STRATEGIC IMPLEMENTATION ANALYSIS ON
BIOLOGICAL PHARMACEUTICALS AND MARKET
ACCESS IN WESTERN CANADA

by

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ABSTRACT

Biopharmaceuticals are a new class of medication that present numerous challenges to the Canadian healthcare system because of their cost, innovativeness, and logistical challenges. XYZ Inc. Canada is preparing itself for the launch of Rolic. Rolic is a novel treatment for asthma that is costly, useful in a very small market segment, and represents significant logistical challenges for XYZ Inc. These challenges are important for XYZ Inc. Canada to overcome as there are many more biopharmaceutical compounds in its pipeline. Competencies gained in the launching of Rolic are competencies that will be invaluable for the eventual market success of other biopharmaceuticals.

Biopharmaceuticals are a significant contributor to the escalating healthcare costs in Canada. These rising costs have changed both the structure of the pharmaceutical market and the stakeholder group that controls it. XYZ must respond to this new market structure and ensure that the needs of stakeholders are fulfilled.

To better understand the stakeholder group in Canada and its needs, current structure and competencies from the United Kingdom are analyzed. This analysis was compared to the current competencies within XYZ Canada and significant gaps explored. To address these gaps, XYZ Canada must make minor cultural changes within its current market access team. In addition, a formal stakeholder action plan must be implemented with a heavy emphasis on patient and advocacy groups. Finally, third parties will play an
expanded role in the Rolic launch including services for risk-sharing, logistics support, co-pay support, and post-marketing surveillance.
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To my wife Carole and my children Jaime, Scott, Brady, and Kristina. This would have never happened without your loving support.
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EXECUTIVE SUMMARY

Biopharmaceuticals are a new class of medication which present challenges to healthcare systems across the world because of their cost, innovativeness, and different origins in comparison with traditional organic chemistry based pharmaceuticals. XYZ Inc. Canada is contemplating the launch of a biopharmaceutical called Rolic. Rolic is expensive, involves logistical challenges, and is indicated for a very small group of asthmatics. The challenge facing XYZ Inc. is gaining market access in Canadian provinces despite all of these challenges. This is an important challenge for XYZ Inc. to overcome as there are many new biopharmaceutical products in its pipeline. Competencies gained in launching Rolic are competencies that will be invaluable for the launching of other biopharmaceuticals, and their eventual market success. The launch of Rolic is a test of the company’s long term competitiveness.

More specifically, as the populace ages health care costs increase. Furthermore, the relationship between technology and healthcare costs is badly understood but invariably assumed to result in higher costs. These higher costs are making marketing more complex. This is because the market has had to respond to rising costs and change its structure. For example, more public and private payers are demanding cost utility data as part of their evaluation criteria. In addition, patients in many countries are finding that they have to share drug costs with their insurer. In order to properly address the marketing challenges of this new class of drug key stakeholders must be identified. This stakeholder group is in many ways the same as for traditional medication, but there are some important differences and some additions. Above all, as healthcare systems learn to
cope with biotechnology and an ageing population, XYZ Inc. must overtly manage each stakeholder group by addressing their unique needs. This must be done in order for Rolic to be successful and company-wide sustainable competence in this area to be developed.

Canada is not alone in its struggle to assemble a workable product dossier for submission to the regulatory authorities. The United Kingdom is also currently planning their approach for a 2005 Rolic launch. The team structure in the UK is different from that currently being used for market access work in Canada. To date, this structure has helped the UK affiliate achieve market access for very difficult new drug dossiers.

Learning from this alternative system as a strategy, XYZ Inc. Canada should adopt the UK structure and lobby the identified stakeholder groups as a part of the launch. An important part of this launch will include third party services such as risk-sharing, logistics support, post-marketing surveillance, and co-pay support. If executed properly, the Rolic launch will serve as a model for future biopharmaceutical launches.

The implementation of this strategy within the Canadian context does however include some risks. Many internal forces could combine to ensure that the current structure will not change. These forces include the propensity of some to resist change. Specifically, cultural change within the XYZ Inc. executive team as well as the market access team is crucial. If these executives can be convinced that efficient teamwork will provide XYZ Inc. Canada with superior results and help the company compete long-term, then implementing cultural change will be much easier. The bottom line is that this
group is responsible to shareholders, and actions directed at increasing shareholder value will always invoke serious consideration.
1 INTRODUCTION

1.1 Project Outline

Recent advances in genome research and the eventual successful mapping of the genome have aided scientists in advancing a new class of drugs. Biological drugs do not involve traditional pathways for treatment but represent a very novel and innovative way to treat disease. Cancer drugs for example, have traditionally targeted their sometimes toxic mode of action at cancerous cells in the body. The problem with this type of approach is that all cells (including the healthy ones) are affected making the patient weak and side effects intolerable. New Biological drugs such as XYZ Inc.' Caglo target the cancerous cells only, leaving the healthy ones intact. 1 Caglo is the world’s first STI (signal transduction inhibitor) which stops the cells responsible for Myeloid Leukemia from splitting, thus halting the growth of this type of cancer.

These new drugs create challenges for the industry, not just because they act through different pathways. Biopharmaceuticals are challenging because they treat a small proportion of the populace at a relatively high cost. This represents a challenge because most governments and private health plans are experiencing ballooning drug costs and immense pressure to control these costs. These costs need to be justified by any firm seeking market access for a new molecule. Pharmaceutical firms must be able to develop internal competencies geared to successfully justifying these higher drug costs to government and private insurers.
The objective of this project is to develop a meaningful strategic direction for XYZ Inc. in gaining provincial formulary access in Canada for Biological drugs while balancing the needs of both shareholders, patient groups, and government and/or private payers. In devising this strategy, market access competencies will be identified for XYZ Inc. to develop internally. These competencies will assist XYZ Inc. in reaching their ultimate goal, which is a successful product launch and continued sales growth for Rolic. This is a very important goal for XYZ Inc., as its future success depends on learning how to develop and retain markets for biopharmaceuticals. This class of drugs represents the future of healthcare, and XYZ Inc. is striving to be a part of that future.

Chapter one will begin with a description of XYZ Inc. and its corporate strengths and weaknesses. Chapter two will provide an external analysis of the current impact biopharmaceuticals are having on the health-care industry. This analysis will first provide a brief description of the current situation, its affects on the sales and marketing function, and the increased complexity of stakeholders involved. Following this, a comparison will be made between the UK and Canada in terms of how each is dealing with new biopharmaceutical entries to their marketplace. Best practices and strategies from the UK will be compared to the current effort in Canada and any important strategic gaps identified. The goal being to understand the exact nature of these challenges and how they have been managed in a country arguably more advanced in handling them. Subsequent to the external analysis, Chapter three will provide an internal analysis of the XYZ Inc. Canada organization. This analysis will address the current market access and marketing competencies within the Canadian organization paying particular attention to
the current strategy for Rolic. Rolic is the newest biological offering from XYZ Inc. in Canada. Any gaps between what will be needed for success (using the UK example), and current competencies will be identified. Chapter four will identify possible strategies XYZ Inc. Canada could employ to gain crucial market access for biopharmaceuticals. Following these identified strategies, Chapter five will recommend one strategy that XYZ Inc. should employ in Canada when requesting market access for Rolic and other biopharmaceuticals in the pipeline.

1.2  \textbf{XYZ Inc. Pharmaceuticals Introduction}

1.2.1  \textbf{Structure}

XYZ Inc. is a world leader in the development of products to protect and improve human health. It was formed in 1996 from the merger of two companies, namely Zasda and Gica. Headquartered in Zurich Switzerland, this firm employs 78,541 people in over 140 countries. Core business units consist of pharmaceuticals (which consists of primary care, oncology, transplantation, ophthalmics, and mature products) and consumer health (which consists of generics, over the counter medication, eye-care, animal health, medical nutrition, and infant & baby). In terms of size, XYZ Inc. ranks fifth (XYZ Inc. has a 4.38% share of the global pharmaceutical market) in global sales.

Within XYZ Inc., most major financial contributors (countries that contribute significant sales volumes) have their own CEO and Vice-Presidents over major functional areas. These functional areas include finance, legal, marketing, sales, and
administration. Countries that have this type of structure include the United States, Mexico, Canada, Japan, and most EU countries. All of the other countries have a local director that reports to a Vice-President in Zurich. Their finance, legal, marketing, and sales function are administered centrally. Local administration is the only function that has some local control. Thus, major countries employ a de-centralized structure, whereas minor countries use a centralized structure for decision-making.

1.2.2 Decision-Making

Within the countries that are considered to be major financial contributors, functional areas set tactical plans and follow-up, but do not devise or implement strategy. All major decisions regarding product mix, product marketing plans, and required financial results are made in Zurich. For example, Canadian marketing executives must submit their annual marketing plans to Zurich six months before the fiscal year begins. These plans are then revised according to global priorities and then sent back to Canada for implementation in the new year. Finance is another area where Zurich wields significant control. Budgets are sent to Zurich six months before the new year begins and Zurich will approve the LE1 (latest estimates 1) budget. This budget is revised in the spring (LE2) and again in the fall (LE3), based on global financial results. If the global results are poor yet the Canadian ones are good, Canada will be asked to cut expenses to ensure that global results are on track.


1.2.3 Risk Profile

XYZ Inc. does business within the highly visible and often publicly-funded healthcare sector. As such, people’s lives and well-being are often at stake when decisions are made within this industry. It goes without saying that the first priority of many is the health and well-being of themselves, their families, and friends. XYZ Inc. and its competitors must deliver on their therapeutic promises to patients, their physicians, and the insurance firms and governments that fund healthcare. Given all of this, XYZ Inc. does have a strong risk profile to deal with.

Two significant risks face XYZ Inc. First — XYZ Inc. must sustain sales and financial growth in order to fund drug discovery that is becoming more expensive over time. If XYZ Inc. brings innovative medicine to market quicker and successfully (faster time not only to market but faster time to commercial success), it will have time to recover costs within the patent period, maintain cash flow for current expenses, and leverage current financial health to tap the markets for future project funding. The huge risk here involves failure of a product or product-line with respect to human life, and the significant downside in terms of litigation and loss of reputation. XYZ Inc. must ensure that all of its products are promoted properly (within the safety parameters of the medication) and that they are safe (that they have been thoroughly tested in line with government safety regulations). Second — XYZ Inc. must maintain their stellar reputation in order to attract top scientists, joint-venture partners, and investment community dollars. If medications fail on the therapeutic and financial side, scientists will go elsewhere and investment will go to a firm with better financial fundamentals.
1.2.4 Capital Structure

XYZ Inc. is a very conservative company. This conservatism has helped the firm maintain an enviable liquidity position so that XYZ Inc. can merge/purchase/or joint-venture its way to increased market penetration (465 million US dollars spent on acquisitions in 2003). Sales growth for 2003 was 18% over 2002 compared to an industry average of 9% (65% of these sales came from pharmaceuticals, 35% from consumer health). At the end of 2003, the group’s equity position was 30.4 billion US dollars. Net liquidity came out at 7.3 billion US dollars in 2003 (total group sales were 24.9 billion US dollars). Free cash flow during 2003 increased 23% over 2002 to 3.6 billion US dollars based on a net income improvement of 6% over 2002. The current ratio for XYZ Inc. at the end of 2003 was 2.4:1 highlighting a very positive liquidity position on the balance sheet.

This liquidity is very helpful if the firm needs quick access to cash. Both Standard & Poor’s and Moody’s agree on the health of the XYZ Inc. balance sheet as their most recent rating was AAA. XYZ Inc. does have the capability to service its debt and debt servicing costs will be lower than other firms with more leverage. In terms of leverage, the debt to equity ratio in 2003 was 20:1. XYZ Inc. continues to fund operations and future growth through its own cash flow.

1.2.5 Manufacturing

XYZ Inc. manufacturing is performed by internal and external parties. Many product lines where therapeutic specifications are less strict have been farmed out to third parties such as Patheon in North America. Products such as Ledol (cream for Eczema)
are manufactured by Patheon as this cream and its application cannot be life-threatening to the patient. XYZ Inc. has many products like Ledol that have more of a mass-market focus. Internal manufacturing (done in Switzerland, Canada, Germany, Finland, US, Spain, France, Italy, UK, and Austria) is performed for products and product lines with more narrow therapeutic windows. In these cases, more strict control over manufacturing process and outcome is implemented by XYZ Inc. Cancer products and immunosuppressant products (products given to organ transplant patients so their immune system does not reject the organ) would be manufactured in this type of facility.

Economies of scope are evident for XYZ Inc. when deciding where and how to manufacture product. Size of the facility often does not indicate where production will occur – but more importantly, the expertise within the facility and the required controls over production will determine the site chosen for any given product.

1.2.6 Product Strategy
XYZ Inc. operates in the very competitive pharmaceutical sector. Within this sector, survival of a firm depends on their ability to innovate. This drive stems from the patent period granted to each new innovation. As such, Pharmaceutical firms must continually develop innovative medicine in order to maintain cash flow, cover expenses, and grow their therapeutic portfolios.

The product strategy employed by XYZ Inc. in the pharmaceutical sector is a differentiation strategy. Emphasis is placed on developing high quality products with
moderate pricing for use by physicians and surgeons. The emphasis on high quality stems from the high standards expected from health care providers and the government regulators that oversee pharmaceutical approvals. Further pressure for high quality comes from the recent advances in genome research. Scientists are actively attempting to isolate disease to specific genetic coding. Some breakthrough drugs have been discovered that target specific genes minimizing side effects and maximizing drug effectiveness. One such discovery was made by XYZ Inc. when they introduced Caglo to the market in 2002. Caglo targets the cells responsible for Chronic Myeloid Leukemia with a miraculous 95% remission rate. The health-care market is now starting to expect new drug discovery to be more targeted with fewer side effects. On the cost side, XYZ Inc. is pursuing a moderate pricing strategy. Many countries regulate the prices pharmaceutical firms can charge (such as the PMPRB – Patented Medicines Price Review Board in Canada) and XYZ Inc. must comply with these requirements.

1.2.7 Marketing
Many of the recent XYZ Inc. product launches have involved a new compound aimed at a known disease-state, but representing a brand new approach to treatment. This approach is high cost as XYZ Inc. tends to be the first mover in the market. As first mover, a lot of money needs to be spent with physicians and surgeons to change their current standards of practice to fit the requirements of the new drug. This approach is difficult and demands a pioneering spirit from those who develop and implement marketing and sales strategies. There have been many times when a particular tactic was not changing physician practice, and the strategy had to change direction a few months
after launch. A recent example involves the product Melzo which is designed for women suffering from Irritable Bowel Syndrome. This syndrome is made up of numerous symptoms including bloating, stomach pain, and constipation. Many physicians across Canada did not treat the entire spectrum of symptoms but emphasized one or the other in treatment. Often the patient consulted their pharmacist to help them supplement their physician prescribed-treatment with other over the counter medications to cover the rest of their symptoms. XYZ Inc. initially emphasized physician sales calls with their product promotion. Six months into this promotion XYZ Inc. discovered that the pharmacists had a lot more say in what patients were using for this condition. As a result, the entire marketing plan was retooled and targeted at pharmacists. In almost every case, this type of promotion emphasizes a pull tactic with customers.

1.2.8 Labour

Within XYZ Inc., labour hired and deployed tends to be highly skilled. As the industry and its dynamics change very quickly, this skilled labour is deployed in a very flexible manner. Important functional areas within each XYZ Inc. country organization include field sales & management, head office marketing; sales, finance, legal, medical, regulatory, and administrative.

At the field level, entry level sales associates must have a minimum of a Bachelor’s degree in either Commerce or the Sciences. As time goes on, these associates must upgrade their general knowledge of specific scientific areas related to medicine. These courses are usually taken through a centralized medical faculty and the associate
must take and pass one per year at a minimum. Field level managers usually have sales experience in addition to a graduate degree.

In most country-level head offices, associates at all levels must have a bachelors degree geared to their specific area. Many at the higher management levels have graduate degrees and/or PhD’s in their field. Any XYZ Inc. associate working within the Medical area must have an MD as a minimum standard.

All associates must upgrade their product (and therapeutic area) specific skills on an annual basis or as needed whenever XYZ Inc. launches a new product. For example, if two new products are introduced in one year all associates involved in the sales & marketing of those two products must take specific training on the medical area they address.

1.2.9 R&D Expenses

XYZ Inc. invests heavily on in-house and collaborative research with other firms. In 2003, XYZ Inc. spent $3.8 billion (15% of gross sales) US dollars on research representing a 32% increase in expenditures over 2002. This in-house research is carried out in three centres – namely; Boston, Vienna, and Zurich Switzerland. At the end of 2003, XYZ Inc. had 10 new medicines in late stage development and 79 other development projects (64 of which are in Phase II/III or registration). In addition to this, XYZ Inc. is active in twelve self-sponsored scientific foundations spread throughout the world. These foundations involve collaborative research with academia with a specific
emphasis on tropical epidemics and diseases. XYZ Inc. is also actively investing in molecular biology and genetics in a separate venture called the XYZ Inc. Institute for Biomedical Research. Initial capital investments of $500 million were instrumental in getting the office and lab complex in Boston built. Ongoing dollars are being spent to attract top researchers and scientists in genetics and molecular biology.

In addition to in-house research, XYZ Inc. is a pioneer in putting together collaborative deals with external researchers. During the period from 1999 to 2003, XYZ Inc. successfully partnered with external research parties two hundred times. In 2004, there are 342 active collaboration projects underway. Finally, XYZ Inc. is ensuring that the results of this research are plentiful and are entering the market in a timely fashion. Over the past four years, XYZ Inc. has won FDA approval for more than eleven compounds – three times more than its nearest competition. This innovation was the result of internal streamlining of development time by twenty-five percent.

1.2.10  Corporate Governance
Recent developments in the US corporate world have shaken investor confidence in corporate management and the accounting and regulatory bodies that oversee them. Examples such as Enron and WorldCom prompted specific legislation in the US aimed at stopping this type of corporate behaviour. Specifically, the Sarbanes-Oxley act was enacted. In 2003, XYZ Inc. implemented corporate changes to ensure they were in compliance with section 302 of this act. Additional measures are currently being made to ensure that XYZ Inc. will be compliant with section 404 in 2004. In addition to corporate
governance, XYZ Inc. continues to strive to maintain an excellent reputation as a
corporate citizen. In 2003, XYZ Inc. supplied the World Health Organization with all of
their leprosy drug needs. XYZ Inc. has also committed to the World Health Organization
to supply the agencies’ needs for tuberculosis medicine over the next 5 years.

1.3 Summary

All of the preceding variables illustrate how the organizational competencies of
XYZ Inc. help align the current XYZ strategy with the market reality. XYZ is involved
in a market that demands constant healthcare innovation and the XYZ emphasis on a high
quality product priced moderately fits this market reality. This high quality product is
produced within a firm culture that spends extensively on R&D and the retention of
talented researchers. The R&D is funded from within as XYZ employs a very
conservative capital structure ensuring that current cash flow will cover current and
future R&D needs. Finally, the team behind the marketing efforts for the innovative
products employs a pioneering pull strategy. Combined together, the organizational
pieces that are XYZ fit neatly together to ensure that the market that demands highly
innovative products gets them.

XYZ Inc. is a healthy and innovative firm. The extensive R&D expenditures
resulting in a healthy product pipeline summarize the XYZ Inc. commitment to constant
innovation. Yet XYZ Inc. global in Zurich still retains significant control over many
daily functions in all of its country affiliates. Canada is no different, senior officials have
very little room to manoeuvre on major strategic decisions. This organizational structure
and culture might hamper the ability of XYZ Inc. Canada to retool its market access plans to fit the new reality created by biopharmaceuticals. In addition, Rolic cannot be successful if best practices and ideas are not shared between countries. This sharing can only take place if XYZ Inc. Canada leaders feel comfortable looking outside of Zurich for guidance on innovative Rolic launch ideas. This project uses the case of launching Rolic to explore this tension between the centralisation of strategic planning and the dynamism in the local market. Tension that on the one hand highlights the differences between the affiliates and Head Office, and on the other hand showcases the value of sharing ideas and best practices across organizational boundaries. The project explores how this tension might be managed better.
2 EXTERNAL ANALYSIS – HEALTHCARE AND BIOTECHNOLOGY

2.1 Introduction

Economic historian Joel Makyr said;

"The patent system encourages ideas that represent radical departures from accepted practice. This patenting system is important in generating the occasional spectacular breakthrough, one that results from a tremendous investment of resources against a low probability of success."

His defence of the patent system as an engine of industrial discovery is a perfect description of the field of biotechnology. One of the most exciting areas of growth within biotechnology is biopharmaceuticals. The patent system is however accused of making the Pharmaceutical industry too special for the good of the healthcare system. This means that it is critical for companies to successfully launch biopharmaceuticals in a way which balances the needs of all stakeholders. This launch should be done despite their varying agendas and assist them in understanding the role of technology in keeping costs down.

Biopharmaceuticals are complex molecules, created through genetic manipulation of living organisms using gene cloning, gene splicing, or cell fusion. In 2003, biopharmaceuticals accounted for 5% of world prescription sales (which total $300 billion annually). Six of the top selling fifty drugs come from the biopharmaceutical sector. Currently, there are three major markets for this type of compound. The United
compound. The United States, European Union, and Japan account for 46%, 30%, and 17% respectively of the total annual sales of biopharmaceuticals. In terms of new products entering the health-care market, eighteen percent of new drugs currently in development are biopharmaceuticals. The speed of market entry is truly amazing as 570% of biopharmaceuticals currently in use were approved by regulatory bodies over the last six years (Schedule I). See Schedule II for a breakdown of the different therapeutic areas currently under investigation within biopharmaceuticals.

Given the recent and rapid introduction of biopharmaceuticals to the healthcare marketplace, this chapter analyzes how their introduction is changing what it takes to successfully compete in this marketplace. Firstly - a Porter Five Forces analysis reveals how biopharmaceuticals have changed the nature of competition. Then the biopharmaceutical market in the United Kingdom will be analyzed. Specifically, the methods used by the XYZ Inc. affiliate in the UK to deal with their stakeholder groups. Out of this analysis, best practices from the UK will then be applied to the Canadian organization. Finally, in light of the learning from the UK comparison the needs of the Canadian stakeholder groups will be analyzed. Based on this, specific recommendations will be made on how traditional approaches to lobbying efforts with these constituents should change.

2.2 Porter’s five forces

In order to understand how biopharmaceuticals are altering the playing field for drug firms, Porters' five forces of competitiveness will be applied to the pharmaceutical
industry. Particular emphasis will be placed on how biopharmaceutical compounds are changing each of the five forces. This is significant because the ability to either produce or license a biopharmaceutical is changing the competitive ability of individual drug companies. The following outlines the current market reality XYZ Inc. and other potential entrants must face in their quest for profitability;

2.2.1 Threat of new entrants

Traditionally, the threat of new firm entry into the pharmaceutical industry has been relatively low. Net patent protection (after regulatory hurdles have been overcome) is usually 5-10 years, leaving a short time frame for marketing and cost-recovery. Firms have a hard time entering the market as one molecule usually costs up to $1 billion to develop. In order to remain profitable, firms must invest significant monies into annual R&D.

Healthy biotechnology firms have good access to venture capital erasing traditional barriers to entry like R&D. Their size can be considered to be an asset when trying to produce innovation in comparison to “Big Pharma” whose recent merger activity may have created firms too large for innovative culture. The shift in the market from traditional pharmaceuticals to biopharmaceuticals is accelerating the threat of new entry. Traditional firms can alter this dynamic by either developing their own biopharmaceuticals or seeking out licensing deals with a successful partner. Either way, firms must successfully launch biopharmaceuticals however they access them. Firms that
do not adapt will be less competitive and are likely to find themselves as possible takeover targets.

### 2.2.2 Power of Suppliers
The bargaining power of suppliers within the pharmaceutical industry has traditionally been low to moderate. Recently, pharmaceutical firms are becoming beholden to the bargaining power of scientists and lab chemists that specialize in different areas such as Oncology. These specialists often work within the biopharmaceutical industry, which is an industry often relied upon for new product innovation. As such, the bargaining power of this group because of the recent surge of biopharmaceuticals has risen dramatically. Firms that do not have the financial resources to pay for their services may see their new product pipeline dry up.

### 2.2.3 Power of Buyers
Within the pharmaceutical sector, buyers have increased the bargaining power from low to moderate to high as the market has changed significantly in recent years. Most drug use occurs in older populations, and the percentage of the population that is over 55 is growing due to the baby boom. Given this, the managed care organizations and government bodies that fund drug use are starting to see huge strains on their annual drug budgets. Any market access file sent to these authorities must have a strong cost utility component. These bodies have the power over drug coverage, and all of their cost utility requirements must be met. In addition, most biopharmaceuticals are injectable and must be administered in a hospital setting. Hospitals and the governments that fund this
use exercise a lot more buying power than individual patients. That said individual patients are gaining power through access to information on the web. Because of this access, patient advocacy groups are becoming a force to be reckoned with.

2.2.4 **Availability of Substitutes**

The availability of substitutes for the pharmaceutical industry is moderate. Generally, most industrialized countries grant patents giving the firm up to twenty-five years of exclusive marketing of their drug. After this term, generic copies are usually quick to market. Biopharmaceuticals are a different story. These molecules are expensive to manufacture and generally require costly logistics. Given this, generic manufacturers may not be lining up to develop copies. Biopharmaceuticals may give their marketers more years of sales growth.

2.2.5 **Competitive Rivalry**

Within the pharmaceutical industry, rivalry is moderate to high. Current industry growth has been moderate (9% in 2003) and each firm has a renewed focus on market share. In addition, firms in this industry have a high fixed cost load to contend with (large sales forces). Pharmaceutical firms marketing biopharmaceuticals tend to see less rivalry within the given particular therapeutic area. This is because many biopharmaceuticals are based on patented genetic data and replication is close to impossible. Given this, firms may be tempted to charge higher prices given the decrease in rivalry.
2.2.6 **Porter Summary**

Biopharmaceutical products have made the pharmaceutical industry more competitive. In order to survive, firms must develop internal competencies that enhance their ability to get this new type of drug to market. If they do, they may enjoy better profits for a longer period of time as well as corporate recognition for helping healthcare systems manage these new products. If they do not, the may see other firms moving ahead of them as these other firms recognized this important market trend and adapted accordingly. The following details two specific changes most relevant to firms that are considering the internal development of biopharmaceutical competencies.

2.3 **How Technology is changing Healthcare**

One of the most striking things about biopharmaceuticals is the rate at which this science is moving forward. This speed is arguably faster than in any other area in the history of healthcare including the introduction of antibiotics. Society and its institutions are having a hard time keeping up with this change. Given this, developing a competence for launching this type of product is one that will reap significant rewards well into the future.

Current biopharmaceutical research areas such as Xenotransplantation, Stem Cells, and Gene Therapy are moving ahead at full speed. Scientists within these areas have developed cloned animals, have grown specific organs within animals for human transplant, and have patented many human genetic DNA sequences. Of course, this is healthcare and the advances are moving into areas that make some uncomfortable.
Specifically, using stem cell technology to grow living cells or fertilizing females with embryos that have certain desirable traits make many feel uneasy. People in general do not see it is necessary to replicate the perceived magic that is the creation of life. Conversely, they do not see the necessity of using organs grown within pigs to prolong it.

Because this technology is so new and fast moving, two significant challenges face governments and regulators when it comes to bioscience. First – the expenses required to discover, test, and produce these drugs are extremely high. These costs are often reflected in the retail price of the drug which can be prohibitive. For example, typical costs \(^5\) per member per month for many managed care organizations in the United States are $20 to $30 per month. In 2004, US-based managed care organizations estimate that these monthly costs will increase by $2.50 to $7.50 per patient per month because of the influx of biopharmaceuticals into the market. (Schedules I,II,& III). Combine this expense with the small group of people who can benefit from these advances, and the pressure on governments in trying to justify spending scarce resources on these therapies is immense. Second – these therapies represent radical new approaches to medical treatment. Regulators the world over are scrambling to put together procedures and protocols to test the safety of these drugs, let alone understand their exact role in cost control and in society.

In Canada for example, the \(^6\) Biologics and Genetic Therapies Directorate is charged with the responsibility of ensuring that the drugs are safe, effective and that their manufacture is properly managed. In Europe, the European evaluation agency for the
The rush to regulate molecules designed for ethically sensitive areas has produced some confusing results. For example, Stem Cell research is an area that has produced its fair share of controversy. Stem cells are the first cells that arise from a fertilized human egg. This cell can divide repeatedly and specialize into any type of cell type for any human function (i.e. liver or kidney). This type of cell is extremely valuable for researchers that want to test certain types of therapies on specific organs or cells. In essence, they are replicating drug efficacy on living cells. In addition, this type of tool allows the researcher to effectively clone an embryo. The controversy comes from the source of stem cells. In some cases, these cells were derived from aborted foetuses. Many groups have complained about the source of these cells and their possible cloning application. As a result, different countries have responded with stem cell research guidelines or regulations.

The problem with these regulations is that they lack consistency from country to country. For example, Canadian authorities have imposed a moratorium on human embryo cloning while those in the UK are allowing cloning for embryos that are less than two weeks old. As for the source of stem cells, Canadian authorities have stated that embryos can be created for the purpose of harvesting stem cells but excess embryos from
in vitro fertilization procedures should be used instead. In the United States, the source of the stem cells is not the issue yet the firms participating in stem cell research cannot receive federal funding unless they pass stringent guidelines. Dealing with and learning from these different national responses to technology and healthcare will be crucial.

Bioscience is bringing radical new discovery to the market at a rapid pace. Regulators are trying to keep pace but are having difficulty doing so. The result has been a patchwork of regulatory bodies and rulings that varies from country to country. Government needs organized groups that it can turn to for unbiased and informative advice. Stakeholders and the constituents they serve can, and should become that important information source. Pharmaceutical firms are starting to discover that stakeholder groups are an important avenue for their marketing efforts.

2.4 Effects on Sales and Marketing

For XYZ Inc. and others, one of the largest roadblocks to effectively marketing biopharmaceuticals is market access for these new compounds. Private insurers, HMOs, and governments are seeing their drug budgets being stretched to the limit. The new compounds are entering the market so quickly, there is no time to understand how best to introduce these new products into the system. As a result, many are taking a harder look at the drugs they approve and cover for their clients. The high costs of biological drugs are only adding fuel to a fire that is already burning. In 1990, pharmaceutical costs represented \(^4\) 11.3\% of global health care budgets. In the year 2000, this percentage has ballooned to 15.5\% with no end in sight. As the aged portion of the global population
increases, the amount of money required to keep this group alive grows. Many countries have responded by implementing cost control legislation.

In Canada for example, the Patented Medicine Price Review Board was established in 1987. This body regulates the prices pharmaceutical and biotech firms can charge for newly approved drugs. In the case of breakthrough drugs (or those offering the populace substantial benefit including biopharmaceuticals), prices charged to Canadians must be equivalent to the median price charged for the same drug in other countries (some EU countries and the USA). In addition; two Canadian provinces, Australia, New Zealand, Finland, France, UK, Italy, Norway, the Netherlands, and several US-based managed care groups (i.e. Blue Cross, Blue Shield) have instituted mandatory cost-effectiveness guidelines before they will consider a new product dossier.

A recent example of the high cost of biopharmaceuticals and its limiting effects on sales and marketing played out in the UK recently. Myriad genetics has recently applied for an EU patent on the breast cancer gene BRCA1 including all therapeutic and diagnostic applications resulting from this discovery. The National Health Service in the UK has strongly opposed this patent as they feel such a patent will place a significant strain on its annual budget. In the United States, Myriad charges $2,400 (US dollars) for the first breast cancer screening test with an additional $500 being charged for any subsequent tests. The National Health Service charges that if the EU grants Myriad a patent, their breast cancer screening costs will balloon out of control.
A second barrier to effective marketing of biopharmaceuticals involves their unknown benefit to society. For example, the United States is currently not granting patents for DNA sequencing. The National Institute of health is questioning the "utility" of a DNA patent to the public good. This literal translation of the patent law in the face of new technology means promising therapy may not come to market. In this case, discoverers of novel DNA sequencing are turning to the EU where such patents are being granted on a regular basis. By taking the moral high ground, regulators in the United States are moving important biotechnology discovery to the EU.

Expensive biopharmaceuticals have put pressure on health care dollars and governments have responded by implementing strict cost control legislation. In addition, some countries are making life more difficult for firms to get a patent granted for biopharmaceutical discovery. The result is a severe limitation on what firms can do to recover their extensive R&D costs. Since traditional marketing is becoming more limited, firms like XYZ Inc. must turn to other methods for market penetration. In the case of Caglo, this is exactly what happened. A prominent Oncologist named Rama Rowbotham had a wife with chronic myeloid leukemia (the disease Caglo treats) and he had attended a meeting where the phase I results of Caglo were presented. Within months, these findings were on the website (thanks to Rama) dedicated to leukemia patients. A few months after that, a petition with 3,030 names on it was sent to XYZ Inc. in Zurich from the CML group. This petition demanded that XYZ Inc. expand its phase I and II trials so that more CML patients could be treated. This action eventually snowballed into an avalanche of advocacy on behalf of this drug. The result was that Caglo received FDA
approval three years sooner than any other drug approval in history. Surely, the right
efforts with the right stakeholder groups can help XYZ Inc. gain market access given the
myriad of current limitations in place.

The importance of stakeholder groups cannot be underestimated. They are very
motivated to keep up with the rapid advance of biopharmaceutical research as its
outcome will have a profound impact on their constituents. Within pharmaceutical firms,
sales and marketing functions also have a vested interest in keeping up with recent
research. As we have seen, in many cases this is not happening. The next step of this
analysis is to look at a country that has taken in relative terms an innovative approach to
the challenges of biopharmaceutical growth. XYZ Inc.' response in the United Kingdom
will be analyzed and its competencies uncovered with the goal of learning from this
group and applying these learning's to Canada.

2.5 The United Kingdom and Canada – a comparison

2.5.1 Introduction

We have learned that biopharmaceuticals have changed the way the game is
played for many firms. Health care itself has changed, so the marketing required has also
changed. In particular, Canadian managers need to look for novel ways and methods for
gaining market access for Rolic. The next step of this analysis is to look outside the
borders of Canada for expertise or structure that could help Canada with their Rolic
launch. The United Kingdom was chosen because of the similarities in government and
healthcare funding between the two countries. With these similarities, theoretically best practices learned from the UK could be applied to the Canadian organization.

At present, there are 400 biotechnology firms in the UK employing approximately 19,000 people. These firms are clustered in the Cambridge, London, and Oxford areas. Overall, the biopharmaceutical industry in the UK is number two in sales globally behind the United States. These sales contribute .6% of total UK GDP and 3% of manufacturing GDP. Annual R&D expenditures in the United Kingdom are about 3.75 billion pounds which represents 20% of total annual R&D Expenditures in the UK. Half of publicly traded biopharmaceutical firms in the European Union are UK-based and these firms represent 2/3 of total market capitalization for biopharmaceuticals in the EU.

2.5.2 Response to Emerging Segments

Within biopharmaceuticals, the emerging areas of research are Xenotransplantation, Stem cell research, and Gene therapy. For each emerging market, the UK has set up regulatory bodies to deal with the resulting market entry issues. For example, the UK has set up the Xenotransplantation regulatory authority that provides ethical guidelines for market entry of such products. In Canada, no such body exists. The Human fertilization and embryology act in the UK covers stem cell research specifically allowing for embryo cloning of embryos that are greater than two weeks old. Canadian legislative bodies are silent on stem cell research and have merely implemented a moratorium on human embryo cloning. Gene therapy is an area where Canada is actively looking at the ethics of research and providing regulation and guidelines. The
Biologic and Genetic therapeutics directorate regulates this research. The UK also regulates this research through the Gene therapy advisory committee.

Both Canada and the United Kingdom do regulate the emerging areas of biopharmaceutical research, with the UK having a significant lead in their willingness to address regulation. Overall, these differences do mirror a patent difference between North America and Europe. Many North American regulators get hung up on the “utility” sections in their patent legislation. They have become reluctant to grant patent rights to biopharmaceuticals where the overall utility to human health has not been proven conclusively. There is a huge North American concern that some new technologies will undermine the public health system by being too costly for the system to handle. The Europeans have taken a different stand, requiring that all new biopharmaceutical patent applications prove public utility on ethical grounds (Article 53 of the European Patent convention). In other words, as long as the ethical benefits outweigh the ethical costs then the patent will be granted. The only way a biopharmaceutical patent will be rejected in the EU is if significant environmental harm can be proven. This difference in patent philosophy between the two continents has resulted in a movement of patent applications away from North America to the European community. There is a real brain drain in leading edge biopharmaceutical patent development away from North America.
2.5.3 **Current Industry Health – United Kingdom**

According to recent research, biotechnology is a sector in which internationalization is occurring at a rapid pace. This is because the sources fuelling industry growth are international in nature. These sources include important inputs such as finance, knowledge, and legal advice. Because of this, most biopharmaceutical firms must look to outside sources for many important inputs in their early growth phases. This trend is particularly true for both Canada and the United Kingdom. Both firms have relatively small domestic markets and both must rely on international expertise in research, development, and financing for their continued growth. Contrast this with biopharmaceutical firms in the United States that have easy access to a large and homogenous market, larger capital pools, and world-class expertise clustered in the Boston and San Francisco areas.

Traditional theories of internationalization espouse that internationalization occurs because;

- the firm desires to increase its customer base
- the firm is successful in its domestic market
- there is surplus of internal resources that can be redirected

Contrast this with the reason many biopharmaceutical firms tend to expand their operations into the international arena. These reasons include;

- the firm has a scarcity of crucial internal resources
- the firm must endure long and expensive product development cycles
- the firm has a strong desire to access complementary resources elsewhere
-the domestic market has an inability to provide favourable conditions for growth.

The second last point outlining the drive for internationalization in the biopharmaceutical arena is very descriptive of the reality facing firms in the United Kingdom. In a survey sent out to 14 UK-based biopharmaceutical firms in the spring of 2001, 59% of respondents (360 structured surveys were sent out with a 31.66% response rate) cited “accessing complementary resources” as their primary reason for going international. Of these, 81.6% are engaged in cross border research, 79.8% in international exchanges of information, and 69.3% in fund sourcing.

In addition to their quest for international pools of capital and expertise, UK-based biotech firms must contend with a myriad of government regulations and intellectual property protection differences in the EU market. The introduction of the EMEA was supposed to eliminate these barriers, yet according to many senior policy regulators working in Europe the need for a local country presence is still needed. In other words, UK-based biopharmaceutical firms can submit their dossiers to the EMEA for regulatory approval but the need is still there to stick-handle product approvals within individual EU countries. Given this, it makes sense to pursue markets where the amount of regulatory tape is minimal. Both the US and Japan would fit this description yet they also pose a challenge for new molecules. Japan and the US are the fastest-growing in terms of biopharmaceutical use, yet these markets are also extremely competitive.
Despite the obstacles present, British biotechnology roared off to an aggressive start in the mid 1990s with 166 UK-based biotechnology firms raising nearly 878 million pounds on the UK exchange. Nearly half of this was raised by four firms - namely Celltech, Porton, British Biotechnology, and Xenova. All of this money was raised despite the fact that none of these firms had a marketable product or profits. The money raised came from the confidence investor’s had in an important asset - senior management. Other biotech launches followed closely with firms like Cantab, Scotia Holdings, Celsis, and Chiroscience. This flurry of activity was followed by a sharp correction in the fortunes of some firms. Porton went up for sale in the late 1990s, and Scotia Holdings applied for creditor protection some years later in 2001. In 1999, Celltech and Chiroscience announced that they would be merging. Many firms were feeling the cash crunch as their development activities were not producing tangible results quickly enough. They needed to either merge, look for external sources of funding, or file for bankruptcy protection. According to many observers, this correction in the UK biotech industry made it stronger. UK firms are currently expanding and embracing internationalization by forming strategic alliances with firms like Hoffmann-La Roche, Monsanto, and Genentech. These alliances are injecting much needed cash, ideas, and country specific marketing expertise into UK firms.

2.5.4 The Current regulatory system in the United Kingdom

All biological molecule dossiers submitted after 1998 must go through the central European regulatory authority - the EMEA. Biopharmaceutical firms can choose one of two options available - the centralized route or the mutual recognition route. The
centralized route means the EMEA evaluates the dossier on behalf of all EMEA member countries and the resulting approval applies to all. The mutual recognition route means that the file is evaluated for entrance into just one member country. If the file is approved in Holland for example, then the biopharmaceutical firm will then approach other member countries asking for mutual recognition of Holland’s approval. Both approval routes require a reference member state (country sponsors the file) and a co-reference state (a co-sponsor). In many cases, the mutual recognition route is preferred for files where the sponsoring firm expects a lot of questions on the submission. In the case of biologicals that often have complicated submissions, most firms opt to pursue the mutual recognition route.

Once a biopharmaceutical is approved for marketing in the UK either through the centralized or mutual recognition routes, a couple of hurdles remain. The Medicine control agency (which is very similar to the Therapeutic Products Directorate in Canada) rubber stamps the approval for the United Kingdom. This rubber stamp indicates the drug being looked at is prescribable for the United Kingdom populace. After the MCA rubber stamp, a more rigorous evaluation occurs at the National Institute for Clinical Effectiveness (NICE). This body makes a judgement call as to whether the molecule is a valuable medicine from a clinical and cost point of view. One of the main criteria used by this body to evaluate medicine is the cost per quality measure. This means that each drug is evaluated in terms of its cost per increase of adjusted life years per patient. This data is then compared with the data from a drug called the active comparator. The active comparator is the drug or group of drugs that represent the current standard of care in the
UK. This approach differs significantly from the evidence required by the US-based FDA. In order to obtain drug approval in the United States, firms must produce clinical data that shows drug improvement in patients over placebo. If this data is statistically robust as evidenced by sound p-values, then the FDA often approves the submission.

The Canadian equivalent of the NICE review against an active comparator occurs at the common drug review (CDR) level. The common drug review looks at both the clinical and cost data of a new dossier submission, and then either approves or rejects it for drug plan coverage in Canada. Australia is also currently employing a drug review process similar to the CDR in Canada and NICE in the United Kingdom.

If NICE delivers a positive review of a biopharmaceutical, then the next step is for the Primary Care Trusts (PCT) to cover the drug. The United Kingdom is subdivided into many PCTs based mainly on geography or population. PCTs are funded by government and run as a non-profit deliverer of health care. PCTs are the main health-provider in the United Kingdom and include a network of physicians that sub-contract to hospitals for services. Each PCT is run by a board comprised of health professionals in the area. If the NICE review is positive, many PCTs will fund the medication for use within their area. On the other hand, if the NICE review is negative then many PCTs will opt out of molecule use making UK market penetration for the drug very difficult.

If the molecule is approved by NICE in the United Kingdom, this body places no restrictions on the price a pharmaceutical firm can charge. Pricing freedom then, is
similar to the situation in the United States where no price controls for biopharmaceuticals are in effect. Given this, the two markets biopharmaceutical firms enter first are the United States and the United Kingdom as they allow pricing freedom and access to a very large populace. Canada, on the other hand has strict pricing controls implemented on each new molecule by the Patented Medicine Pricing Review Board (PMPRB).

2.5.5 Lessons Learned from the United Kingdom-Structure and Access

Like Canada, the United Kingdom has Medical, DRA (department of regulatory affairs, and HP (health policy) departments that all play a crucial role in putting product dossiers together. One difference between the two is a large department in the UK called the Market Access group. This group consists of 70-80 people whose main focus is market access for new molecules. No such group exists in Canada as HP, sales, and marketing must perform needed tasks.

The UK market access group has four main functions;

- the Health Technology Appraisal team compiles pharmacoeconomic data for NICE submissions.
- the New Product Marketing team prepares strategies for new drug marketing.
- the KOL development team prepares plans and tactics aimed at grooming Key Opinion Leaders (product champions) for a new launch.
- the Health Care team calls on PCT’s to ensure they list newly approved drugs.
The salient competencies of this group are important to any market access challenge. Specifically, this group is currently formalizing a standard operating procedure for a client influence plan. This plan includes all required external contact points (patient groups, ministerial leaders, clinician bodies) and assigned internal personnel to facilitate market access before and after a successful NICE submission. A second competency of this group is their ability to convince marketing personnel to narrow their focus for new product submissions. A recent example will compare this competency to the current situation in Canada. XYZ Inc.' Ledol is a product indicated for treatment of eczema in adults and children. Ledol has very few provincial listings as the marketing group wanted to gain the entire market for eczema. The market access group in the UK knew this would not be possible given the clinical data available for NICE submission. They knew that the cost per quality measure would not be good enough for a UK listing. Instead, they convinced marketing that the cost/utility data for a subgroup (kids with moderate facial eczema) was better. As a result, this group was the one targeted in the NICE submission and the approval for Ledol was just announced. In this case, the structure employed in the UK (the market access group) and its competency was the difference between Ledol being listed in the UK and not in all Canadian jurisdictions. Added to this, the formalized influence plan within this group was also critical to the successful Ledol listing. NICE personnel will request formal submissions from clinician bodies when considering dossier approval. In the case of Ledol, XYZ Inc. market access personnel were able to successfully lobby four important groups influencing the content of their NICE submissions. These groups were; British Association of Dermatology, National Eczema society, Royal College of General Practitioners, and the Primary Care
2.5.6 Lessons learned from the United Kingdom – Structure & Pricing

The existence of the market access team does not mean that the pricing decision is easier in the UK. Both XYZ Inc. Canada and UK are limited to the pricing instructions received from head office in Zurich for any new product. The difference is in the flexibility employed by the market access team when making their NICE submission. Knowing that they cannot change the price, the UK team looks for a patient subgroup for which the cost utility data is very positive. (NICE has very restrictive criteria for dossier approval – Table 1);

Table 1 – Nice Cost Per Quality Parameters

<table>
<thead>
<tr>
<th>Cost per quality for drug</th>
<th>Dossier approved</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 30,000 pounds</td>
<td>Yes</td>
</tr>
<tr>
<td>20,000 – 30,000 pounds</td>
<td>Maybe</td>
</tr>
<tr>
<td>&gt; 30,000 pounds</td>
<td>No</td>
</tr>
</tbody>
</table>

This sub-group then becomes the basis for their NICE submission with a higher probability of success. Some recent Canadian dossiers did not successfully identify a subgroup and listing became a challenge.
2.5.7 **Canadian Comparison**

Any biopharmaceutical wanting to access the Canadian market must get initial approval from the Biologic and Genetic Therapeutics directorate. This initial approval of drug prescribability is similar to the EMEA review in Europe. In Canada, the next step involves the Common Drug Review which is modelled after NICE in the UK. The CDR was instituted in September of 2003, officially centralizing the market access point for biopharmaceuticals. The Canadian Coordinating Office for Health Technology Assessment (CCOHTA) is the body that introduced the Common Drug Review (CDR) to the Canadian marketplace. The CDR mandate is to evaluate new product submissions and provide listing recommendations for publicly funded drug benefit plans. Prior to CDR, each province had an expert committee evaluate each new product dossier and make recommendations on whether the product should be listed.

Most provinces will now use the CDR ruling to decide whether or not to list a new product. The only decision now made at the provincial level is how much product use should be funded if the CDR ruling is positive. For example, if the CDR recommends listing some provinces will restrict the funding of the molecule by instituting strict approval criteria for patients requiring the drug. These restricted listings have been instituted because many newer drugs are costly and many provincial health ministries are seeing their budgets frozen or restricted.
To date, the CDR has reviewed submissions for five biopharmaceuticals and recommended only three for provincial plan coverage. The drugs are Kineret, Enbrel, and Remicade and all three are indicated for Rheumatoid Arthritis. Provincial listing agreements vary from province to province, but all provide significant restrictions to patients requesting coverage. In Alberta for example, Alberta Health and Wellness will cover these drugs only if the following restrictive criteria are met;

- Patients are eligible for drug use only if they have tried other therapy (namely Methotrexate and Leflunomide for Kineret) and have seen no significant improvement.
- The drug must be initiated by a specialist in Rheumatology who agrees to actively and consistently participate in a post-marketing surveillance study. The patients must also consent to their participation in this study.
- Initial coverage for patients will be restricted to 8 weeks worth of therapy. For continued coverage beyond 8 weeks (but no longer than 12 weeks) the patients must be assessed by their specialist and meet specific “responder” criteria. If they meet the criteria, then coverage for drug use will be extended for a period of six months. After six months, the patients must again be assessed by their specialist and the specialist must again confirm “patient response”. If such response is confirmed, another six months worth of therapy will be approved. This six month cycle will continue as long as the patients are on the drug.
Canadian provincial bodies are basing some of their recent access decisions for biologics on solid cost data. For example, 90% of current biologics on the market (and many of those in late stage development) require administration by injection or infusion. 70% of these agents then, must be administered by a healthcare professional. Given this, injectables tend to cost health-care systems about ten times more than traditional prescription drugs. Canadian provincial healthcare ministries understand these systemic costs are over and above the actual purchase costs of biopharmaceuticals. It is because of this understanding that they have erected such restrictive criteria for drug coverage and use.

Given that NICE and CDR are almost identical in how they evaluate product dossiers, the only telling differences between market access efforts in the UK and Canada are: how the initial dossier (including cost/utility data) is put together and the structure used to make it work. Historically, Canadian regulatory authorities have emphasized the clinical rigour of a dossier submission. As such, pharmacoeconomic data was often compiled in-house by Canadian health policy staff. The recent inclusion of the CDR in the regulatory process and its emphasis on cost utility data, places a new emphasis on this part of the dossier submission. XYZ Inc. Canada needs to ensure that this data is well thought out and comprehensive in nature. It should leave little doubt in the minds of CDR personnel as to the cost utility of a biopharmaceutical entry. This is particularly important given the opinion held by many regulators that biopharmaceuticals are too expensive.
The UK structure can be successfully applied in Canada on a smaller scale. This structure can help Canadian officials manage stakeholders more effectively in gaining market access. Specific groups within health policy and marketing/sales can take on tasks that ensure dossiers include the right cost data and that all stakeholders are successfully lobbied. A standard operating procedure outlining duties and assignments for each launch should be set up. This team should work together from day one right after the Canadian NLT (national leadership team) approves the drug for launch.

In order to encourage such a structure in Canada, market access team members must be convinced that the UK model is necessary. Recent regulatory wins such as Ledol could be used as examples of the possible positive outcomes of such a structure. In addition, setting up a joint task force for the Rolic file including market access specialists from both countries would be helpful. Leaders in Canada would have close working contact with UK group and learn from their protocols and common practices.

2.6 Biopharmaceuticals and Stakeholders

2.6.1 Introduction

The UK comparison has outlined the importance of having a detailed and actionable plan for stakeholder groups. This section describes the different stakeholder groups, their importance, and whether they can be developed as more effective advocates for Rolic. If they can, then the Rolic market access plan must include specific goals to reach these groups.
Since its inception, the pharmaceutical industry has had to consider many stakeholder groups when pondering introduction of a new molecule. On the payer side, governments and the taxpayer/ratepayer that pay for their services have tremendous influence. Firms must respect the need of payers to balance overall patient health with responsible costing. From a manufacturing point of view, pharmaceutical firms have had to consider local residents and their natural environment in deciding on plant locale and operating standards. Pharmaceutical firms also have to consider the health care providers including Doctors, Nurses, technicians, and other professionals that advocate and prescribe the drug's use. This group has high ethical standards that must be respected when drugs are tested and marketed. Finally, regulatory bodies' charged with maintaining global health standards must be listened to. Groups such as the World Health Organization (WHO) have challenged the intellectual property rights given to pharmaceutical firms in the face of country-wide epidemics such as the HIV problem in South Africa. Many firms responded by challenging the right of the South African government to manufacture cheap copies of more expensive patented drugs. The result was a public chastisement of these firms by the WHO, and significant reputational losses for the international pharmaceutical firms involved.

The current increase in the development and marketing of biopharmaceuticals has changed the dynamics of this stakeholder group. Payers, environmental groups, health care professionals, regulators, and health organizations are still important. The very nature of biopharmaceutical compounds elevates the stakeholder group to a higher, more
comprehensive level. All humans have DNA, genetic traits, and a strong desire to protect their individuality and privacy. Many people also have a certain reverence for the uniqueness of life (including animal life) and the ability of humans to create it.

Biopharmaceuticals will have to consider this global need until their unique approach to medicine is more widely accepted and proven. In short, many of the populace are scared when confronted with discovery involving cloning, selective genetic targeted medicine, DNA databases, and Xenotransplantation. These areas are radically new and perceived as scientific intrusion into their last realm of privacy - their own body and its unique genetic makeup.

Concerns over the ethics of biopharmaceuticals abound. The following underlines the reasons for these concerns;

- By 1996, more than 1000 patents for human DNA sequencing have been granted. Most of these patents (76%) have been granted to private firms.
- The United States and the EU have granted patents for genetically modified animals ("Dolly" in the UK, and the Harvard Mouse in the United States).

Given this, it is interesting to note that the EU (Article of the European Patent Convention) has a policy to evaluate any new patent dossiers on ethical grounds. If environmental harm in any form can be foreseen, then the patent will be rejected.
The stakeholder group has expanded from the traditional model of payers, environmental groups, health care professionals, regulators, and health organizations. The very nature of biopharmaceuticals and their novelty means that a wider net must be cast to include all stakeholders. Specifically, advocacy groups representing the therapeutic target must be included. They are the groups most acutely affected and yet they may include many with unfounded fears.

2.6.2 System Ethics

Within the context of stakeholder responsibilities, biopharmaceutical firms must also address systematic ethics. Despite numerous attempts to regulate pricing, the ultimate responsibility for pricing decisions lies with each sponsoring firm. Many argue that it is the government’s job to help set pricing (the Canadian model). Other would argue that a multiple stakeholder model is appropriate such as the one attempted by many US states. However, laws drafted in these US states \(^{10}\) say that a biotechnology firm must look after “legitimate stakeholder interests.” This statement begs the obvious question—what distinguishes legitimate stakeholder interests from others? The ultimate responsibility for biopharmaceutical pricing lies with the firm marketing that compound. With this being so, one could argue that stakeholders should exert significant pressure on the CEO to price products so that all stakeholders needs are met. As has been shown, this is not the case as most CEO’s work with some degree of \(^{10}\) “organizational slack” where they often make important decisions without significant pressure from shareholders. The optimum solution for addressing stakeholder concerns involves the delicate balance between profits (which will fund further discovery) and maximum utility for the populace.
that benefit from medical discovery. In many cases, society must rely on the professionalism of corporate managers. This intangible restriction is often the best way to ensure that other professions such as lawyers, doctors, and accountants perform their duties so that stakeholder needs are met. This same ethic could be applied to corporate managers in the biopharmaceutical area with the proper training.

It is up to pharmaceutical firms to educate their own managers on the ethics of pricing and marketing biopharmaceuticals. As has been witnessed many times, this will often not happen on its own. Industry associations can, and should introduce executive training on stakeholders needs and addressing these needs in an ethical manner.

The following table summarizes the current stakeholder situation for XYZ Inc.;
### Table 2 – Biopharmaceutical Stakeholders

<table>
<thead>
<tr>
<th>High Power</th>
<th>Payers—Private and Public</th>
<th>Health Care Professionals</th>
<th>Regulatory Bodies</th>
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<tbody>
<tr>
<td></td>
<td>Individual Patients</td>
<td>Advocacy Groups</td>
<td>Health Organizations</td>
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<td></td>
<td></td>
<td></td>
<td>Environmental Groups</td>
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<td>Low Power</td>
<td>Low Interest</td>
<td>High Interest</td>
<td></td>
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<td></td>
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</tbody>
</table>
2.6.3 Stakeholders – Individual Patients

Generally, this group is relatively large and consists of a geographically dispersed group of individuals. As such, many are not organized into interest groups and do not understand the benefits of new biopharmaceutical therapy. In the case of biopharmaceuticals, the group that represents potential patients is small relative to the entire population. Yet when compared to other stakeholder groups, this group does consist of a large number of people. Pharmaceutical firms like XYZ Inc. should not ignore the potential impact this group could have on market access decisions for a drug like Rolic. The best strategy for this group would be to mobilize them to become more interested and thus, move them from the low to high interest quadrant. This can be done relatively easy through direct to patient advertising but the cost is sometimes prohibitive.

A recent direct-to-consumer campaign for the XYZ Inc. drug Melzo is a good case in point. Melzo is a treatment for Irritable bowel syndrome and has a very large potential market (affects 20% of Canadian adults). During April and May of 2004, a direct to consumer campaign was put together that highlighted the disease state. The TV spots were put on daily during programs with historically high viewer interest (such as Friends, Survivor, and Frazier). The total cost for this program was in excess of $1 million.

A second way to mobilize this group is through a bottom-up advocacy strategy. Focus groups can be organized before a product launch to include highly visible patients affected by any new biopharmaceutical. In obtaining their opinions, this group can be instructed on the unique benefits of a new drug. This group can then be encouraged to in turn, lobby their respective patient advocacy group. In the case of Rolic, focus group
patients can (after focus group sessions) lobby their respective lung associations or asthma society. This action should then become the catalyst for the advocacy group to lobby government authorities to speed up their market access decision for Rolic. In the early growth phases of Rolic, a direct to consumer campaign would be too costly. However, the bottom up advocacy strategy could work in moving this stakeholder group from low power to high power.

2.6.4 Stakeholders – Environmental Groups and Health Organizations

Both of these groups tend to show high interest in any new drug, but tend to have minimal power when it comes to making market access easier. The challenge is to maintain the high interest but move this group to the high power quadrant. In order to mobilize these groups they would need to have a higher profile with government and insurance firms. Historically, this has not happened as groups like the World Health Organization and Greenpeace have insisted on maintaining a very independent image. Any actions undertaken by this group that would jeopardize this independence would inflict some damage to their reputation and ability to maintain funding (and raise funds). Given this, the costs of moving these two groups from low power to high power would not be outweighed by the benefits to XYZ Inc.

2.6.5 Stakeholders – Advocacy Groups

Advocacy groups generally advocate patient’s rights to governments and regulators worldwide. In Canada for example, each province has a chapter of the Schizophrenia society. Their role is to ensure that governments fund drugs and other
health-related programs that aid and assist patients with Schizophrenia and their families. These societies are non-profit groups and rely on others for their funding. Specifically, most of their funding comes from the Mental Health arms of provincial health ministries. When new drugs come on the market that treat Schizophrenia, these groups lobby their respective provincial drug plans to ensure that they are aware and are evaluating the respective dossiers. This type of strategy is called a top-down advocacy strategy. In some cases, the provincial chapters are not convinced that a new drug entry is beneficial for their constituents and do not put a lot of effort into lobbying for coverage.

Advocacy groups also pride themselves on being independent. This group can be mobilized effectively to press for drug coverage in any given province or jurisdiction. Pharmaceutical firms must tread carefully and ensure that all work with these groups respects their independence. Yet – if the message is focussed on the benefits to the patient groups they represent, in every case advocacy groups can be powerful allies. XYZ Inc. must seek out, and work with provincial patient advocacy groups in getting the message of their biopharmaceutical to the proper groups. If they do, they can move this group from interested with low power to interested with high power. In many cases, provincial drug managers respect the opinions of independent groups whose sole purpose is to improve the quality of life for their patient group.

2.6.6 Stakeholders – Private and Public Payers

This group has high power because they make the final decision on whether or not a drug will be paid for. Yet this group is low on the interest scale. This is because they
generally have little interest in the therapeutic benefit of drugs or their long-term upside to society. Agencies such as the common drug review (CDR) rate any new drug based on clinical benefits and cost/benefit utility. The payer group takes this analysis and makes a yes or no decision on coverage. Their interest is not in the ultimate benefit – but whether they can afford to cover the drug based on its regulatory review.

XYZ Inc. and other firms contemplating launch of a biopharmaceutical must determine whether the payer group can be moved to the high interest quadrant. If so, marketing efforts targeted at this group will be much more effective. In the case of private insurance, experience to date has show that this group is relatively receptive to marketing efforts. However, the real challenges lie in the recent shift of power within this payer group. In many cases across Canada, private insurers are following the lead of provincial drug plan managers in their coverage decisions. In Alberta for example, most private insurers are following the lead of Alberta Health & Wellness in determining what drugs they will cover for their clients. Given this, the provincial drug plans and their expert committee’s should be the target stakeholder group. In the short to medium term, this group is relatively inaccessible because of independence criteria for their committee work. In the longer term, this group could be moved from high interest to high power. It should be XYZ Inc.’ long-term strategy to find ways to partner with the government payer group as both have a common interest in decreasing health care costs.
2.6.7 Stakeholders – Health Care Professionals and Regulatory Bodies

Both of these groups are already in the quadrant that represents the most productive groups from a market access targeting perspective. They both have high interest in any new biopharmaceutical entry, and wield a lot of power in determining whether the molecule is covered. XYZ Inc. should continue to maintain this group in this quadrant ensuring that dossiers submitted represent their needs and concerns. Over the longer term, XYZ Inc. should sponsor advisory groups that include these important stakeholders. The continued use of this practice could eventually ensure that needs and concerns of these groups actually converge with the needs and concerns of XYZ Inc.

2.6.8 Stakeholders – Summary

This analysis has shown us that the current effort with some stakeholder groups are sufficient and productive (Health Care Professionals, Regulatory bodies). XYZ Inc. should continue to sharpen its efforts with these influential and interested groups. Some groups can be influenced, but the cost to move them to another quadrant is not outweighed by the benefits of such an effort (payers, environmental groups, health organizations). Finally, there are certain stakeholder groups where XYZ Inc. is clearly not doing enough. Specifically; advocacy groups and individual patients are stakeholder areas where XYZ Inc. should invest more time and effort.

2.7 External Analysis Summary

Healthcare and the marketing practices used have changed significantly with the advent of biopharmaceuticals. The challenge facing healthcare is the confusion created
within important stakeholder groups by this new type of therapy. Many regulators are struggling to deal with their desire to provide cost effective healthcare with a new and unknown class of drugs. They are not sure about the benefits of costly therapy indicated for a very small portion of their populace. This dissonance is also creating significant problems for pharmaceutical firms trying to create sales growth. The job of firms like XYZ Inc. has become more difficult as regulators and other stakeholders groups are becoming more vigilant. Market access is no longer a guarantee despite the breakthrough nature of new molecules introduced. Firms need to expand their web of influence to include stakeholders groups they have never considered before. The UK comparison taught us that new groups can be accessed in a systematic and productive way. Canada needs to use this knowledge and structure in planning their launch of Rolic.

As we have seen, regulators and many pharmaceutical firms are not currently coping with the speed of change being ushered in by biopharmaceuticals. If Canada can develop a competency in launching biopharmaceuticals, then they will have mastered a market challenge that few firms or regulators have. Given that the speed of discovery is not likely to slow down, then an acquired competency for launching these drugs could be a real source of sustainable advantage for a firm. The next section will focus on the current competency levels at XYZ Inc. in both Canada and the UK. This will help highlight what still needs to be done in terms of developing such a competency.
3 INTERNAL ANALYSIS

3.1 Introduction

XYZ Inc. is currently marketing two biopharmaceuticals with good sales results. Tacrol is an extension of a well established line of drugs for immunology. Caglo is an extremely successful drug indicated for chronic myeloid leukemia. The current challenge facing XYZ Inc. is ensuring that Rolic and other pending biopharmaceutical launches obtain similar market access to what Tacrol and Caglo currently have. This will be a difficult task as the market and affected stakeholder groups change almost daily. XYZ Inc. Canada must ensure that it has sufficient internal competencies to adapt to this changing market.

The objective of the internal analysis is to outline the intricacies of the Rolic molecule. The drug is targeted to a very specific market with daunting logistical challenges. The XYZ Inc. market access team will then be profiled including the current protocol and structure in place for assembling new product dossiers. Following this, strengths and weaknesses of the current team will be discussed and analyzed. Finally, key learnings will be outlined that should assist the XYZ Inc. Canada market access team to execute a successful Rolic launch.
3.2 Rolic

3.2.1. Molecule Introduction

Rolic is a monoclonal antibody injection XYZ Inc. is currently licensing from a US-based biotechnology firm. The drug targets the very large and lucrative Asthma market. Recent US data shows that 32-40% of patients with asthma report that it interferes significantly with their activities of daily living. As such, the market to improve patient’s lives is robust and growing. Rolic - the molecule was launched in late 2003 in the United States and has enjoyed a 35% growth rate in its initial launch year. Average dosing based on the US experience is three 150mg kits per month. One kit of Rolic is priced at $575, so average monthly costing for patients is $1,725 per month or $20,700 per annum.

Initial patient data on Rolic is promising but not groundbreaking. In one of two clinical studies, asthma exacerbations were reduced by half an exacerbation per patient over a period of 24 to 28 weeks. Peak flow increased by 6% versus placebo. Forced expiratory volume in 1 second improved by 4% vs. a 1% improvement with placebo. Patient symptom scores also improved by 1 point (on a 0-4 point scale).

A second trial showed that patient use of the healthcare system showed good reductions. Unscheduled office visits were reduced by 14 per 100 patient years, emergency visits by 2 per 100 patient years, and hospitalizations by 3 per 100 patient years. In all, prelaunch data for Rolic does show clinical improvement for patients and reductions in the use of the healthcare system.
Patients will be unable to obtain Rolic unless they qualify within strict criteria. Each Rolic patient must be an adult (12 years of age or older) and had an initial consultation with an allergist or respirologist. These patients must show a positive skin test response or in vitro reactivity to perennial aeroallergen. Zurichine levels for IgE must be between 30 and 700 international units per millilitre. In addition to these criteria, patients must weigh less than 150 kilograms. The attending physician must also confirm the following symptoms:

- Night-time symptoms and limitation of daily activity requiring rescue with an inhaled short-acting B2-agonist several times a day or at night

OR

- Inadequate control despite optimal treatment with fluticasone 500 micrograms twice per day or equivalent plus a long-acting inhaled B2-agonist or despite treatment with oral corticosteroids.

Given this restrictive criteria, the Canadian launch will be for a small percentage of the population.

Overall – the asthma market in Canada is quite large and growing. In 2003 for example, pharmaceutical sales for Asthma were $582 million with projected growth at about 3% per year over the next six years. The market itself is still dominated by bronchodilators and inhaled steroids (see Schedule IV). Despite this dominance, there are many clinical concerns over steroids and many Canadians remain uncontrolled. Given this, the market for Rolic is promising as an anti-IgE compound with no direct
competition. Direct competition for this market segment is not expected until 2009/2010.

An external analysis was performed for XYZ Inc. outlining the potential patient market for Rolic (see Schedule V). XYZ Inc. Canada is forecasting an initial penetration of 3,000 patients. This is a very conservative figure and should be attainable if the launch is well planned and executed.

3.2.2 Rolic – Logistical Challenges
Given that Rolic is an injectable biological that requires refrigeration, must be administered approximately 20 minutes after the package is opened, and injected patients must be observed post-injection many logistical challenges arise. To deal with these issues, XYZ Inc. has partnered with Ronim Canada. Ronim is a specialty logistics firm set up specifically for full logistical support (see Schedule VI) for Biological pharmaceuticals. They provide caregiver education, insurance coverage analysis and support (CAP), special refrigerated logistics, and local injection site clinics across Canada. Each step of the complicated process for this drug is covered. XYZ Inc. is counting on this partner to ensure that patients are getting the right injection at the right time, with a drug that has been properly stored. In addition to this, Ronim will assist XYZ Inc. in ensuring that all patient drug costs are properly reimbursed through provincial or private drug plans. In the cases where a patient does not have sufficient coverage, XYZ Inc. is going to provide co-pay assistance (CAP). CAP is a program designed to give patients financial assistance for their Rolic purchase if their current plan
does not cover all of the costs. The patients must meet the following criteria in order for this assistance (CAP) to apply:

- Patients must provide their insurers with a certain amount of co-pay
- CAP will conduct patient eligibility assessments based on means-based analyses.
- CAP will offer to subsidize a large portion of the cost to the patient for the co-pay requirement.
- Deferrals of payment will also be granted to minimize delays in initiating therapy.

As is evident, XYZ Inc. has made every effort to nullify any potential logistical problems related to the Rolic launch.

3.2.3 Rolic – Canadian Market Access Plan

According to the Canadian Product manager, Rolic has some unique attributes that will form the core of the market access and marketing plan. The drug will:

- fill a current unmet need with severe allergic asthmatics
- increase compliance for patients (twice a month therapy vs. daily)
- reduce corticosteroid use (which is perceived by many as damaging)
- reduce visits to emergency departments and the related systemic costs
- improve patient’s quality of life (this data set is very strong for Rolic)

The approach to selling these benefits to regulators and end-users will be very similar to the approach used in the United States. XYZ Inc. has planned on employing a dedicated sales force of nine specialist representatives whose only drug detail will be Rolic. The
market targeted (targeting was very successful in the US as 95% of Rolic patients are still on the drug compared to another Biological called Remicade where less than 60% are still on the drug initiated) will be specific and quantified for these sales personnel. In addition to sales force efforts, preliminary top-down emphasis will be given to two advocacy groups; namely the Canadian Asthma Society and the Canadian Lung Association.

3.3 **Market Access at XYZ Inc. Canada**

3.3.1 **Structure**

Currently, there are two main groups whose goal it is to gain market access for any new biopharmaceutical launched by XYZ Inc. These two groups perform two distinct functions; executive and functional. The executive is called the XYZ Inc. leadership team (NLT) which consists of all Vice-Presidents and the President. This team evaluates potential drug opportunities based on information provided by the Drug and Regulatory affairs department (DRA), the Medical department (Medical), and the Health Policy department (HP). Medical provides clinical outcomes for the drug based on their clinical trials to date. DRA advises the NLT on the nuances of the potential product monograph. Finally, HP outlines the potential market access opportunities and glitches that may be forthcoming in the Canadian market. Based on all of this advice (and direction and guidance given from Zurich), the NLT makes the decision on whether to launch a biopharmaceutical in Canada.
The functional part of the process involves DRA, Medical, and HP. Each group has a distinct function important to the quality of the new product dossier. Medical runs the phase II and phase III trials looking at how the drug performs in Canadian patients. DRA takes this data and compiles it into a complex legal and clinical document called the product monograph. Basically, the monograph is a roadmap instructing health professionals (doctors, pharmacists) on how to use the drug, in what circumstances, and what to watch out for. HP puts the market access plan together including the pharmacoeconomic portion of any dossier. Each functional area is divided up into groups of specialists (for example drug reimbursement managers in Health Policy) that work on files related to a therapeutic area. For example, HP has reimbursement managers for oncology, cardiovascular, primary care, respiratory, and transplant.

3.3.2 Process

The first step of any market access plan includes the STRAP plan from head office in Zurich. This is a five year strategic plan outlining the proposed launches for upcoming products. The NLT in Canada uses this as a base from which to develop their own STRAP plan. Once they decide on a molecule launch, the Medical, DRA, and HP departments work together to compile a dossier. As mentioned, this dossier includes clinical data, the monograph, and in some cases pharmacoeconomic data. The completed dossier is sent to the BGTD for approval in Canada. If approved, an expanded dossier is sent to the CDR including comparative data with the current standard of therapy. If CDR gives the dossier their blessing, HP uses it as a basis to compile customized dossiers for submission to each province and private payer group.
3.3.3 Competency Gaps

Four very specific challenges lie ahead for the Rolic team. First – the data used for market access is not complete. Currently, there is no usable pharmacoeconomic data available for inclusion in the Rolic product dossier. A model was developed in Zurich that no country has used to date. This data proved inconclusive and ineffective in assisting a launching country in gaining market access for this molecule. Canada discussed developing cost utility data internally but did not as budget funds were short and it was feared that the data would also be inconclusive. As the CDR in Canada and NICE in the UK both place particular emphasis on cost utility data, the policy teams in both countries could be in for a rough regulatory ride. The current fallback position for dossier preparation is the disease management approach. The emphasis will be on the clinical benefits of Rolic. This approach worked for another highly successful biopharmaceutical launch in Canada, namely Caglo. However, Caglo treats Chronic Myeloid Leukemia and many patients would die without Caglo treatment. In this case, many regulators opted for Caglo coverage as cost considerations took a back seat to patient mortality outcomes. Rolic patients are not facing a life and death scenario, but improvement in life quality. Regulators may not deem quality of life sufficient for approval of this expensive biopharmaceutical.

This particular challenge for Rolic is not an insurmountable one. Regulatory bodies including the CDR do demand good cost utility data. However, HP has three skilled health economic specialists on staff. The solution involves getting these specialists involved much earlier in the dossier creation process. Early involvement
would allow these professionals to advise on whether the data is strong enough for a full submission. If not, then a sub-group submission should be contemplated.

The second obstacle is the approach being taken by the Canadian brand team. They are modelling the launch after the United States. This is problematic as the US FDA places more emphasis on side effect profile and drug versus placebo data than on cost utility. This explains why the drug was approved so readily in the United States. However, any Canadian dossier that does not include good cost data may get held up. In addition, the United States has access to significantly more resources to ramp up their share of voice in the marketplace. Currently, the United States is utilizing three XYZ Inc. and three Genentech sales forces in direct selling efforts. Canada is expected to receive Notice of Compliance (NOC) from the Biologic and Genetic Therapeutics Directorate (BGTD) in Mid-August of 2004. The brand team had expected to then hire and train their dedicated sales force over the next two months in expectation of a November 2004 marketing launch. This desire was ground to a halt by a recent announcement from the current XYZ Inc. Canada president. In early July 2004, he announced that there would be no further additions to the field force in 2004. Given this, the Rolic brand team will not be able to ramp up marketing until March 2005 at the latest.

The US-style launch is not the real problem posed here. The problem involves the experience level of the smaller sales force that Canada will employ. If inexperienced representatives with minimal industry contacts are hired then the Rolic market
penetration will be delayed. The only way to improve the required competency is to hire experienced representatives away from other established firms.

Third – there is a distinct lack of teamwork between Medical, DRA, and HP. After NLT makes their decision, there is a lack of cooperative effort in ensuring that the dossier meets all of the needs of XYZ Inc. and the market. Each group goes into their silo and minimal interaction occurs on shared issues and needs. The recent problems with Ledol (a non-steroidal cream for Eczema) are telling. The submitted dossier for this drug included an indication for mild to moderate eczema. A very similar molecule by Wajis called Portol had been released to the Canadian market almost a year earlier. This drug had an indication for moderate to severe eczema. Ledol is competing with this molecule and has not had similar market access success. The reason is that many provincial formularies favour the less expensive generic corticosteroids for the mild to moderate range of this disease. In their opinion, the only unfulfilled segment of the market was the moderate to severe patient and this void was easily filled by Portol. When Ledol came on the market, very few formularies covered the drug as it was now competing head to head with the cheaper corticosteroids. If HP had communicated this market reality to medical before many of the clinical trials were finished, then protocols could have been rejigged to ensure that the moderate to severe indication was imminent.

The competency gap identified here has a lot to do with leadership at the NLT level. At their insistence, the other groups will work together for dossier compilation.
This request has to be formalized as a standard operating procedure for each and every launch.

Fourth – HP is currently not reviewing dossier content from other XYZ Inc. country affiliates to ascertain if sections would be appropriate for Canadian authorities. Both the Medical and DRA departments are liaising on a regular basis with their counterparts in other XYZ Inc. countries. Health Policy is not doing any regular idea sharing as they assume country specific regulations are too different from country to country. With the introduction of the EMEA in Europe and the general globalization of biopharmaceutical regulations, more similarities are bound to exist. To date, one step has been taken to formalize idea sharing for regulatory submissions across country boundaries. Recently, Zena Patch (Director of Research and Health Economics at XYZ Inc. Canada) attended an international meeting with all of her other XYZ Inc. counterparts from all over the world. She attended this meeting with the very influential Health Economic & Pricing group from Europe. The hope is that more idea sharing will occur so that XYZ Inc. Canada can glean successful market access data from other XYZ Inc. affiliates.

Again, as alluded to in the previous section some strides forward are being made in this area. The HP department is starting to formalize the sharing of ideas across country borders. This competency gap will get smaller as more and more meetings and other opportunities for sharing are organized.
3.3.4 **The Market Access Team – Strengths**

Within XYZ Inc. Canada, the one shining star involved in dossier preparation is the DRA department. Lead by George Pan-Figo – this team is second to none in terms of experience and ability. Many difficult dossiers have been approved in Ottawa thanks to this team. George Pan-Figo is an industry veteran with years of experience with federal bureaucrats. He has a strong team backing him up with extensive experience in a variety of scientific settings. The Medical department is also a very strong department with many MDs and clinical research experts on staff. Health policy is the smallest of the three players with a recent mandate to grow staff complement. This mandate was a result of the recent exponential growth of XYZ Inc. Canada. As a result, Health policy recently (in 2003) hired reimbursement managers to cover all of the different therapeutic business units within XYZ Inc. Canada.

3.3.5 **The Market Access Team – Weaknesses**

As outlined in the previous sections, the team needs to formalize the protocol for idea sharing with other countries and include health economic specialists earlier on in the process. In addition, teamwork needs to be advocated at the highest level. Finally, hiring decisions for new team members need to consider the experience level of the new team member. These actions have more to do with policy changes than with individual competencies. Health Policy, Medical, and DRA all have a strong line up of seasoned professionals who know their market and clients very well. The only competency weaknesses involve the secondary support to market access considerations – namely, sales management and field personnel.
There has been a tremendous amount of turnover lately within the product management and sales groups. For two years now, human resources have had a policy of rotating product managers between many product management positions. The result has been a distinct lack of continuity in leadership for crucial product management positions. Rotated product managers have less experience with their assigned drug, and field sales personnel do not know who to call for specific product questions or concerns. The result has been an over-reliance on outside consultants to develop actionable marketing and sales plans. More experienced product managers would temper consultant proposals with their own specific experience. In the field, XYZ Inc. has also experienced a double whammy in terms of maintaining crucial client relationships. As XYZ Inc. grows, they are bringing more and more new representatives on. These representatives do not know their new drugs, territories, or clients. In addition, there has also been a lot of representative movement from territory to territory or from territory to head office. This movement has also disrupted the crucial client-representative relationship.

3.4 Internal Review – Key Learning’s

Rolic is a complex and expensive molecule. The targeted market is relatively small and includes a group of specialists (Respirologists, Allergists) that XYZ Inc. personnel have not called on for almost five years. In addition, the mode of delivery and storage requirements for Rolic have forced XYZ Inc. Canada to include Ronim as part of the drug marketing costs. Yet the molecule has enjoyed strong growth in the United States and is considered revolutionary for the patient group needing treatment. The
difficult decision is not whether to go ahead with launch, but how to go about gaining the maximum market access in Canada.

In order to obtain market access, certain internal problems must be addressed. The market access team must formalize the teamwork needed to properly build a solid dossier. This dossier must include pharmacoeconomic data which may have been used successfully by other XYZ Inc. affiliates. Once the dossier is built, advocacy needs to be well planned and sales efforts carried out by a well trained team. Currently, the team does not have an actionable plan that includes all stakeholders in an effective way. Once internal issues are addressed, the stakeholder targets need to be expanded and their concerns addressed in the product dossier.
4 STRATEGIC ALTERNATIVES

4.1 Introduction

Notice of Compliance is expected for Rolic in October of 2004. This is the official notification from Health Canada that XYZ Inc. can produce and market the drug in Canada. Subsequent to this, CDR and provincial dossiers must be submitted as well as marketing plans finalized. Within this short time frame, XYZ Inc. Canada must choose a strategic alternative that will ensure the maximum market access in all provinces. Market access for the Canadian group is important as their results are often compared to those of the United States. Given that the United States saw a 35% market penetration in the first year, the pressure is on Canada to do likewise.

The challenge facing XYZ Inc. is developing a strategy that utilizes all of their current competencies while reaching out to important stakeholder groups. As we have established, stakeholder groups are the key to success in the market access game for any firm launching a new biopharmaceutical. In addition, minor structural changes may be necessary given the UK competencies uncovered by this analysis.

The objective of this section is to outline four different strategic directions for the Rolic launch. Each objective has its own strengths and weaknesses. Each option will be evaluated against specific criteria designed to include all of the key learning’s from the previous sections. The four alternatives will be explained and then evaluated using the criteria outlined. Finally, a summary will follow outlining how each of the options fared.
4.2 The Alternatives

4.2.1 #1 - No Launch

One potential strategy for the Canadian affiliate is not to launch Rolic. Rolic is expensive, involves logistics difficulties, and suffers from a lack of quality cost data to justify its costs to regulatory personnel. In addition, XYZ Inc. does not currently have a presence in the respiratory market and would have to incur significant expenses hiring and training personnel for sales and marketing.

This strategy involves a couple of significant long-term risks for XYZ Inc. Canada. First, XYZ Inc. has a molecule in its pipeline called $QAB149$ which is currently in phase II/II trials. It is considered one of five molecules that have the potential to be first-in-class or best-in-class. This drug is showing great results in patients suffering from asthma and chronic obstructive pulmonary disease. In a few years the drug will be entering global markets. If affiliates like Canada have already established relationships with key opinion leaders in the respiratory field, then the launch will be smoother and more effective. Rolic introduction will assist the organization to establish these crucial links to key players in the Canadian respiratory field. Second, the 2004 sales budget for XYZ Inc. Canada is $573,325,787. To the end of June, sales are tracking for a $15 million shortfall. XYZ Inc. needs to launch Rolic as it is in desperate need of sales to make its annual stretch target.

4.2.2 #2 - Launch Rolic in Canada using the existing model

The proposed launch model for the Canadian market has many advantages. It is
cost effective and includes a comprehensive plan to ensure that complicated logistics are handled smoothly. The plan is utilizing best practices learned from the Canadian Caglo launch and the Rolic launch in the United States. Both top-down and bottom-up advocacy is also planned with the marketing group. Top down means that there is going to be money set aside to work with the Lung Association and the Asthma Society in garnering support for Rolic. ‘Bottom up’ means that plans are in place to hold focus group sessions with allergic asthma sufferers. These sessions are designed to educate and motivate key individuals to help XYZ Inc. lobby governmental bodies.

The launch plan seems sound but is built on a shaky foundation. The Rolic team is assuming that it can achieve similar success to the US utilizing a similar plan. Yet this is not sound thinking as US FDA approval requires only clinical data that looks good when compared to placebo. If this data is good and the p-values sound, then the dossier gets approval. In addition, the US market is dominated by privately run managed care organizations. These organizations have traditionally wanted to see outcome studies that demonstrate quality of life improvements for patients. Rolic has very strong outcome data so coverage for these types of organizations was easy to obtain.

The Canadian situation is very different. Private payers are looking more and more to the coverage decision made by provincial drug plans. Provincial drug plans are looking to the common drug review for leadership on coverage issues. And the common drug review insists on quality cost utility data against an active comparator. XYZ Inc. Canada does not possess good cost utility data that compares Rolic to the current standard
of care. To think that the CDR will approve Rolic because outcome information is solid and plentiful is naïve. In addition, we have learned from the United Kingdom that an actionable advocacy influence plan is crucial. This plan must include advocacy groups, individual patients, and clinician bodies to be successful. In addition, the Canadian market access group (which consists of three groups) need to align their actions and improve teamwork. Finally, the CAP program which is set up to help patients with Rolic costs assumes third party coverage for its co-pay system. If the dossier fails, then third party insurers may also opt out and the CAP program will be inoperable.

4.2.3 #3 - Launch Rolic in Canada & Rework the Cost Data and Targets

This alternative takes the existing marketing plan and changes it slightly to ensure that the dossier is more palatable for the common drug review. XYZ Inc.'s assumption that 20,100 Canadian patients per year could be eligible for Rolic therapy may be casting the net too wide. This is because cost–effectiveness data may only be valuable in a subgroup of these 20,100 patients. The XYZ Inc. market access team needs to have a preliminary meeting looking at the clinical data and possible subgroups. If there is a subgroup where the cost data could prove to be robust in terms of cost per quality life year, then that data should be crunched and analyzed. The preliminary CDR dossier could then be prepared highlighting the positive cost utility for the subgroup. This approach assumes that two important things happen within XYZ Inc. First – it assumes that DRA, Medical, and HP will work more as a team in analyzing the costs and prospective dossier submission. Medical will provide the clinical data, HP the health economics specialists, and DRA the advice on wording and fact inclusion. If this
happens, a subgroup analysis and submission may be the best way to go. Second, XYZ Inc. Canada should liaise with UK market access officials. XYZ Inc. UK is also looking at their Rolic submission and has a particular competency in identifying subgroup data that looks promising.

This alternative will also use the existing XYZ Inc. Canada marketing plan for the identified subgroup. The only items missing from this model is a formalized protocol for ensuring that the three market access groups work together. In addition, it does not include a formalized advocacy plan including all identified stakeholder groups. Of special interest, are the patient advocacy groups and the clinician bodies. As we have learned from the UK, this plan needs to be formalized with a dedicated group identified for lobbying efforts.

4.2.4 #4 - Adopt the UK Model for Market Access

The first order of business for this alternative involves the internal workings of the market access team. As mentioned; DRA, Medical, and HP need to work as a team in assembling an effective dossier. The Market Access group in the United Kingdom is the model we will try to emulate within the budget constraints of the Canadian affiliate. Currently, the market access group in the UK has dedicated health economic specialists and an opinion leader development team. Assuming that XYZ Inc. Canada will not be able to make any additions to head count, minor adjustments to the existing team are advocated.
HP in Canada needs to ensure that health economic specialists are involved in dossier preparation from the beginning. Any concerns about the robustness of the economic data should be immediately communicated to the marketing group. This is especially important if in the opinion of HP, the target market needs to be adjusted to include a subgroup of the original clinical participants. In addition, HP needs to take the lead in ensuring that an advocacy influence list is drawn up including clinician bodies and advocacy groups. This list should be reviewed by all three groups to ensure that no important advocate body is missing. Once finished, HP needs to put together a Gantt chart outlining which groups should be visited, by whom, and in what time frame.

The next important item to be addressed is the marketing plan that will be used if the dossier is successful at the CDR level. In addition to the advocacy influence actions, bottom up advocacy should be implemented as the individual patient is a stakeholder group with potential. As planned, focus groups with key individuals should go ahead so they can influence their provincial patient association chapters. According to the XYZ Inc. UK personnel, the key opinion leader work involves actions that are significant at all levels. In order for opinion leaders to embrace Rolic, they must receive the message from individuals they trust. XYZ Inc. must spend a little extra money to hire specialist representatives with strong existing relationships within the asthma community. This will mean hiring them away from other pharmaceutical firms.

In addition to hiring, XYZ Inc. must go a step further with their CAP plan for patients. Ronim’s involvement needs to be expanded to include post-marketing
surveillance, stopping rules, and risk sharing. Post marketing surveillance must include the local hospital-based asthma educators as administrators of the data. Ronim can contract with these clinicians to ensure that all side effects, lifestyle improvements, and response data is assembled and recorded. This data can then be forwarded quarterly to the provincial drug plan managers. The asthma educators must be included as they are a clinician body that has tremendous influence on the drug use of individual asthmatics. Participation in the study will ensure that this influential group is exposed to the drug and its outstanding outcomes. Stopping rules involve identifiable outcome parameters that each patient must reach (such as peak flow, other drug use, etc). If they do not reach these milestones, a protocol must be in place to ensure that they go back to their original drug treatments and be taken off of Rolic. Risk sharing is an agreement that drug plan managers must buy into. XYZ Inc. will provide Rolic free for the first two to three months until clinical response is confirmed. After this confirmation is documented, it will be the responsibility of the province to pay for the rest of the medication required by the patient.

4.3 Evaluation

The following table outlines specific criteria against which each strategic alternative will be evaluated. These criteria or goals are based on key learnings taken from the preceding internal and external analysis. Each goal is given equal priority and weighting. The goals have been ranked against each alternative based on a 0-5 scale with 0 representing no ability to meet the goal and 5 representing excellent ability to meet the goal;
Table 3– Strategic Alternative Ranking

<table>
<thead>
<tr>
<th>GOAL</th>
<th>#1</th>
<th>#2</th>
<th>#3</th>
<th>#4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dossier includes pharmacoeconomic data</td>
<td>0</td>
<td>0</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>Client influence plan incl. stakeholders</td>
<td>0</td>
<td>2</td>
<td>3</td>
<td>5</td>
</tr>
<tr>
<td>Subgroup potential analyzed</td>
<td>0</td>
<td>0</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>Logistics covered incl co-pay</td>
<td>0</td>
<td>5</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>Formalized teamwork plan</td>
<td>3</td>
<td>2</td>
<td>3</td>
<td>5</td>
</tr>
<tr>
<td>Info sharing with other affiliates</td>
<td>3</td>
<td>2</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>Experienced reps hired</td>
<td>0</td>
<td>5</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>Groundwork laid for QAB149</td>
<td>0</td>
<td>5</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>Sales growth</td>
<td>0</td>
<td>4</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>Post-marketing surveillance, risk-sharing</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>5</td>
</tr>
<tr>
<td>Stopping rules</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>5</td>
</tr>
<tr>
<td>Total</td>
<td>6</td>
<td>25</td>
<td>41</td>
<td>55</td>
</tr>
</tbody>
</table>

This ranking clearly shows that alternative #4 offers XYZ Inc. the best chance for a successful market access campaign for Rolic. These findings are based on recommendations from previous chapters.

4.4 Conclusion

The model having the best chance of success for XYZ Inc. is #4. Adopting the UK model for market access will assist XYZ Inc. to include all of the important elements
needed for their plan to work. This analysis assumes that all participants will cooperate and that significant cultural change within the current market access team and NLT is possible. The next section will look at the possibility of cultural change not taking place. If this change is not achievable, then the goal of mirroring the success seen in the UK will not be attained.
5 RECOMMENDED STRATEGY

5.1 Introduction

This analysis has outlined a clear direction for XYZ Inc. Canada to follow as it assembles an effective market access dossier for Rolic. The choice that fits all of the evaluation criteria is a hybrid of the Canadian, American, and British experiences. The most important facet of the proposed strategy is its emphasis on important stakeholder groups. The ever-changing face of healthcare can be managed if the right stakeholder groups are included in marketing plans and the stakeholders as a whole are managed with the aim of balancing the different agendas they have. In addition, XYZ Inc. needs to help stakeholders understand how new technology can best be introduced into their individual healthcare systems.

The challenge for XYZ Inc. lies in the difficult task of changing human behaviour. Clients can be visited and structures changed, but day to day work habits are the toughest things to change. This section will outline the proposed strategic alternative followed by the inherent risks involved with such a change for XYZ Inc. Canada. One of these risks involves the unwillingness of XYZ Inc. personnel to embrace proposed changes. Finally, specific actions will be proposed to help mitigate these risks.
5.2 Proposed Strategy

XYZ Inc. Canada should adopt the UK market access model for their introduction of Rolic into the Canadian market. As described in the preceding analysis, this model can be adjusted for the current Canadian budgetary reality. The UK model will assist XYZ Inc. Canada reach out to the two important stakeholder groups identified in the stakeholder analysis, namely advocacy groups and individual patients. XYZ Inc. Canada already works with these groups. The difference will be the introduction of a formal plan including groups not previously visited such as clinician bodies and asthma educators. This effort describes a change in how XYZ Inc. interacts with its external customers. The definition of external customers will also be broadened significantly as a result of adopting this strategy.

The UK comparison also outlined the importance of a separate market access group as part of the formal XYZ Inc. structure. The group specialized in health economics and market access strategies; two things that XYZ Inc. Canada needs to work on. By changing the dynamics of the current market access teams (DRA, Medical, and HP) and how they interact, Canada can mirror the UK competencies without making wholesale personnel and alignment changes.

One final measure includes expanding the role of Ronim to look after surveillance studies, stopping rules, and risk-sharing. This will cost more, but will show provincial drug plan managers that XYZ Inc. is serious about their long-term commitment to the patients.
Implementation of the proposed measures will not guarantee success for Rolic. By attempting to cover as many angles as possible, the probability of success for XYZ Inc. Canada is improved. More importantly, XYZ Inc. Canada will be laying the important groundwork for future biopharmaceutical launches into the Canadian marketplace.

5.3 Inherent Risks

In trying to change the way the current market access team operates, XYZ Inc. may experience some employee opposition. Some HP or DRA employees will oppose such a plan insisting that the current protocol is sufficient. In addition, earlier involvement for health economic specialists may not pan out as their competencies have not been put to such a difficult test. XYZ Inc. may find that it needs to outsource the pharmacoeconomic portion of any dossier which will erase any perceived economies of using in-house expertise.

Experience in the United Kingdom may not be the best model upon which to build an advocacy plan. Many internal employees may feel that the regulatory situation in the UK is too different causing them to dismiss any plans based on the UK model. Finally, Ronim Canada may not be prepared to expand their current role for Rolic to include post-marketing surveillance and risk-sharing. All of these factors may combine to make the implementation of the proposed strategic direction very difficult.
5.4 **Required Actions**

In order to deflect internal opposition to structural and procedural changes, the HP group needs to take the lead in developing and implementing training for all market access team members. This training will outline the new protocols including specific examples of market access success from the UK. The health economists need to cut their teeth on a smaller project before they jump into the Rolic file. A simpler file involving a new indication for a mature product could be a good starting point. Senior health policy, DRA, and medical personnel could then evaluate whether the economist team is ready for a larger file based on their success with the smaller one. The perception that the Canadian regulatory environment is not comparable to the UK one can be easily handled. When HP implements their new protocol training, they need to include half a day on the workings of the CDR and it’s comparability to NICE. At this point, a teleconference with one of the market officials in the UK would be beneficial in answering any poignant questions. Finally, Ronim Canada should be involved with the new marketing plans for Rolic at a very early stage. They can then decide whether they are willing and capable to take on an expanded role. If not, XYZ Inc. will then have time to find a new partner.

5.5 **Conclusions**

The market access plan modelled after the UK including extensive stakeholder involvement should work. XYZ Inc. Canada is likely to experience some difficulty getting all employees to buy in to the concept. They may even find that essential third party partners are unable to shoulder their expanded role for Rolic. However, the plan is based on sound protocol successes in a country very similar to Canada. In addition, the
plan involves important groups that have a significant stake in the successful entry of Rolic into the Canadian market. Given these two realities, any short-term pain taken on to convince internal team members to buy into the concept will pay off in long-term sales growth.

The competence required to bring a biopharmaceutical successfully to market is important for XYZ Inc.' long term prospects. Team members should be encouraged to take pride in their role and to learn from the experience. The longer term goal for XYZ Inc. is to continually update this competence and share this competence with other XYZ Inc. affiliates.
New Biological Drug Approvals

Year

# of approvals


0 5 10 15 20 25 30 35 40
The Biotech Pipeline Current Breakdown

- Respiratory
- Metabolic
- Blood & Coagulation
- Cardiovascular
- Infectious & Viral Diseases
- Nervous System
- Diagnostics
- Ophthalmic
- Vaccines
- Gynecology
- Other
- Cancer
Settings Where Biologics are Used

- 55% Ambulatory Care
- 27% Hospital Inpatient
- 18% Patient-Caregiver
Asthma - Canadian Market Share
by Product

- Short-Acting Beta-Agonists
- Inhaled Steroids
- Combo Steroids
- Anti-Leukotriene

August-February: 2001-2004
Patient Flow: Who are the target patients?

1. StatCan
2. Canadian Consensus Asthma 1999; StatCan
3. 1999 Global Decision Report
4. 2000 Decision Resources Report
5. Assessed based on US plan + clinical trial recruitment experience in Canada
**CAP – Process Overview**

1. Educate Physicians, Nursing Staff
2. Diagnostic and dose setting
3. Rx and CAP registration

**CAP**
- Reimbursement
- Assist physicians in coverage requests
- Lobby for Pt coverage

**Coverage Approved?**

- YES
  - CO-Payment assessed by CAP
  - To patient

- NO
  - Pts monitored
  - Reports are sent back to MD

**To physician/clinic**

**THERAPY INITIATED**

**CAP coordinates administration site and delivery for Pt**

**CAP ships product & ancillary supplies**
END NOTES


Interview with Carl Gain, Vice-President, Immunology and Transplantation Business Unit, XYZ Inc. Pharmaceuticals Canada Inc. June 2004.


Interview with Della Sadler, Melzo Product Manager, XYZ Inc. Pharmaceuticals Canada Inc. May 2004.

Interview with Hubert Charlone, Vice President, Health Policy, XYZ Inc. Pharmaceuticals Canada Inc. June 2004.


Interview with Lena Fong, Director of Health & Technology Appraisal, XYZ Inc. Pharmaceuticals United Kingdom. July 2004.

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Fong, Lina. Director of Health & Technology Appraisal, XYZ Inc. Pharmaceuticals United Kingdom. Interview, July 2004.

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