patent protections."

Ainsworth, S.J.(Ed) (2004) also mention a strategic move for "pharmaceutical companies who no longer sees any opportunity to extend patent life on a prescription only product, may opt to

petition FDA for over-the-counter status", which could "help maintain revenue flow on the product for a least a few additional years."

Comment 2: A splendid literature review, wide-ranging but all relevant (to the objective), logically structured and well argued.

Methodology

Semi-Structured Interviews

Bain Company and its followers strongly believe that the Blockbuster Model is broken, and it is time for a change. While, Rasmussen (2002) emphasized that the management literature outlines the efforts that Eli Lilly has made through the 1990s to improve the focus and efficiency of its drug development pipeline for its blockbuster drugs. It shows that Eli Lilly was a strong supporter and believer of Blockbuster Model. However, since there is a huge change within the industry in recent years and more blockbuster model shortcomings have been revealed, what will happen to Lilly's strategy? I listened to the inside story from the industry itself and carried out four semi-structured interviews with managers from four different departments: R&D, Marketing, IT and Finance.

Interviews carried out within Eli Lilly Company managers focused on their understanding of the blockbuster model including the benefits and shortcomings, their future expectation and other affective elements. Interviews were varied according to interviewee's position and roles within the company.

Case study on Merck's withdrawn of VIOXX

Before VIOXX's withdrew out of global market, it was a blockbuster success marketing in 80 countries, taken by 2million people and generating up to $2.5 b sales in 2003. This particular product's life cycle fully reflected blockbuster model's benefits and risk. From its long term investment, approval and launching, and appreciated 4 years patent sales to the time of global withdrawn, "it blew a $2.5 billion hole in Merck's revenues and stirred up a storm of suspicion". (Aftershoxx - Lam 2004).

VIOXX does not only have a huge impact on Merck itself, but also an impact on COX-2s inhibitors, including Pfizer's two blockbuster drugs: Celebrex & Bextra. VIOXX also caused crucial critics to Food & Drug Association for heavily emphasising on pre-marketed products but lacking of after launching monitoring.

By studying on VIOXX case can clearly illustrate the dependency between single blockbuster drug and company's overall performance; high risk of single product dominate company's revenue; importance to increase R&D productivity and drug portfolios. Assuming VIOXX's life cycle will not terminate until its patent expiry, it will also face competition from generics and Merck needs backup strategies to compensate revenue after VIOXX losing patent.

Online Secondary Data

Gilbert, Henske & Singh (2003) (Rebuilding Big Pharma's Business Model) (The Business & Medicine Report) calculated cost of a new drug by factoring commercialized cost – drug launching. From the period of 1995-2000 to the period of 2000 – 2002, the total cost for a new drug getting to the market increased from $1.1billion to $1.7billion, ROI decreased from 9% to 5%, the probability of reaching 12% ROI has been reduced from 30% to 15%.

However this approach defined a ROI decline by comparing a 2 years ROI from the period of 2000-2002, with 5 years ROI from the period of 1995-2000. This is not strong enough to demonstrate the failure of blockbuster model. Decline of ROI could be caused by drug under

performance and ‘market shrinks’; could be caused by short time scale. Besides, any unexpected incidence could make a significant change, typically for recent hot topic regarding bird flu, made normal flu vaccine becoming a blockbuster. Also regarding to R&D and drug launching cost, strategies and new techniques could be introduced to reduce it in order to give a high ROI. For instance, their approach looked at in-house produced drugs only, while many companies start using outsourcing to reduce R&D cost and increase productivities. Finally, their approach did not value those drugs that did not make through clinical trial. According to Augen (2002) that compounds that failed clinical trial because patient subpopulations could not be characterized at a sufficiently detailed level can now be “rescued” and re-evaluated, which means, those drugs might become valued added products.

Comment 3: The critical discussion of the Gilbert, Henske and Singh paper above is interesting but might be better placed in the literature review with a brief reprise here of the aspects directly relevant to the methodology. The detail above seems to interrupt the logical flow of the methodology.

Therefore, I would like to collect online secondary data business consultant companies’ research focusing on drug portfolio. By focus on top pharmaceutical companies’ drug portfolios, understand their potential for future blockbuster drugs, from near term to 2007, to long term to 2010.

Comment 4: The chosen approaches in the methodology make sense but represent a great deal of work. A case on the viability of the blockbuster model could probably be made with a little less material, for example without using the Vioxx case or focussing on the Vioxx case but without the industry analysis.

Data & Information

I have outlined certain area of data I need initially, however, following the development of dissertation itself, more detailed and systematic data will be desired. Therefore, further data & information will be carried out accordingly.

Top Pharmaceutical Companies

Economist(2005), Prescription for change, Economist, 6/18/2005, Vol. 375 Issue 8431, Special section p3-5, 3p, provided a latest list of Big Pharma firms by sales:

A – Company
B – Pharma sales, $bn 2004
C – Market capitalization, $bn: end 2000
D – Market capitalization, $bn: end May 2005

A	B	C	D
Pfizer	51.1	290	207
GlaxoSmithKline	32.8	178	145
Saofi-aventis	27.4	49	128
Johnson & Johnson	24.7	146	200
Merck	23.9	216	71
Novartis	22.9	128	131

A – Company
B – Pharma sales, $bn 2004
C – Market capitalization, $bn: end 2000
D – Market capitalization, $bn: end May 2005

A	B	C	D
AstraZeneca	21.7	89	69
Roche	17.8	91	112
Bristol-Myers Squibb	15.6	146	50
Wyeth	14.3	83	58
Abbott Laboratories	14.3	75	75
Eli Lilly	12.7	105	66
Schering-Plough	6.9	83	29
Bayer	6.4	39	25

Sources: IMS Health; Thomson Datastream

Top Pharmaceutical Companies Drug Portfolios

UBS Investment Research (2005), Global Pharmaceutical – Portfolio Scores, UBS Investment Research, 21 March 2005. The manager from the R&D department I interviewed provided me with this report. It provides extremely value information regarding the top ten pharmaceutical companies, portfolio scores, including generic exposure, growth from in-line, late-stag pipeline portfolio, soft patent risk and Net Portfolio scores. Further more it also including Stock valuations reflective of product portfolio scores. However, I need to tailor data and design an appropriate valuation method to fit with my dissertation research objective.

R&D Productivities

Shaw (2004), Drug Discovery and Development, Reed Business Information, November 1st 2004 stated that: “between 1995 and 2000, one of every eight compounds put in preclinical trials reached the market, compared with just one of every 13 today. Odds of FDA approval of a given drug have dropped to 50% from 73%.” However, companies can now combine in-house produce with outsourcing to increase R& productivities. Also, Rasmussen (2002) mentioned companies use mergers and acquisitions to improve drug development.

Stock Price

I might need to look at the single blockbuster impact on company stock price; for instance, the announcement of VIOXX withdrawn had a direct impact on Merck’s stock price. This could be found from Merck’s website, news website. However for further requirement on other company stock price changes, I need to look at historical prices rather than limited on journals. Datastream would be an ideal tool, however has extreme access limitation. Alternatively, I could use Yahoo.com to look at historical price, disadvantage of using this resource is: it only allow me to look at one company each time, with daily, weekly and monthly price only.

Drug Launching Process & Time Scale

Yanni, M.,(15th Oct 2004), How Drugs get to market, The Star-Ledger, Retrieved 17/11/2004, from noted the process from FDA approval to drug launching: Preclinical Research; Clinical

Studies; Phase II; Phase II; Phase III; Initial Review; The Technical Review Process; Yes or No Decision and Final Steps.

Market Segmentation and Forecast

For general market segmentation and forecast I can get information from industry profiles which I obtained from university library catalogue. Understanding the market segmentation and its growth or decline trend in the near future can help me understand the market environment and limitation. The table below is an example from the United States Pharmaceutical industry profile. It can be seen from the 'percent growth' column that the forecast of Pharmaceutical market value declined from 2003 to 2007, with a slight increase in 2008. This Market trends might have effect on Blockbuster drug on market performance.

Table United States Pharmaceuticals Market Value Forecast: $billion, 2003 – 2008

Year	$ Billion	% Growth
2003	217.5	10.80%
2004	238.1	9.50%
2005	259.3	8.90%
2006	280.7	8.30%
2007	302.1	7.6%
2008	325.2	7.70%
CAGR, 2003 - 2008		**8.4%**

Source: Datamonitor DATAMONITOR

Others

There are other issues I might look at as additionals to expand the research objective. By studying the Merck's VIOXX case, I may also look at similar component COX- 2 drugs on the market. Investigation was carried out after VIOXX's drug safety issue rose in 2004, which have significant impact on Pfizer's blockbuster drugs Celebrex & Bextra. Secondly, FDA (Food and Drug Association) has strong influence in pharmaceutical industry; especially its regulation and drug approval process has strong restriction on drug launching and patent bottom line. Thirdly, VIOXX case also revealed the ethical issue that by knowing VIOXX's side effect of heart attack and strokes in 2000. Without informing the public, Merck Company continued to sell VIOXX for another four years in order to gain huge investment return. Finally, I might briefly mention investor's expectation on pharmaceutical innovation and blockbuster model.

Comment 5: Overall, an impressive, scholarly piece of work on a highly ambitious and challenging topic.

NOTE: The student started on this while on placement and had done quite a bit of background reading before the start of the final academic year. Marks connected with (background) research and understanding of the subject matter were particularly high.

Comment 6: Well presented. Although the language is quite flawed in places this does not significantly detract from being able to understand what is said.

Bibliography

NOTE: The bibliography and Appendix IV – Further reading list total 7 pages. The final dissertation had a bibliography of 9 pages. Thus the student had gathered nearly all the literature eventually used by the proposal stage. This is quite unusual and reflects the amount of time the student spent working before the start of the final year.

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Appendices

Appendix I - Chapter Plan

Appendix II – Timetable

Appendix III - Interview 1

Appendix IV - Further Reading List

Appendix I - Chapter Plan

Chapter 1: Introduction

It will briefly introduce dissertation structure, research objective, methodology and the goal I try to achieve. It will also introduce the case of VIOXX and the background of the Pharmaceutical "Blockbuster model".

Chapter 2: Literature Review

This chapter will cover literatures I reviewed related to Pharmaceutical blockbuster model. It will focus on Singh & Gilbert's research study and their theory.

Chapter 3: Methodology

3.1 Interviews

Four interviews with Eli Lilly Company managers from four different departments provided broad information related to the Blockbuster model from insiders point view.

3.2 Case Study – Merck's VIOXX

Case study focused on Merck's VIOXX global withdrawn. This typical case can demonstrate a blockbuster drug's life cycle from its launching till its dying out the market.

3.3 Secondary Data Collection

Online internet searching for secondary data from recommended sources. In order to support the "blockbuster model" critical factor analysis, this chapter will particularly focus on drug portfolio, R&D scale and drug patent risk.

Chapter 4: Merck's VIOXX

4.1 VIOXX's Life Cycle

Briefly look at VIOXX life cycle from its Approval and Launch to its withdrawn. Information will be based on its annual sales before withdrawn and product side affect.

4.2 Internal Impact

Briefly look the internal impact on Merck's stock price, Market position, and Sales revenue by the withdrawn of VIOXX.

4.3 External Impact

4.3.1 VIOXX's Impact on FDA

The case of VIOXX increased public pressures on FDA (Food & Drug Association) regarding drug safety issues. FDA is tackled for its clinical trial limitation and lacking of monitoring for after launching product.

4.3.2 VIOXX's impact on COX 2 – Product

COX 2 component products have been suspected due to the VIOXX case. Further investigation on blockbuster drugs Celebrex and Bextra caused impact on Pfizer.

Chapter 5: Beyond the VIOXX

5.1 Define Blockbuster Model

Introduce the blockbuster model background and define its model structure and briefly summarize current performance within the industry.

5.2 Blockbuster Products Success & Failure

Briefly illustrate success and failure blockbuster products cost and sales from year 1990 to year 2005.

5.3 Blockbuster Reasoning & Critical Factor Analysis

5.3.1 Blockbuster Reasoning

Analysis blockbuster historical success reasoning from internal companies' quality and external environment.

5.3.2 Critical Factor Analysis

Analysis Blockbuster Model's critical factor, focus on R&D Scale, Soft Patent and Pipeline & Drug Portfolio three areas to define blockbuster model's bottom-line.

5.4 Current Pressures & Difficulties

Objectively analysis exiting model's pressures and difficulties within the industry, combined with the change pace of the industry including, uncertainty over Pipeline sufficiency; patent expiry; increasing R&D and tightening of regulatory pressures.

5.5 Threats

Analysis industry environment to define elements that threatening blockbuster models including, new competitors, new technologies, techniques and challenges; patients and customers desire; distribution network and generic competition

.5.6 Opportunities

Define the opportunities to extent blockbuster model through productivities increasing and new technologies improving; generic medicine could become opportunity rather than threat.

Chapter 6: Others

6.1 FDA

FDA regulation and drug approval process has strong restriction on drug launching and patent bottom line.

6.2 Ethical issue

VIOXX case revealed the ethical issue that by knowing VIOXX's side effect of heart attack and stokes in 2000, Merck Company still continue selling VIOXX for another four years.

6.3 Investor

Briefly look at investor's view pharmaceutical innovation and blockbuster model.

Chapter 7: Conclusion

Summary above issues and conclude the argument of if existing blockbuster model can still move on, if yes, what the bottom line is.

Appendix II – Timetable

Item	Objective	Notes	Time
1	Preparation		
1.0	Dissertation Proposal	Submission	9th Dec 05
1.1	Literature Review	Further literature review & additional reading	19th – 23rd Dec 05
1.2	Methodology	Four semi structured interviews;	last interview will be in 20th Feb 06
		Merck's VIOXX case study and related information collection;	9th - 14th January.
		Online source to obtain secondary data	2nd Jan – 8th Jan 06
1.3	Data Sorting	R&D Scale Data	Data sorting time from 16th Jan – 20th Jan 06
		Patent Risks	
		Drug Portfolio	
		Others	
1.4	Specification	Specify Dissertation structure, format and revise chapter plan	27th – 28th Jan 06
2	Execute		1st Feb 06
2.1	Literature Review	Chapter writing & structuring	1st – 5th Feb 06
2.2	The Case of VIOXX	Writing & Structuring	6th - 8th Feb 06
		Merck's VIOXX	
		Merck Internal Impact	
		External Impact	
		Other similar cases	
2.3	Beyond the VIOXX	Chapter Planning & Structuring	15th Feb 06
2.3.1	Define the Model	Writing & Structuring	17th Feb 06
2.3.2	Blockbuster drug success or failures	Research & Writing	20th – 22nd Feb 06
2.3.3	Blockbuster Reasoning & Critical Success Factor	R & D Scale Analysis	26th - 28th Feb 06
		Soft Patent Risk	
		Drug Portfolio Risk	
2.3.4	Pressures and Difficulties	Structuring & Writing	3rd – 5th Mar 06
2.3.5	Threats & Opportunities		
2.3.6	Companies Strategy	Mergers	

Item	Objective	Notes	Time
	Evaluation	Drug Licensing	6th – 9th Mar 06
		Other Strategies	
2.4	Others	FDA Influence	13th – 15th Mar 06
		Ethical Issues	
		Investors Expectation	
2.5	Conclusion	Structuring & Writing	16th – 17th Mar 06
2.6	Chapter 1- Introduction	Structuring & Writing	18th Mar 06
2.7	Abstract		19th Mar 06
3	Review & Updating		
3.1	First Review Updating	Review with Prof Puff	21st Mar 06
		Self Updating	22nd – 25th Mar 06
3.2	Second Review Updating	Review with Prof Puff	28th Mar 06
		Self Updating	29th – 1st Mar 06
3.3	Final Review	Review with Prof Puff	7th April 06
		Self Updating	8th – 12th April 06
3.4	Break	Break	15th – 26th April 06
3.5	Final Updating	Self Updating	27th – 31st April 06
4	Finishing		
4.0	Submission	Printing & Biding	1st – 2nd May 06
		Submission	3rd May 06

NOTE: The timetable is quite detailed and quite closely linked to the chapter plan. Again, this reflects the amount of time the student had already put in before the start of the final year.

Appendix III - Interview 1

Interview with: * *

Position: * *

Date: 14th June 2005

Time: 15:00 – 16:00

NOTE: Before any interview such as this takes place, the student must get the Ethics Approval Form signed by their supervisor and it must cover the ethical considerations connected with the interview.

Q 1: Government policies have a huge influence in the Pharmaceutical companies; if we look at UK and US respectively, in which way do you think US government or policies has made Pharmaceutical companies easier to compete than UK.

A: Yes, I think there are quite a few differences between UK and US market in terms of Government Policies. The first one I can think is Advertisement. In the US pharmaceutical companies can advertising drugs in public to introduce product to customers directly. However, in the UK, the law restrict company to do so; therefore we only can rely on doctor's prescription.

Recently, US Government has introduced a new tax legislation to allow returning profit from overseas to US in order to develop and expand local business. Cash return to US can contribute companies' capacity and dimension. In US company is free to set drug's price without consider about government line. While in Europe, there are price pressures from Government. Especially the UK government introduces PPRS policy to reduce pharmaceutical company's Marginal profit and drug price in order to control and reduce NHS cost.

Q 2: What advantages or disadvantages do you think European market is having now compared to US Market?

A: As I mentioned in the last question, US market is more attractive because there is no government price control. This is the disadvantage we have in the European Market. There is always some additional cost in UK, considering about Animal Health and other effects.

Other disadvantages could be different currencies, for example UK is in Stirling, and others are in Euros, it will cause difficulties in cash collections and exchange rate. There is another element I want to mention here is "Parallel Import", for example in UK, if we sale drugs in Spain we have to set lower price according to Spain Government policy, however, distributors can import drugs from Spain in lower price and resale in UK in higher price than Spain Market but lower than UK market. However same case happened in US, distributor import drugs from Mexico & Canada and resale in the US market, difference is it has been treated illegal by FDA (Food and Drug Association). However, European Market does have its advantages, the Euro group is bigger than US in terms of amount of countries and European Union is still expanding.

Q 3: Do you know if there are other organisations having impact on Pharmaceutical companies' business processing?

A: Surely in US, FDA the Food and Drug Association has a strong impact on pharmaceutical industry, their speed on drug approval will direct effect drug patent's bottom line. Also strong regulation on manufactures also has put lost pressures on our companies. We have equivalent organisation in Euro, (EMAE), also we have National Clinical & Trial institution, there are still other organisations and parties could effect pharmaceutical company's business processing.

Q 4: What makes a successful pharmaceutical company?

A: There are quite a few core elements contribute a successful Pharmaceutical company, first of all, company has to create products that meet customers' needs. Then, the company itself have an integrity working force, enable to work efficiently and create work efficiency. Key thing in Pharmaceutical company is on R&D, therefore, innovation is extremely important to drug discovery and development. Next element is Sales & Demand Realisation capabilities; turnovers will be generated by sales. Therefore sales capacity is a core area as well. Also first in class medicine treat and the ability to heal deceases all determine if a pharmaceutical company's successes.

Q 5: What do you think of this Pharmaceutical's Blockbuster Mode?

A: In my mind, it is ground situation product with large sales, which drive expectation in future growth, and drive R& D and support the continue growth in making investment on R&D and demand realisation. It enables the company to make commitment to investors, in long term to increase in and out house productivities and capabilities.

Q 6: Do you know how pharmaceutical companies get into this Blockbuster Situation?

A: Well, I think it starts by company discovering the drugs that being desired by large amount of customers, then, meet the markets' needs and satisfied the investors' expectation. Therefore huge revenues have been generated enable the company to continue expanding their investments on R & D to create next blockbuster drugs. Basically, I think this is a long-term life cycle, start from a small snowball, then rolling bigger and bigger.

Q 7: Nowadays, lots big pharmaceutical companies are facing variance of difficulties, however, what are the challenges this blockbuster model has created to big pharmaceutical companies at the moment?

A: I think the challenges are those risks that associated with them. Firstly, R&D addresses medical needs, without new drug discovery & development; company will not stand a growth. Secondly, blockbuster drugs have strong dependencies, especially relying on patent protection. Once patent is challenged before deadline, company will have difficulties to meet the expectations.

Another problem is Price pressures; cheap medicine normally will stand a priority on the market. Also, if the government force companies to reduce blockbuster drugs' price, there will be less turnovers generated. Blockbuster model put company in a strong dependent & risky situation; some companies simply rely on one or two products.

Q 8: What do you think those companies who chose Mergers & Acquisitions to survive this difficult time?

A: Mergers & Acquisition as strategies are likely to be short-term benefit. There are always opportunities on reduce cost and improve R&D. However, in long term, companies still have to rely on R&D to create new components, to produce new drugs. The ability of having new product is the key to survive.

Q 9: Are there any other possible solutions do you think those companies could adapt in order to survive?

A: Yes, surely there are lots strategies, they can use for internal structure adjustment. For example, building company's flexible capacities, by reducing fixed elements, by having contractors rather than permanent employees. Especially in sales forces, recruiting part time employees, to increase sales capacities, also easy to reduce in the future. Companies need to

concentrate on R&D. There are so many ways they can improve it, for example, in house discovery, buy in component or build partnership, enhance technology & innovation, licences new products and so on.

Q 10: Lilly is a strong pipeline pharmaceutical company, what are the key reasons that Lilly can mange to maintain this?

A: Obviously strong pipeline requires a strong foundation. Lilly is managing to keep a strong pipeline, because we have spend a critical mass investment on R&D and manufacture to increase our discovery opportunities and manufacture capacity. We combined in house and out house production, buying in the right products and licensing them instantly.

Q 11: Strong competitions between pharmaceutical companies, kind of push innovation forward, however, during lab discover and innovation, there are bound to have significant cost wastage, why don't they merge their R&D together in order to save cost?

A: First I will not say those costs are wastage. All of those costs spending on R&D are kind of investment, which leads companies' competitions. If you do not have the product, you will lose the market, disappoint the investors. Of course duplicating research always existing in R&D, and they all cost a significant amount of money. That is why even the government is trying to get involved in order to reduce these expenses. However, R&D is the core function; this situation just reflects the nature of the pharmaceutical industry. I don't think mergers will be realistic if the competitions still exist.

Q 12: Which competition elements can easily make a pharma company standing out?

A: There are lots of elements could make a pharma company standing out. However, R&D innovation and Sales & Demand Realisation are two core function areas to determine a pharma company's successes. Of course there are lots other support functions to support those two core functions from products' Research, Commercialise to Launching, for example manufacture, IT, Finance etc.

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