UNIVERSITY OF NOTTINGHAM

Scenario Planning as a Tool for Long Term Strategic Planning

The Generics Drug Industry in the European Union

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EXECUTIVE SUMMARY

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As costs associated with medical care continue to increase, and populations continue to age, member states of the EU are increasingly concerned about their long-term public spending budgets. Generic drugs have been targeted by EU policy makers as replacements to high cost pharmaceutical drugs so as to bring healthcare costs down. The EU has taken several measures in the recent past to increase competition in the generic drugs industry within the EU marketplace.

As competition increases in the EU generics market over the coming years, firms within the pharmaceuticals drug industry in the region must explore new strategies so as to thrive and prosper in the long term. Decisions on making the best use of available resources must be made and strategies must be reformulated to determine actions going into the future. These long-term strategies will help companies determine their current and future positions, and ultimately, the relevant steps that they need take presently to maintain their market positions.

This report seeks to analyze the current EU macro-environment and provide possible future (twenty year timeframe) scenarios to which players within the generic drugs market can prepare themselves for so as to attain a competitive position in the long-term. The scenarios that were crafted after a thorough macro environmental analysis are: the positive scenario *("Todo es Bueno!"*), the negative scenario (*"Nein, nicht gut!"*) and the mixed scenario (*"Deux Union Europeenne!"*). After the scenario crafting phase, opportunities and threats were identified for the possible future scenario, and thereafter, versatile strategic recommendations were made.

Based on the scenarios, the report proposes strategies and recommendations by combining the implication of the scenarios' opportunities and threats. The report advices 7 strategies that producers can use to add value to their internal strategies and/or further examine the implication of the recommendations presented.

The report argues against traditional strategic polar thinking (cost leadership or differentiation) and proposes players to use mixed strategies. It suggests producers to identify the key ingredient that differentiated themselves from competitors. It promotes investing on research to soften the blow of sudden technology changes, identify new technologies to improve business processes, and research to develop new formulation patents. It also suggests producers to invest in stakeholder management, focus on green technologies, proposes investigating the advantages of strategic manufacturing location (i.e. Turkey), and finally, suggests formulating strategic alliances to organizational learning.

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1 INTRODUCTION

The European pharmaceutical generic drugs sector has been an area of continued attention for many years. On a national level, rising expenditures on drugs are posing a threat to the accessibility and financing of health care. With a growth rate faster than GDP and the health care sector as the whole, the pharmaceutical generic drugs industry has been subjected to increased competition and numerous national cost containment strategies.

Primarily healthcare policy is a national concern (reimbursement and pricing) in the European Union (EU), however there is increasing involvement from EU policymakers. The EU not only wants to ensure the delivery of satisfactory public health, but also wants to encourage competitiveness and innovation because this industry contributes not only towards levels of employment but also towards EU trade balances which are of high strategic importance for the union. However, subsequent reports such as the suggest that Europe in competitiveness in comparison to the United States of America, European countries from the Eastern region. Several indicators such as Research and Development (R&D), Data monitors, etc. highlight that the EU pharmaceutical generic drug sector has been at a disadvantage against its competitors. Furthermore, current EU regulations and policy governed under European law are exerting influence. This includes the European competition law, the EU Social chapter and the Four Freedom (goods, workers, capital and services). The result is expanding regulations, for example anti-trust laws, an increasingly harmonized marketing authorization procedure and significant influence on the way member states organize their health systems under the European Court of Justice ruling.

The EU ideology of a Single European Market has yet been restrictive in attempts to increase competition within the marketplace. Member states are unwilling to give up their national regulatory authority because –depending on their specific policy goals– the predominant fear is that it will have a negative impact on their domestic industries (e.g. job loss) and their health care systems (e.g. higher prices for pharmaceuticals). This fear holds back national support of a Single European Market and often the policy emerges in the use of the subsidiary principle.

Additionally the rise of pharmaceutical generic drugs (which are drugs with expired patents or no patents) in the global market, particularly in the EU, has led to the entry of new players into what was once the domain of large multinational pharmaceutical corporations. With the decline of new patented drugs into the market, generic drug manufacturers are increasingly posing a threat as they offer cheaper alternatives for many European governments who are struggling to manage healthcare costs (Loftgren, 2002). Hence as a result, European governments have worked to create a more favorable environment for generic drugs manufacturers to prosper, making it a challenge for multinational pharmaceutical companies to maintain their market positions.

Lofgren, (2002, p.3) states, “the highest market share for generics is found in countries where the industry historically had the greatest pricing freedom, including Germany, the Netherlands and the UK.” In terms of growth potential, the Association of the British

Pharmaceutical Industry (2007) states that the EU's generics drug market is worth €7 billion, with an annual growth rate of 10 - 15% as compared to the annual growth rate of around 7 - 9% for the pharmaceutical sector overall. This rapid growth rate highlights the fact that the continued rapid expansion of the global generics sector is undeniable, making it worthwhile for multinational pharmaceutical companies to examine the prospect of establishing their presence in this increasingly competitive market. It is therefore important for industry players to consider various environmental scenarios in preparation of new opportunities and challenges that lay ahead.

This report seeks to investigate the future business environment of pharmaceutical generic drugs industry within the EU. What are the key macro-environmental factors that affect the business environment of the pharmaceutical generics drugs industry in the EU? What are realistic and plausible scenarios for the future course of the macro business environment of pharmaceutical generic drugs industry within the EU? What strategies are recommended to the pharmaceutical generic drugs industry players within the proposed scenarios?

1.1 OBJECTIVES

The main objective of this report is to conduct a macro environmental scan of the pharmaceutical generic drugs industry and project possible future business environments in the form of plausible scenarios. A thorough EU macro-environmental analysis will be conducted to identify the key factors that could shape the future business environment for generic drugs players, followed by strategic recommendations for internal decision-making.

1.2 SCOPE OF THE REPORT

This report focuses specifically on the EU and the scenarios are 20 year projections from the period of 2010-2030. The report is restricted to the macro-environmental analysis and will not detail industry analysis, market/competitors analysis, and internal analysis. Additionally, the analysis will be conducted with the consideration that the customer base is predominantly government and insurance funds (i.e. institutional purchases).

1.3 PROJECT PROCESS FLOW

To achieving the aforementioned objectives, the project was divided into three phases:

1. Phase 1 – Research: this is the stage where the scope is defined, research is conducted and data is collated.

2. Phase 2 – Scenario Building: this is the stage where the data will be analyzed and the scenarios will be crafted.

3. Phase 3 – Recommendations: the final stage where strategic and commercial recommendations will be proposed.

Detailed description of the project process flow has been discussed in Part II: Project Process & Research.

1.4 REPORT STRUCTURE

The layout of the report is as follows:

1.4.1 PART I: LITERATURE REVIEW & RESEARCH METHODOLOGY.

Tasks:

- Literature Review: A comprehensive literature review is provided in this section and the following topics are discussed:
  - ❖ The Probable and the possible: This section details the academic perspective of forecasts and scenarios, the characteristics and elements that make an effective scenario are explored.
  - ❖ Understanding Scenario Planning, Scenario aspects and challenges: These sections introduce the concepts and objectives of scenario planning (scenario thinking). Italso critically reviews scenario planning vis-à-vis approaches and methods. It also highlights the challenges organizations face during scenario planning.
  - ❖ Scenario planning techniques, Strengths & Weaknesses: This section critically reviews scenario planning vis-à-vis approaches and methods. It also highlights a case study and discusses the challenges organizations face during scenario planning.
- Research Methodology: This section details the research methods used to achieve the objectives of this report and the following topics are discussed:
  - ❖ Qualitative & Quantitative Research: These sections review qualitative & quantitative research methodologies and define the approaches used to conduct primary and secondary research.
  - ❖ Research Tools, Sampling & Administration: These section reviews the various tools used to conduct the research and identifies the specific administrative tools used.

1.4.2 PART II: PROJECT PROCESS, RESEARCH & ANALYSIS.

Tasks:

- Project Process: This section details the processes that were subscribed to the project and the following sections are discussed:
    - ❖ Project Thematic Diagram: This section is a graphical representation of the project process flow.
    - ❖ Project Process Flow: This section details the various stages of the project.
- Research and Analysis: This section details the research findings and the following sections are discussed:
    - ❖ Stakeholders: This is a graphical representation of the various stakeholders in the European pharmaceuticals market. Their functions, policy and objectives are represented systematically.
    - ❖ PESTLE Factors: This section is a detailed environmental analysis of the various PESTLE factors identified under the scope of the project.
    - ❖ PESTLE Factors Tabulated: This is a tabular representation of the various PESTLE macro-environmental factors identified under the PESTLE factors section. This table also highlights a grading system to show relevance to scenario planning.
    - ❖ Policy Governance Trends: This section graphically represents the predicted policy trends based on the findings of the quantitative research conducted as part of the project methodology.

1.4.3 PART III: SCENARIOS & STRATEGIC RECOMMENDATIONS.

Tasks:

- Scenarios: This section describes the scenarios crafted from the analysis conducted under the research and analysis stage in Part II. Scenarios crafted are listed under the following sections:
    - ❖ TodoesBueno!: Anoptimistic scenario of the macro-environmental factors is represented.
    - ❖ Nein, nicht gut!: A pessimistic scenario of the macro-environmental factors is represented.
    - ❖ Duex Union Européenne!: A duality of the macro-environmental factors is represented.

- Scenario Evaluation & Implication: This section evaluates the economic environment described in the scenarios. Based on the macro findings, it hypothesizes the EU generic drugs industry and identifies possible opportunities and threats.
- Strategic Recommendations: This section combines the opportunities and threats identified in the scenario evaluation and implications stages and lists strategies and recommendations specific to generic drugs players.

1.4.4 APPENDIX 1

Appendix 1 includes the following:

- PESTLE Factors: This section is a detailed environmental analysis of the various PESTLE factors identified under the scope of the project. 40 PESTLE factors are researched and evaluated.

1.4.5 APPENDIX 2

Appendix 2 includes the following:

- Qualitative research questionnaire: This section contains the snapshot of the qualitative questionnaire used as part of the project research.
- Quantitative research questionnaire: This section contains the snapshot of the quantitative questionnaire used as part of the project research.

1.4.6 APPENDIX 3

Appendix 3 includes the following:

- Responses and key points from interviews conducted: The section transcribes the interviewees and highlights key elements that were used to supplement the project research.

1.4.7 APPENDIX 4

Appendix 4 includes the following:

- Presentation Slides: This section contains a presentation that summarized the details of the report on a collection of slides.

PART I LITERATURE REVIEW & RESEARCH METHODOLOGY

2 LITERATURE REVIEW AND SCENARIO PLANNING THEORY

2.1 OUTLINE OF LITERATURE REVIEW

The review identifies three main areas where the literature on scenario planning is defined.

The first part describes the scenario and scenario planning origins, concepts and definitions. A considerable body of extant is revealed in the following sections, drawing on literatures, assumptions behind the practices and theoretical frameworks.

Later subsections describe scenario planning topology and processes. Various literatures are reviewed on the methodologies used to govern the scenario planning process. These will describe elements, characteristics and models, and critically evaluate the findings.

The third part will evaluate a case study that holds relevance to the project scope. In this section we will also review the strengths and weaknesses of scenario planning.

The section following the literature review will define the methodology formulated specific to the project requirements.

2.2 INTRODUCTION TO LITERATURE

The business environment is highly dynamic and it compels enterprises and organizations to constantly develop and adapt to new concepts, technologies, products and realities. The ability to identify and adapt to future market changes has now become a determinant to the competitiveness of organizations. “To add, the capacity of the firms to deal with the uncertainties and to adapt quickly to major changes has become a crucial factor to success and a major challenge for managers” (Varum & Melo, 2010).

Traditional planning is often based upon the acceptance that the application of professional expertise to achieve well-defined goals will ensure efficient and effective management. However such plans often fail to consider the variety of local conditions or the propensity for novel situations to create extraordinary surprises (Scott, 1998). This uncertainty can lease to costly failures and thus scenario planning, a technique for decision-making in the face of uncontrollable uncertainties, offers the “conservationists a method for developing more resilient conservation policies” (Holling & Meffe, 1996).

2.3 THE PROBABLE AND THE POSSIBLE

2.3.1 THE PROBABLE – PREDICTIONS, FORECASTS, AND PROJECTIONS

Predictions are different things to different technical disciplines and to different people (Sarewitz et al., 2000). An acceptable definition of an ecological prediction can be the probability distribution of the specified variable over a specified time in the future, conditional on current conditions, specified assumptions about the rivers, measured probability distributions of model parameters, and the measures probability that the model itself is correct (Clark et al., 2001). Prediction is the best possible estimate of the future conditions. Lesser the sensitivity of predictions to the drivers, better the result (MacCracken, 2001).

In contrast to predictions, forecasts are best estimated from a particular method, model, or individual. They are widely understood by decision makers as forecasts that may or may not be true (MacCracken, 2001). They are more objective in contrast to predictions that are subjective and do not rely heavily upon assumptions over drivers that may have unknown, imprecise or unspecified probabilities.

Predictions have three fundamental and interacting problems: uncertainty, contingency, and reflexivity (Carpenter, 2002). In many cases, predictions are not rigorously evaluated; particularly the model of uncertainty is ignored even though statistical methods are available to address these issues (Clark et al, 2001). If uncertainty is evaluated by model forecasting, it can be found that the forecast inherits uncertainty. In addition drivers that are reflective of human behavior constrain the possibility of predictions (Funtowicz & Ravetz, 1993).

Uncertainty can be confusing and demoralizing and can lead to inaction or “paralysis by analysis” rather than decisive action. However, uncertainty can be viewed as an opportunity (Ney & Thompson, 2000). It can lead to the “acknowledgement of humility” as participants are ignorant of what the future brings (Peterson et al., 2002). Uncertainty can inspire action because the future is not already determined but rather created by the plan and actions of people.

Scenario planning is closely similar to adaptive management (Walters, 1986), and is a management approach to comprehend uncertainties into accounts and to supplement decision making.

2.3.2 THE POSSIBLE – SCENARIOS

Before understanding and defining scenario planning, it is necessary to understand the definition of scenarios. Lynch (2003) describes scenarios as detailed and plausible views of how the business environment of an organization might develop in the future based on groupings of key environmental influences and drivers to change about which there is a high level of uncertainty. Scenarios are also be defined as “…an internally consistent view of what

the future might turn out to be – not a forecast, but one possible future outcome" (Porter, 1985). These definitions highlight the difference between scenarios and forecasts: single point forecasts developed from an analysis of present day trends can be placed within a wide range of uncertainties in the future, and therefore, there is a high probability of getting forecasts wrong (i.e. missing the mark). It is also important to understand that scenarios are not projections, predictions or preferences about the future, but rather they are coherent and credible alternative stories about the future (Cornelius et. al., 2005).

To create a better understanding of scenarios, Table 1 below lists the characteristics that make a scenario.

TABLE 1: CHARACTERISTICS OF SCENARIOS

Characteristics of scenarios.			
i.	**Internally consistent**	ii.	Time-limited
iii.	**Coherent**	iv.	Ordering perceptions
v.	**Plausible**	vi.	Based on assumptions
vii.	**Interconnected events**	viii.	Different possibilities
ix.	**Relevance**	x.	Based on past/present
xi.	**Challenging**	xii.	Based on pre-determined events
xiii.	**Representative**	xiv.	Trent outcomes
xv.	**External**	xvi.	Imagined
xvii.	**Narrative**	xviii.	Decision-making tool
xix.	**Boundaries/framework**	xx.	Progressive

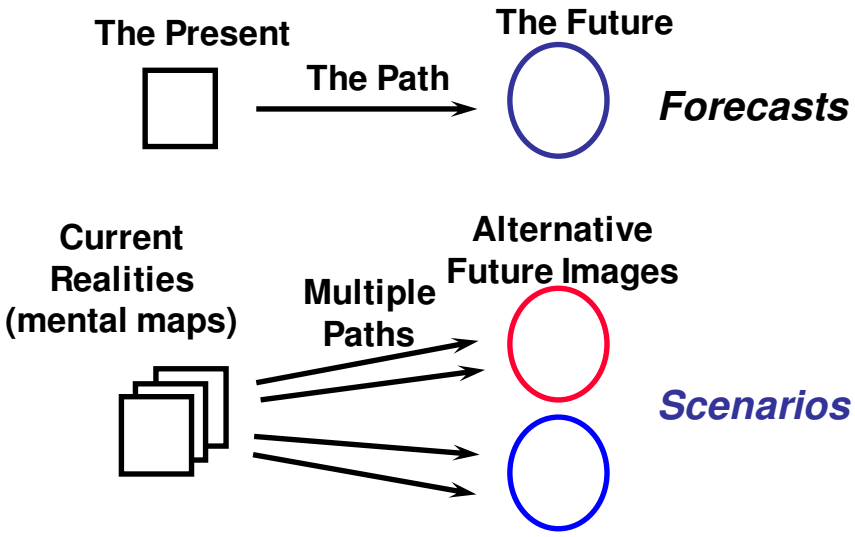
Source: Extracted from the definitions of scenarios listed by Bradfield et al. (2005).

In addition to the characteristics, listed below are various elements of an effective scenario:

- A good story about changes that may possibly occur in the future within a particular environment
- Can capture a listeners imagination
- Written in a past or present tense to give the impression that trends and events have already occurred (what should we do now?)
- Helps clarify the causes and effects of developments
- Makes a listener challenge his/her mental models and assumptions about the future
- Helps enable strategists define and assess a range of future actions
- Seen as an important element of strategy development

The key difference between forecasts and scenarios is that, forecasts predict the present across a single path into the future. Scenarios on the other hand are multiple possibilities that encompass uncertainties into cross dimensional paths. They are multiple projections and are representatives of futures. Figure 1 below is a graphical representation that highlights the key differences between Forecasts and Scenarios.

FIGURE 1: SCENARIOS VS. FORECASTS



Source: (Cornelius et al., 2005)

2.4 UNDERSTANDING SCENARIO PLANNING

Scenario planning or scenario thinking originates from the military, however their use in organizational decision making were developments from the scenario techniques developed by Kahn, at Rand Corporation, and Berger in France post World War 2 (Van der heijden et al., 2002). During this period several business scenarios were published. It is however the business scenarios developed by Royal Dutch Shell (1970s) that were the first to receive worldwide attention. Pierre Wack at Shell led a team of strategists and formulated the concept of "reperceiving the future" (Tibbs, 1998). Scenario planning is not a process of forecasting but foresight that evaluates multiple futures of the business environment. "It considers multiple and equally plausible futures" (Ringland, 2003).

The planning consists of developing possible representations of a firm's potential future that makes different assumptions about the driving forces of markets and includes uncertainties (Kotler, 2003). Private and public organizations both face business environments which are very diverse. To cope with this diversity companies must be prepared. It is the duty of strategists to be able to see the plausible futures and their changes in business environment. They may consider a question such as "What will we do if it happens?" and accordingly, strategists will observe and adopt one scenario as the most plausible future and as time passes regard or disregard such a scenario.

2.5 SCENARIO ASPECTS AND CHALLENGES

Scenario planning is one of the many tools that strategists and marketers use to plan. It is one of the tools in a strategists' arsenal that is used to predict on the assumptions that if strategists cannot predict the forecast, then they consider a variety of foresights, thus strategists might be able to hit the right one (Porter, 1985). They are not forecasts but rather plausible future structures of environmental factors and relative uncertain variables of influences.

Scenario planning helps improve decision making by allowing more complete considerations of outcomes and their implications (Fuller-Love 2006). They are the first step to strategic planning. If strategic planning is to succeed, scenarios then must be properly factored into the organization's plan. The process can be done by observing, monitoring and understanding the changes and complexities in the business environment. As business environments become volatile or undergo rapid changes or both, it may be advisable for distinct approaches combining one or more views in order to understand future outcomes.

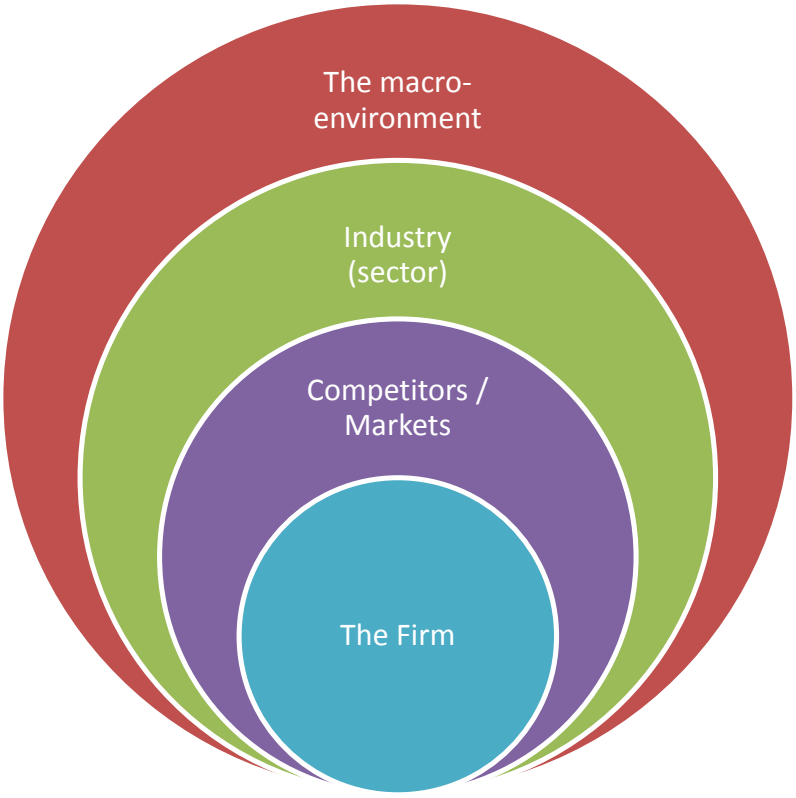
Building scenarios has traditionally become an outward looking process designed to extend the awareness of potential changes in the external environment (Mason & Herman, 2003). By casting strategies as scenarios, companies can benefit from traditional scenario planning with accelerated decision making for organizations in highly dynamic environments. Two approaches can be practiced by companies; the first is building scenarios from configuration factors. This is done by:

1. Identification of high-impact, high uncertainty factors in the environment
2. Identification of different possible futures by factors
3. Building scenarios of plausible configurations of factors

The second approach is the thematic scenario method (Shaukat & Ringland, 2003). Detailed scenario planning techniques are discussed in a later sub-chapter.

It can be concluded that organizations can create many scenarios. However decision making involves organization focusing on the most possible options. Factors such as capital investment, etc. need to be considered. This is because of a range of effects scenarios have on diverse industrial stakeholders.

FIGURE 2: EXPLORING CORPORATE STRATEGY



Source: (Cornelius et al., 2005)

Figure 2above shows the various and different environments as well as the complexities associated with these environments due to the many separate issues in the business. Changes in lifestyle, consumer behavior and buying patterns are all the additional factors that need to be considered when planning scenarios, which complement strategy development and decision making. It is an important strategic tool for companies as marketers see the choices available through scenario planning and the options are screened to match possible scenarios. Scenario planning thus can lead to an emergency plan in order to meet the requirements of these possible future scenarios. As a result, it is important that scenario planners observe, monitor, and imagine the possible future changes to the business environment.

2.6 OVERVIEW OF SELECTED SCENARIO PLANNING TECHNIQUES IN PRACTICE

Scenarios, despite their story-like characteristics, follow systematic and recognizable steps. It is a highly interactive process with intense and imaginative qualities. There are several different approaches to scenario planning and these share common or similar aspects. The process usually starts by clarifying the decisions to be made, challenging mental maps that shape people's perceptions, and hunting and gathering information from various sources. The next steps are analytical: identify the driving forces, the predetermined elements and the uncertainties. Thereafter, two or more thoughtfully composed scenarios are plotted, each representing a distinct plausible future. The deeper structure and their underlying logic

are further 'fleshed' to reveal their crucial differences. Finally, the key event and turning points that would channel the future towards one scenario are identified. Phelps et al., (1998) suggest that scenarios are built according to four stages:

- Define scope
- Database construction
- Building scenarios
- Choosing strategic options

Numerous methods are available in literatures, ranging from simple models to highly complex, qualitative or quantitative models. It should be realized that there is no one method or one specific model to developing scenarios, and some of the methods are briefly described in Table 2 towards the end of this sub-section.

2.6.1 TYPE 1: THE EIGHT-STEP SCENARIO PROCESS BY UTE VON REIBNITZ

Ute von Reibnitz (1992) argues that the ability to create distinctive future situations allows strategic planners to deal with scenarios that fall between two extremes. In her book she proposes eight steps.

1. Task analysis: (goals, strategies) this is the stage where the objectives, goals and strategies of addressing the issues are identified.

2. Influence analysis: (factors/areas, system dynamics) this is the stage where the strengths and weaknesses profile is drawn up; following is then a matter of acquiring knowledge of the system dynamics/structure of the associated areas. The advantage of this scenario technique comes from the ability to account for minority votes.

3. Projections: this stage is part of the scenario workshop which calls for visionary thinking ability. Descriptors are identified from different areas of influence.

4. Clustering alternatives, consistency analysis: this is the stage where the projections are clustered and checked against each other for consistency. It is done using a consistency matrix to largely view and collate the views of the descriptors.

5. Scenario interpretations/developments/visualization: this is the stage where the scenarios are interpreted and described in a creative/imaginative way.

6. Consequence analysis: (opportunities, risks, and actions) this is the stage where possible opportunities and risks are identified.

7. Analysis of disruptive events/wild cards: this is the stage where opportunities and risks are utilized and contained. This is also the stage where forecasts and scenarios differ by incorporating the uncertain 'wild card's' into future scenarios.

8. Scenario transfer: (developing core strategy, monitoring system) this is the final stage where the strategies and measures in the previous two stages are evaluated. (Schwab et al., 2003)

2.6.2 TYPE 2: THE EIGHT-STEP SCENARIO APPROACH BY PETER SCHWARTZ

Peter Schwartz (1996) president of *Global Business Network* is a pioneer in the field of scenario development. He is the well-known author of 'The Art of the Long View'. The approach of Schwartz is to look for archetypal plots, which are reoccurrences in human history, and fit the driving forces to them. The process starts with the critical issue: 'what impending decision keeps you awake at night?' This then leads to questioning the key factors that determine the success or failures of the issue. 'What are some of the driving forces creating changes in the wider world?' The driving forces are ranked by importance and uncertainty: most important and most uncertain. Scenario logics are selected and the scenario matrix is created. The next step is to flesh the scenarios by referring to the key factors, and a selection of plausible events that might create that state has to be incorporated. 'How does the decision look in each scenario?' A SWOT analysis is suggested, and the final step is to identify leading indicators that are heading towards one or another of these scenarios.

2.6.3 TYPE 3: SCENARIO PLANNING BY MICHEL GODET AND FABRICE ROUBELAT

Godet and Roubelat (1999) suggest that building scenarios and strategies should be done using simple and rational tools to stimulate the imagination. They have elaborated a toolbox which classifies problem solving methods as follows:

1. Asking the right questions and identifying key variables: futures workshops and structural analysis using the 'MICMAC' methods.
2. Analyzing trends and actors strategies: retrospective studies and 'MACTOR' method.
3. Reducing uncertainties to realizable scenarios: morphological analysis using expert methods such as Delphi, cross-impacts.
4. Identifying and assessing strategic options: a multi criteria analysis and 'MULTIPOL' method.

Broadly, the process comprises of three major stages (1) construction of the basis, (2) identification of major issues, and (3) construction of scenarios. (Arcade et al., 1999).

TABLE 2: COMPARISON OF VARIOUS APPROACHES OF SCENARIO TECHNIQUE

Author(s)	Definition	Aim/ Purpose	Types/Categories	Concept
Peter Schwartz (1996)	Scenarios are tools for ordering one's perceptions about alternative future environments in which today's decisions might be played out. In practice, scenarios resemble a set of stories, written or spoken, built around carefully constructed plots. Stories are an old way of organizing knowledge. When used as a strategic tool, they confront denial by encouraging in fact, requiring the willing suspension of disbelief. Stories can express multiple perspectives on complex events and scenarios give meaning to these events.	▪ To highlight large scale forces that push the future in different directions. ▪ It is about making these forces visible, so that if they do happen, the planner will at least recognize them.	No types or categories identified.	Eight steps: 1. Identification of the focal issues or decisions. 2. Identification of key forces in the local environment. 3. List of the driving forces (social, economic, political, environmental, technological forces): "What are the macro-environmental, and technological forces listed in step 2?" 4. Ranking of key factors and driving forces by importance and uncertainty. 5. Selection of scenario logics, in effect, the axes along which the eventual scenarios will differ. 6. Fleshing out the scenario – the logics give the skeleton of the scenarios and returning to the key factors and trends listed in step 1 and 3. 7. Exploration of the implications. 8. Selection of leading indicators and signposts.
Von Reibnitz (1988, 1992), Schwab, Cerutti, von Reibnitz (2003)	A scenario approach that involves developing future environment situations (scenarios) and describing the path from any given present to these future situations. These scenarios cover the "edges" of the scenario funnel.	▪ Create alternatives in case of uncertainties and to assemble them into highly consistent scenarios. ▪ Scenarios are recommended whenever the problem is complex, uncertain and has long-term effects. ▪ Corporate identities should be developed and tested in tandem with the development of strategies on the basis of worked out scenarios. ▪ Development goals and strategies (master and alternative strategies) ▪ Re-examining existing goals and strategies. ▪ Assessing strategic decisions.	Scenario approach suggests to: ▪ Include quantitative and qualitative information/ data. ▪ Use explorative scenarios. ▪ Develop three types of scenarios in the scenario building process: trend extrapolation, best-case and worst-case scenario.	Eight steps: 1. Task analysis (goals, strategies). 2. Influence analysis (areas/ factors, system dynamics). 3. Projections. 4. Clustering alternatives, consistency analysis. 5. Scenario interpretation/development/visualization. 6. Consequence analysis (opportunities, risks, actions). 7. Analysis of disruptive events/ wild cards. 8. Scenario transfer (developing core strategy, monitoring system).

Author(s)	Definition	Aim/ Purpose	Types/Categories	Concept
Heinecke, Schwager (1995)	Scenarios are alternative, plausible and consistent pictures of the future which consist of logically suited premises and the description of development paths of possible futures built on the present situation. They give not a future forecast or prognosis of what will happen but consistent pictures of what could possibly happen without evaluating the probability of becoming reality.	Scenarios ▪ Foster systematic thinking on external influencing factors. ▪ Reveal basic assumptions. ▪ Help to identify strategic gaps, structural changes and disruptive factors. ▪ Lead to a different awareness of problems. ▪ Make decision-makers more sensitive to future potentials. ▪ Reduce misjudgments. ▪ Help to formulate and evaluate visions and strategies.	Scenario approach suggests to: ▪ Include quantitative and qualitative information/ data. ▪ Link intuitive (deductive) and model based (inductive) methods/ tools. ▪ Use explorative scenarios (not normative or descriptive ones). ▪ Build scenarios for managers at the level of the corporation and SBUs.	Eight steps similar to von Reibnitz: ▪ Identification of influence areas/ factors. ▪ Identifying descriptors, projections. ▪ Consistency analysis and/or cross-impact analysis. ▪ Scenario interpretation. ▪ Analysis of disruptive factors/wild cards. ▪ Consequence analysis. ▪ Elaborating core strategy, scenario transfer linking scenario technique with other methods/ tools (e.g. creativity techniques, Delphi, risk analysis, cluster analysis).
Michel Godet, FabriceRoubelat (1997), Godet (1987), Godet, Roubelat (1996)	A scenario is a description of a future situation and the course of events which allows one to move forward from the original to the future situation.	▪ Stimulate strategic thought and communication within companies. ▪ Improve internal flexibility of responses to environmental uncertainties, and provide better preparation for possible system breakdowns.	▪ A distinction is made between possible scenarios (everything that can be imaged), realizable scenarios (all that is possible, taking account of constraints) and desirable scenarios (they are possible but not all necessarily realizable). ▪ According to their probability, these scenarios may be termed reference, trend based, contrasted or normative. ▪ A trend-based scenario whether it is possible or not corresponds to the extrapolation of trends at all points where choices are to be made. ▪ It is among the realizable scenario, which has a higher than zero probability, that we find contrasted (unlikely) scenarios and the field of development where the most probable scenarios are found. ▪ As regards desirable scenarios, these are found certain within the possible zone and are not all necessarily realizable.	Three major stages: 1. Construction of the basis and identification of essential variables. 2. Identification of major issues at stake and key questions for the future. 3. Elaboration of exploratory scenarios.

Table 2: Comparison of Various Approaches of Scenario Technique. Source: (Mietzner & Reger, 2004)

2.6.4 CASE ANALYSIS: SHELL OIL SCENARIOS – SUCCESS STORY

During the early 1970s, Shell Oil used scenario planning to evaluate the organizations long-term decisions and strategies. Around this period world oil prices were low and expected to remain low. However Shell scenario planners considered a possible price rise, contrary to expectation. Because by then there was uncertainty involved over how much the prices would rise by, traditional forecasting approaches were inappropriate. Strategy planners at Shell then used scenario planning and identified a number of tensions, and realized that at some point of the oil production, oil was kept better in the round than sold suggesting a number of possible changes in the status quo. One of these scenarios envisioned a time where countries would form a collation and control oil prices. This scenario was considered radical, but still plausible. This exercise lead Shell to adjust the business practices and hedge against the potential for high oil prices by increasing the efficiency of its refining and shipping operation. These changes, combined with the ability to respond to the oil prices allowed Shell to adapt to a world of expensive oil much faster than its competitors.

2.7 STRENGTHS AND WEAKNESSES OF SCENARIOS – FUTURE RESEARCH

Shell scenarios in the 1970s pointed out "a change in the paradigm of futures research from forecasting towards foresight" (Mietzner & Reger, 2004). Forecasting is considered as a prediction function of what is expected to happen in the future, in relation to a particular event. Whereas foresight is the ability to see what ones future needs are likely to be ranging from different possibilities. However there has been a shift in scenario planning techniques from a more quantitative modeling process to a more qualitative oriented process. These techniques have several strengths and weaknesses, and these are discussed below.

2.7.1 SCENARIO PLANNING STRENGTHS

1. They are not forecasts but foresight, and the strength of scenarios is that they do not describe one future but several realizable or desirable futures placed side by side.

2. Scenario planning and scenarios incorporate imagination, and challenge long-held internal beliefs of organizations. Their use can change corporate cultures, compelling managers to rethink radically the hypothesis that has founded their strategy.

3. Scenarios are an appropriate way of recognizing 'weak signals', technological discontinuous or disruptive events and including them into long-range planning results in organizations better handling new situations.

4. Scenarios and scenario planning can create a common language to deal with strategic issues by opening a strategic conversation within the organization.

5. The process supports organizational learning and decision making is improved as participants share the aims, opportunities, risks and, strategies and later support the coordination and implementation of action.

6. There are a variety of different scenario planning techniques and the process of building scenarios are very flexible and can be adjusted to specific tasks/situations.

2.7.2 SCENARIO PLANNING WEAKNESSES

1. The scenario planning process is very time-consuming.
2. It requires a lot more qualitative approaches and in practice this is a difficult task.
3. It requires extensive in-depth research of all the various factors and this makes scenario building even more time consuming.
4. It could be difficult not to think about extreme scenarios during the building processes.

The practice is fairly practitioner-driven and there is very little academic literature on failed scenarios leading to wrong decision-making. However, it is a handy initial tool for strategic decision making and does promote managers to re-evaluate their strategies.

3 RESEARCH METHODOLOGY

The following section outlines the research methodologies that were used in achieving the objectives of this project. Data-mining has been conducted using both primary and secondary resources. It is important to note at this point that due to time constraints and availability of resources the project has focused largely on secondary data. However this data has been successfully complemented with information gathered from primary resources.

3.1 QUALITATIVE RESEARCH

Qualitative research is a method of inquiry appropriated in many different academic disciplines, traditionally in the social sciences but also in market research and further contexts. Qualitative researchers aim to gather an in-depth understanding of human behavior and the reasons that govern such behavior. The qualitative method investigates the *why* and *how* of decision making, not just *what*, *where*, *when*. Hence, smaller but focused samples are more often needed, rather than large samples.

Qualitative methods produce information only on the particular cases studied, and any more general conclusions are only hypotheses (informative guesses). Quantitative methods can be used to verify which of such hypotheses are true.

3.2 QUANTITATIVE RESEARCH

Quantitative research focuses on a systematical empirical investigation of the quantity properties, their phenomena and the relationships. Measurement processes are focal to quantitative research because they provide the fundamental relationships between the empirical observation and the formulated mathematical/statistical expression of the quantitative relationship.

3.2.1 RESEARCH TOOL – STRUCTURED INTERVIEW

One of the tools used to populate the research in this project was structured interviews. The aim of this approach is to ensure that each candidate is presented with exactly the same questions in the same order. The candidates are evaluated using a common rating scale, and the interviewers are in agreement on acceptable answers. This ensures that answers can be reliably aggregated and that comparisons can be made with confidence between sample subgroups or between different survey periods. Organizing a structured interview questionnaire requires 8 distinctive steps:

1. Conduct a Job Analysis
2. Determine the competencies to be assessed by the Interview
3. Choose the interview format and develop questions
4. Develop rating scales to evaluate candidates
5. Create interview probes
6. Pilot-test the interview questions
7. Create the interviewers guide
8. Document the development process

Two sets of questionnaires were prepared. The first set represented 26 interview questions encompassing the most relevant factors identified under Part II Project Process, Research & Analysis – PESTLE Factors Tabulated. These questions provided qualitative information in context to the factors defined and supplemented the secondary research. The second questionnaire represented 26 policies and required candidates to forecast/project them on a *Likert* scale. This was done with the purpose of quantifying the likelihood of policies on the scale below:

1. Fully national
2. Predominantly national
3. 50/50

4. Predominantly European

5. Fully European

The survey questionnaires have been included in Appendix 2 – Questionnaire for informatory purposes.

3.2.2 RESEARCH TOOL – FOCUSED (SEMI-STRUCTURED) INTERVIEW

In addition to structured interviews, semi-structured interviews were also conducted. This technique is used to collect qualitative data by setting up a situation that allows the candidate time and scope to talk about their opinions on a particular subject. The focus of the interview is decided by the researcher as there may be areas the researcher is interested in exploring further. The objective is to understand the respondent's point of view rather than make generalizations about behavior. It uses open-ended questions, some suggested by the researcher and some that may have arose naturally during the interview. The researcher tries to build a rapport with the respondent and the interview is like a conversation. Questions are asked when the interviewer feels it is appropriate to ask them. They may be prepared questions or questions that occur to the researcher during the interview. The wording of questions will not necessarily be the same for all respondents.

This technique was used to interview candidates, who were not experts in the pharmaceutical/generic drugs industry but experts in functional areas (e.g. Strategy, Healthcare general, etc.).

3.2.3 SAMPLING – QUESTIONNAIRE

The questionnaire has been administered to selective candidates who match any of the criteria mentioned below:

1. Experts with extensive experience in pharmaceuticals industry.

2. Experts with extensive experience in industrial economics.

3. Experts with extensive experience in the EU healthcare sector.

4. Experts with extensive experience in pharmaceutical/generic drugs industry.

5. Experts with extensive experience in legal/regulatory policy in the EU.

6. Experts with expertise in formulating functional strategies.

For extensive research, 30 candidates were shortlisted based on their credentials. However, 7 candidates responded positively while the remaining candidates were subjected to unavailability. Although this sample was smaller than earlier expectations, it did not deter the research as most of the candidates met more than one criterion of selection. Additionally, the secondary research conducted produced extensive data to supplement any gaps.

3.2.4 ADMINISTRATION METHOD – TELE-CONFERENCE INTERVIEW

Following the preparation of the interview questionnaire and identification of the sample size, administration strategies were formulated. Questionnaires can be administered in writing, orally, in person, via telephone interview, by email or by posting. Each method has specific advantages and disadvantages. The selection of which method to be followed depends on the question content and complexity. Costs are always a consideration and emailing surveys is usually the least expensive option. It can be generalized that if the same data can be extracted from different methods with the desired accuracy, then the least costly should be considered. Table 3 represents the modes of administration with regards to advantages and disadvantages.

TABLE 3: ADMINISTRATION METHODS

Type	Advantage	Disadvantage
Mail interview	Answered at respondent's convenience, Privacy from interviewers expectations, Visual inputs and visual scales.	Lowest response rate, Doubts cannot be clarified, Researcher has little control over when the survey will be returned.
Self-administered questionnaires	Excellent during pilot phase, Balances question clarity and answer confidentiality, Researcher can monitor completion rates, Highly consistent instruction.	High costs because researcher need to be present, Pilot study can be done with non-target segment.
Electronic interviews	Lowest Cost, Quickest dissemination, Quickest results, Large population.	Low confidentiality, Internet access.
Personal interviews	Small sample/group, Most confidential, Honest answers, Incentive schemes.	Poorly generalized sample, Very expensive.
Telephone interviews	No geographic proximity, Personal Interview, Longer more complex questions.	Slightly expensive.

The administration method selected was predominantly telephone interviews and personal interviews. This is due to the inherit complexity of the questionnaires and their relative answers.

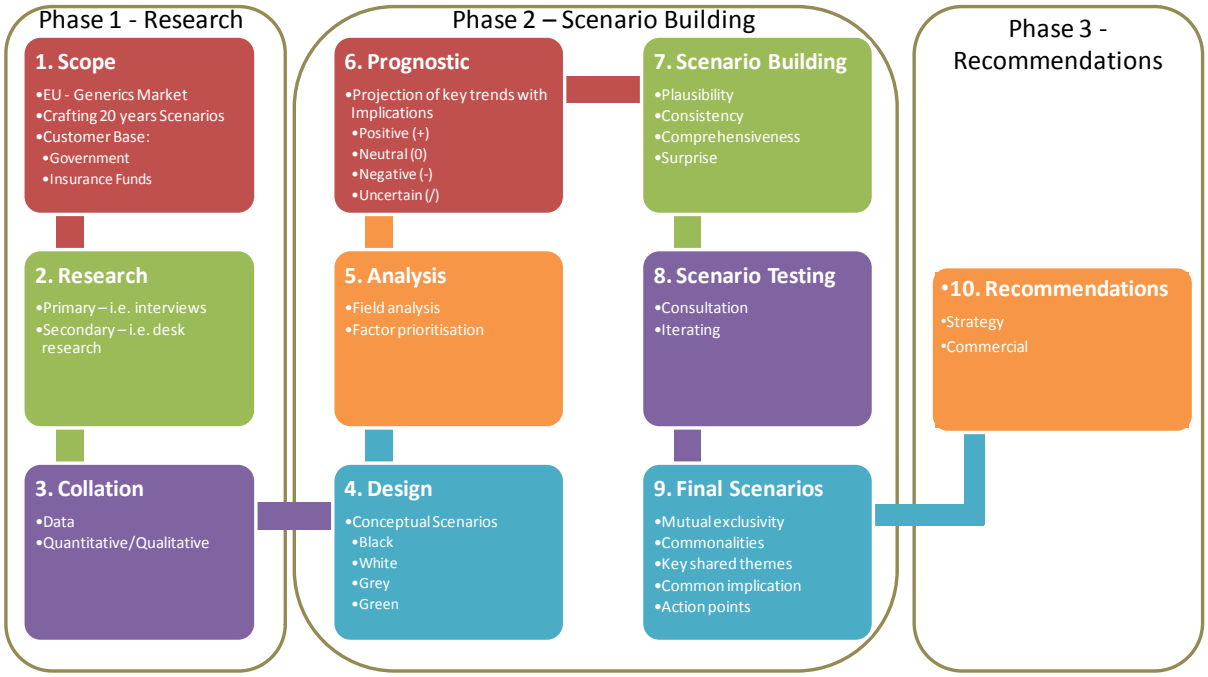
PART II PROJECT PROCESS FLOWS, RESEARCH & ANALYSIS

4 PROJECT PROCESS

4.1 PROJECT THEMATIC DIAGRAM

Figure 3 below is a graphical representation of the project process flow.

FIGURE 3: THEMATIC DIAGRAM OF PROJECT PROCESS FLOW



Source: Author

4.2 PROJECT PROCESS FLOW

This section details the project process flow as represented by the Project Thematic Diagram in the previous sections. The project process flow has been divided into three phases:

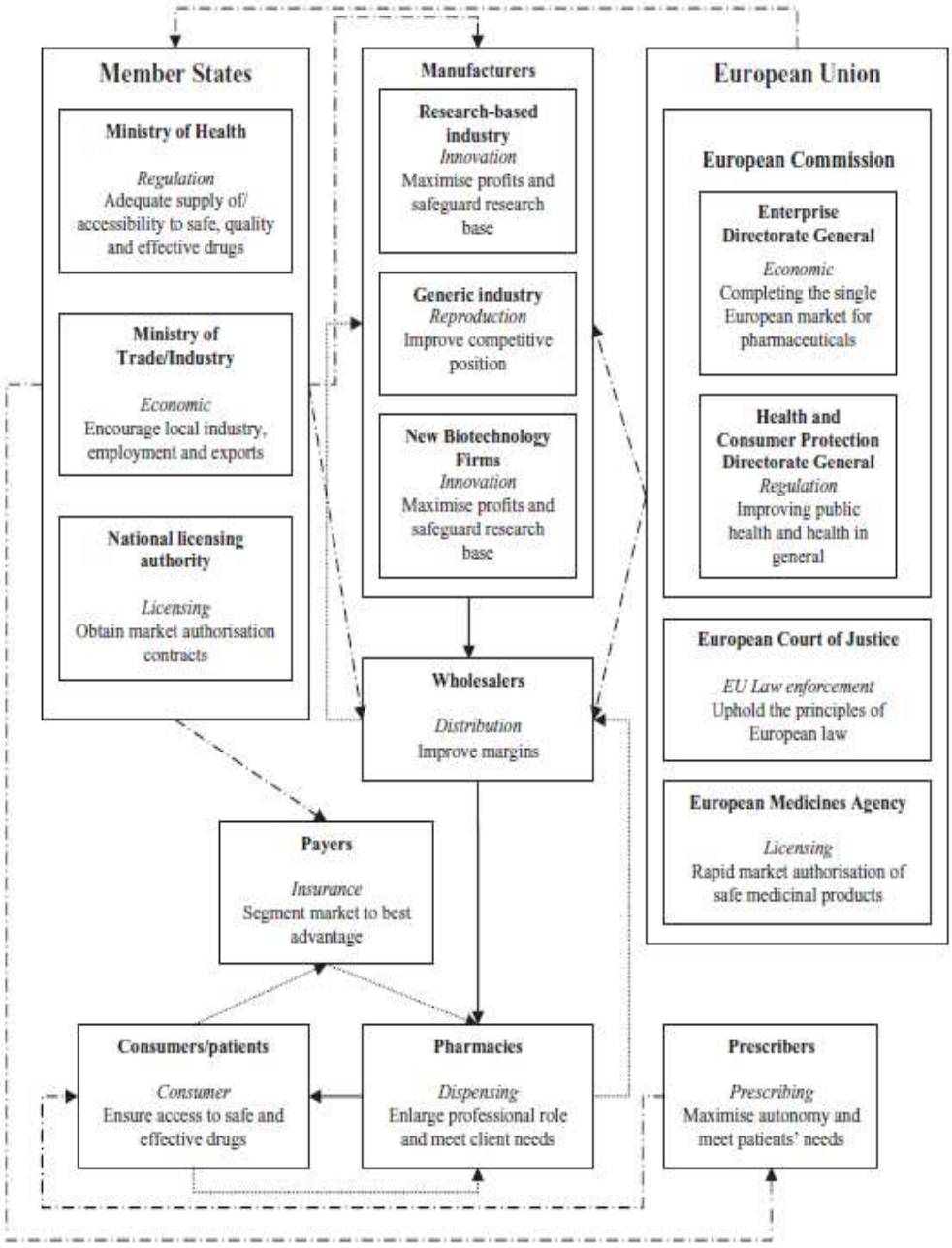
1. Phase 1 – Research: this is the stage where the scope is defined, research is conducted and data is collated.
2. Phase 2 – Scenario Building: this is the stage where the data is analyzed and the scenarios will be crafted.
3. Phase 3 – Recommendations: the final stage where strategic and commercial recommendations will be proposed.

Details of the various stages are described in the proposal supplemented with this report.

5.1 STAKEHOLDERS: PHARMACEUTICAL INDUSTRY

There are several direct/indirect stakeholders involved in the pharmaceutical industry and Figure 4 (below) is a diagrammatic representation of the stakeholders and their interactions. It is important to understand these interactions in order to govern the scenarios and propose relevant strategies.

FIGURE 4: STAKEHOLDERS IN THE EUROPEAN PHARMACEUTICAL MARKET



Source: Ginneken & Busse (2010).

5.2 PESTLE FACTORS

The project has identified 40 PESTLE factors and assigned weight based on the researchers' initial opinion with respect to their relevance to the Pharmaceutical/Generics Industry. Table 4 (below) lists the PESTLE factors identified and their assigned weight.

TABLE 4: TABULATED PESTLE FACTORS & ASSIGNED WEIGHTAGE

PESTLE	Factor Identified	Assigned Weight
Political		Low 1 - 5 High
1	EU Expansion & Integration	4
2	EU Regulatory Framework	4
3	EU Monetary Policy	4
4	EU Fiscal Policy	4
5	EU Preferential Trade Agreements (PTA's)	3
6	EU Patent Protection	4
7	EU Price Regulations	3
8	EU Political Stability	2
9	EU War & Conflicts	2
10	EU Market Intervention/s	4
11	EU Tax Policy	4
12	EU Trade Barriers and Tariffs	4
Economics		
1	EU Economic Growth Rate	4
2	EU Unemployment	2
3	EU Outsourcing/Offshoring	3
4	EU Infrastructure Quality	2
5	EU Business Cycles	3
6	EU Disposable and Discretionary Income	4
7	EU Exchange Rates	3
8	EU Inflation Rates	2
9	EU Interest Rates	2
10	EU Financial Markets	2
11	EU Savings Rate	2
Social		
1	EU Demographics	4
2	EU Education	2
3	EU Entrepreneurial Spirit	2
4	EU Lifestyle changes	3
5	EU Social Mobility	3
Technology		
1	EU New Products and Research & Development ('R&D') Expenditure	4
2	EU Biotechnology	5
3	EU Incremental & Disruptive technologies	4
Legal		
1	EU Labor Laws	2
2	EU Health and safety regulations	2
3	EU Consumer Protection	4

4	EU Benefits System	4
5	EU Anti-Trust Laws	4
Environment		
1	EU Environmental legislation, Social Responsibility, Sustainability & Global Climate Change	3
2	EU Waste Product	3
3	EU Non-Governmental Organisations (NGOs)	4
4	EU Packaging	2

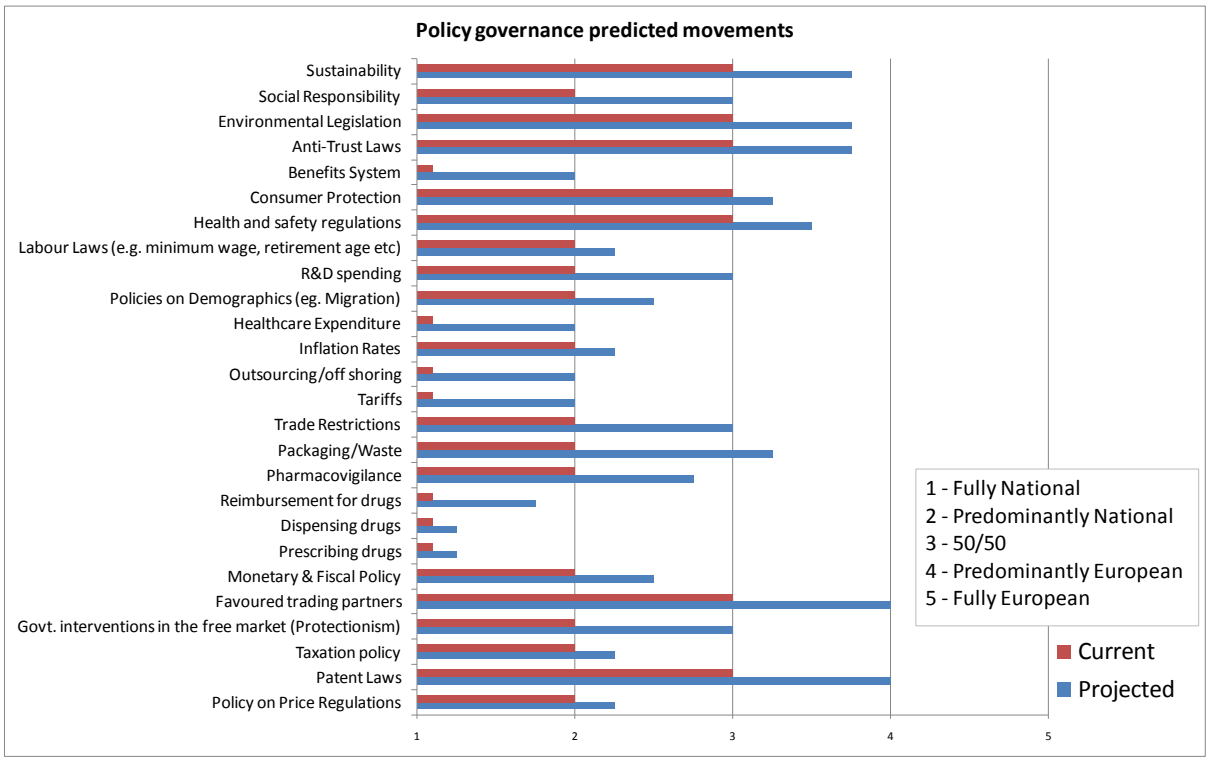
Source: Authors interpretation

The factors identified are further explored in Appendix 1.

5.3 POLICY GOVERNANCE TREND

Our quantitative research projected the following trends in policies that are directly and indirectly related to the scope of the project. Table 5 below highlights the opinions of experts and specialists over the possible policy trends in the future circa 2030.

FIGURE 5: POLICY GOVERNANCE PREDICTED MOVEMENTS

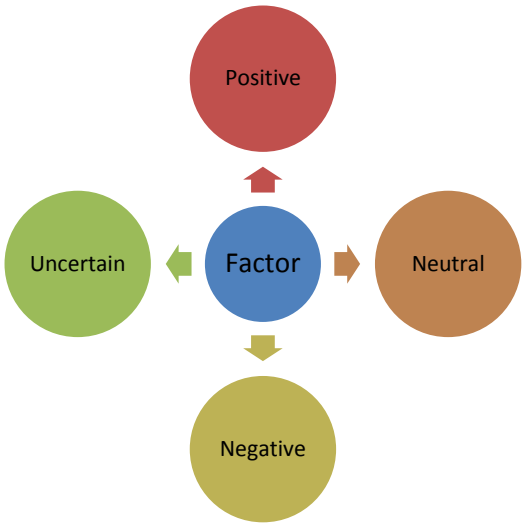


Source: Authors research

6 PROJECT ANALYSIS

Following the research phase, key trends identified from the researched factors were projected 20 years into the future as defined under the factor prognostics stage (see project process). The projected trends were clustered under 4 categories based on the project team's evaluation of their impact to the future of the generic drugs market in the EU: (1) Positive, (2) Negative, (3) Neutral, and (4) Uncertain. Figure 6 below is a graphical representation of the process.

FIGURE 6: FACTOR PROGNOSTICS



Source: Authors interpretations

Additionally, these projected trends were graded on a scale of relevance vis-à-vis scenario creation. The grading was on a scale of 1-5 with 1 being low relevance and 5 being high relevance. It is important to note here that only key trends were projected – based on the second round of relevance rating of the factors done following the PESTLE research phase.

6.1 FACTOR PROGNOSTICS

6.1.1 PROJECTION OF KEY MACRO FACTORS (POSITIVE):

1. EU Expansion and Integration. Relevance 4.

Croatia, Bosnia and Herzegovina, Serbia, Montenegro, Macedonia, Kosovo, Albania and Turkey are now members of the EU. After acceptance of these new members, the EU slows down on granting other nations accession into the EU.

2. EU Regulatory Framework. Relevance 5.

The EU has a uniform policy on generics – all member states have to comply with the EU policy on generics, and now, the average generic uptake percentage in the EU is at par with the uptake percentage in the US. There is a separate body in the EU that specializes in, and has the authority to approve generics.

3. EU Monetary Policy. Relevance 4.

The Eurozone now includes all countries that are part of the EU including the countries that recently gained accession. The Euro is the sole currency operating amongst all member states. This has reduced transaction costs and exchange rate risks, and has brought about stability throughout the EU regional economy.

4. EU Fiscal Policy. Relevance 4.

The EU and the ECB are stronger. Austerity measures have strengthened the financial and economic stability of a majority of member states. There is strict governance by the EU regulators with regard to fiscal deficits and debts.

5. EU Preferential Trade Agreements (PTA's). Relevance 3.

Several countries and regional blocks have signed preferential trade agreements with the EU. This has increased competition, lowered prices and expanded the market for generic drugs in the EU.

6. EU Outsourcing/Offshoring. Relevance 3.

Outsourcing and offshoring is strongly encouraged by the EU and the levels of outsourcing and offshoring by European corporations have now skyrocketed. Organizations in the EU are now extremely competitive globally as the achieve economies of scale and lowered cost structures. These activities have made industries within the EU thrive.

7. EU Pricing Regulations. Relevance 4.

There is across the board harmonization across the EU on the use and implementation of market based measures to reduce prices. Market based interventions (such as internal and external reference pricing) are used extensively in all member states across the EU. This has reduced drug prices dramatically. In countries with complete health care insurance coverage, the EU has imposed market based interventions to reduce prices and the EU has also implemented policies to ensure that efficiencies are achieved and bureaucracies are reduced within national healthcare systems.

8. EU Political Stability. Relevance 2.

The EU is now united and there is strong political will and leadership as member states are subscribed under one banner towards achieving long-term objectives. They have recognized the importance of unity in an environment of cut-throat global competition. National concerns are now at par with European concerns.

9. EU Market Interventions. Relevance 4.

The EU is responsible for a collaborative market intervention and there is greater integration and harmonization amongst all member states. This collaborative effort is complementing free-market trade and competition thus enforcing cost containment strategies particularly

with regard to lowering healthcare costs. This is done by direct market demand and supply interventions as part of a central policy within the EU.

10. EU Economic Growth Rate. Relevance 3.

Austerity measures taken by member states have reduced fiscal deficits and debts. The EU now maintains a positive growth rate as a whole and economies of member states are now vibrant and stable. Unemployment and inflation is under control and provides a favorable economic environment for organizations to grow and develop. The free-trade policy within the EU is promoting competition and organizations are more resilient and efficient in foreign markets.

11. EU Unemployment. Relevance 3.

The overall EU unemployment rate and volatility in unemployment rates in most member states is low. Youth unemployment is low and governments are effective in promoting the life cycle approach to work. They are encouraging lifelong learning and improving support systems for EU citizens to find jobs. There is also strong support for diversity and inclusion in the workplace. New industries have come along within the EU and helped diversify the region's economic base.

12. EU Financial Markets. Relevance 3.

Financial markets are stable, secure and efficient throughout the EU. EU regulators have stringent monitory systems to ensure stricter reinforcement and compliance to measures and closer integration of efforts. There is harmonization of standards and regulations and this has insured stability within the financial markets throughout the EU.

13. EU Business Cycles. Relevance 3.

There is little volatility in business cycles and output. Inflation and interest rates have become stable. Economic activity between core and periphery member states is as divergent as it was in the past. Less volatility in business cycles across the EU has insured stability and positive growth rates across the member states.

14. EU Exchange Rates. Relevance 2.

All member states have now joined the Euro zone and have eliminated exchange rates risks, reduced transaction costs and created exchange rate stability throughout the region this has had a positive impact towards economic growth.

15. EU Inflation Rates. Relevance 2.

The EU has achieved stability in inflation rates through sound policy by the ECB and disparities in economic conditions between original and new member states have been reduced. This has resulted in positive economic growth across the region.

16. EU Interest Rates. Relevance 2.

The ECB has adapted a policy of stabilizing inflation by stringent interest rate control across the member states thus promoting economic growth and reducing disparity in inflation figures.

17. EU Trade Barriers and Tariffs. Relevance 3.

The EU has relaxed non-tariff trade barriers in an effort to increase competition within the EU. This policy is lowering prices and enhancing efficiencies across the EU.

18. EU Savings Rate. Relevance 2.

The savings rate has increased as industries have picked up in the region, unemployment and inflation rates are low. As citizens are living longer, the EU has encouraged more savings by all citizens.

19. EU Education, Entrepreneurial Spirits & Social Mobility. Relevance 2.

The EU coordinated strategy of improving education amongst the local workforce has upgraded the standards of workforces to meet the needs of employers for high-skilled workers. Additionally immigration policy has been designed so as to allow only immigrants with specialized skills to relocate to the EU and fill the gaps in the skilled workforce as required. Member states have realized the need for social mobility and are promoting and supporting social mobility across the social hierarchies within their economies. There is an added advantage in that immigrants have higher levels of entrepreneurial spirit and this has led to increased levels of SME business activity within the EU.

20. EU Lifestyle Changes. Relevance 4.

Citizens of the EU are enjoying very high standards of living. Preventive care levels have increased, the population is more active and obesity and related diseases levels have dropped. This has lead to healthier lifestyles across the EU member states and lessened the burden on healthcare systems. Life expectancy levels are highest in the EU as compared to other parts/regions of the world.

21. EU Attitude towards Generics vs. Patented Drugs. Relevance 3

Generic drugs are now widely accepted in all societies as suitable replacements towards patented drugs. The attitudes towards generics drugs are now positive.

22. EU Counterfeit Drugs. Relevance 3.

The EU has undertaken successful initiatives to curb the proliferation of counterfeit drugs. Policies and regulations have led to the implementation of strict measures to ensure that the value chain does not source from counterfeit producers. Prosecution and enforcement activities have led to the lowest levels of counterfeit drugs within supply chains.

23. EU Advances in Genomics. Relevance 3.

Rapid and numerous developments in genomics have lead to targeted preventive treatments of numerous diseases. Certain diseases have been treated well in advance leading to lower hospital patient populations. The EU has collaborated effectively on advancing genomic sciences because it has recognized the great potential with regards to preventive care. Additionally genomics sciences have led to more targeted forms of treatments and niche drugs. Patients are now being diagnosed for genetically inherited diseases and treatments are available well in advance to ensure that patients do not contract diseases to which they are genetically prone.

24. EU Drug Delivery Systems. Relevance 3.

Drug delivery systems have been improved to a level whereby side effects on patients have been curbed. More targeted compounds can now be released to specific parts of the body reducing the timeframe of treatments. Additionally nanotechnology enabled drug delivery systems have been developed and many small biotech companies have emerged in this field across the EU. More advances with regard to nanotechnology are anticipated as the EU is now focused on exploring this field of science to improve the overall healthcare of its citizens.

25. EU Biotechnology Systems. Relevance 3.

Technologies such as pharmacogenomics, stem cells, gene therapy have advanced as alternatives to conventional treatment. 50% of new drugs launched into the market are derived from the fields of biotechnology. These treatments are now being made available by generic drug companies as well as the big-pharma companies.

26. EU Consumer Protection. Relevance 3.

EU Consumer protection policy has increased transparency across all industries especially healthcare ensuring transparency in manufacturing, sourcing and dealings. This has lead to increased consumer confidence levels. Consumer protection regulations are now harmonized across all EU member states.

27. EU Benefits Systems. Relevance 3.

Significant reforms have occurred throughout the EU with regards to benefits systems. The private healthcare sector has developed tremendously throughout the EU to a level where an average of 50% of the care for all EU citizens is provided from this sector. The main reason this has occurred is because EU member states have tried to reduce public spending, fiscal deficits and debt levels. In addition they have incorporated more market forces into the healthcare systems to improve efficiencies, reduce bureaucracy and improve the overall quality of their healthcare systems.

28. EU Anti-Trust Regulation. Relevance 3.

Numerous anti-trust cases initiated by the EU against players in the industry found to have the aim of gaming the system have resulted in a freer and more secure market trading environment. EU regulators are now seen as strict enforces of anti-trust laws and this scenario has benefited the EU market. The main goal of the EU has been to promote fair competition amongst players and this goal has now been realized.

29. EU Waste Management. Relevance 2.

The impact of the pharmaceutical and generic drugs industry on the environment has been significantly reduced especially with regard to waste products. Chemicals used in the industrial production of drugs are environmentally friendly due in large part to strict regulation and enforcement throughout the EU. The carbon footprint of the pharmaceuticals industry as a whole has been severely reduced across all member states.

30. EU NGO's. Relevance 3.

NGO's are now considered key stakeholders within the entire pharmaceutical and generics industry. The effect of this has been an increase in CSR activity, ethical supply chains and more sustainability practices.

31. EU Packaging. Relevance 2.

Numerous advances have been made in packaging technology. Materials used are more sustainable and environmentally friendly. Additionally packaging of drugs are now more patient (user) friendly, and better packaging has led to extended life cycles of use for numerous drugs.

6.1.2 PROJECTION OF KEY MACRO FACTORS (NEGATIVE):

1. EU expansion and Integration. Relevance 4.

The EU has put the brakes on its expansion. Only a few countries have been allowed accession over the past several years: Turkey, Croatia, and Bosnia and Herzegovina.

2. EU Regulatory Framework. Relevance 5.

Member states are still fragmented and generics drug uptake is a national policy concern. The uptake percentage is high in some EU member states while very low in the remainder.

3. EU Monetary Policy. Relevance 4.

The Euro Zone has collapsed. All member states have reverted to their old currencies and economic policy is now a national level concern.

4. EU Fiscal Policy. Relevance 4.

Fiscal policy is now a national level concern and the financial stability of member states is precarious due to high fiscal debt levels. Austerity measures have not been exercised in numerous member states and EU member states that have not met the requirements of the EU with regards to lowering fiscal deficits and debt levels have been exempted from the Union.

5. EU Preferential Trade Agreements (PTA's). Relevance 3.

EU has now set higher standards of requirements with regard to preferential trade agreements. EU has taken a protectionist stance and has raised the standard to trade with Non-EU countries by tightening trade policies. This is done by higher quality requirements and trade quotas resulting in restricted foreign trade.

6. EU Outsourcing/Offshoring. Relevance 3.

Outsourcing and offshoring levels are low in many member states. Member states are now in full protectionist mode in accordance to the rising pressures of local populations to lower national unemployment levels.

7. EU Pricing Regulations. Relevance 4.

There is fragmentation across EU and member states are imposing national price control measures. Market based measures are not exercised across the EU and more purely administrative measures (such as central price controls) are being imposed in numerous member states. These administrative price regulations pose as a hindrance to the entry of generics into these countries.

8. EU Political Stability. Relevance 2.

The EU has fragmented with member states further prioritizing national interest over a collaborative effort. This fragmentation has weakened the EU.

9. EU Economic Growth Rate. Relevance 3.

The EU is made up of weak and strong economies. Strong 'core' member states such as Germany, UK, and France have stabilized their economies by national austerity measures while 'periphery' member states still suffer from stagnant or negative GDP growth rates.

10. EU Unemployment. Relevance 3.

The average EU unemployment rate is high and there is high volatility numerous labor markets. High levels of unemployment can be found in member states across the EU and this has affected social cohesion and economic growth rates. Youth unemployment is high and has lead to social tensions. Governments have moved more towards a protectionist stance and spending on social benefits has increased while tax revenues have been reduced.

11. EU Business Cycles. Relevance 3.

There is high business cycle volatility throughout the EU because of the persistent differences in economic activity between 'core' and 'periphery' member states. Business cycle volatility has led to a negative impact on growth rates of several member states across the EU.

12. EU Exchange Rates. Relevance 2.

The Euro zone has collapsed and countries have reverted to their original national currencies. This has increased transaction costs and created exchange rate instability throughout the EU resulting in poor levels of economic activity and low growth rates.

13. EU Inflation Rates. Relevance 2.

The volatility of energy and food prices has translated into high rates of inflation especially amongst the new member state and states within the 'periphery' of the EU. This has directly affected business cycles thereby leading to negative effects to the EU economy as a whole.

14. EU Interest Rates. Relevance 2.

Interest rates are volatile throughout the EU region, with low rates in the 'core' states, and higher rates in the 'periphery' states. This has led to significant disparities in economic growth rates across the region.

15. EU Trade Barriers and Tariffs. Relevance 3.

The EU has increased the number of non-tariff barriers in an attempt to protect local industries from foreign competitors. This protectionist stance had embedded inefficiencies amongst EU based firms and has led to increased pressures from non-EU firms to open up the EU market. At this time, countries outside the EU have very strong economies, and these countries have also adopted protectionist measures in retaliation. This has led to shrinking global markets for products manufactured within the EU.

16. EU Savings Rate. Relevance 2.

The savings rate is low across the EU. This is partly due to low growth in the economy combined with high unemployment. Inflation has risen private healthcare is now a very small part of health care systems within the EU. As savings rates are low, member states have realized that the only way that most citizens can get healthcare is if it is provided at no cost by the government.

17. EU Demographics. Immigration and Fertility rate. Relevance 3.

There is no harmonized policy for immigration within the EU and member states, because of high employment combined with negative attitudes towards immigrants, have limited migration of immigrants into their countries. Because of aging populations and low fertility rates, the work force needs of the industry growth are not being met. Additionally workers

from new member states do not possess the right skills criterion making it difficult for economies to progress.

18. EU Counterfeit Drugs. Relevance 2.

Counterfeit drugs have now proliferated the EU marketplace. Member states, due to budget constraints have failed to enforce counterfeit drug control measures. Citizens have resorted to buying medications 'off-the-street' and a black market for numerous drugs has emerged. Drugs are being smuggled across borders, and the illegal trade of medications is thriving.

19. EU Benefits Systems. Relevance 3.

No significant reforms have occurred throughout the EU with regards to benefits systems. The private healthcare sector has been replaced in many countries by public healthcare systems. Private healthcare has developed only to a level where an average of 25% of the care is provided from this sector in most member states. This has led to increased public spending, larger fiscal deficits and debt levels in many EU member states. Efficiencies are low and bureaucracy levels are high.

6.1.3 PROJECTION OF KEY MACRO FACTORS (UNCERTAIN):

1. EU Monetary Policy. Relevance 4.

The euro zone is smaller and now consists of only members with strong economies and the criterion for membership into the euro zone is much stricter. Member states that have weak economies and do not meet the strict criteria of being part of the euro zone are subject to exclusion from the euro zone.

2. EU Fiscal Policy. 4.

EU still has weak member states that are subjected to weak financial economies. These member states are suffering from high levels of fiscal debt and high levels of government spending. To stimulate economic activity, EU member states with strong economies are supporting weaker member states with bail-outs and injections of investment funds.

6.1.4 PROJECTION OF KEY MACRO FACTORS (NEUTRAL):

1. EU Intellectual Property Protection. Relevance 2.

The EU has strong patent protection policies and does not grant patent extensions. There is strong commitment to ensure that organizations do not behave opportunistically with regards to patent policies and strict measures are exercised otherwise. This factor has been regarded neutral because generic drugs are off-patent and are not governed under this policy.

2. EU Infrastructure Quality. Relevance 2.

The EU has established the long-term single multi-modal network that integrates land, sea, and air transport networks throughout the EU region and has kept pace in further developing infrastructure. Because this development has kept pace, it has neither positively nor negatively affected industry in the EU.

3. EU War & Conflict. Relevance 2.

The EU holds unity to the stated goals of the EU when founded: to act as a force of stability, cooperation and understanding in the wider world. It follows the trend of addressing conflict through diplomacy rather than explicit military action. The way of the past whereby individual member states would engage in military action in parts of the world to serve their national interest has been replaced with a more unified EU diplomatic stance.

4. EU Market Interventions. Relevance 4.

Market interventions are predominantly national concerns and subjected to several factors at a national level. Several member states are practicing different interventions to control costs as some bear positive results and other don't. Because the EU is not yet fully integrated at present and member states currently have individualistic policies, it does not hold a collaborative effect on industries in the future thus this possible scenario has been regarded as neutral with regard to future impact.

5. EU Tax policy. Relevance 2.

Tax policy is a national concern and this scenario has not been subjected to much change. These is no across the board harmonization in member states tax systems. There is however a common consolidated corporate tax base which exists for firms across the EU eliminating the need for filing separate accounts in each country and separate accounting practices from country to country.

6. EU Disposable and Discretionary Income. Relevance 2.

Most countries within the EU have national insurance healthcare systems therefore discretionary income does not play a significant role with respect to the future of the generic drugs industry in the EU. There are still significant levels of disparity across the EU with citizens in urban regions having more disposable incomes compared to those in rural regions.

7. EU Demographics. Immigration and Fertility rate. Relevance 3.

Over the coming years the EU will have a harmonized policy in immigration. The policy is designed in a manner to allow enough migration to offset the effects of aging populations and low fertility rates. Additionally because of EU expansion, high youth populations from countries that have been allowed membership in the EU (for example: Turkey, etc.) will bring in enough workers to meet the needs of the economies. Therefore there will neither be a negative or positive impact on industry in the EU.

8. EU Labor Laws. Relevance 2.

Freedom of movement of workers from one member state to another is still the right of any EU citizen. This policy has not been subjected to change and therefore remains neutral with regard to the future of the EU economy.

9. EU Health and Safety. Relevance 3.

As has always been the case, health and safety regulation are stringent and EU policy makers are determined to ensure that all drugs meet H&S requirements. Because this policy has not been subjected to much change it remains neutral.

6.2 FACTOR PROGNOSTICS TABULATED

Table 5 below is the tabulated representation of the factor prognostics stage and their respective relevance to EU generic drugs industry.

TABLE 5: FACTOR PROGNOSTICS

Factor Prognostics and Relevance to EU Generic Drugs Industry							
Positive Projection		**Negative Projection**		**Neutral Projection**		**Uncertain Projection**	
EU Regulatory Framework	5	EU Regulatory Framework	5	EU Market Interventions	4	EU Monetary Policy	4
EU Expansion and Integration	4	EU expansion and Integration	4	EU Demographics. Immigration and Fertility rate	3	EU Fiscal Policy	4
EU Monetary Policy	4	EU Monetary Policy	4	EU Health and Safety	3		
EU Fiscal Policy	4	EU Fiscal Policy	4	EU Intellectual Property Protection	2		
EU Pricing Regulations	4	EU Pricing Regulations	4	EU Infrastructure Quality	2		
EU Market Interventions	4	EU Preferential Trade Agreements (PTA's)	3	EU War & Conflict	2		
EU Lifestyle standards	4	EU Outsourcing/Offshoring	3	EU Tax policy	2		
EU Preferential Trade Agreements (PTA's)	3	EU Economic Growth Rate	3	EU Disposable and Discretionary Income	2		
EU Outsourcing/Offshoring	3	EU Unemployment	3	EU Labor Laws	2		
EU Economic Growth Rate	3	EU Business Cycles	3				
EU Unemployment	3	EU Trade Barriers and Tariffs	3				
EU Financial Markets	3	EU Demographics	3				

EU Business Cycles	3	EU Benefits Systems	3				
EU Trade Barriers and Tariffs	3	EU Political Stability	2				
EU Attitude towards Generics vs. Patented Drugs	3	EU Exchange Rates	2				
EU Counterfeit Drugs	3	EU Inflation Rates	2				
EU Advances in Genomics	3	EU Interest Rates	2				
EU Drug Delivery Systems	3	EU Savings Rate	2				
EU Biotechnology Systems	3	EU Counterfeit Drugs	2				
EU Consumer Protection	3						
EU Benefits Systems	3						
EU Anti-Trust Regulation	3						
EU NGO	3						
EU Political Stability	2						
EU Exchange Rates	2						
EU Inflation Rates	2						
EU Interest Rates	2						
EU Savings Rate	2						
EU Education, Entrepreneurial Sprits& Social Mobility	2						
EU Waste Management	2						
EU Packaging	2						

Source: Authors interpretations

PART III: SCENARIOS & STRATEGIC RECOMMENDATIONS

SCENARIO 1: *"TODO ES BUENO!"*

June 30th, 2030:

Nigel wakes up at 9am with a nudge from Jeeves. As he opens his eyes, Jeeves' shiny fluorescent eyes are flashing with joy, and there's a big smile on his face. "Good morning Jeeves", Nigel says as he rubs the sleep from his eyes. "Hello Nigel, hope that you slept well" Jeeves replies in a friendly tone. It's been a year since Nigel bought his robotic butler Jeeves from the Japanese company with a showroom on Bond St in London. Jeeves is a butler robot, programmed to provide basic solutions for Nigel's day-to-day needs around the house. "Nigel, would you like me to update you on the agenda for today?" Jeeves asks. "I know that you have the day off from work, but you've got an important telepresence interview appointment at 10am" Jeeves says as he magically glides across the floor and into the kitchen. "Absolutely Jeeves, I remember" Nigel says as he gets out of bed. Yes, the interview is quite important, Nigel thinks to himself. Nigel's employer, an Indian pharmaceutical company based in New Delhi has had him conduct some research on the EU macro environment in an effort to craft the following year's strategy for the company's European expansion plans. Juan Cervantes is quite an important member of the Spanish parliament, and therefore, his views on the current EU environment will be crucial in supplementing Nigel's research. As Nigel sits on his leather couch, he commands the computer screen to come on. The wall, which turns into the screen, blinks on. "Today's news" Nigel commands as he reclines back into the couch. The virtual TV anchor relates the key events of the day around the globe. The big story is regarding the civil unrest in the Xinjiang province of China. "How do you think this will turn out Jeeves?" Nigel asks as he points towards the screen. "Well, I think that the Chinese government is going to quell the violence in Xinjiang, but pockets of unrest will continue to spread throughout the country" Jeeves replies. He's right, Nigel thinks to himself. "So Jeeves, let me have my interview questions on the screen, and get a hold of Mr. Cervantes. Maybe he's ready for our interview" Nigel says. The screen switches onto a different template, and Nigel's pre-written questions appear. Jeeves goes to the command board next to the screen and transfers in his commands through a wireless interface. "Mr. Cervantes is available Nigel, and he can start the interview in 5 minutes" Jeeves says. Nigel then steps into his bedroom to quickly dress up. After putting on a shirt and pants, Nigel then steps back into the living room. "OK Jeeves, I'm ready" says Nigel. Jeeves then steps into the adjoining room as Mr. Cervantes' voice comes through on the surround speakers. The interview has begun. Juan Cervantes' telepresence silhouette magically appears into the room from a projector on the wall…

Nigel: Good Morning Juan!

Mr. Cervantes: Hola Nigel, how are you doing today?

Nigel: I am well, how about yourself?

Mr. Cervantes: Muy bien Nigel. Are you ready to fire away your questions?

Nigel: Sure! You do know what our interview is about right? Jeeves sent you a draft of our questionnaire, and a brief on the purpose of the interview yesterday. Your office did receive his file right?

Mr. Cervantes: Yes, Jeeves did send the file through. I am quite ready to answer all your questions.

Nigel: OK. Let's start then. The first question is: How are things going in the new EU member state economies?

Mr. Cervantes: Todo es Bueno Nigel. The integration of the new states has been going very well. Croatia, Bosnia and Herzegovina, Serbia, Montenegro, Macedonia, Kosovo, Albania and Turkey are fully on board, and these countries have done quite well over the past few years in meeting the criteria of the EU with regard to getting their economies in order. As you know, they've also all joined the euro zone, and positive GDP growth rates are being forecast for all these economies in the next few years.

Nigel: Yes, that's been going quite well. I'm so glad that the political leadership situation within the EU has been sorted. The Turkish presidency of the EU has been quite successful, and all the efforts of European leaders over the past decade seem to be bearing fruit. It's so great to have a united Europe! Can you tell me a little more with regard to the rate of generics uptake within EU states?

Mr. Cervantes: Generic uptake levels are now at par with the level in the US thanks to the EU's uniform policy on generics. The central EU body that was set up to specialize in and approve generics has been quite effective. Additionally, member states have been very compliant with policies from Brussels on increasing generics usage. You should pay close attention to the new preferential trade agreement that will soon be signed with the Union of African States. That could play a big part vis-à-vis market expansion plans for European based pharmaceutical and generics companies over the coming years. This will also be quite important in the sense that there will be increased competition in this industry from pharmaceutical and generics manufacturers in Africa. But then again, they have a long way to go before they can match the low prices and excellent quality of medicines being produced in India by the big European pharma companies.

Nigel: Yes, I agree. The European pharma's have been very successful in outsourcing certain functions to India, and in off shoring their manufacturing there as well. How else have EU member states succeeded in getting their medications prices so low?

Mr. Cervantes: There has been across the board harmonization across the EU on the use and implementation of market-based measures to reduce prices. The use of Internal and external reference pricing over the past decades has played a big role in reducing prices. In countries with national health care insurance like the NHS in the UK, the EU has been effective in imposing market-based interventions and also in implementing policies to ensure that efficiencies are achieved and bureaucracies reduced.

Nigel: Can you tell me more on how effective the austerity measures have been over the past decades? And how has this benefitted the EU as a whole?

Mr. Cervantes: Todo es Bueno! The austerity measures were vital! Since they started around the year 2010, they've been very effective at reducing fiscal deficits and debt levels. Amongst the strong EU member state economies, GDP growth rates are up, and industries

are thriving. Unemployment is down, and inflation is under control in most EU countries. The austerity measures also helped stabilize the economies throughout the region. Business cycle volatility in the EU has been reduced. As I said earlier, the austerity measures were vital, and the current stable period of strong growth may not have been possible without the austerity measures.

Nigel: How about the financial markets?

Mr. Cervantes: Financial markets are stable, secure and efficient throughout the EU. EU regulators have stringent monitory systems to ensure stricter reinforcement and compliance to measures, and here again, closer integration and collaboration amongst member states within the EU has made this possible. There is harmonization of standards and regulations as well. So, as I said, TodoesBueno!

Nigel: What can you tell me about non-tariff trade barriers?

Mr. Cervantes: Todo es Bueno! The EU has cut back on many of these barriers, and this has in fact helped open up many markets for EU companies, as well as increased the flow of goods into the EU.

Nigel: How about lifestyles of EU citizens?

Mr. Cervantes: Todo es Bueno! Citizens of the EU are enjoying high standards of living. Preventive care levels have increased, the population is more active and obesity and related disease levels have dropped. People in the EU are living a very healthy lifestyle, and life expectancy levels are up.

Nigel: Has the EU been effective at reducing the amount of counterfeit drugs in the marketplace?

Mr. Cervantes: Todo es Bueno! The EU has undertaken successful initiatives to curb the proliferation of counterfeit drugs. Policies and regulations have led to the implementation of strict measures to ensure that the supply chains are free of counterfeits. Prosecution and enforcement activities have been very effective.

Nigel: Tell me more about the advances in Genomics.

Mr. Cervantes: Todo es Bueno! Rapid and numerous developments in genomics over the past decade have led to targeted preventive treatments of numerous diseases. Certain diseases have been treated and cured well in advance thanks to Genomics, and hospital patient populations have been reduced. Patients are now being diagnosed for genetically inherited diseases and medications have been developed to treat people well in advance.

Nigel: What about drug delivery systems?

Mr. Cervantes: Todo es Bueno! Drug delivery systems have been improved to a level whereby side effects on patients have been curbed. More targeted compounds can now be released to specific parts of the body reducing the timeframe of treatments. Additionally,

nanotechnology enabled drug delivery systems have been developed by many small biotech companies.

Nigel: What about biotechnology?

Mr. Cervantes: TodoesBueno! Technologies such as pharmacogenomics, stem cells, gene therapy have advanced as alternatives to conventional treatments. 50% of new drugs launched into the market are derived from the field of biotechnology. These treatments are now being developed by both pharmaceutical and generics companies.

Nigel: Tell me about the benefits systems in the EU member states.

Mr. Cervantes: Todo es Bueno! Significant reforms have occurred throughout the EU with regards to benefits systems. The private healthcare sector has developed tremendously throughout the EU to a level where an average of 50% of the care for all EU citizens is provided from this sector. The main reason this has occurred is because EU member states have tried to reduce public spending, fiscal deficits and debt levels. In addition they have incorporated more market forces into the healthcare systems to improve efficiencies, reduce bureaucracy and improve the overall quality of their healthcare systems.

Nigel: How about waste management and packaging of medications.

Mr. Cervantes: The impact of the pharmaceutical and generic drugs industry on the environment has been significantly reduced especially with regard to waste products. Chemicals used in the industrial production of drugs are environmentally friendly due in large part to strict regulation and enforcement throughout the EU. The carbon footprint of the pharmaceuticals industry as a whole has been severely reduced across all member states. With regard to packaging, numerous advances have been made in packaging technology. Materials used are more sustainable and environmentally friendly. Additionally packaging of drugs is now more patient (user) friendly, and better packaging has led to extended life cycles of use for numerous drugs.

Nigel: You have been very helpful Juan! Any final comments?

Mr. Cervantes: As I've said over and over, TodoesBueno Nigel! We've come a long way in the European journey, and now finally, the hard work of many years and strong political will for unity in the Union is paying huge dividends. I see a very bright future for industry in the years ahead!

Nigel: That's jolly good. Are you going to watch the World Cup final in Barcelona? Who do you think will win?

Mr. Cervantes: Yes! Nigeria will beat Turkey for sure! The Nigerians have got a solid team, and the Turks will have their hands full.

Nigel: I agree. Thanks again Juan, and I'll contact you again if necessary. Good bye for now.

Mr. Cervantes: Gracias Nigel. Take care.

Juan leaves the room in the blink of an eye as Jeeves re-enters the room. “How did the interview go Nigel?” Jeeves asks. “Very well Jeeves. I think I’ll go to Paris for Dinner. Book me a ticket on the bullet train. That’ll get me there in 2 hours…

SCENARIO 2: “NEIN, NICHT GUT!”

August 19th, 2030:

Egyptian reporter Heba Aly is on an assignment for Bloomberg News. She left Cairo at 9am, and is scheduled to arrive in Frankfurt by 11am via Express Europe flight A410. The airplane she's on, manufactured by China Aircraft Manufacturers, is a new solar powered Super jet capable of a cruise speed of up to 2,000km/h. What a dream ride Heba thinks to herself, as the airplane touches down on the tarmac at Frankfurt International. Super-fast, super luxurious and zero carbon emissions! As Heba leaves the airport, she's struck by the number of tourists from India and China that have congregated outside the airport waiting for their tour shuttle to arrive. Over the past decade or so, tourism has been an industry that has thrived in Europe. As China and India have shared the second and third spots respectively on the rankings of largest world economies (with the US economy still barely clinging on to first place), the now affluent citizens of these two nations have been swarming all over Europe visiting the many tourist destinations across the continent. Heba gets on Frankfurt's super underground, and within minutes, she's at the doorstep of the Frankfurt Grand Hyatt. Her meeting with Economist Jurgen Deitrich is scheduled for 12noon, and so Heba has some time to grab a quick bite at the automated Café in the hotel lobby. She picks her meal from the display screen in the Café, a Cappuccino with biscotti, and flashes her mobile phone across the pay pad. The pay pad beeps, and a quick look on her mobile phones screen reveals that she's been charged 10 Deutsche Marks. As Heba takes a seat in the café, she puts on her eyeglasses, which have a computer display on the lenses. She pushes in some commands on her mobile phone, and the latest news of the day start flashing across the eyeglass lenses. The big stories of the day: a baby boy's birth on the moon has led to the human colony there surpassing the 20,000 mark; a huge celebration is taking place in Astoria, Oregon as that city opens its massive water desalination plant that will supply a monthly output of 20 million gallons from the Pacific Ocean to all States on the West Coast of America, and that Ukraine has finally agreed to become a part of Russia after years of negotiations. As Heba sips the last of her Cappuccino, her mobile phone flashes, and she can see that Jurgen Deitrich has arrived at the Hyatt hotel for the interview. Heba tidies up her table, and leaves for the conference room…

Heba: Hello Herr Jurgen!

Jurgen: Guten Tag Heba. How are you doing today?

Heba: I am well, how are you?

Jurgen: I've had a rough morning to be quite frank. It's so hard to get an agreement with the regulators you know!

Heba: Yes Herr Jurgen, I totally understand.

Jurgen: So, I looked through your interview questions last night. Are you ready to start the interview?

Heba: Yes Sir!

Jurgen: I see that you're doing a news story for Bloomberg News on the current economic environment in Europe for the Pharmaceuticals industry. I had a chance to do some research these past few days, and I think that I'm quite prepared to answer all your questions.

Heba: Thank you so much Herr Jurgen!

Jurgen: Ok, so let's start with your first question then.

Heba: Sure! Please tell me what you know about integration efforts within the EU. Also, tell me about the EU's future expansion plans.

Jurgen: Heba, in two words, nicht gut! As you know, since 2007, the EU has only granted accession to Turkey, Croatia, and Bosnia and Herzegovina. These countries integrated into the EU at a very slow pace since gaining accession. There are still numerous disparities between the economies of these states and the 'core' member states. The EU has become very wary of expansion, and as of right now, there seems to be very little political will and unity in the EU on the issue of granting accession to more states.

Heba: What about the re-establishment of euro zone? Are things looking positive on that front?

Jurgen: Nein, nicht gut! Again, as you're aware, the euro zone collapsed in 2017. All member states reverted to their old currencies. The fiscal crises' in Greece, Spain, Portugal and Ireland about twenty years ago took many years to sort out, and these crises' put a tremendous financial burden on the stronger economies within the EU at the time. Frankly, the stronger economies just did not want to continue bailing out the weaker economies. Several EU member states were predicted to follow the same path that the aforementioned countries had followed. High levels of public spending and high debt levels were forecasted in many 'periphery' member states, and we all pretty much reached a point where national interests became far more important.

Heba: In your opinion, how did the breakdown of the euro zone impact the EU?

Jurgen:Nicht gut! At the time, it seemed like reverting to old currencies was the right way to go, but looking back, the break-up of the euro zone caused tremendous long-term damage to the EU's competitive position in the global economy. There has been increased volatility in business cycles and unemployment levels across many member states. Additionally, transaction costs went up. All these factors resulted in lower levels of economic growth across the EU. In hindsight, we should all have remained united at the time, but as I said, national governments went into protective stances, and this short-term way of thinking had a huge negative impact on the EU as a whole.

Heba: The austerity measures worked well for the UK economy did they not?

Jurgen: Yes! That was the smart way to go. The UK economy got its public spending under control by 2015. This helped the British economy gain a foothold and become more competitive in the years that followed. If only more member states in the EU would have cut

back on public spending at the time, and got their fiscal budgets and debt levels under control, we would all be in a much better economic condition now.

Heba: So, protectionism was a bad stance for EU member states to take?

Jurgen: Protectionism? Nein, nicht gut! The protectionist stance taken by almost all EU member states since then has led to low economic growth rates, industries moving out of the EU, and high unemployment and inflation rates. These conditions impacted 'periphery' states quite severely, and these states were already dealing with numerous economic problems at the time. Additionally, all the preferential trade agreements that had been signed previously were affected negatively due to numerous protectionist non-tariff barriers. With EU states becoming more protective of their own national economies, countries outside the EU retaliated by implementing numerous trade barriers as well.

Heba: There have also been several issues with regards to labor strikes in numerous EU member states since, correct?

Jurgen: Nicht gut! The labor unions have gotten stronger in countries like France, Spain and Greece. Youth unemployment levels have gone up significantly in many member states and this scenario created a vicious cycle whereby public spending for benefits had to go up to maintain social cohesion and to curb social unrest.

Heba: Tell me about inflation rates.

Jurgen: Nein, nicht gut! High energy and food prices have translated into high inflation rates especially within the weaker EU economies. Again, this created a negative vicious cycle scenario, and has had a negative impact on economic growth rates in many member states.

Heba: Tell me about immigration policy in the EU.

Jurgen: Nein, nicht gut! There has not been a harmonized stance on immigration policy. Many member states, due to negative attitudes towards immigrants within their populations, severely cut down migration into their countries. This has affected industry growth rates as businesses have not been able to find skilled workers.

Heba: What do you have to say about benefits systems in the EU?

Jurgen: Nein, nicht gut! Reforms to benefits systems in the EU have been going at a snail's pace for many years. Due to high unemployment, low savings rates and ageing populations, governments in many member states have enormous public spending levels. The private health care sector has been growing at a very slow rate. Efficiencies are low in national health care systems and bureaucracy levels are still quite high.

Heba: So Jurgen, there has been very little progress over the past two decades on several important macro environmental issues throughout the EU right?

Jurgen: Yes. We now refer to the decade from 2010 to 2020, as "the lost decade." This decade was a transition period for the EU as member states were recovering from the global financial crisis at the start of the decade. Additionally, many member states were

contemplating their futures during this decade. From 2020 to 2030, a lack of unity and political will, increased fragmentation on policies, and increased protectionism have all led to very slow progress in the EU on many fronts during this decade. So, looking back on how things have gone in the EU over the past decade, all I can say is Nicht gut, Heba. Nicht gut!

Heba: OK. So now, with regard to the pharmaceutical industry in the EU, what is the situation?

Jurgen: Again, Nicht gut! The fragmentation of member states led to increased price controls at national levels. Generics were thought to be a smart way to reduce spending levels at one time, but now, due to a lack of harmonization, and the existence of different prescription policies in many EU states, generic uptake levels across the EU are still not at par with the generic uptake level in the US. Additionally, price controls in many countries posed as a hindrance to the entry of generics into these countries. Some member states have high uptake levels and some still don't. Many of the big pharma companies have moved their manufacturing bases outside the EU. Additionally, there have been plenty of opportunities for these companies in the Asian, Latin American and African markets.

Heba: Well, thank you so much for your time Jurgen. You have been very helpful.

Jurgen: Danke Heba. Are you flying back to Cairo immediately?

Heba: No Jurgen, I have the next two days off. I think I'll head down to the Amalfi Coast for a short vacation. I can hop onto the bullet train in Frankfurt and be in Naples by this afternoon. The one thing that Europe has made a lot of progress on over the past decades has been the transport and infrastructure system throughout Europe. It's so easy to get around these days!

Jurgen: Yes Heba. You are right. Score one for the EU on that front. Enjoy your time in Italy and all the best with your story for Bloomberg News…

Heba and Jurgen shake hands and part ways. As Heba is leaving the hotel, she notices again the large number of tourists from China and India in the hotel lobby. Thank god there has been progress elsewhere in the world; Europe would have been in far more choppy waters if it hadn't been for economies elsewhere in the world getting their act together over the past decade Heba thinks to herself…

SCENARIO 3: “DEUX UNION EUROPÉENNE!”

July 20th, 2030:

Ajay Bhakshi has just arrived at the Charles de Gaulle Airport in Paris. Ajay's trip has a two-fold mission: the first is to interview Monsieur François Girbaud, the EU's new trade commissioner, and the second is to watch the highly anticipated cricket match between England and France. Ajay works for the Indian Pharmaceutical company Vijay Pharmaceuticals. The company was formed in 2025, and is in the process of exploring market opportunities in the EU. As for the cricket match, the French national cricket team is highly favored to beat the English team. The good form of the French team has been quite the talk of the cricket world over the past few years. France, a country which long considered cricket an English sport, had not been enthusiastic about cricket till 2015. In recent years, the French team has become quite dominant, and this showdown with England has been the hot-topic in Paris and London for the past few weeks. Ajay is anxious to get out of the overcrowded airport. He picks up his bags, and heads towards the taxi stall. There's a fleet of electric powered taxis waiting, and Ajay hops into the first one in line. As he gets into the taxi, he speaks into his google translator device: "Sir, please take me to the Paris Ritz. How much will that cost?" The google translator device translates his speech into French, and a speaker on the device conveys a fluent French voice to the taxi driver. The taxi driver replies in French, and his google device then converts his speech in English: "No problem sir. The trip will cost you 120 Euros." As the taxi leaves the airport, Ajay turns on the television screen in the taxi. The news of the day, in French, is on the screen. Ajay changes the TV setting to Hindi, and pays close attention to the news. The top global stories of the day are: Iran and Israel sign a peace treaty after years of war, and the Chinese Yuan is now the official currency in the Union of Asian Nations. The taxi arrives at the Ritz, and Ajay flashes his credit card over the pay pad. "Merci monsieur!" Ajay tells the taxi driver, and walks into the Ritz hotel lobby with his bags in-tow. As Ajay gets into the hotel lobby, he notices Mr. Girbaud sitting in the lounge area. He walks over to him and introduces himself…

Ajay: Monsieur Girbaud, how are you sir?

Monsieur Girbaud: Ajay! I am well, how was your flight from Mumbai?

Ajay: Excellent. I really like the Ritz hotel, quite swanky eh?

Monsieur Girbaud: Ah, yes. It is indeed a jewel in the heart of Paris. It's so great that the entire hotel is now 100% green. I mean, the entire building is solar-powered, and there aren't even any solar panels to be seen anywhere on the entire building. Quite impressive how they're able to pull that off nowadays.

Ajay: Yes, quite remarkable. So, are you ready for the interview? Did you get a chance to skim through the questionnaire that I sent you last week?

Monsieur Girbaud: Yes, I am ready. Fire away…

Ajay: So, let's start with this issue of Deux Union Européenne that I've been hearing a lot about lately. Tell me more…

Monsieur Girbaud: Oui! Deux Union Européenne. This situation has been evolving for many years, and now, we can almost clearly distinguish the presence of two unions. There is no longer a united European Union. There is a union of the strong 'core' states and a separate union of the 'periphery' states. Basically, the 'periphery' states decided that their interests were not ever a concern of the 'core' states. The 'core' states always looked out for their own interests, while the weaker states were always getting a very tiny piece of the pie. So, these weaker 'periphery' states have now found a way to work amongst themselves to realise their own objectives.

Ajay: So there is no integration basically?

Monsieur Girbaud: Oui. There was some integration many years ago, but as the global marketplace became more and more competitive, the EU policymakers were dominated by the strong states, and these states always succeeded in having the policymakers craft policies that addressed only their needs.

Ajay: So, how has this affected the business environment in the EU?

Monsieur Girbaud: The deux Union Européenne scene has been good only for the states that are currently part of the euro zone. As you know, back in the 2010's, the euro zone started kicking out the member states that had large public spending levels and high debt levels. So now, there are only ten states within the euro zone, and these states have the strongest economies. The rest have always been, and continue to play catch up. And they've been trying to play catch up basically without much support from EU policymakers.

Ajay: So give me some more specifics with regard to disparities in economic conditions.

Monsieur Girbaud: Within the stronger states, there is positive GDP growth, low unemployment and inflation, and low volatility in the business cycle. And in the weaker states, these economic parameters have been, and continue to head into the opposite direction.

Ajay: Tell me about the labor markets and some more on policies such as immigration and healthcare.

Monsieur Girbaud: As I said earlier, unemployment levels are low in the stronger economies, and so, income levels are higher in these states. As unemployment levels are high in the weaker non euro states, there are stronger labor unions and strikes by workers almost every month. The stronger states have been smarter when it comes to immigration policy. They've been able to control migration and they've been able to bring in skilled workers from other parts of the world as needed. Workers in the weaker states have very high levels of unskilled labor, and because of the lack of jobs, these states have had a closed door mentality on immigration policy – they've shut out migrants from outside the EU. As for healthcare, again, there is the deux Union Européenne dynamic. The stronger euro zone states have systems that are 50-50 public/private while the weaker states have national healthcare systems that are 100% funded by the governments. Therefore, the stronger economies have very efficient healthcare systems with excellent quality care and very low

hospital populations, while the weaker states systems are very inefficient, with poor quality care and extremely high patient populations.

Ajay: And lifestyle quality is quite poor in the non euro zone states as well right?

Monsieur Girbaud: Oui. Again, deux Union Européenne. In the weaker states, quality of life of citizens is low, with lower life expectancy rates. The citizens of the weaker states have more health related problems at earlier ages, and hence, as I said earlier, patient populations are high in these states.

Ajay: So, tell me more about how these dynamics affect the scene with regard to the pharmaceuticals and generics drug industry in the EU.

Monsieur Girbaud: Well, with regard to counterfeit drugs, these have infiltrated the systems in the weaker states very significantly. The rate is about 40%. In the stronger states, the infiltration percentage of counterfeit drugs stands at about 5%. There is also a very negative attitude with regard to generics in the stronger states. There has been a lot of bad PR about generics coming into the stronger states, and citizens of these states just do not trust pharmaceuticals manufactured outside the EU. Additionally, NGO's and consumer protection agencies have been very effective in painting a bad picture of generics coming into the EU from countries outside the EU. In fact, generics are also looked upon in a very negative light in the weaker states because of the high levels of counterfeit drugs and numerous fake internet pharmacies.

Ajay: What about the reputation of pharmaceuticals with regards to impact on the environment?

Monsieur Girbaud: Again, deux Union Européenne. In the stronger EU states, the pharmaceuticals companies have 100% green buildings, low levels of waste in manufacturing, and 'green' packaging. But in the weaker states, these same pharma companies have not invested in 'green' technologies and they've placed very little emphasis on reducing waste and utilizing 'green' packaging materials. This is mainly because of the fact that governments in the weaker states have strict price controls, and the pharmaceutical companies have therefore lower investment levels in 'greener' manufacturing processes and materials.

Ajay: One final question then Monsieur Girbaud, who will win the big cricket match today?

Monsieur Girbaud: Ha Ha Ajay! I knew that you'd ask me that at some point. All I can say is: Vive la France! Ha Ha!

Ajay: I must say that I am not surprised by your answer. I am going to watch the big match at the Stade de France this afternoon you know? I'm really looking forward to this twenty-twenty match up.

Monsieur Girbaud: Aaah, enjoy yourself Ajay. All the best, and if you have any more questions later, feel free to contact me.

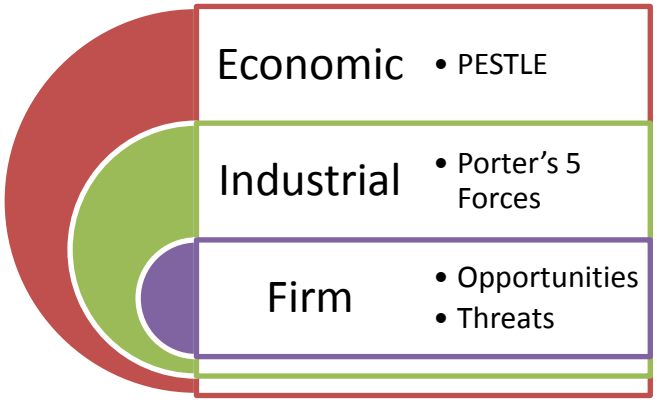
Ajay: Thank you very much Monsieur Girbaud. You have been most helpful…

Ajay reaches over and shakes Monsieur Girbaud's hand vigorously, and the two part ways. As Ajay leaves the café, he enters the hotel lobby. This is indeed a magnificent hotel Ajay thinks to himself as he looks around. He then departs from the hotel front door, and outside, the sun is shining. What a beautiful day to watch some cricket Ajay thinks as he hails the taxi parked at the taxi stand…

7 SCENARIO EVALUATION & IMPLICATION

To formulate recommendations and strategies, the project will first evaluate the scenarios using the three levels of organizational environment. These can be broadly divided into: external economic environment, industry environment, and firm level environment with their respective frameworks as represented in the Figure 7 below.

FIGURE 7: 3-LEVEL OPERATIONAL ENVIRONMENT



Source: Authors Interpretation.

The EU economic environment has already been described in the Scenarios and the PESTLE factors prognostics in previous chapters. In order to evaluate the scenarios and their implications we have proposed a 4 step approach:

1. Identify key descriptive phrases that summarize the EU economy circa 2030
2. Hypothesize the possible EU generics drugs industry circa 2030
3. Identify firm level opportunities and threats
4. Summarize possible scenario implications

The sub-sections below evaluate the scenarios using the 4 step approach as mentioned above.

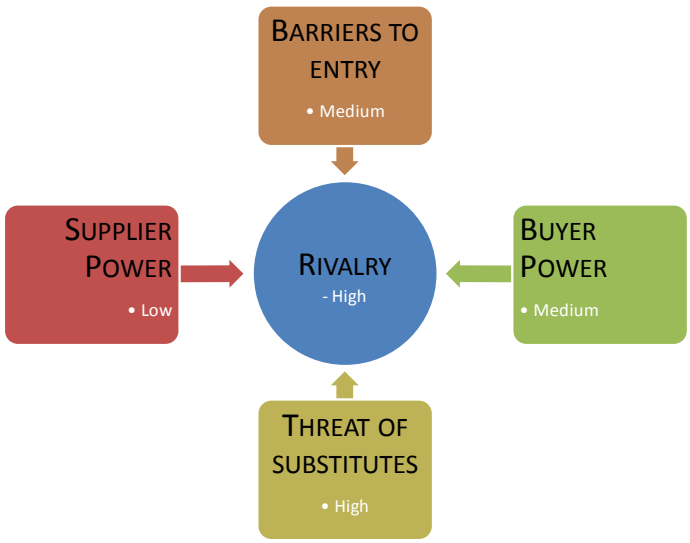
7.1 SCENARIO 1: "TODO ES BUENO!" EVALUATION & IMPLICATION

Step 1: Possible descriptive phrases of the EU environment circa 2030:

1. Expanded and expanding EU
2. Growing Economy
3. Cooperation
4. Harmonization
5. Political leadership
6. Common currency
7. Stringent regulatory frameworks
8. International free market
9. Business environment stability
10. Improved lifestyles
11. Global competition
12. Revolutionary Technology
13. Market information
14. Many choices
15. New entrants
16. Environment friendly
17. Social responsibility
18. Low public spending
19. Low unemployment
20. Aging population
21. Mature industry

Step 2: Industry analysis using Porter's 5 forces (1985), Figure 8 below represents the strengths of the forces involved.

FIGURE 8: PORTER'S 5 FORCES EVALUATING SCENARIO 1



Source: Authors interpretations

Step 3: Possible opportunities and threats that are presented to EU generic drugs industry players. Table 6 below lists the various possible opportunities and threats.

TABLE 6: OPPORTUNITIES & THREATS SCENARIO 1

Opportunities	Threats
Integrated global markets	Disruptive technology
New technologies	Intense global competition
New Products	Substitute products
Affluent society	Increased buyers power
Aging population	Increased due diligence and compliance standards
Less bureaucracy	Spreading prophylactic approaches
Harmonized policies	Price control
Expanding EU	
Growing attentions to healthcare	
New therapies and delivery systems	
Increased use of generic drugs	
Positive attitude for soft medication (OTC drugs)	
Expanded health insurance sector	
New diagnosis and new social diseases	
Quality focus	
Environmental focus	
Differentiation focus	

Source: Authors interpretations

Step 4: Evaluating the economic environment (PESTLE), industry environment (Porter's 5 forces), and firm level (opportunities and threats) we notice that the EU generic drug's industry in 2030 is subjected to near-perfect competition and is not an attractive industry. In this scenario we can assume that players in the EU generic drugs industry find it difficult to achieve cost leadership because perfect competition dictates marginal costs equal to average costs. However; it also implies that the markets are both allocatively and productively efficient. Furthermore; we notice that generic drugs industries are using differentiation strategies to enhance and extend their product portfolio.

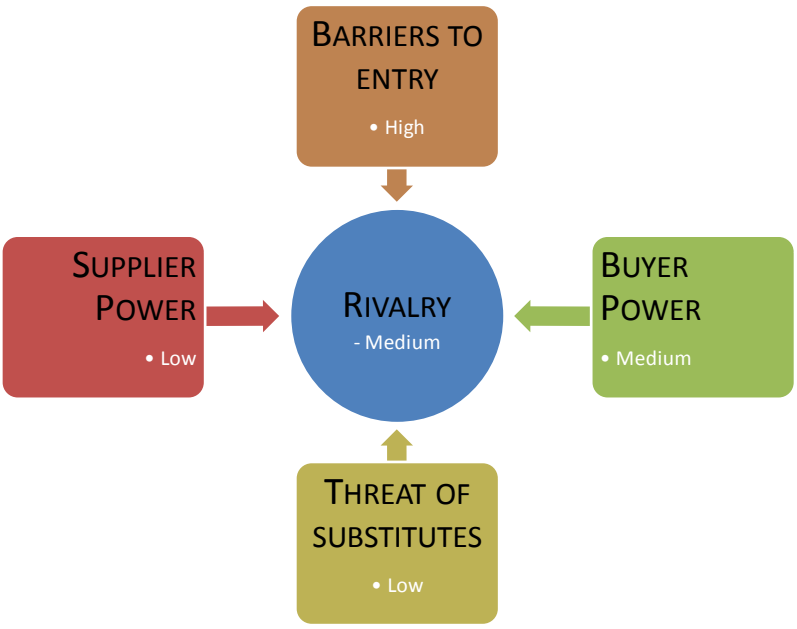
7.2 SCENARIO 2: "NEIN, NICHT GUT!"

Step 1: Possible descriptive phrases of the EU environment circa 2030:

1. EURO Zone disintegration
2. Disparity in EU member state economies
3. Weak global competitive position
4. Protectionism
5. Fragmentation
6. Political instability
7. Low EU GDP
8. Slow/Stagnant EU expansion
9. Volatile Business cycles
10. High inflation
11. High transaction costs
12. Aging population
13. High unemployment
14. High public spending
15. Low morality
16. Strong labor unions
17. Less competition

Step 2: Industry analysis using Porter's 5 forces (1985), Figure 9 below represents the strengths of the forces involved.

FIGURE 9: PORTER'S 5 FORCES EVALUATING SCENARIO 2



Source: Authors interpretations

Step 3: Possible opportunities and threats that are presented to EU generic drugs industry players. Table 7 below lists the various possible opportunities and threats.

TABLE 7: OPPORTUNITIES & THREATS SCENARIO 2

Opportunities	Threats
Long-term contracts	Disruptive technology
Lobbying	Intense global competition
Secure large market share	Substitute products
Aging population	Counterfeit drugs
Market knowledge	Increased buyers power
Hedging Finances	Increased due diligence and compliance standards
Multi-strategy	Spreading prophylactic approaches
Growing attention to healthcare	Price control
Government support	Parallel import
Cost leadership	Transaction costs
New therapies and delivery systems	
Increased use of generic drugs	
Positive attitude for soft medication (OTC drugs)	
New diagnosis and new social diseases	

Source: Authors interpretations

Step 4: Evaluating the economic environment (PESTLE), industry environment (Porter's 5 forces), and firm level (opportunities and threats) we notice that the EU generic drug's industry in 2030 might still be an oligopoly and remains to be an attractive industry. In this scenario we can assume that players in the EU generic drugs industry can use multi-strategies, explicit market knowledge and government support to strengthen the barriers to entry from foreign competition. They might also have ability to achieve cost leadership, and secure large market share throughout the EU.

7.3 SCENARIO 3: "DEUX UNION EUROPÉENNE!"

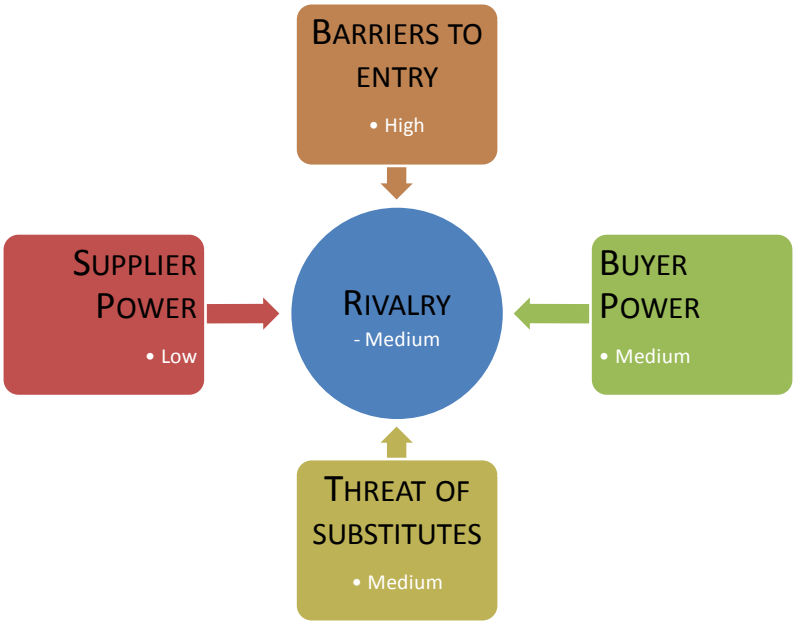
Step 1: Possible descriptive phrases of the EU environment circa 2030:

Deux EU

- EU Zone
    1. Growing Economy
    2. Cooperation
    3. Harmonization
    4. Political stability
    5. Strong EURO
    6. Stringent regulatory frameworks
    7. Consumer protection
    8. International free market
    9. Business environment stability
    10. Improved lifestyles
    11. Revolutionary Technology
    12. Market information
    13. Many choices
    14. Environment friendly
    15. Social responsibility
    16. Low public spending
    17. Efficient healthcare systems
    18. Low unemployment
    19. Aging population
    20. Non – EU Zone
    21. Weak Economy
- Non-EU Zone cooperation
    1. Protectionism against international competition
    2. Low GDP
    3. Political instability
    4. Consumer protection
    5. Volatile Business cycles
    6. High inflation
    7. High transaction costs
    8. Weak global competitive position
    9. Aging population
    10. High unemployment
    11. High public spending
    12. Low morality
    13. Poor healthcare systems
    14. Strong labor unions
    15. Less competition

Step 2: Industry analysis using Porter's 5 forces (1985), Figure 10 below represents the strengths of the forces involved.

FIGURE 10: PORTER'S 5 FORCES EVALUATING SCENARIO 3



Source: Authors interpretations

Step 3: Possible opportunities and threats that are presented to EU generic drugs industry players. Table 8 below lists the various possible opportunities and threats.

TABLE 8: OPPORTUNITIES & THREATS SCENARIO 3

Opportunities	Threats
Dual markets	Disruptive technology
Multi-strategies	Intense global competition
Multi-positioning	Substitute products
Aging population	Counterfeit drugs
Growing attention to health	Increased due diligence and compliance standards
Quality focus	Spreading prophylactic approaches
New therapies and delivery systems	Price control
Increased use of generic drugs	Parallel import
Positive attitude for soft medication (OTC drugs)	Transaction costs
New diagnosis and new social diseases	
Environmental focus	
Strong barriers to entry	
Secure large market share	

Source: Authors interpretations

Step 4: Evaluating the economic environment (PESTLE), industry environment (Porter's 5 forces), and firm level (opportunities and threats) we notice that the EU generic drug's industry in 2030 might still be an oligopoly and remains to be an attractive industry. In this scenario we can assume that players in the EU generic drugs industry can use distinct strategies to suit the two different EU's with a variety of choices. They might also have the ability to achieve cost leadership strategies in the non-EU Zone countries and differentiation strategies in the EU Zone, thus securing large market share throughout the EU.

8 STRATEGIES AND RECOMMENDATIONS

Scenarios are used to challenge implicit and explicit assumptions, stretch strategic thinking and foster organizational learning (Tenaglia& Noonan, 1993). It is suggested to organizations to organize workshops to further expand and develop these scenarios. Use the scenarios to challenge or test current strategies. Identify new robust strategies and risk, and setup monitoring units to identify signs & indicators for each scenario. In order to propose a set of strategies and recommendation, the project has combined key repeated opportunities and treats. Table 9 below lists combined opportunities and threats observed in the three hypothetical scenarios.

TABLE 9: OPPORTUNITIES & THREATS SCENARIOS COMBINED

Opportunities	Threats
Integrated global markets	Disruptive technology
New technologies	Intense global competition
New Products	Substitute products
Ageing population	Increased due diligence and compliance standards
Less bureaucracy	Spreading prophylactic approaches
Harmonized policies	Price control
New therapies and delivery systems	
Increased scope for use of generic drugs	
Positive attitude for soft medication (OTC drugs)	
Expanding health insurance coverage	
New institutional purchases	
New diagnosis and new social diseases	
Focus (Quality, Sustainability & Differentiation)	

Source: Authors interpretations

Figure 11 below is a schematic diagram that represents the opportunities and threats of the three scenarios. The threats list highlighted in the center of the diagram represents the common threats of each scenario.

FIGURE 11: OPPORTUNITIES AND THREATS THEMATIC DIAGRAM

Source: Authors interpretations

8.1 RECOMMENDATIONS

1. Revisit your generic strategies

Low cost or differentiation? In line to EU generic drugs industry circa 2030, our scenarios have identified intense foreign competition as we head towards globalization. Porter suggests that a firm's competitive strength ultimately falls into one of two categories; cost advantage or differentiation. If these strengths are applied in either a narrow or a broad scope, we get three generic strategies, cost leadership, differentiation, and focus. These strategies can also be used to influence the industry forces as shown in Table 10below:

TABLE 10: GENERIC STRATEGIES AND INDUSTRY FORCES

Industry Force	**Generic Strategies**		
	Cost leadership	Differentiation	Focus
Entry Barriers	Ability to cut prices and achieve economies of scale can deter potential entrants	Customer loyalty to brand can discourage potential entrants	Focusing develops competencies that act as entry barriers
Buyer Power	Ability to offer low prices to powerful buyers	Large buyers have less power to negotiate because of few close alternatives	Large buyers have less power to negotiate because of few close alternatives
Supplier Power	Better insulated from powerful suppliers	Ability to transfer price i.e. supplier prices to customers	Suppliers have influence because of low volumes, but a differentiation-focused firm is better able to pass on supplier price increases
Threat of Substitutes	Use low prices to defend against substitutes	Differentiating attributes reduce threat of substitutes	Specialized products & core competencies protect against substitutes
Rivalry	Able to compete on price	Brand loyalty to fend against rivals	Rivals cannot meet differentiation focused customer needs

Source: Authors Interpretations of Porter's Generic Strategy

There are significant advantages and disadvantages to the three types of strategies. Cost leadership strategies are upstream strategies. In the event of a price war, industries who focus on cost leadership can maintain profitability while the competition suffers losses. Even

without a price war, as the industry reaches maturity, firm who can maintain cost leadership will remain profitable for long periods. However, cost leadership positions root from internal strengths which requires continuous capital investment for new production technologies and assets, skilled resources in designing efficient manufacturing, high level of expertise in manufacturing and efficient distribution channels, thus; cost leaders are not innovation focused. Whereas, differentiation strategies offer unique attributes to products and services that are perceived as valuable to customers and differentiated from competitors. They specialize in downstream strategies with strengths in leading research and development, skilled and creative product development teams, strong sales and marketing teams, reputation for quality and innovation. In summary, it is assumed that cost leaders cannot innovate and that differentiators have strong brand equity to retain customer. However, as we head towards global competition, such assumptions can be futile. Global competitors might not select polar strategies, but choose mixed strategies, where they focus on achieving cost leadership and innovation. Therefore we suggest EU generic drugs players to revisit traditional strategic thinking and not focus explicitly on polar strategies.

2. The key ingredient

What is your ingredient? In all our scenarios we have identified the infiltration of counterfeit drugs into the EU generic drugs market. Scenario 2 & 3 explicitly highlights the growing percentages of counterfeit drugs where as it is implicit in scenario 1 as the problems were solved using strict regulatory measures. In light of such a potential threat, our scenarios predict that irrespective of the economic environment, counterfeit drugs will be a serious concern and government/s and/or NGO's will take strict actions to curb their infiltration. These strict actions can lead to significant transaction costs as supply chains are scrutinized by either private or public bodies. Additionally, counterfeit drugs might instigate negative publicity to generic drugs; especially those manufacturers that are cost focused (low quality) or internationally sourced. It might even lead to tighter non-tariff trade barriers and/or a complete boycott of Non-EU produced generic drugs being purchased by institution. These threats however could represent opportunities for generic players in the EU. Players can use distinctive strategies such as local manufacturing, marketing, brand building, etc to improve authenticity/quality perceptions and create new customer value propositions.

3. Don't be penny wise with research

Penny wise with research? Technological changes, adaptations and breakthroughs in the next 20 years can create and/or destroy industries. Possibly the greatest threat to the generic drugs industry is technological changes i.e. biotechnology, genomics, delivery systems, etc. New products/developments by pharmaceuticals are strong substitutes to generic drugs with approximately 20 years of protection. In the event of a revolutionary technology change as described in scenarios 1 & 3, we can predict high levels of competition in generic drugs industry fighting over a share in a contracting market. In this case we suggest generic drugs players to allocate resources that aim to research and identify the technology changes and their implications. This practice will reduce the surprise element and generic players can hedge risks by diversifying their product portfolio with unrelated

product mixes. We also remind generic players to incentivize innovation as generic drugs can have patents on formulation if not the active ingredient.

4. Stakeholder Management

Are my stakeholders happy? Stakeholder management is about managing the expectation of multiple actors or constituents who have a stake (not necessarily financial) in the company. Effective interaction with key stakeholder or groups could be a critical competency for the future success in the generics drug industry. In our scenarios we have highlighted several stakeholders' i.e. Labor unions, NGO's, EU commissions, member states, etc. and their growing influence over the generic drugs industry. The challenge presented here is to understand their relationship with the commercial model of the generic drugs player and formulate plans and strategies to capitalize upon. The EU represents great potential for stakeholder management techniques as careful management can strengthen barriers of entry, provide a competitive edge, etc. We therefore recommend generic players to allocate explicit resources in marketing, sales, and research and development that will review and critically evaluate stakeholder landscape, including existing stakeholder knowledge, relationships and plans.

5. Give in to the green

Go Green! Our scenarios 1 & 2 have envisioned worlds where there is focus on environmentally friendly 'green' practices. We believe that in future there will be tighter environmental regulations and organizations that have already invested in green practices will sustain a competitive advantage. It is suggested to generic players that they focus on sustainability concepts not just on business process improvements but those that have related environment friendly implication. Sustainability is a continuous improvement practice; we recommend techniques such as carbon monitoring (i.e. supply chain), green building (i.e. manufacturing facility, head office quarters), drug recycling, ethical sourcing, as key differentiating elements that will not only defend from environment regulations but also increase stakeholder value proposition.

6. Strategic Location

Can location matter? We recommend EU generics players to investigate the possibility of sourcing manufacturing from EU countries rather than foreign countries. There are two distinct rationalities behind this recommendation. Firstly, sourcing manufacturing from EU member states (established members, new members, or potential members) can prove cost efficient in the long-run. For example, evaluate the possibility of Turkey housing the generic players manufacturing facility. In the short-run logic might dictate that this is not a cost efficient option because Turkey lacks the infrastructure or resources to achieve economies of scale. However in the long-run when Turkey's infrastructure develops, it might provide strategic location advantages. These advantages could have huge transaction cost savings (i.e. reduce the rising international logistics costs, free trade, protectionist stance from foreign trade, etc.) and provide a competitive advantage against international generic drugs exporters.

The second advantage is the opportunity to exercise corporate social responsibility. As part of the EU mission of developing and supporting EU member states economies, life styles, etc. such a move will provide generic player the opportunity to support and develop the chosen member states economy. This move will help generic players reposition their customer value propositions and also strengthen stakeholder value propositions.

7. Face the enemy

Confront or partner? In all our scenarios we have discussed the inevitable global competition, and advocate that organizations who do not achieve significant economies of scale will find sustainability difficult. Even if there are artificial entry barriers by protectionist stance of the government, military strategies, buying the competition, etc. it will still eventually be subjected to foreign competition. In our supplemented report, we have discussed the Indian and Chinese generic industry and the potential it has to becoming global generic drugs leaders due to the various economies of scale and resources. In light of this potential we recommend EU generic players to form strategic alliances with players from India and China explicitly for organizational learning. By alliances either by mergers & acquisitions or joint ventures, generic drugs players from the EU will develop capabilities to achieve economies of scale and strengthen their ability to compete globally.

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APPENDIX 1

1. FACTOR RESEARCH

1.1 POLITICAL FACTORS

1. EU Expansion & Integration

In May 2004 the EU expanded in a 'big bang' fashion from the original 15 member states to 25 states, and in 2007, two more countries (Bulgaria and Romania) joined the EU. Over the next few years there are expectations for accession into the EU amongst several nations in Eastern Europe. Unlike the 'big bang' expansion of 2004, membership from henceforth will likely occur in piecemeal fashion. Croatia will more than likely be the first of many countries that will join the EU, followed by others waiting patiently in the pipeline namely Bosnia and Herzegovina, Serbia, Montenegro, Macedonia, Kosovo and Albania. Turkey has been in vigorous negotiations for entry into the EU for many years and there has been talk of accession by the year 2015. Although Ukraine is not a candidate country yet, the Ukrainian government has initiated processes to negotiate a multitude of free trade agreements with the EU.

Having stated the above, there are issues that may delay or even block accession efforts e.g. euro zone sovereign debt woes and rampant corruption within many Eastern European nations. Over the past few years, there has been a rise in Euro skepticism, and "while pro-European political elites have steadily moved ahead with European integration, citizens appear increasingly wary of the project" (De Vries, Nd). The divergence in opinions between the political elite and the general public was visibly manifested through recent voting referendums in France, Ireland, and the Netherlands. These referendums resulted in votes against the expansion of EU powers thus making the vision of seamless integration within the EU increasingly difficult to attain. Politicians have swayed over this development towards the direction of the voting public, and "as a result, contestation over European integration appears to have transformed from a "sleeping giant" in domestic politics into a reality (van der Eijk and Franklin 2004). Interviewee Jonathan Farrington was of the opinion that EU expansion is likely to slow down over the coming decades and that of the current candidate countries, Turkey will be the most likely to gain accession into the EU.

2. EU Regulatory Framework

The European Union conducted and completed a review of EU pharmaceutical legislation (Directive 2001/83/EC and Regulation 2309/93) and there was a policy consensus formulated between the European commission, the European parliament, and the European council in March, 2004. The law adopted "contains a number of important advances towards making lower-priced generic medicines more readily available to European patients and healthcare systems" (European Generics Medicine Association). This law, which came into effect in November, 2005 also addressed the market protection needs of originator pharmaceutical companies (that initially developed and patented drugs) so as to protect their research and development investments for new treatments. Additionally, a "bolar exemption" policy was instituted to allow generic manufacturers to prepare production and regulatory procedures in advance such that generics could be available for

sale immediately upon the expiration of patents. The whole idea behind this regulatory framework was to have a uniform policy (vis-à-vis the active promotion of generics) across the EU to replace the fragmented approach that existed before e.g. health insurance organizations in the UK, Germany, the Netherlands and Denmark heavily promoted generics to lower health care expenditures, while similar organizations in countries like Spain, Greece, Italy and France did not.

With regard to policy, fragmentation still exists amongst EU member states on the rights of pharmacists to override doctors' prescriptions of branded drugs by dispensing generics instead (without first consulting the prescribing doctor or the patient). There are several reasons as to why generic substitution is disallowed in certain countries: liability issues in the event of adverse effects on patients, the notion that economic issues may override patient needs, and the view that this practice is a price control measure which can hamper free competition in the marketplace. Additionally, pharmaceutical companies in the EU have attempted to limit the bolar provision by creating patent linkages. "Patent linkage is the practice of linking market approval — or the pricing and reimbursement status — for generic medicines to the patent status of the originator reference product" (European Generics Medicine Association). Fragmentation could also be perpetuated as a result of member states having the freedom to make decisions e.g. on whether certain drugs can be approved for substitution by generics. There is no separate organization within the EU (as there is in the US) that specializes in, and has the authority to approve generics.

3. EU Monetary Policy

"The motivation for establishing the European Monetary Union (EMU) was partly political and partly economic in nature" (Hamada et. al., 2009, p. 42). Economic considerations included: facilitation of trade, elimination of currency exchange costs/uncertainties, pursuit of strong economic growth rates and lowering unemployment rates. The key political objective was to promote integration in Europe in order to avoid future conflicts.

The Maastricht Treaty (1992) set out a timetable for economic and monetary convergence in three successive stages. The third stage of the timetable led to the establishment of a single monetary policy that would be overseen by the European Central Bank (ECB). Additionally, at this stage, the euro became the common currency of eleven member states (with Greece joining later in 2001). At present, there are sixteen countries within the EU that use the euro as their currency, and all the countries which joined the EU in 2004 and 2007 are required at some point to join the euro-zone. However, "huge budget deficits and bigger public debt piles accrued during the global recession mean most candidates will not meet the Maastricht criteria for four or five more years" (Reuters, 2010). Of the candidate countries, only Estonia is ready at present, with its 2011 euro bid expected to get a go ahead from the EU on May 12.

There are however several factors which candidate countries are pondering as they contemplate the decision as to when to join the euro-zone. These include the current debt crisis in Greece, a spike in bond yields in southern European states, and arguments across the euro-zone bloc on whether budget offenders deserve aid. Additionally, countries are apprehensive about being tied in to policies delivered to them from Brussels, and there is

concern about surrendering their own interest rates and currency flexibility. Moreover, "intensifying speculation over whether the euro zone can itself hold together as its weakest members struggle has fuelled resistance among policymakers to admitting another country capable of a Greece-style fiscal meltdown" (Reuters, 2010). Having said this, a recent poll shows that economists see most candidates (the Czech Republic, Poland, Hungary, Romania, Bulgaria and Latvia) joining by 2015. In conclusion, the benefits of a common currency within the EU will not be fully realized until all EU members join the euro-zone and economic fundamentals within all nations that are part of the bloc are consistently sound.

4. EU Fiscal Policy

"The sustainability of public finances is a key policy issue for the European Union" (Afonso, 2009, p.731). The Eurozone Stability and Growth Pact (SGP) adopted in 1997 consisted of fiscal monitoring by the European Commission and the Council of Ministers. Member states unable to comply with the following criteria would face possible sanctions after multiple warnings: an annual budget deficit of no higher than 3% of GDP and a national debt lower than 60% of GDP. The aim was to ensure that inflationary pressures on the European economy would be held in check, and that member states would have a tight grip on their fiscal budgets. It is important to note that fiscal discipline within EU member states has important implications with regard to monetary policy within EMU (European Monetary Union) member states. A lack of coordination between fiscal and monetary policies within the EU is currently a key issue that regulators have to address (Ardy, 2010, p. 3). The European Central Bank (ECB) is responsible for monetary policy, but what is currently unclear is who is responsible for the overall fiscal policy of the EU. "Current developments in Greece make clear that the rules of the European Stability and Growth Pact (SGP) were neither strict enough nor enforced strictly enough" (Bofinger, 2010, p.1). The European Stabilization Mechanism (ESM) adopted on May 9th 2010, together with supporting measures of the ECB, were significant steps towards solving the current fiscal crisis within the Eurozone. However, these steps have led to "a decline of reputation in the case of the ECB and a weakening of incentives for fiscal consolidation" (Bofinger, 2010, p.2). Over the coming years, it remains to be seen if EU regulators can collectively take a more stricter and proactive stance on Eurozone member states fiscal matters, and if fiscal deficits can be significantly reduced so as to ensure low and stable inflation rates over the long-term.

5. EU Preferential Trade Agreements (PTA's)

"Preferential trade agreements (PTAs) comprise a variety of unilateral, bilateral, or regional arrangements which favor member parties over non-members by extending tariff and other nontariff preferences" (Ahearn, 2010, p.1). In the post-war period, the EU has been central to the proliferation of PTA's; the EU itself is the world's largest preferential agreement. At present, the EU has most-favored-nation (MFN) trading status with ten countries: Australia, Canada, Taiwan, Hong Kong, China, Japan, Republic of Korea, New Zealand, Singapore, and the United States. These ten states accounted for 43.9% of the EU's total merchandise imports in 2009, up from 40.4% in 2008 (Ahearn, 2010).

The EU's PTAs have until now been "mainly characterized by differentiation, flexibility, and relatively modest ambition in terms of market-opening" (Ahearn, 2010, p.14). The content of agreements has varied based on numerous factors: level of economic development of partners, importance vis-à-vis security concerns, sectors that constitute competitive challenges. With regard to pharmaceuticals, future trade agreements will likely contain clauses that will protect intellectual property rights e.g. in an EU-India trade agreement (not yet finalized), transnational companies from the EU would promote "data exclusivity protection" which would give them exclusive rights over their test data for a period of 8-10 years (Paulus, 2009, p. 7). This scenario would create delays in competition from Indian generic drug manufacturers seeking to develop cheaper versions of patent protected drugs for domestic sale. On the other hand, exports to the EU of drugs whose patents have already expired will likely increase as a result of an EU-India free trade pact.

6. EU Patent Protection

"Patents provide the patent owner with the legal means to prevent others from making, using, or selling the new invention for a limited period of time, subject to a number of exceptions" (www.Europa.Eu). The World Trade Organization TRIPS agreement (Trade-Related Aspects of Intellectual Property Rights) identifies the protection period as twenty years, and over this period, inventions can be protected whether they are a product or a process. The TRIPS Agreement makes provision for limited exceptions to patent rights: the research exception (researchers are allowed to use a patented invention to advance science and facilitate technology transfer) and the "Polar provision" (to speed up the process of marketing a generic drug). Additionally, the TRIPS agreement offers flexibility vis-à-vis compulsory licensing and parallel imports in an effort towards striking a balance between promoting access to existing drugs and promoting R & D for new drug development. In summary, the agreement "aims to ensure that adequate rules on the protection of intellectual property are applied in all (WTO) member countries" (www.Europa.Eu). In comparison to the United States, the EU has recently been much more active in "addressing the consequences of what they perceive as imperfect intellectual property (IP) laws, thus reshaping the substantive standards for IP protection" (Czapracka, 2009, p. ix). The goal of the EU vis-à-vis IP protection policies is to stimulate innovation and to increase competition so as to spur economic growth. Even though member states of the EU have IP protection regulatory power, this power has been significantly eroded by EU competition law; laws of member states may be and have been challenged by EU regulators. Interviewee Angela Farrell is of the opinion that there should be harmonization across the EU with regard to Patent protection as most requirements across the region are standardized and are not significantly different. Within the EU pharmaceutical sector, the case of *AstraZeneca* shed some light on the stance that regulators will be taking against dominant pharma companies. The ruling against *Astra Zeneca* indicated "that a dominant company must refrain from exploiting uncertainties in applicable laws to preserve its exclusive rights" and that "acquisition and enforcement of IP rights will be subjected to greater antitrust scrutiny in the EU" (Czapracka, 2009, p. xi).

7. EU Price Regulations

There is an important distinction to make with regard to price regulation in pharmaceutical markets: products that need a prescription to be sold, and products that do not (Barros, 2010). For pharmaceutical products that do not need a prescription (over the counter), the patient may decide which product to purchase based on prices. For products that need a prescription, the physician is the crucial decision maker, and regulators can provide incentives to physicians to prescribe lower cost products. Additionally, a distinction can be made with regard to pharmaceutical products under patent protection and those whose patents have expired. In the latter case, price regulation systems can utilize competition from generics as a way to bring prices down. It is often the case that for over the counter products price regulation does not exist. The strongest form of intervention in the case of prescribed products is governments setting the prices/imposing price caps. There are also indirect price controls such as rate-of-return regulations, and where competition between branded drugs and generics exists, reference pricing systems exist in numerous countries (Barros, 2010). There are also some countries which regulate prices in cases where competition exists between generics and branded drugs. In countries with complete health insurance coverage, pharmaceutical companies set the highest possible prices because no additional demand is created even though price competition exists. In Europe, several countries have opted for international referencing rules whereby the price of a pharmaceutical product is determined by the price in a set of reference countries. With regard to the entry of generics into a market, the existence of price regulations in a particular country poses as a hindrance to the entry of generics into the country. In summary, countries in Europe use two main mechanisms for price regulation: purely administrative measures (such as direct price controls) and market-based interventions (such as reference pricing). Recent trends in Europe are more towards market-based interventions, but there are still countries that utilize administrative measures e.g. on May 3rd 2010, Greece imposed a weighted average of 21.5% price reductions on a total of 12,500 medicines (2,500 originator branded products and 10,000 generic products) in an effort to save 1.9 billion euros annually[1]. On the issue of the future prospects of harmonization vis-à-vis price regulations across the EU, interviewee's Angela Farrell, Gregor Siebert and Hillary Jones were extremely skeptical.

8. EU Political Stability

The recent global financial crisis as well as the debt crisis in Greece has exposed fractures vis-à-vis political stability within the European Union. Additionally, events within specific European countries have also shed light on increasing levels of apprehension about political unity within the EU e.g. In June 2009, a ruling by Germany's constitutional court on whether the European Union's Lisbon treaty was compatible with German law asserted unambiguously that the EU "remains an association of sovereign states" and that the European parliament "is not a body of representation of a sovereign European people" (Barber, 2009). Current trends strongly indicate that "Europe is unraveling in a tangle of

[1] *Greece puts into effect draconian new drug pricing regulations, despite protests from industry* (www.thepharmaletter.com).

national interests" (Stephens, 2010). Even though fractures are forming within the union, there are many issues which call for member states within the EU to act together. These include the aforementioned financial and monetary crises, as well as issues such as global warming, terrorism, uncontrolled migration, a newly assertive Russia, the emergence of economic powerhouses in Asia (namely China and India), the war in Afghanistan, and Iran's nuclear long-term ambitions. Many experts are pointing towards a lack of political leadership within the EU as a key problem area. Politicians within EU member states are trending more towards sacrificing long-term European strategic gains for short-term national tactical gains as they try to shelter their anxious voters from the insecurities that are becoming evident as a consequence of a borderless Europe. With regard to unity within the EU, "the risk is not so much of a great rupture - though if Greece defaults the immediate shocks will be profound" (Stephens, 2010). Political stability within the EU is intrinsically linked to how united member states can be heading into the future. The more fractured the union becomes, the greater the risk of long-term instability within the region will be

9. EU War & Conflicts

The European Union (EU) claims for itself the status of a 'world player'[2] and the explicit stated goal of the EU is to "act as a force for stability, cooperation and understanding in the wider world" (www.Europa.Eu). In 1992, efforts to attain more unity were formalised through the Common Foreign and Security policy (CFSP) in the treaty of Maastricht. As a result of later conflicts in the Balkans and in Africa, the EU created a European Security and Defense Policy (ESDP) under which "military or police forces can be sent to areas of crisis to carry out humanitarian operations, peacekeeping, crisis management and even peacemaking" (www.Europa.Eu). It is important to note here that the EU does not have a military force of its own, but instead relies on member states' military units as part of UN or NATO forces. Diplomacy is seen as a key approach by the EU, and military intervention is seen as more of a peace-keeping initiative so as to address the root cause/s of current or potential future conflicts. The EU as an entity is currently involved in numerous global diplomatic efforts e.g. the situation in Iraq; the Israel-Palestine conflict; the nuclear ambitions of Iran; tensions between North and South Korea, missions in the Balkans etc. Having said this, when it comes to foreign policy – especially security-related aspects, the attainment of the EU's goals and objectives depends on unanimous agreement between all 27 member states. Member states have greatly differing conceptions of what security means, and many constitutional theorists have acknowledged that "an unusual degree of…independence and secrecy of executive action in foreign and military affairs was allowed in the name of the national interest" (Menon, 2010, p. 80). There is freedom among member states to choose from a variety of instruments and arenas to achieve their national security objectives; states can act on their own authority e.g. the UK in Iraq, via NATO e.g. the Kosovo intervention, via the EU using NATO e.g. the EU mission in Macedonia, or using the EU alone e.g. in the Democratic Republic of Congo (Menon, 2010, p. 81). Critics of the approaches the EU has taken towards conflict resolution in numerous cases have pointed

[2]European Commission, A World-Player - The European Union's External Relations (European Commission,2004).

out that because of a merry-go round in foreign policy the EU is not taken credibly as a player in global conflict management scenarios[3].

10. EU Market Intervention/s

Currently in the EU, with regard to government intervention into the free market, "the great majority of countries have some form of intervention, be it price controls, profit limits, reimbursement levels to pharmaceutical consumption, etc." (Barros, 2010, p.4). The main objective of interventions is cost containment, because health care expenditures have been growing faster than GDP in most European countries. Intervention strategies have been focused on the demand as well as supply side of the market, and some measures have been aimed at reducing the pharmaceuticals industry market power. "Demand-side interventions are aimed at patients and physicians" while on the supply side, "price controls, profit controls, and different layers of administrative authorizations for reimbursement of pharmaceutical expenditures by patients have been experimented with" (Barros, 2010, p. 8). Profit control as an intervention mechanism is used only in the UK, while margins are administratively set for retailers (pharmacies) and wholesalers in Denmark and Portugal. Reference pricing (as a mechanism of intervention in the free market) is quite common, and this occurs at both internal (within a country) and external levels (based on prices outside the country). Prescription practices are non-mandatory (i.e. not forced upon member states by EU regulators), and therefore these practices vary between member states and consequently affect levels of generics uptake. There is also the aspect of insurance coverage whereby third-party payers (insurance companies, sickness funds, and national health services) that are directly managed by governments affect the market significantly. The existence of insurance coverage leads to overconsumption and therefore overspending within the system (Barros, 2010). The trends that have been gaining momentum within the EU in recent years include: more market interventions by governments on the demand-side, cost-sharing (where patients pay a certain percentage of the bill), and external reference pricing. Additionally, policy makers within the EU have adopted numerous measures aimed at promoting generics as a way to increase competition within the marketplace.

11. EU Tax Policy

The European Commission's tax policy strategy has been explained in a Communication of 23 May 2001 on "Tax policy in the European Union - Priorities for the years ahead" (Europa.eu). In this Communication, the commission explicitly states that there is no need for an across the board harmonization of member states' tax systems. Therefore, member states can freely choose the tax systems that they consider most appropriate based on their own preferences. The EU will only act (vis-à-vis tax policy) in cases where action/s by member states are unable to provide for effective solutions, and the general view is that better co-ordination of national policies can solve most tax-related problems. The goal of the EU is to focus on the elimination of tax obstacles related to all forms of cross-border economic activities as well as the eradication of harmful tax competition practices by member states. Additionally, the EU is determined to ensure that tax policies support wider EU policy goals stated in agreements such as the Lisbon Growth and Jobs strategy as well as

[3] Gaza war shines spotlight on EU foreign policy (euobserver.com).

objectives stated in agreements on the environment and energy. With regard to company tax policy, multinational firms are presently filing separate accounts in each country that they operate in and operating on the principle of separate accounting, and this, in the view of the Commission, is extremely inefficient. Additionally, this practice leads to profit shifting to low-tax jurisdictions thereby creating disputes amongst governments and firms on the appropriate transfer prices for intra-company transactions (Bettendorf et. al., 2009). The Commission believes that "the only systematic way to address the underlying tax obstacles which exist for companies operating in more than one Member State in the Internal Market is to provide companies with a consolidated corporate tax base for their EU-wide activities" and presently, a Common Consolidated Corporate Tax Base Working Group (CCCTB WG) has been set up by the Commission to achieve this objective (Europa.eu).

12. EU Trade Barriers and Tariffs

The European Union Council Regulation (EC) No 1110/1999 of 10 May 1999 states that "duty-free treatment should be given to designated pharmaceutical active ingredients bearing an international non-proprietary name (INN) from the World Health Organization" and that "additional INNs and products used for production and manufacture of finished pharmaceutical products should be granted duty-free treatment" (Europa.eu). However, a case study that was conducted on non-tariff barriers (NTB's) that affected India's exports of pharmaceuticals to the EU concluded that, in general, Indian exporters faced numerous NTB's related to (i) packaging and labeling regulations (ii) standards, (iii) uniformity requirements, (iv) labor standards, (v) documentation and related procedures and (vi) company and product registration[4]. It is usually the case that when tariffs are eliminated by countries, wide-ranging NTB's are introduced as a means of protecting domestic manufacturers. NTBs have mushroomed from a mere 389 in 1995 to 1,895 in 2009 (Dhar, 2010) and additionally, NTB's are also creeping into Preferential Trade Agreements (PTA's). If the European Union wants to promote free trade and competition within the EU then non-tariff barriers will have to be eliminated.

1.2 ECONOMIC FACTORS

1. EU Economic Growth Rate

As a result of the recent global financial crisis, GDP rates started to contract within EU states around the second quarter of 2008, leading to five consecutive quarters of contractions; the recession experienced within the EU was the deepest, longest and most broad-based in the history of the EU[5]. Percentage rates of GDP contraction ranged from -2¼% in France and

-5% in Germany and Italy to around -7½% in Slovenia and Ireland. Outside the euro area, where contraction rates were more severe than within the euro area, Denmark, Sweden and the UK registered contraction rates of around -4½%. The contraction rates were mainly

[4] *The world isn't flat* – India Today (May 1st, 2010).
[5] European Economic Forecast – Autumn 2009 (European Commission Economic and Financial Affairs).

as a result of losses in trade and investment that came about as a result of the global financial crisis. Additionally, other factors of significant importance vis-à-vis the fall in GDP growth rates were: the collapse in fixed capital formation and strong stock liquidation. With regard to private consumption spending, the impact was not that significant – in fact, because spending rates did not decline by much, this may have in fact served as a stabilizing factor. Increases in public spending and the forceful policy responses to the financial crisis by governments also played a big role in stabilizing GDP rates. External demand for EU products and services from high growth rate economies outside the EU (such as in India and China) also helped contraction rates from increasing even further. At present, the EU is going through a transition phase, and going into the future, uncertainty remains high. Interviewee's Gregor Siebert and Jonathan Farrington were of the opinion that economic growth over the foreseeable future will remain flat. As economies outside the EU recover from the global financial crisis, and exports from EU member states to these economies continue to increase, GDP growth rates within the EU should start to rebound. The most crucial factor with regard to GDP rates going into the future will be whether governments within EU member states can get their deficits and debts under control i.e. all member states will need to robustly and effectively address the issue of sustainability of public finances. Other factors of significant importance include: private domestic spending rates within EU member states, the adverse effects of ageing populations, levels of unemployment, and rising oil and other commodity prices. There is also the issue of divergences within economies across all EU states; all member state economies will need to work collectively towards eradicating persistent divergences in competitiveness positions. This scenario will be ongoing into the long-term as new member states are allowed accession into the EU, and the domestic as well as external environment becomes increasingly competitive.

2. EU Unemployment

Eurostat estimates that 23.062 million men and women in the EU, of whom 15.771 million were in the euro area (EA-16), were unemployed in June 2010. The euro area unemployment rate (seasonally-adjusted) was 10.0%, and among EU member states, the lowest unemployment rates were recorded in Austria (3.9%) and in the Netherlands (4.4%), and the highest rates were in Spain and Latvia (20.0%), and Estonia (19.0%). The Youth (under 25s) unemployment rate was 19.6% in the euro area and 20.3% in the EU. It is important to note that unemployment levels move in a cyclical way (related to business cycles) and that factors such as labor market policies as well as changes in demographics have an impact on these rates over longer periods of time. Long-term unemployment is one of the major concerns of policymakers – there are short-term financial and social effects, and over longer periods, high levels of unemployment can negatively affect social cohesion as well as economic growth rates. Additionally, social tensions related to high levels of unemployment can lead to increased protectionist measures by governments. There can also be increased pressure vis-à-vis government spending on social benefits and reduced tax revenues, and these aspects can significantly impact government budget and debt levels. "Within the context of the European employment strategy, there are a number of measures that are designed to help encourage people to remain in work or find a new job, including: the promotion of a lifecycle approach to work, encouraging lifelong learning, improving

support to those seeking a job, as well as ensuring equal opportunities" (European Commission). Reducing volatility in unemployment rates has also been a key aim of policymakers and currently, the highest levels of volatility have been registered by regions on the EU periphery, while lower levels of variability are generally located in the central areas of the Union (Ezcurra, 2010, p.13). In order to achieve this aim, policy-makers often attempt to attract new industries that will diversify their region's economic base (Baldwin and Brown, 2004).

3. EU Outsourcing/Offshoring

In this era of global competition, firms have been facing increasing cost pressures, and this has in turn led to increased outsourcing. There are primarily two motives for outsourcing according to Alajaasko (2009), and these are reduction of labor costs and access to new markets. A recent survey conducted by Eurostat (the statistical office of the European Communities) presented some important findings on the topic of outsourcing by European firms (Neureiter, 2010). The period of the survey was 2001-2006, and numerous firms (from various sectors) in twelve European states (one non-EU) participated on a voluntary basis. Of the firms surveyed, about 16% reported to be engaged in international sourcing; countries where outsourcing was most predominant included Ireland, the United Kingdom, Denmark, Finland and Slovenia. Most of the international sourcing took place intra- EU, and the manufacturing sector was most impacted. In fact, overall employment in the manufacturing sectors of the European countries covered in the Eurostat survey "declined by 11.5 from 1999/2000 to 2006/2007" (Neureiter, 2010). Among business support functions, distribution and logistics as well as marketing and (after) sales were most commonly outsourced. High skill jobs were outsourced by firms only in instances where close proximity was not an important aspect with regard to service provision (Blinder 2007). Additionally, job losses within the high-skill category were predominant in sectors and countries where most firms rated market access as the most important motive for international sourcing. So will firms within the EU continue to outsource in the patterns identified above? Numerous factors such as high unemployment rates, ageing populations, increased competition etc. may affect outsourcing decisions in the future. At present, EU regulators have not drafted any comprehensive legislation on outsourcing practices amongst member states, but as the factors identified above continue to have a negative impact on member state economies, there may be a need to do so. With regard to the generics industry, there are clear manufacturing cost advantages in countries like India. At present, India has "the highest number of pharmaceutical manufacturing plants outside of the United States approved by the food and drug administration" (asia-manufacturing.com).

4. EU Infrastructure Quality

Currently, the EU member states contain 5 million km of paved roads of which 61,600 km are motorways; there are 215,400 km of rail lines, of which 107,400 km are electrified; navigable inland waterways traverse 41,400 km (European Commission – Mobility and Transport). The long-term goal of the EU is to establish a single multi-modal network that integrates land, sea, and air transport networks throughout the EU region. This goal was one key element of the Lisbon strategy for competitiveness and employment in Europe. Growth

in traffic within the EU, which is expected to double by the year 2020, will require a trans-European transport network (the initiative has been named TEN-T) as described previously, and this network will require an investment to the tune of 500 billion Euros (from 2007-2020). Funding will be obtained through the implementation of community financial instruments and by loans from the European investment bank. At present, there is growing concern that "the process is not going fast enough and that the ambitious targets will not be reached" (Euroactive.com). As a result of the recent economic downturn, many countries are keeping a tight grip on their wallets, and once again, political will is popping up as a key hurdle towards progress on initiatives such as TEN-T. The Kok report, which was presented in 2004, identified the main reasons for slow progress on the Lisbon strategy as "an overloaded agenda, poor co-ordination and conflicting priorities" (Euroactive.com).

5. EU Business Cycles

Several studies have been conducted on the effects of business cycle volatility vis-à-vis effects on long term economic growth rates. In a pre-budget report titled *Stability and Steady Growth for Britain*, the British government is clear in its belief that "the sharp volatility in output, inflation and interest rates seen in the UK over the past thirty years damaged Britain's long-term growth potential" (HM Treasury, 1999). In a comprehensive study covering the period 1961 to 1997, and using data from 24 OECD economies, a conclusion was reached that economic growth is damaged by business cycle volatility (Kneller & Young, 2001). Other studies have shown that strong links exist between the business cycles in the US and in the euro area (Agresti & Mojon, 2001). Within the EU, there are persistent differences in levels of economic activity between 'core' and 'periphery' member states (Giannone et. al., 2008). It is important to note here that Canova, Ciccarelli, and Ortega (2008) found no European cycle prior to the mid-80s, while an EU cycle emerges in the 1990s that is common to EMU (European Monetary Union) and non-EMU members. Since business cycles have hardly changed since the beginning of the EMU, the benefits of a common currency vis-à-vis business cycles and long-term growth rates of EMU economies have not been realized. In the aforementioned 'core' economies, there may be less volatility since levels of GDP per capita and growth rates are highly synchronized, but as a whole, the EU has to achieve this same level of synchronicity amongst all 27 member states to achieve business cycle stability, and consequently positive long term economic growth trends (Giannone et. al., 2008). As more nations are in the pipeline to join the EU over the coming years, the challenge within the EU will be to reduce business cycle volatility throughout the EU (amongst the 'core' 'periphery' as well as new member states) to ensure long term benefits with regard to stability and growth.

6. EU Disposable and Discretionary Income

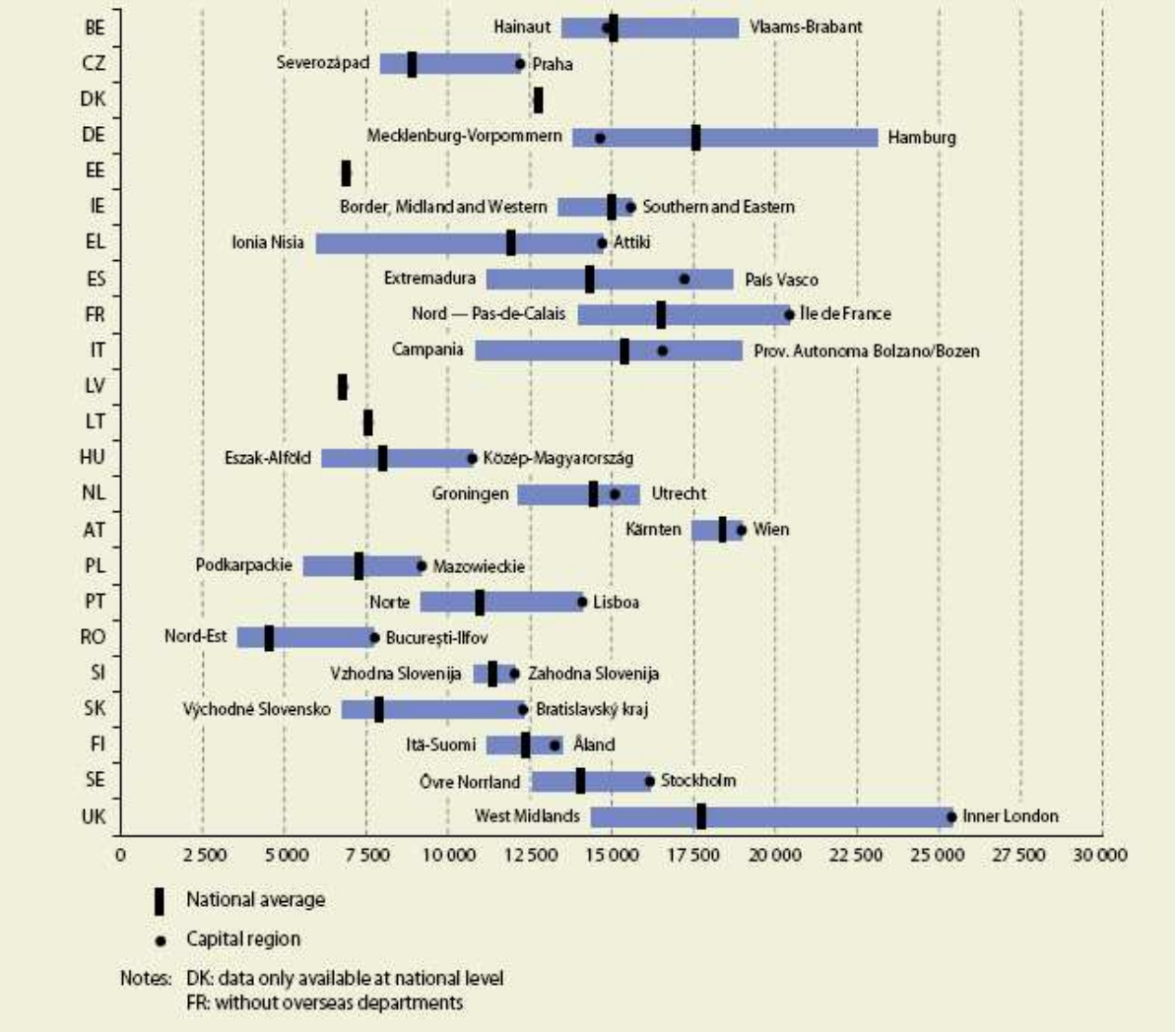

Figure 1: Disposable income of private households per inhabitant Source: European Commission – Eurostat

Figure 1 above contains data collected by Eurostat from 23 EU member states over the period 2001-2006. Disposable income is measured in purchasing power consumption standards or PPCSs, and the bars on the graphs that represent each country have a comparison of PPCSs between Capital regions and National averages. The lowest figure for disposable income PPCSs is 3,610 per inhabitant in NE Romania while the highest is 25,403 in the UK around inner London. Of the 30 regions with the highest levels of disposable income PPCSs per inhabitant, 11 are in Germany, 9 in the UK, 4 in Austria, 3 in Italy, and 1 each in Belgium, France and Spain. The bottom thirty regions include 13 Polish and 7 Romanian regions, 4 regions in Hungary, 2 in Slovakia, 1 in Greece. It is quite clear to see that there are significant variations in levels of disposable income between the original 15 EU member states and states that gained membership after 2004. On average, disposable income in the EU in 2006 amounted to 87.2% of primary income, and this figure was 87.0% in 2001, therefore, little change has occurred over the five year period of the survey. This signifies that over the five-year period, the scale of state intervention and other transfers

hardly changed (Eurostat.ec). However, a measureable trend towards a narrowing of the spread in regional values did occur over the five-year period: the difference between the highest and lowest values fell from a factor of 8.5 to 7.0 while for primary income the difference between regions went up from a factor of 10.4 to 11.0. The challenge for EU policymakers would be to reduce disparities in disposable income over all the regions surveyed over the coming years.

7. EU Exchange Rates

The main goals of the European Union in establishing the EMU was to eliminate exchange rate risks, reduce transaction costs and to create exchange rate stability within the region. Ten years after the establishment of the monetary union the effort has been successful, however, there are some major challenges that lay ahead which if not properly addressed may in fact threaten the very existence of the euro-zone. First off, "a constitutional problem looms on the horizon as the countries of Central and Eastern Europe qualify for membership in the European monetary union" (Kenen, 2010, p.4). Only three small countries (Slovenia, Cyprus, Malta) have qualified for membership into the EMU, and there are other much larger countries waiting in the wings (current and future EU member states). "With the addition of these and other EU countries, the ECB's Governing Council will become unmanageably large, and the plan adopted by the ECB for rotating membership is, in my view, unsatisfactory" (Kenen, 2010, p.5). Additionally, banking and financial systems in Central and Eastern European countries are much more exposed to the consequences of mounting flights of capital and currency attacks (Gros, 2010). Furthermore, situations like the huge appreciation of the euro in 2006 and 2007 impaired the external competitiveness of some euro-area countries such as Spain and Italy, and situations like these in the future will call for swift intervention by the ECB to reduce the negative economic impact on certain member states economies (Kenen, 2010). Over the long-term, fiscal responsibility and discipline, as well as more economic flexibility and political unity are factors that could threaten the survival of the euro zone. As we head into the future, there is a likelihood that EU member states may revert to their old currencies due to the problems/challenges already mentioned. In this scenario, the prospects of achieving numerous objectives within the EU (e.g. long-term economic growth across the region) could be severely jeopardized.

8. EU Inflation Rates

Inflation Rates (% change on preceding year) – Euro Area (2005–10)

	2005	*2006*	*2007*	*2008*	*2009e*	*2010f*
Belgium	2.5	2.3	1.8	4.5	0.0	1.3
Germany	1.9	1.8	2.3	2.8	0.3	0.8
Ireland	2.2	2.7	2.9	3.1	−1.5	−0.6
Greece	3.5	3.3	3.0	4.2	1.2	1.4
Spain	3|4	3.6	2.8	4.1	−0.4	0.8
France	1.9	1.9	1.6	3.2	0.1	1.1
Italy	2.2	2.2	2.0	3.5	0.8	1.8
Cyprus	2.0	2.2	2.2	4.4	0.8	3.1
Luxembourg	3.8	3.0	2.7	4.1	0.0	1.8
Malta	2.5	2.6	0.7	4.7	2.0	2.0
Netherlands	1.5	1.7	1.6	2.2	1.1	0.9
Austria	2.1	1.7	2.2	3.2	0.5	1.3
Portugal	2.1	3.0	2.4	2.7	−1.0	1.3
Slovenia	2.5	2.5	3.8	5.5	0.9	1.7
Slovakia	2.8	4.3	1.9	3.9	1.1	1.9
Finland	0.8	1.3	1.6	3.9	1.8	1.6
Euro area	2.2	2.2	2.1	3.3	0.3	1.1

Table 1: Inflation Rates EU. Source: Commissions (2009). Source Eurostat

As is evident from the above table 1, inflation rates within the Euro area have been quite stable over the period 2005-2010 – with the exception of the period of the global financial crisis. In 2008 there was a fear of stagflation (falling economic growth and rising inflation) followed by a deflationary period in 2009. The main reasons as to why inflation went up drastically from 2007 to 2008 were increases in food and energy prices. The fall in 2009 was mainly due to a fall in energy prices as well as downward pressure on producer prices. Stability in inflation rates is a key objective for EU policymakers, but since there are numerous disparities in economic conditions within the region, the goal of stabilizing inflation across the EU becomes ever more challenging. Within CEE (Central and Eastern European) member states recently granted EU accession, inflation became a problem to reckon with immediately after these states abandoned their centrally planned and largely fixed price systems (upon joining the EU), and in fact, inflation has remained a problem to the present day (Staehr, 2008). The CEE states that are now a part of the EU have had higher inflation rates than the "original" EU member states, and this scenario is likely to negatively affect these countries international competitiveness. In addition to the factors driving inflation already identified previously, the higher inflation in the new member countries is partly resulting from the catch-up process as capital deepening and high productivity growth in the traded sector drive up inflation" (Staehr, 2008, p.31). As uncertainty persists in new member states, and as these countries continue to experience higher economic growth rates as they play catch-up, inflation could creep up within the EU wide region over the coming years. Additionally, energy and food prices are likely to increase in the future as global demand rises, and this scenario could also lead to higher inflation rates.

9. EU Interest Rates

Interest rates, set in the euro zone by the European Central Bank, have an enormous effect on economic growth rates as well as inflation. When the Euro zone was initially formed, "Milton Friedman predicted that the new entity would collapse when faced with an economic crisis pitting the interests of one group of countries, against those of another group" (Boyd, 2009, p.1). Friedman's contention was that when difficult decisions were necessary, policymakers would have to support initiatives favoring larger economies over smaller ones. This prediction by Friedman would come true as immediately after the formation of the euro zone, the ECB lowered interest rates to make the German and French economies (which were slumping at the time) more competitive. This led to severe effects on markets in smaller countries like Greece and Spain which were already experiencing high rates of inflation at the time; the sudden availability of cheap credit (due to the low interest rates) ushered in a wave of spending, and this in turn led to higher inflation and a rapid increase in prices and wages.

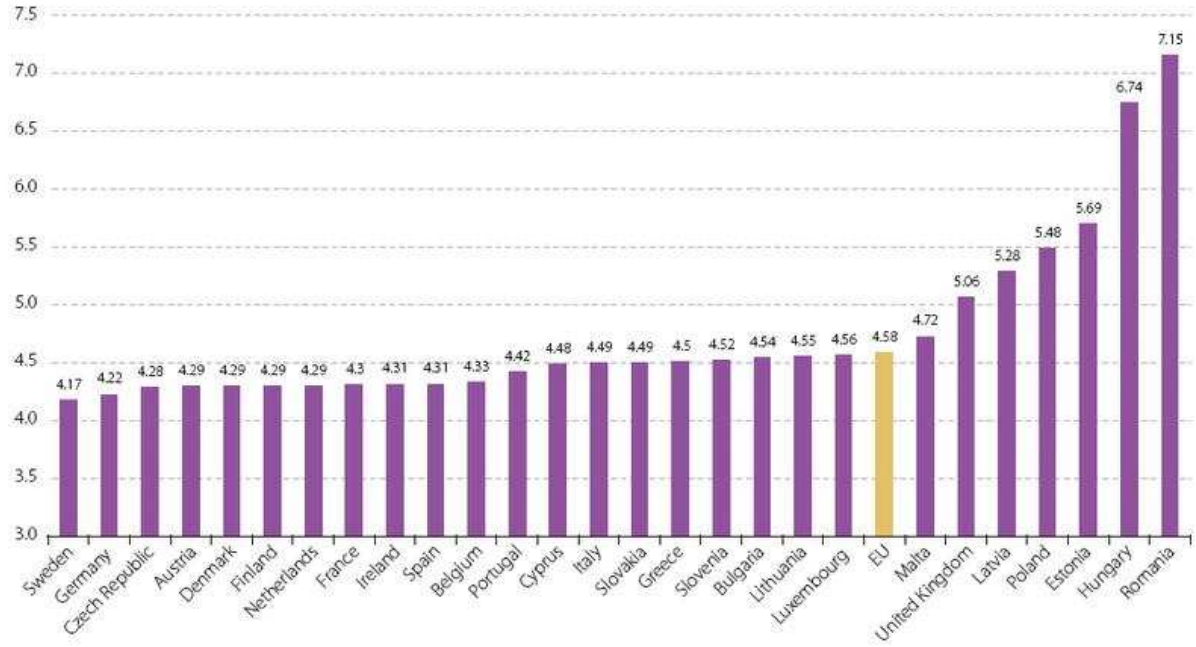

Figure 2: Long-term Interest Rates in European Countries (2007). Source: Eurostat

As is evident from the Figure 2, long-term interest rates still vary in the EU across countries, with lower rates in the "core" member states, and higher rates in "periphery" states like Romania, Hungary, Estonia, Poland and Latvia. If the EU wants to avert severe effects on markets such as described in the case of Greece above, then, interest rates will have to be streamlined across the region. "Long-term interest rates are one of the convergence criteria indicators for Economic and monetary union, according to Article 121 of the Treaty establishing the European Community; Article 4 of the Protocol on the convergence criteria annexed to the Treaty states that a Member State has to have an average nominal long-term interest rate that does not exceed by more than two percentage points that of the three best performing Member States in terms of price stability" (Europa.eu).

10. Financial Markets

The financial markets are the pivotal function of a modern economy. By aiming towards an increased level of integration, there will be a more efficient allocation of economic resources and long term economic performance (European Commission, 2005). It has therefore been the EU's policy to complete a single market in financial services (being a crucial part of the Lisbon Economic Process[6]) for addressing EU's global competitiveness.

Since the economic crash and subsequent global crisis there have been calls for closer monitoring of the financial system and better EU coordination. With the perceived failure of the Lisbon Strategy outlined in 2000 (Wyplosz, 2010), many parties have urged a relook at the model particularly with the current global economic crisis afflicting the EU. Since the collapse of the US investment bank Lehman Brothers in September 2008, there has been no shortage of politicians rushing to prescribe what is to be done differently in the financial sector in the future (Dullien & Herr, 2010).

The financial crisis has made it clear that the financial markets are in clear need of reforms and far more effective regulations are necessary to govern the future growth of the financial markets in the EU. While the topic has now refocused on the Eurozone crisis, the financial market regulation at both national and EU level has been experiencing a great deal of changes. Strength and confidence in financial markets will need to be re-established as pointed out by the Director General (2010).

The European Commission has presented several draft directives that are undergoing evaluation by the decision making bodies around Europe. Unlike the US, the EU has had several attempts at harmonizing the financial markets (through the Lisbon Process) albeit these efforts have not entirely been successful. While all the financial institutions in Europe are very closely linked to each other, there has been a lack of a uniform basic regulation for financial supervision as national governments tend to pursue that which is in the best interest of their own countries rather than the region as a whole. This therefore allowed institutions from neighboring countries to enter into risky transactions in those markets with tight supervision but greater access of capital. The European Commission is now letting several directives to be considered for legislative purposes.

1. Higher capital requirements for banks.
2. Establishment of a European ratings agency that independently evaluates securities of issuers.
3. New rules for Derivatives Trading and Securitization.
4. Creation of a European System for Financial Supervision (with a Risk Board being set up alongside) that issues mandatory instructions to national supervisory authorities.

[6]The Plan was to an action and development plan for the EU between 2000 and 2010.Its aim was to make the EU "the most competitive and dynamic knowledge-based economy in the world capable of sustainable economic growth with more and better jobs and greater social cohesion," by 2010.It was set out by the European Council in Lisbon in March 2000 (EUROPA, 2000)

This however will be a challenge to the EU as such measures would potentially affect the sovereignty of individual national governments to pursue national policies, something which several European nations are not willing to give up as seen in the Greek crisis. Such directives are not expected to be introduced by end 2010 with expectations gathering that these directives themselves will be 'watered down' from their original form making them 'toothless'vis-a-vis enforcement purposes (Dullien & Herr, 2010).

11. Savings Rate

Savings rate are higher amongst several EU nations as compared to US households in general (Harvey, 2004). There has been a decline in recent years as per researcher Tina Aridas (2010) from the Global Finance Magazine. Ms. Aridas has stated that between '2007 and 2008, the European Union's household saving rate was lower than in the euro area, due mainly to the low saving rates in the UK and the Baltic countries. The US saving rate was low compared with both the EU and the euro area. With the passing of the worst effects of the global crisis from 2008, EU households are again faced with the euro confidence crisis that constrains the region's ability to recover faster than other regions (as it struggles with unemployment, high deficits and generally bearish economic prospects outlook) (IMF, 2010). As of July 2010, figure 3 below highlights the EU household savings rate, which is still declining as many households face decreasing real disposable incomes.

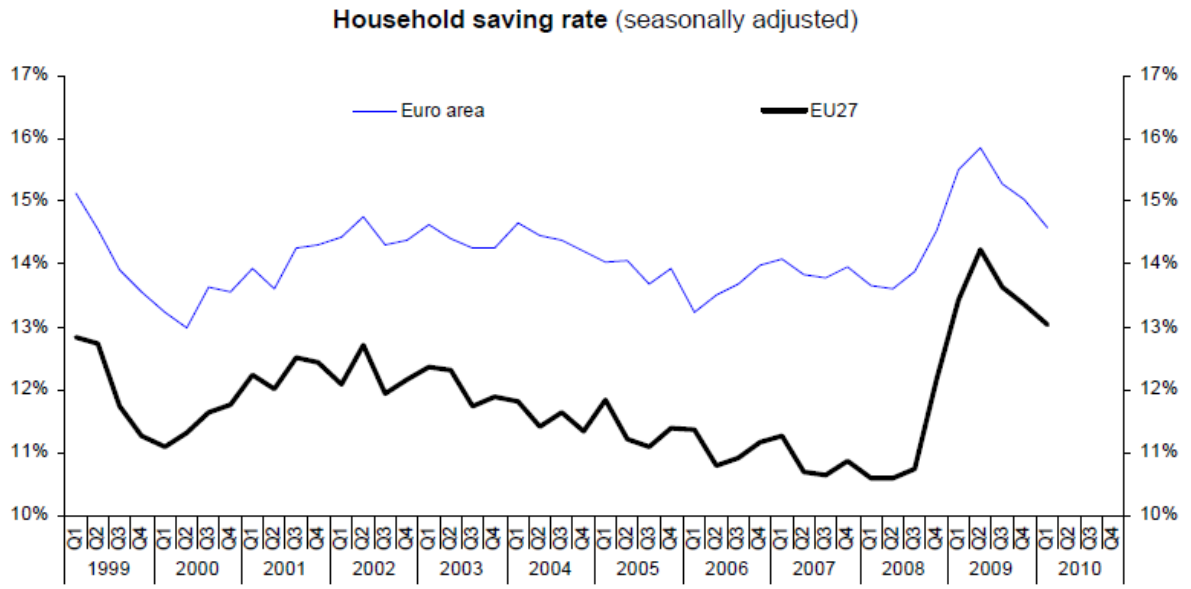

Figure 3: Household saving rates in Euro area and EU 27 member states. Source Eurostat

The general household will now need to brace itself for further cuts in income as major EU member nations embarks on tough public spending cuts (Traynor, 2010). Recovery in European economies is expected to be gradual and uneven as most of the savings gain from budget cuts is utilized for loan repayments for past debts incurred.

1.3 SOCIAL

1. Demographics

Based on the latest 2008 projections done by the Commission of the European Communities ('EUR-LEX'), the EU is facing unprecedented changes in the regions populations. This development would represent numerous challenges for member state governments as they would have to review and adapt existing policies. Demographic ageing, i.e. the increase in the proportion of older people, is above all the result of significant economic, social and medical progress giving EU citizens the opportunity to live a long life in comfort and security which is not without precedent in the region's history (EUR-LEX, 2006). This has become one of the main challenges for the EU as the following demographic trends observed throughout the member countries with various magnitudes.

Fertility rate: Fertility rate at the last estimates for 2008 by EUR-LEX stands at just over 1.5 children with a growth forecast of 1.57 by 2030 (2009, p.21). In all EU countries, the fertility rate would likely remain below the natural replacement rate of 2.1 births per woman which is the rate needed in order for each generation to replace itself. A period of slow growth, and in most cases actual decline in the population of working age people within the region will constraint member states' abilities to grow from within (due to human capital constraint). A fact illustrated below (Figure 4); despite entry of further new members, the rate remains below average required for repopulation.

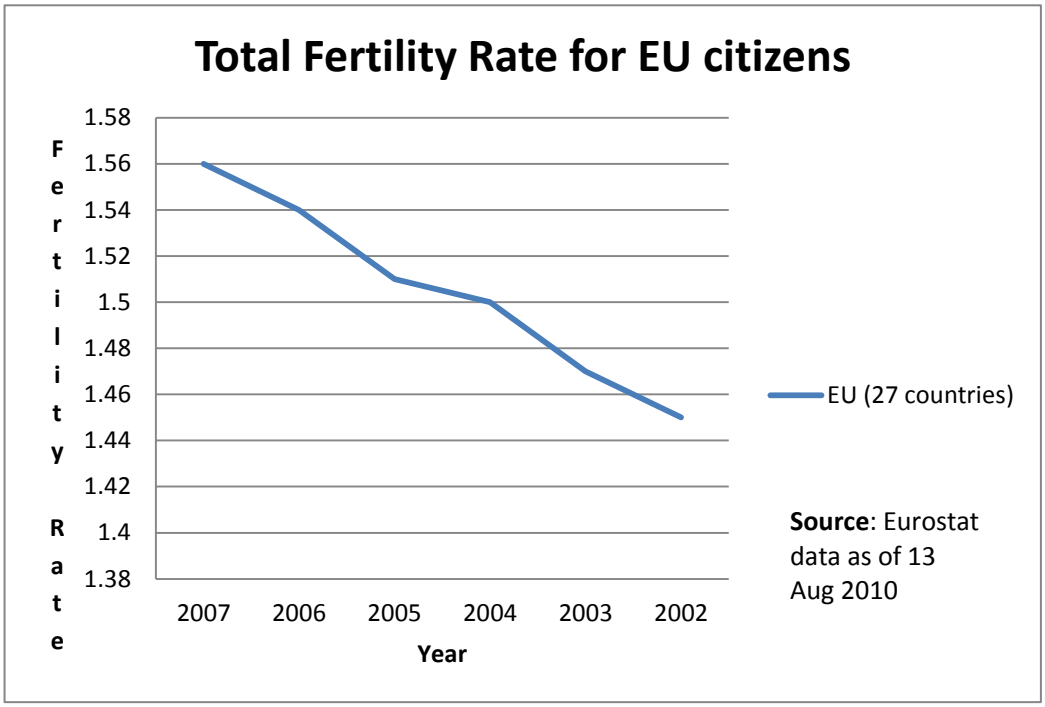

Figure 4: EU citizens' fertility rate 2002 to 2007

Mortality rate: The life expectancy has been rising steadily since the 20th Century, with an increase of two and a half years per decade. As compared to countries around the world, EU citizens hold the record of highest life expectancy (EUR-LEX, 2008). It is undeniable that the proportion of EU citizens above the average age of 65 will climb further in time as seen in

Graph 6. The EU projects that life expectancy for males would increase by 8.5 years over the projection period, from 76 yrs originally in 2008 to 84.5 yrs by 2060 (EUR-LEX, 2009). For females, life expectancy at birth would increase by 6.9 years, from 82.1yrs in 2008 to 89yrsin 2060, marking a narrowing life expectancy gap between both genders. Most of these increases in life expectancy will come from recent EU member states (Estonia, Poland, Hungary, Slovakia etc). Children in the EU today will face a high chance of living to their 80s or 90s in the long-term especially if they are from Western Europe with mid-high socio-economic status.

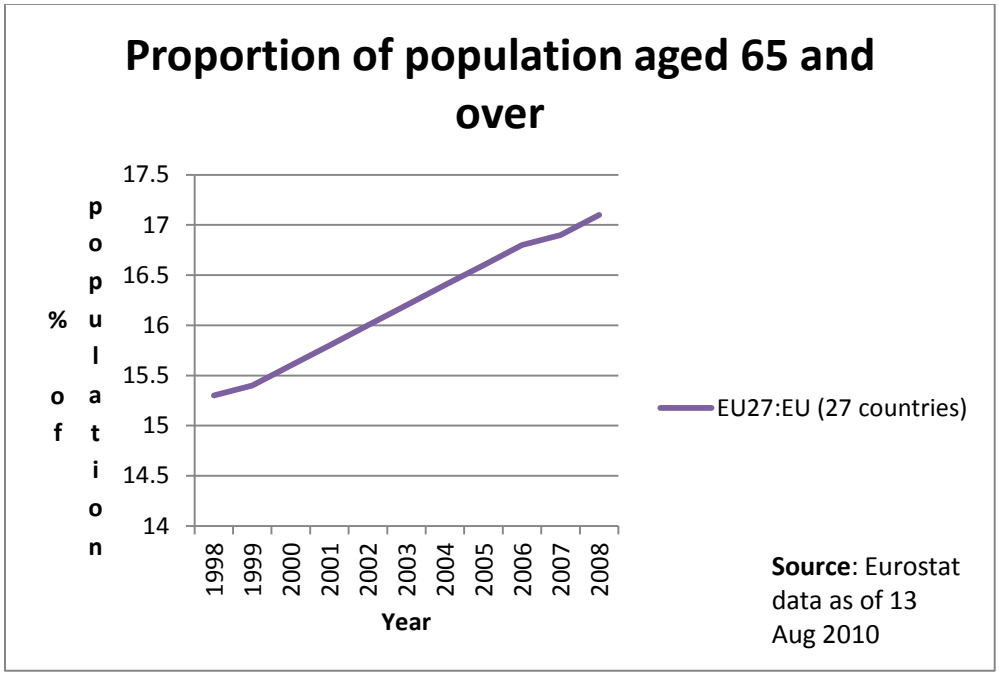

Figure 5: Proportion of population aged 65 and over. Source Eurostat

Net Migration: Migration already plays a predominant role in population growth today. In many Member States, the size of net migration determines whether the population still grows or has entered a stage of decline (EUR-LEX, 2009). Annual net inflows to the EU are assumed to total 59 million people, of which the bulk (46.2 million) would be concentrated in the euro area. The trend according to the EUR-LEX study, assumes that this will decelerate over the projection period, falling from about 1,680,000 people in 2008 (equivalent to 0.33% of the EU population) to 980,000 by 2020 and thereafter to some 800,000 people by 2060 (0.16% of the EU population). Interviews conducted by our project team concur with the importance of migration noting that there will be a continual need for foreign talent to drive further economic growth in the EU. It is therefore only a matter of time for the EU to work towards a harmonized migration policy for its member states.

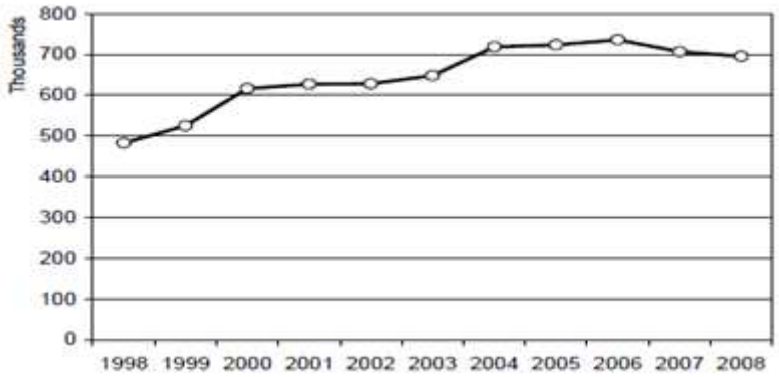

Figure 6: Total acquisitions of citizenship in the EU-27. Source Eurostat

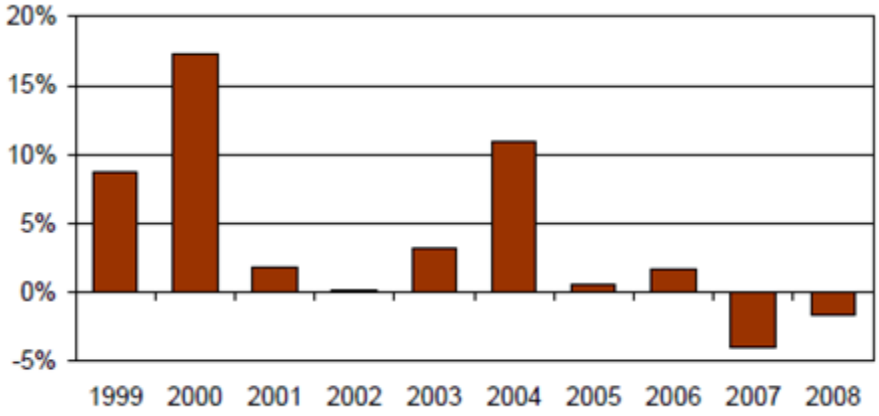

Figure 7: Total acquisitions of citizenship in the EU-27, relative change on previous year. Source Eurostat.

In recent years, Moroccans and Turks represent the largest migrant group with the highest number of citizenship recorded in France, Italy and Spain. There has been a slight decline in the acquisition of EU citizenship since 2007 with the numbers slightly below 700,000 or 2 % in 2008 alone. Researchers have however pointed to the decline as being primarily due to the current economic climate and the tightening of immigration rules. This will not be a hindrance as making full use of the global labor supply through net migration will be increasingly important.

2. Education

Education and training have an important place in the Lisbon strategy for jobs and growth (European Commission, 2009). EUR-LEX studies expect that the ratio of children and young people to the working-age population will shrink over the coming decade. Nonetheless, education and training systems in the EU are generally improving. The EU benchmark on mathematics, science and technology graduates was already reached before 2005 (refer graph 9). New growth has been registered in maths, science and technology graduates whose numbers were more than the original target set. However, owing to the trends in birth rates, this is likely to become unsustainable unless the birth rate increases or foreign skills are imported into the EU.

Likewise, benchmarks on early school leaving, completion of upper secondary education and lifelong learning were the opposite, with literacy rates amongst young children on the decline. The respective countries will now need more effective national policies to address this trend of decline.

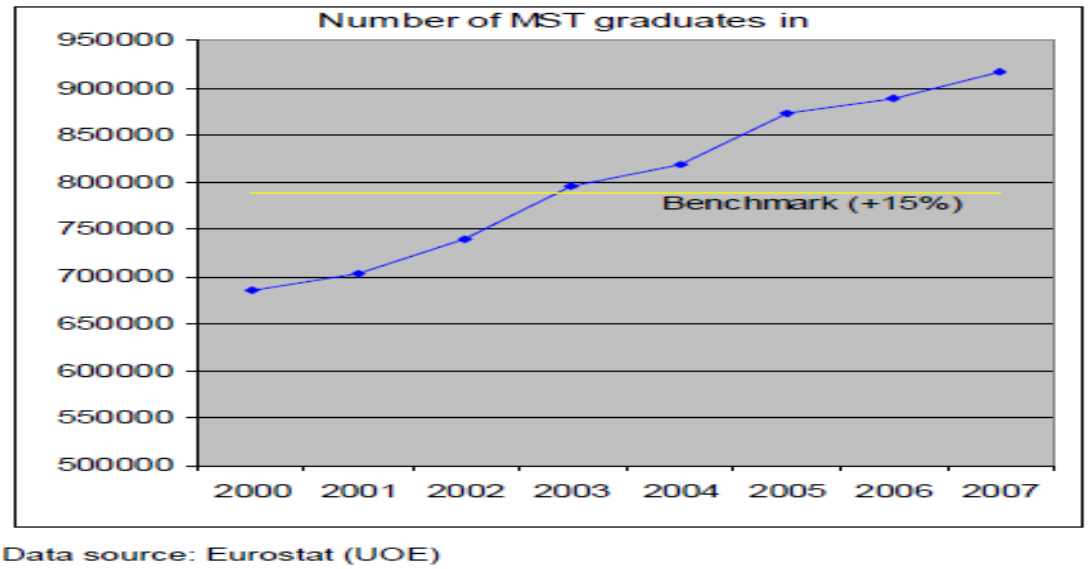

Figure 8: Number of graduates in Mathematics, Science and Technology ('MST') in the EU. Source Eurostat

3. Entrepreneurial Spirit

The Commission defines "Entrepreneurship" as 'the mind-set and process [needed] to create and develop economic activity by blending risk-taking, creativity and/or innovation with sound management, within a new or an existing organization' (EurActiv.Com, 2004). SME's are considered the backbone of the European economy, providing jobs for millions of European citizens and SME's are also the basis for economic innovation. Back in 2004, conditions for SME's and start-up companies were not as favorable in the EU as they were in the US making entrepreneurial initiative and risk-taking less developed in the EU. EU citizens are almost evenly divided in their preference for being self-employed or having employee status with many still preferring the comfort of being a salaried employee (European Commission, 2009). In general results showed that from 2007 to 2009, EU citizens views on entrepreneurs are mixed with almost all countries more likely to agree that entrepreneurs are only concerned with profit or that they exploit other people's work to their own benefit. The EU population in general prefers to either save money, or use it to buy a house, or to repay their mortgages, rather than embarking on risk taking ventures that threaten their way of life.

The high level of migrants to particularly wealthy EU Member States will however serve to showcase their entrepreneurial spirit in these economies. As many arrive with the intention of making a better life for themselves and their families, and with the majority of the SME's coming mainly from this group of people, there will certainly be no lack entrepreneurial spirit in the EU in the near future.

4. Lifestyle changes

Recent evidence shows that in industrialized countries people do not only enjoy longer life expectancy rates, but they are also experiencing better health conditions in old age due to both healthier lifestyles and more effective pharmaceuticals allowing people with chronic diseases to control the adverse effects of illness (European Commission, 2009). The continuing improvement of the populations' healthy ageing in the EU reflects the desire for sustainable lifestyles, and a healthy environment amongst the people moving forward. With the Maastrich Treaty, the explicit mentioning of public health as an area of competence of the EU reinforces the expectation that having a sustainable, healthy lifestyle will be the way forward for the EU. Clearly, pharmaceutical drugs (patent or otherwise) will continue to provide a vital service to the EU population.

Changing household and family trends need to be taken into account as the number of low-income, single parent families' increases. As a result of higher involvement of women in the work force, the economic crisis along with the spending cuts instituted at present is expected to create a more prudent, budget oriented household as the situation forces families to rein in their spending for essentials. Healthy lifestyles will become a more viable daily practice as a preventive measure against sickness as compared to incurring medical bills in the household due to illness.

Preventive Healthcare: As stated in an interview with Ms. Angela Farrell (2010), preventive healthcare would become a normal trend as medical cost continues to increase. As with having more elderly people in the population in the EU at present, the prevalence of chronic and serious medical conditions remains on the rise. It is therefore no surprise that this becomes an area for further focus by the state governments that seek to control existing healthcare budgets (Hewitt Associates, 2010). Unlike the US healthcare system, EU states adopt a universal provision of heath care with at least, the basic aspects of heath care provided free to its citizens (Przywara, 2010). Therefore the WHO has pointed out that "if not successfully prevented and managed, they will become the most expensive problems faced by our health care systems" (WHO, 2010). Because several diseases such as cardiovascular diseases, cancer, diabetes and chronic respiratory diseases - are linked by common preventable risk factors, healthcare authorities around the world (including the EU) have found it more cost-effective to put proactive preventive practices into action rather than continue with responsive-oriented healthcare systems. Amongst other measures, standard procedures by EU health authorities will involve providing information, education, programs and support to those in 'risk-groups' within the general population.

5. Social Mobility

A simple meaning on the term 'social mobility' refers to the degree to which an individual or group's status is able to change in terms of position in the social hierarchy. Populations with the greatest access to education, and adopting a more tolerant if not more open attitude towards the society, will tend to experience a higher level of social improvement (Blanden et al, 2005). Historically, EU social mobility levels are mixed based on Blanden's research study (2005) and Breen (2004) as countries like the UK and Ireland are seen as generally

more rigid with any mobility associated with parental income and educational attainment. Over the years since the formation of the EU, the mass migration of citizens with different social background has presented a difficult task in further upgrading mobility within societies. With the economic crisis, younger generations in EU member states will now struggle to scale upwards, especially with the loss of family income and limited government support, marking a risk that any cycle of poverty that an individual household will face is repeated. This is more so as essential costs such as health care become more costly towards households attempts toward improving living standards while at the same time aiming to scale towards a better way of life for themselves.

1.4 TECHNOLOGY

1. New Products and Research & Development ('R&D') Expenditure

Increasingly, R&D spending by the pharmaceutical industry has been on a decline, forcing leading drug manufacturers to rely on existing lines of drugs for revenue generation (Kollewe, 2010). Based on a report by CMR International disclosed in The Guardian newspaper, the level of R&D spending had slipped by 0.3% in 2009 following a 6.6% drop in 2008, marking an increasingly difficult period as leading pharmaceutical companies' show only 7% of sales originating from new drugs launched within the past 5 years. A decline in the success rates for new drugs to be introduced into the market is a major factor as the industry faces a "patent cliff[7]" and this is a scenario in which generic manufacturers will increasingly benefit. In recognition of this, pharmaceutical groups have embarked on M&A routes with smaller firms, joint development with academic institutions/commercial competitors for new drugs while reducing cost incurring activities. Introduction of blockbuster drugs (such as Pfizer's Lipitor) has been stagnant, with generic drug makers from India and China crowding the pharmaceutical scene, making it tougher for the big pharmaceuticals companies to incur healthy margins that can finance R&D expenditures for future drug development.

Genomics testing: Since the discovery of DNA and the associated study of it, this has been marked as one of the major breakthroughs in genetic testing (Amgen Scholars, 2009). Utilizing technological advances over the years, genomics testing allows for a more-accurate diagnosis of genetic diseases and therefore facilitates early treatment at an earlier stage. It also provides patients with both an understanding of possible risks for certain diseases and possible preventive measures long before the disease even forms within the body. Genomics testing in Europe however, suffers from a lack of widespread acceptance as compared to the US (Ramanathan, 2008) owing to the protection laws governing the genetic data obtained from such tests. The processing of genetic data in Europe has been subjected to stronger protection as provided in the Directive 95/46/EC and the national laws of the EU member states implementing it (Ramanathan, 2008). However, as EU residents' healthcare costs grow, the development of an integrated knowledge base combining the insights of sciences, humanities and social sciences will be required to inform policy and to plan for the rational implementation of new healthcare services. EU health communities have

[7] A term described when a firm or industry loses the monopoly granted by one or more patents.

recognized the benefits of genomics testing for healthcare prevention with the need for a strong integrated, interdisciplinary European link to manage the sheer volume and complexity of this emerging genomic knowledge (EUPHA, 2010). The EU has viewed genomics in a more positive manner as seen in one of its main theme for the Sixth Framework Program (that funds research work on genomic studies on diseases) to exploit this knowledge for human health as well as economic benefits (CORDIS, 2009). Genomics testing will continue to grow as more benefits are uncovered from researchers in the EU, with long term plans by the EC being provided towards nurturing such growth.

There are multiple benefits of genomics for both pharmaceutical and generics makers as pointed out by Philips et al (2004). According to the research carried out, genomics is likely to provide a "multitude of new drug targets, enable the development of drugs that avoid problematic genetic variants in drug-metabolizing enzymes, and increase the development of preventive interventions for patients identified as being at higher risk for future diseases" (Philips et al, 2004, p.428). Interviewee, Ms. Angela Farrell has pointed out the interest of many in the medical field to create more targeted forms of treatment. Genomics allows this as it allows drug therapies with greater efficiency and safety, which of course leads to higher prices due to the added value this can bring to patients. Genetic profiling in patients enrolled during the early testing phase for drugs will allow for shorter testing time this can increase approval chances amongst the health authorities. Drugs that previously were unsuccessful can be re-examined by targeting them to patients with specific genetic profiles i.e. 'niche drugs'. Generic drug makers will eventually benefit as such avenues open wider markets for patients upon expiry of patents or if possible, spurn development of 'niche drugs' rather than reliance on original drug makers.

Drug delivery system: This is an area that has become increasingly popular within the pharmaceutical industry based on interviews with Ms Angela Farrell and Mr. Gregor Siebert. It is reported that at present, failure of drugs clinical trials are mainly due to the failure to deliver the compounds to the area of the body where it is needed most without going through some interaction with the entire human body (Cientifica,2007). It is therefore considered a very valuable and important development for any technology that enables direct delivery of drug compounds without triggering any or no side-effects on the patients. One of the EU's focus areas is currently nanotechnology-enabled drug delivery systems for patients. While there are delivery systems using laser, injection, sprays etc. nano particles are receiving particular attention owing to more development going on in this field. Drug development is a very costly affair for patent holders especially with the decline of new drugs being discovered each year. Many new biotech companies have become acquisition targets owing to keen interest towards this field.

The future of nanotechnology is in a completely uncharted territory. It is almost impossible to predict everything that nanoscience will bring to the world considering that this is such a young science field today (Nanogloss, 2009). The field however is viewed as a revolutionary advancement but potentially controversial with its ability to bring materials to life. Religious and ethical issues aside, scientist are hoping that the further understanding of this technology would contribute towards improving the healthcare of populations globally in

the future. If successful, pharmaceutical companies should view this field as their next line of income as existing drug making expertise dries up.

2. Biotechnology

With 20% of new drugs launched from market each year derived from biotechnology (EFPIA, 2009), the biotechnology field has long been a promising development for the medical and healthcare purposes. Areas such as pharmacogenomics, nanotechnology, stem cells and gene therapy are becoming part of a growing emphasis by medical professions. With a vision to improving design and production of drugs within a human's genetic makeup, this field has become a new alternative for medicines, as previous reliance on conventional drugs (through use of chemical reactions) for treating illness have become scarce and increasingly difficult to produce. Using biomedicine, which creates drugs based on living molecules that are associated with specific genes and diseases, EU scientists under the JRC-EU[8] in 2007 have pointed out encouraging responses towards treatment of genetically inherited diseases such as hepatitis B, cancer and diabetes. JRC further pointed out that human medicine and healthcare are the most prominent fields for modern biotechnology with a high share of publications and patents targeted towards this sector (2007).

The direct and indirect elements of R&D works for biotechnology would add towards EU's GVA[9] and improving state of heath for EU citizens as part of the context of the EC's objective of making the EU "the most competitive and dynamic knowledge-based economy in the world, capable of sustainable economic growth with more and better jobs and greater social cohesion" (JRC-EU, 2007, p.5). Numerous researchers suggest that biotechnology can offer patients more and better healthcare choices. The biomedical healthcare industry is viewed as the pharmaceutical industry's external R&D centre and source of product innovation (EMCC, 2005).

However, the strength of the biomedical healthcare industry differs widely between European countries. As of 2003, the UK is considered to have the most mature industry as compared to other EU states (EMCC, 2005) but this has narrowed as other EU states nurture their own industries.

At this time, there has been a lack of attempts towards producing generic versions of biotechnology drugs. Many of these drugs are very expensive because they are so difficult to produce owing to complex molecules involved (Montgomery, 2009). Furthermore, regulatory guidelines are still lacking on existing bio-medicines due to the different arrangements governing both the US and EU member states (Manley, 2006). However as expertise and experience continue to grow (especially with the campaign by EGA's biosimilar drugs), it is only a matter of time before biotechnology becomes a huge part of patient healthcare in the EU and around the world.

[8] Joint Research Centre – European Commission
[9] Gross Value Added

3. *Incremental & Disruptive technologies*

To practitioners in the drug industry, incremental (or sustainable) technologies will come in form of mostly new drugs for an existing class with similar action mechanisms but these drugs will '...differ in features such as, therapeutic profile, metabolism, adverse effects, dosing schedules, delivery systems, for example' (GSK, 2008). Incremental technologies are in this sense, seen as innovation capacity, which is according to Wertheimer & Santella, 'the lifeblood of the pharmaceutical industry' (2009). The current issue surrounding this subject matter has largely pertained to criticism that the developments of 'me-too[10]' drugs have led to time wasting, been a drag of existing resources, (R&D, money etc.) and have aimed towards 'fleecing unsuspecting consumers' (Wertheimer & Santella, 2009) particularly as the patented drugs life is ending. Generic manufacturers in the US and Europe have been particularly vocal towards this practice as it alleges pharmaceutical companies use this method to extend patent life span's through introduction of small changes that deprive generic manufacturers access to such drugs (and therefore an anti-competitive practice). It is therefore a contentious issue as both individual corporations such as GSK and its trade representative in the EU (the EFPIA) continue to debate this publicly, and with the European Commission.

Other incremental technologies that serve to complement the medical drug industry arise from rapidly improving testing, diagnostic, and other technologies (Brill & Robbins, 2005) which allow better and more targeted drugs in the heath care sector thus ensuring the continued relevance of conventional medical drugs in the market.

Disruptive Technology here is both a worry for patented and generic manufacturers as witnessed by the continued interest in biotechnology as the new alternative in medical discoveries. With the continued slow progress in the creation of 'blockbuster' drugs from conventional pharmaceutical research, EU policy makers have continued to show further interest in biomedicine thru policy development initiatives such as funding (EFB, 2010). Pharmaceutical giants too, have gradually increased R&D spending in this field with many companies embarking on M&A activities with existing biomedical companies (i.e. Pfizer's acquisition of Wyeth) besides growing internal resources to sustain their business.

1.5 LEGAL

1. *Labor Laws*

The legal framework of the EU is vast and diverse due to the numerous countries within the union and hence only an overall review of selected laws and regulations is discussed in this report. It is however noted that European generic medicine companies face the problem of disharmonized implementation of new pharmaceutical legislation in member states (EGA[11], 2007) as well as cost constraints as a result of legislative requirements imposed by EU member states.

[10] Drugs within the same chemical class as one or more others already on the market (Wertheimer &Santella, 2009)
[11] The European Generic Medicines Association

Europe's legal systems are largely founded on Roman Law and Germanic customary law and therefore these systems share a common linkage. Legal systems have been highly influential in shaping national codes and have given rise to legal frameworks that rely less on case law and 'precedent' cases occurring elsewhere for countries within the European continent (FedEE, 2010). The attraction for EU citizens pertains to the freedom of movement of labor. This is because every EU national is entitled to take up and pursue employment in the territory of another member state under the same conditions as the nationals of the host state (EU Treaty Art 1 and Regulation 1612/68). When first introduced, the movement was aimed at facilitating a competitive environment for member states to pursue economic growth as it provided labor mobility for EU businesses to move workers to any member state for the best optimal outcome, thus generating further growth for all member states.

Since 1969 (Strauder v City of Ulm) a 'de facto' body of general human rights principles has been introduced by the European Court of Justice (ECJ) to avoid clashes with national constitutional rights when making their decisions (FedEE, 2010). This therefore mounts the complexity for any business as host states may impose conditions relating to linguistic competence where this is directly relevant to their employment (ECJ case reference C-397/87).

2. Health and safety regulations

HS regulations play an important role in the medical drugs industry owing to the test type and chemical process used in production facilities. European Agency for Safety and Health at Work imposes directives on EU member states under Article 137 of the TEC[12] which ranges from workplace and safety equipment, chemical agents exposure, physical hazards, and biological agents to sector specific provisions. These directives are updated regularly to reflect the current trends in the EU workplace. Pharmaceutical and generic manufacturers therefore face high costs in time and labor as they try to maintain compliance to the various health and safety codes introduced from time to time. This is not all negative however as the existence and monitoring of HS regulations ensures that medical drugs produced are at the highest quality for usage by patients anywhere. Generic manufacturers, unlike original medicine developers, do not share as much compliance concerns owing to the lesser amount of work activity required for rolling out their drugs as most (if not all) the main risk has been carried out by the patent holders instead.

Nonetheless, HS regulations for patients are given equal weight by both pharma and generic players making such environment tough for the EU drug industry as it monitors all adherences to standards imposed by the EU governmental agencies.

3. Consumer Protection

Consumer protection is provided for under the EC's Consumer Policy for the 493 million EU consumers. The Consumer Policy supports the aims laid out in Articles 153 and 95 of the Treaty establishing the European Community, which promote the interests, health and safety of European consumers. The policy stresses on market transparency, consumer

[12]Treaty on the Functioning of the European Union

protection, and consistency in operational objectives for all EU member states. This therefore puts both pharmaceutical and generic drug manufacturers on notice with regard to being transparent in their dealings, manufacturing methods, and using ingredients that comply with the highest level safety standards for EU patients. With the EU internal market having the potential to become the world's largest retail market (CEC[13], 2009), the market has remained largely fragmented along national lines, forming 27 mini-markets[14]instead, therefore making it a challenge for EU consumers that engage in cross-border disputes as a result of consumer purchases outside their own home countries. The CEC report has quoted that despite the technological advancement (i.e. e-commerce) "business and consumer behavior lags far behind, restrained respectively by internal market obstacles and a lack of confidence in cross-border shopping" (2009, p.2).

Despite the still predominantly fragmented nature of retail markets around the EU, the CEC's view is that cross border trade liberalization would be the key to unlocking the potential of the EU retail market (CEC, 2009), and has therefore continued to push for further liberalization of various business sectors around the EU. It is therefore inevitable that EU markets will become gradually consolidated into one single market once consumer protection regulations are harmonized across all member states. As better informed and educated EU consumer numbers grow, the medical drug industry will be one of the growing focus for protection of patients across individual state borders once quality benchmarks are established in the healthcare sector for all EU states to comply.

Counterfeit medicine: This problem was first addressed in 1985 (Pharmaceutical Technology Europe, 2010) in the World Health Organization (WHO) meeting with experts. With the explosion of e-commerce from the year 2000, the problem has increased substantially, with the magnitude difficult to access due to the variety of the information sources available (WHO, 2010). While the European Commission proposed several features to be present on the medicines (i.e. mass serialization, seals etc) (British Generics Association, 2010), counterfeit medicine remains a growing threat. Currently, counterfeiters have tended to focus on expensive patented drugs rather than generics, but as global acceptance of online purchasing increases, counterfeit drugs are increasingly being detected in the supply chain. This is an issue of major concern for generic manufacturers as any products discovered as counterfeit can easily harm patient confidence in generics. As over 50% of the medicines purchased online are found to be counterfeit (WHO, 2010), monitoring of counterfeit drugs particularly those purchased from online sources has become a necessity for the pharmaceutical industry.

Patient Data Protection: Usage of online purchasing for medicines by patients on illegitimate sites has resulted in the risk of private and personal health information being disclosed publicly to unscrupulous operators (Berstein, 1999). The issue of spamming has become a major concern for most internet users as likewise for sick and vulnerable patients that choose to source cheaper medications i.e. generic drugs. Private health and financial information (i.e. credit card numbers) can be compromised to criminals and this confronts the pharmaceutical companies with bad publicity should anything negative occur.

[13] Commission of the European Communities
[14]As of date of the report published.

4. Benefits System

Welfare benefits across EU Member states are largely generous with many offering free/ low cost medical care for citizens upon their reaching the legal retirement age. Continued development in the EU region resulted in many of the member states developing some of the best health care systems in the world (Eurostat, 2010) in an attempt to deal with the ageing demographics within the region. The provision of generous benefits is however facing challenges on several fronts. The current severe recession that is affecting the global economy and the recent Euro zone crisis has left many national treasuries under pressure due to the rising costs as well as depleting financial resources towards financing heath care. As many citizens of the EU grow older, the trend of declining birth rates which has lowered the number of younger people to replenish societies has resulted in many EU populations resorting to allowing foreign migrants into the region.

Migration has been responsible for large increases in the EU population over the past few years (Eurostat, 2010) with many foreigners coming from non-EU member states. Generic drugs will gradually become the medicine of choice due to the lower costs of these drugs. Public spending has the potential to be restricted by many governments and there will be a trend towards encouraging EU citizens to consider private health care for the more 'expensive' diseases. The struggle towards providing a financially sustainable health care system in the EU will continue towards the near future and beyond.

5. Anti-Trust Laws

EU's antitrust laws represent an important part of the market integration efforts by the EC as the EC seeks to enhance a free market trading environment. Given that there are numerous national companies in all the member states, antitrust laws for the EU are particularly geared towards addressing this under Article 107 of the Treaty. This is particularly important with regard to both competition policy and the creation of the European single market and could be rendered ineffective when member states are free to support national companies as they see fit.

With the pharmaceutical market being heavily regulated at national levels, this leaves less room for competition on prices and therefore market forces cannot realize their full effect here as they do in most other industry sectors within the EU (European Commission, 2010). Currently, the EC is focusing more on attempts by companies to delay or hamper the introduction of generic medicines or of new innovative drugs that may compete with products already on the market (European Commission, 2010). This issue has long been a concern raised by the European Generic Medicines Association in their arguments with the original pharmaceutical companies using intellectual property to maintain their grip on their patented drugs.

Pharmaceutical companies who try to prolong patent protection for a product may breach EU competition rules which are enforced by the EC. The recent AstraZeneca case which resulted in the pharmaceutical company being fined €60 million is an example of commitment by the EU towards encouraging competition within the industry for both pharmaceutical and generic manufacturers. Both industries must take care in ensuring that

whatever business practices deemed anticompetitive (M&A, parallel trade, state aid) have to be approached carefully as the EU market gradually expands and grows over the decades to come.

1.6 ENVIRONMENT

1. *Environmental legislation, Social Responsibility, Sustainability & Global Climate Change*

The EU has some of the highest environmental standards in the world, developed over decades to address a wide range of issues (EUROPA, 2010). As awareness on climate change, biodiversity and sustainable development increases amongst the EU population, it is therefore undeniable the effect it has on the pharmaceutical/generic drug industry. Companies with industrial biotechnology involvement (that produce pharmaceutical compounds) will face issues relating to genetic modification and its impact on patients thereby making it a serious issue to address as this field continues to grow for medical R&D.

The European Parliament views the field of biotechnology to have vast potential in pharmaceutical innovation, in creating new cures and with less impact on the environment during manufacturing (Europarl[15], 2004). It does acknowledge the concerns by some that having too much legislation governing biotechnology would only stifle innovation, competition, as well as reduce incentives towards "orphan drugs" (for rare diseases) and it aims to provide policies that serve to encourage this area of development carefully.

There will be continuous ethical questions that need to be addressed to the public as it involves the life and death of living organisms (Europarl, 2004), the very factors that have shaped the deepest religious, ethical and cultural heritage of humanity as enshrined in the EU Fundamental Rights Charter. Cross border cooperation in research on ethical usage of this technology would be the way forward towards reducing such skepticism.

2. *Waste Products*

Growing awareness of environmental impacts and the need to conduct tests to evaluate such effects are creating cost pressures for the pharmaceutical industry (EEA[16], 2009). Our project teams discussion with Ms. Hilary Jones of Pfizer led to our knowledge that there is a need for drug manufacturers (generic or otherwise) to be well versed with the latest EU drug legislation and best practices adopted by surrounding countries (i.e. Sweden[17]) in order to compete in the EU market. Used and unused API's[18] have a considerable implication for waste streams especially in wastewater and river sources making this a growing concern in the EU. Therefore, there has been an effort to control the level of chemicals used for industrial production (drugs included) as outlined in the EU's REACH[19] Regulation, while promoting the concept of 'Green Pharmacy' (EEA, 2009) in addressing this issue. All

[15] European Parliament
[16] European Environment Agency
[17] Sweden adopts a stringent policy towards the environmental disposal of medical drugs in the system.
[18] Active Pharmaceutical Ingredients
[19] Registration, Evaluation, Authorization and Restriction of Chemical Substances

interviewees agree concurrently that while the environmental factors are not high on their agenda, it is nevertheless a significant consideration factor when planning for business sustainability and competitiveness in the future.

3. Non-Governmental Organizations (NGOs)

The role of NGOs will become ever more crucial as the industry serves to maintain a social responsibility outlook with all stakeholders. Patient rights and other public interest groups can at times be barriers during the decision making process. Their involvement with the company through partnerships and continuous engagement can contribute towards the sustainability and effectiveness of projects while introducing innovative approaches and community participation (World Bank, 1995). This working partnership is gradually gaining acceptance in various sectors and governmental organizations and would be an important feature for businesses that is concerned about their continued business sustainability and their impact on the business landscape. This is especially so when working in a complex and diverse business environment such as the EU. Pharmaceutical and generic companies can use this chance to create innovative solutions toward new/existing drugs that serves to the best benefit of patients in the EU and the world as a whole.

4. Packaging

On Sanofi-Aventis website, the company states that it 'must protect the product's physical and chemical integrity in order to ensure pharmaceutical-grade quality for the product's entire life cycle' (Sanofi-Aventis, 2010). Present packaging methods by the producers (i.e. plastic bottles, glass, paper etc) to protect medicines are judged to be environmentally unfriendly owing to the use of plastic components which are difficult to dispose off in an environmentally safe way. Hence, there are constraints owing to the limited capacity for suppliers to produce suitable, environmentally friendly packaging within the marketplace.

Advances in the production of medicine have resulted in a need not only for enhanced protection against various environmental factors (moisture, heat, light, oxygen, mechanical forces) but also for packaging to play a more integral role in delivery e.g. stability and shelf life. As a result of strict EU legislation, drug packaging itself has undergone changes in response to these developments. Plastic components are gradually being reduced with biodegradable plastics used instead, while refillable packets are being introduced by pharmacists for recurring patients.

Manufacturers are examining the use of prefillable inhalers and syringes for meeting the requirements while further discoveries are being made in new bioengineered medicines (Plastemart, 2008). Given that there is no other cost efficient solution with drug packaging at the moment for new storage methods, manufacturers will continue to rely on bottles and bags for patients to keep until a more cost effective delivery mechanism is found especially in the field of biotechnology.

APPENDIX 2

1.1QUALITATIVE QUESTIONNAIRE

EU Macro-Environmental Scan Questionnaire

1. With regard to intellectual patent laws, how can legislators enhance competition within the EU drugs market?
2. Will countries within the EU trend more towards protectionism or open and free trade?
3. What changes can you project vis-a-vis the EU's policies on off shoring? (specifically related to the pharmaceutical industry)
4. Will the European Union retain the policy of "no need for an across the board harmonization of the Member States' tax systems?"
5. What are your expectations with regard to the EU's future expansion/integration policies?
6. What actions and/or trends can you forecast with respect to monetary policy within the EU? How likely is the prospect of the Euro being the only currency within the EU? Will the Euro survive or will countries revert to their previous national currencies?
7. How likely is the prospect of Fiscal policy integration within the EU?
8. What changes can you project vis-a-vis the EU's policies on import laws to support or hinder the flow of pharmaceutical products manufactured outside the EU?
9. In March 2010 the European Commission made a commitment to "renew the EU strategy to promote Corporate Social Responsibility as a key element in ensuring long term employee and consumer trust". How could this commitment possibly affect the pharmaceuticals/generics industry in the EU over the coming years?
10. In what ways do NGO's influence policy on pharmaceuticals within the European Union? Do NGO's have a stance/role on the sale and use of generics within the EU?
11. What role will the movement towards sustainability have on the pharmaceuticals/generics industry over the coming years?
12. What is the likelihood of a unified legal framework within the European Union on a community patent system?
13. What are the projected trends with regards to benefits policies within European Union member states? Will there likely be a unified policy on benefits across the EU?
14. What changes are likely to occur over the coming ten-twenty years within the European Commission's environmental legislation policies that could possibly affect the sale of generics in the EU?
15. What is the likelihood of the EU adopting a unified pricing regulation structure in the pharmaceutical industry?

16. What trends can you forecast vis-à-vis the EU's favored trading partner policies? Will the EU trend more towards free trade or protectionism? Which countries do you expect to be granted Most Favored Nation (MFN) status by the EU over the coming years? Will India be granted MFN status? If yes, when do you anticipate this to occur? How will EU trade policies affect the pharmaceuticals industry over the coming years/decades?

17. What technological advancements (disruptive and/or incremental) are most likely to have a significant impact on the future of the generics drug industry?

18. Over the coming years/decades, in which specific areas do you anticipate developments vis-à-vis pharmaceutical industry cost structures and value-chains?

19. Are there any current or forecasted factors/indicators that are likely to have a significant impact on GDP growth rates within the EU?

20. What are the expectations with regard to EU member states' discretionary income patterns and what specific EU policies/actions (current or future) are likely to have an impact on these patterns?

21. What are your projections regarding business cycle volatility within the EU over the coming years and what policies/actions can the EU central bank adopt to ensure business cycle stability?

22. Can you project any significant changes in immigration policy within the EU - with regard to migration within member states and migration from non-EU countries? What is the prospect of a harmonized immigration policy within the EU?

23. What are the current and projected future trends (ten-twenty years) with regard to the life-styles of citizens within the EU? How will these trends specifically affect healthcare practices?

24. In what ways do NGO's influence policy on pharmaceuticals within the European Union? Do NGO's have a stance/role on the sale and use of generics within the EU?

25. Will EU member state governments increase/decrease healthcare spending (as a proportion of overall budgets) over the coming years/decades?

26. What changes do you project with regard to the private healthcare sector in the EU over the coming years/decades?

1.2 QUANTITATIVE QUESTIONNAIRE

Please click on the drop box and select the projection of t
policy over the next 20 years in the EU. After selection
please **save the file** on your desktop and e-mail it to
lixazk@nottingham.ac.uk

Policy	
Policy on Price Regulations	
Patent Laws	
Taxation policy	
Govt. interventions in the free market (Protectionism)	
Favoured trading partners	
Monetary & Fiscal Policy	
Prescribing drugs	
Dispensing drugs	
Reimbursement for drugs	
Pharmacovigilance	
Packaging/Waste	
Trade Restrictions	
Tariffs	
Outsourcing/off shoring	
Inflation Rates	
Healthcare Expenditure	
Policies on Demographics (eg. Migration)	
R&D spending	
Labour Laws (e.g. minimum wage, retirement age etc)	
Health and safety regulations	
Consumer Protection	
Benefits System	
Anti-Trust Laws	
Environmental Legislation	
Social Responsibility	
Sustainability	

Notes: The following 5 options are to be selected by the respondents

Fully National

Predominantly National

50/50

Predominantly European

Fully European

APPENDIX 3

1. RESPONSES AND KEY POINTS FROM INTERVIEW CONDUCTED

1.1 ANGELA FARRELL. INTERVIEW ON 2 AUGUST 2010

Explains that revenue generation for most pharmaceutical companies are made through volume production of drugs. This is in line with an ageing customer base in the EU which is growing and therefore providing adequate supply of medicine is important by the respective EU government.

Agrees that demographic age trend will increased throughout EU, therefore companies should be in the positions to meet healthcare need of such population through increased supply of pharmaceutical drugs.

Consumer attitude towards prescription of generic / original brand is mixed throughout EU owing to the different policies adopted by the member states in healthcare prescription.

In terms of new technology developments, she views that original growth driver for generic companies are increasingly complex due to the more sophisticated drug delivery system requirements. This will hold back generic drugs development growth as R&D cost for original is already high.

However as result of the sophisticated environment today, the ability for patented pharmaceutical companies to introduce new drugs is also decreasing. A problem not evident for generic manufacturers as it does not spends so many resources as patent drugs makers especially for the established generic players.

Different approaches to market was suggested (both patented and generic) such as effectiveness of drugs administered into patients, monitoring of drugs dispensed– expanding more effective use of original drugs (genomics used) to the selected population which responds more favourably to such drugs (also for enhancement of existing drug products).

In terms of R&D area – suggest more niche drugs development focus now rather than massive investments in the mass producing the drugs volume. However the industry cannot rely too long on this strategy, doesn't see R&D to be more complex that generic can't copy in this step. Generic players will continue to adapt as they always have over time.

Developments for the drug industry are more incremental rather than disruptive type especially with the dearth of new products coming into the market at present.It is therefore in her view that there won't be any major changes in the pharmaceutical industry that makes generic manufacturers life tough to follow.

In terms of a variety of delivery system:

Explains that there is a trend towards preventive healthcare throughout most markets in the EU, new developments such as installation of monitoring system at home to regulate drug intake are being considered especially with the older and weak patients.

Points out that the people are becoming aware of use of genetic technology – marking a potential to generate new markets for pharmaceutical companies. She cautions however that there is an incline to take protective measures as compared to past to restrict certain aspects of this technology.

Certain drugs dosage may be reduced as studies show its actual effectiveness on the patients administered. This will result in drugs becoming more tailored towards patients requirement in future in her view.

Opinion on nanotechnology: agrees on its application for the drug delivery system will useful in treating illness. Government will become more committed to generics rather than reliance on new patented medicine as this source dries up.

Manufacturing will more centralised in future as pressure of decreasing cost increases. Also raised the possibility of it moving toward larger, higher volume manufacturing sites elsewhere that might in non-EU region (India, China, Brazil etc).

Difficulties pointed out with pharmaceutical industry situation in the EU: As EU healthcare system mostly cater with providing massive range of drugs (for different symptoms), wholesaling operations will be consolidated further (possibly between companies) to address the efficiency aspect of delivery throughout the EU.

When further discussing, she explains that wholesalers here will want to consolidate in her opinion. This is because the margins are getting smaller as selling price drop but development cost aspect on the other hand, remains unchanged significantly. This is where generics benefit as making a new drug is seldom a priority for generics. Should this be unsuccessful, she sees that profit margins by pharmaceutical sector might be re-examined to address this.

During interview, raised a question on the possibility of the middleman being removed from the supply chain. However, Ms Angela also pointed out the risk of supply security especially with counterfeit drugs circulation becoming an issue for the pharmaceutical sector. When pressed further, her view was that the current supply chain is process is viewed as not so important as compared to the price factor for original manufacturers.

Tendering practice might be practiced by every EU member state government in future. But points out that this could be complicated due to the various stakeholders involved in the whole chain which has long relied on past practices.

Not much progress on harmonisation of pricing as in reality, it has always relied on market force to determine pricing in each country.

Agrees that there have always been parallel pricing issues afflicting medical drugs in the EU. This is because pricing for some drugs in demand tend to be more expensive in some states hence a 'grey' market exist for those that wants such drugs which people will be tempted to supply it even at risk. This problem cannot be solved easily owing to complexity in reality for uniform pricing.

She is also sceptical of harmonisation prospect (for pricing) as every EU member states has different agendas in many of such issues. This is because each country wants to obtain the best value for money for their citizens. Therefore, harmonisation may not necessary benefit EU member states with lower income levels compared to the stronger EU members and vice-verse. It is therefore in her opinion that unless there is a strong EU will to impose it on all members, this option is unlikely to happen.

Patent laws:

Explains that there has been attempts to extent patent life (changing / enhancing existing core patent drugs just before expire) as reported in media.

The issue for thought was that this depends on how quick the generic drugs manufacturer exploit it upon expiry of the patent (main thing is to produce the necessary commercial quantity especially just before expiry possible to make a profit)

On query by the team that whether this causes competition enhancement to be difficult?:

Explains that extending patent life must also be matched with having more benefits for innovation for the patent drug manufacturers.

For generic sector, this will be the other way around.

How to encourage generic players more into the market?

She is of the opinion that this is more on fine tuning the existing provision. But there is expected to have not many changes to enhance competition other than existing mechanism.

Suggestion to allow substitution on certain category of drugs in order to encourage more competition but points that this strategy is tricky for such strategy.

Sees a trend towards free trade in the EU but with limitations in some areas, one of which could be the pharmaceutical industry.

Not optimistic on harmonised tax system for drug companies so long as pricing is not set especially. Also points out economic factors which also affect this step as each country has its own unique policies and factors towards managing their own economies.

Points out that attitude of branded products vs generic for prescription in different EU states differs – it is therefore a barrier for the business.

Highlights from her experience that incentives for pricing will likely persuade how the popularity on drug usage. Therefore, generic drugs will always have a place in the market

Regulatory approval issues has always been a problem for any pharmaceutical companies but once that's cleared, it's should be a straight forward in her opinion.

A commercial incentive for pricing to push acceptances of any drugs is important for its success. Volume and pricing are the most important factors that any generic business would need to consider in whatever strategy it operates.

On whether EU has the appetite for branded generic, explains that the company to look at promotional policy of respective governments to see business opportunities for the company.

Notes for some drugs to succeed in the market, pressure from consumers on having familiar products can be a deciding factor in some drugs sales.

When suggested by team on using refillable bottles, it could be 1 aspect for some generic business to promote but regulatory / health issues might be barrier in this sense. In her view, environmentalist issue on packaging is negligible compared with concerns of unused drugs disposed being a more pressing concern in the EU.

Trend on counterfeiting will continue to rise however; her opinion is that there will always be technology developed eventually to check any uncontrollable rise in the EU. Pharmaceutical industry will need to be on guard on any new trends in counterfeit as well as detection method.

At this moment, more information disclosure might be required on the packaging by EU governments in future.

Regulatory compliance will increase, might impact generic drug pricing due to the cost compliance.

She however feels that despite the attitude of some consumer markets in the EU, the consumer will still eventually go towards generic compared to the branded originals in these markets.

Patent issue should be harmonised in her opinion as most requirements are standardised and are not significantly different. However, political constraints might upset such measures and therefore, more studies need to be considered on this.

In terms of heath care system, doesn't think that it might be harmonised so easily due to different system practiced by each member states

1.2 HILARY JONES. INTERVIEW ON 3 AUGUST 2010.

On query pertaining to patent laws, she points out that the latest ruling by the EU will provide further clarification of patent laws.

In her opinion, restriction of free trade is not possible due to EU- Rome Treaty which prohibits such practices amongst EU members

Therefore, she is confident that legislation on free trade will remain unchanged – does not see any trend on protectionism in her opinion

Query on risk of outside medical drugs being imported into the EU. She responds that this is not possible for import of drugs produced outside as there are simply so many stringent regulations to comply – points out examples such as regulations on marketing, GMP, manufacturing, import laws as EU must provide valid marketing authorisation, parallel import licenses etc. It is therefore not possible of the risk.

Highlights that the environment is getting stricter due to increase of outsourcing activities to 3rd world countries by drug companies. Outsourcing here is in the sense of obtaining the APIs for producing the relevant drugs.

Directs attentions to the proposed EU legislation on counterfeit – EU Ruling 2001/83 which will impose new laws on 3rd party manufacturing sites on level of EU standards compliance.

Points out that Sweden has a high standard on drugs impact on environment which has been closely followed by EU legislations for similar enactments.

Also point out importance of REACH legislation – although more to do with chemicals, some elements touch of pharmaceuticals – example: legislation on manufacturing standards and impact on environment

The current situation is that EU is now tightening regulations on the existing rules especially those that touches on impact of the pharmaceutical against the environment.

Of the opinion that it is not possible for harmonised pricing of the medicines in the EU.

1.3 GREGOR H. SIEBERT. INTERVIEW ON 3 AUGUST 2010.

Has a negative impression on any developments pertaining to EU from political and healthcare policy as the region has too many differences.

Only positive aspect in his view comes from technology development. Something which EU can work together he explains.

His view on the significant technology impact will be new applications form for drugs to administer into patients.

Delivery system, administering of medicine into the patients, packaging for elderly could be a potential areas for pharmaceutical companies to improve further.

Biological developed drugs has positive impact for pharmaceutical but not for generic due to their lack of familiarity with such technology.

In future sees development of drugs will be more value, cost-sharing between companies on manufacturing due to the high cost if developed individually. Further thinks that as part of

the ways of enhancing efficiency, cooperation will be more on costly development stage of drugs between all patented drug manufacturers.

Not likely to adopt unified pricing regulation although EU is trying to do so. But many industry players hope to narrow the differences in time.

Cost reducing is one of the ways looked by companies operating in the EU environment and is not surprising given the rising cost over the years for developing new drugs.

Stability of the economy is still unknown in her personal opinion and expects it to be relatively flat in the future.

Agrees that ageing group is of a concern and therefore migration policy will continue to change to accommodate foreign talent to enter EU. Therefore, thinks there might be a harmonised immigration policy for the EU in next 20 years.

Lifestyle and differences between EU states will continue to narrow to similar trends and hence a higher chance of acceptance of EU members pertaining to the standard regulations over the years.

There will be a focus on better delivery of drugs as it is one of the main developments in the pharmaceutical industry in recent times.

Sees NGOs as having a strong influence on the industry and the government for example: HIV groups efforts in pushing for the rights of such patients in the EU healthcare in the past. There are many more such pressure groups that will continue to highlight their plights to authorities. Explains that this is something the industry has accepted and worked with over the years.

1.4 JONATHAN FARRINGTON. INTERVIEW ON 11 AUGUST 2010

View on free trade: it will continue to grow as EU governments struggle with rising budget deficit (concerns on finding ways to obtain cheaper cost) but will be balanced by the need to perform strategic assessment on liberalisation of certain sectors to protect jobs for their citizens.

Opinion on EU Expansion: It will slow down with Turkey being the most next likely candidate to be considered for admission. This is because EU admission criteria is based on more political stability rather just concentrating on economic criteria. EU will not want developing country that are risk of adding instability to the economic union. Political factors will ensure that Turkey comes closer to EU circle even if it is not a full member.

Tax regulations will not be uniformed owing to the differences in the system.

Euro currency will not make any further progress than where it is currently in the future at this stage. While not likely, there is a possibility that countries might revert back to national

currencies especially for the bigger country that have centre right govt – like Germany or France which will be likely to follow this due to public pressure.

View that there will be some pressure to conform to a uniform fiscal policy but not likely to be 100% full compliance by the member states themselves.

Healthcare policy is a member internal competence, not a EC competence consideration to be a member of the EU. This therefore cannot be a factor for harmonisation in this case.

Govt will continue to squeeze cost structure of the drugs sold through EU member states. Generic will enjoy a competitive advantage in this as their cost structure is already low.

Sees that there will be continued economic stagnation in the EU for the foreseeable future.

In general, EU residents have less disposable income as a result of tax imposed. Wage will continue to be stagnant due to economic environment. Therefore, consumer spending will be tight with higher savings rate instead.

In terms of business cycles, there won't be any extreme boom / bust. Rather, it will be a flat or gradual decline in economy. This is something that ECB will not have much influence here as national government will need to play a heavier involvement in addressing the business cycle.

Feels that there will be tightened migration policy especially with the economic conditions depreciation. He is of the opinion that there won't be any chance of harmonisation of migration policy.

Healthcare issues: With the obesity on the rise, his personal opinion is that people will become unhealthier but this will be compensated with improving health care that leads to increase lifespan of the population.

Opportunities in the horizon: Private health care biz will grow especially in developing country which are doing well. Drug companies should aim to establish business relationship with the competitors in this sector.

1.5 JOHN RICHARDS. INTERVIEW ON 12 AUGUST 2010

Query on biggest mistake in industry: Mergers and having larger R&D department would lead to more creativity. The reality is that this has not given the results expected. The type of research in the past conducted are not helping in creating new drugs nowadays. As stated by him: "the type of science used has run out of steam".

Views that many companies have not had much in the pipeline hence the merger exercise as a result.

Explains that many companies are looking towards smaller start up companies especially biotech given the vast potential in this field. Spotting those with good ideas – either buying technology, purchasing the company outright, creating partnership or strategic alliances.

Query on where is the new treatments going to come from?

Agrees that new treatments will come from the new types of sciences like biotech, stem cells etc.

Suggested to us on the easiest ways to look at the scenario. Look at the 2 dimensions where it could be. i.e European Harmonisation, rich budgets for healthcare.

For a company in the EU to succeed, he suggest that these are following factors to consider.

- Market Size, healthcare legislation in each country, how to distribute products to the prescribers in the systems. Generics has to compete with existing branded products which may be performing satisfactory towards patients

Likelihood of existing products going generic?

Explains that attitude amongst patients has to change as well in order for generic products to ever get a foothold in the market.

One of the ways would be for government to switch to more generic supply of medicine. That way, patients will be exposed to the availability of such drugs for their illness.

Tailoring drugs to suit individual needs. Also adds that this could be a major trend in the future. Also suggest that delivery methods should be more creative in order to capture the market. There cannot be a single strategy as EU has a wide and diverse system of governance to consider.

1.6 DR DAVID LIU. INTERVIEW ON 15 AUGUST 2010

Discussion about generics and topic explanation conducted by the team.

Opinion is that there is a cost pressure going on in the EU authorities with the rising deficits and healthcare. Therefore, generic manufacturers will benefit in the EU market by going on cost basis.

Original patent drug manufacturers would require support to continue in the market when the patent expires. Two key support advantages that the companies would have is – (i) Trust and (ii) quality.

Pointed out that from his experience, with the opening of the market to generics, regulation enforcement tends to be poorer. Lax overview and quality control is of concern as a result of this. However, this problem occurs globally and is not restricted to the EU.

Counterfeit drugs are a concern in the pharmaceutical industry now. As pointed out, NHS suffers 15% faulty rate annually due to the presence of such drugs in the system. This is due to the pressure to source for the cheapest source as a result of cost cutting and recession afflicting the countries. In most cases many of the offenders are producers are from India, China – countries which are still lax in the quality control and supervision.

It is inevitable that drug companies look for opportunities to outsource their drugs production but there is a risk that such manufacturers might not comply with what is request if left to their device putting pharmaceutical companies reputation at risk.

Suggestion in such situation: In order to sell drugs, company should ensure that the manufacturing value chain is supervised closely in the foreign factories it has, this way brand and quality is assured to customers.

Another suggestion is that pharmaceutical companies do not stay with the low cost business model in order to compete with the generic manufacturers. Rather, perform targeting marketing by selling products to governments in the EU, institution in the EU and private hospitals in the EU. Leverage on the existing position it has rather than compete direct with generic.

Suggested strategy for scenario development. Within EU, if product loses patent. It will be best to move out of the existing market and head towards higher level of manufacturing expertise. I.e move upmarket, target more high tech industrial innovation (i.e biotechnology) rather reliance on low cost labour.

The problem with low cost is the quality issue by generics. This represents an "Achilles Heels" for such manufacturers especially with many originating from developing countries. As elaborated further, company like Pfizer can consider making a branded generic brand of its product by leveraging on the reputation of its company reputation in the market. This could be used to counter-generic marketing which do not possess the same level of brand perception amongst the patients. To do that, the company must accept that is strategy entail high cost (if manufacturing is done in the EU) but must aim for cost efficiency. Otherwise, if manufactured overseas, the key worry is to ensure that there is controls are overseen by the original companies themselves. The key point here is to emphasize on brand leveraging and protecting its reputation in the market as part of the original company's patent product: Sell on guarantee of the product quality.

Another recommendation for consideration. Go strongly on evidence-based medicine in new markets such as China & India. A growing trend globally especially in Europe in order to gain acceptance in new markets. By going on medical based therapy, drug integrity is stronger. In NHS for example, this has been the criteria when evaluating potential drugs for purchase.

When going to new markets with evidence based approach. Educating the public where it markets will enforce this strength especially against traditional medicine.

Honesty is going to be the best weapon when approaching this evidence based strategy. Pharmaceutical companies are in general do not have a really good reputation. Promoting honesty and clarity in their messages will improve brand perception as well.

If the generic market proves to be too competitive, suggestion might also be to consider exiting it. Venture into new areas such as supplement market. Acknowledge that this is competitive but company might want to consider an industry that is still relevant to their core advantages. An example would be to serve the growing ageing population in many markets around the world. This is a mass market which can be profitable unlike niche drug development. However, he pointed out that niche drug has a higher area of potential to develop. This is important in creating a competitive advantage against other competitors and not just generic. Build on innovation to survive.

How do we that?

Link up with a global network of universities. Allow some form of profit sharing mechanism that encourage creativity and participation that makes use of the university's expertise and resources. That's the way of moving into the niche market.

Drop a pyramid structure which is a top down approach to all subsidiaries in a group. Develop a web / network of companies that operate under 1 organisation instead.

We note his consistency on maintaining one point throughout the discussion

IMPORTANT: Remember the ethical component when deciding the environment of the company (honest)

Green marketing will be big in 20 years is acknowledged to be a major factor but drug manufacturers main concern would be in the area of ethics and honesty towards the public.

He urged to look at weakness of competitors to capitalise on competitiveness when competing against generic players. For example, quality emphasis is an issue in India and China owing to lack of education, attitude of the population on its importance. Ethical marketing can be strongly emphasized especially if the company is to compete in such markets especially in developing countries. It is an area where generic players can't compete as this involves the mindset of the population.

Technology will improve substantially in the future but there will still be a need for a human interface when it comes to the making the right decision on drug prescription. There will also be growing number of lower level subordinates handed the responsibility of prescribing the drugs which were held by doctors previously. Not all is lost as the range of drugs available will continue to be restricted. Therefore we expect the control regulations to continue to play a role in healthcare sector.

1.7 DR PETER SWANN. E-MAIL RESPONSE

EU Macro-Environmental Scan Questionnaire

1. With regard to intellectual patent laws, how can legislators enhance competition within the EU drugs market?

I'm not sure I fully understand the question. As it stands, patents give (effectively) a monopoly for a restricted period of time and then there is open competition after that period expires. I can't see any likelihood of a fundamental change in this, though the optimum lifetime of a patent (in years) is always a subject of debate.

2. Will countries within the EU trend more towards protectionism or open and free trade?

For intra-EU trade, the answer must be a move towards the removal of any barriers to trade within the EU. That project is largely complete for the old EU, but there is still some way to go for the new members of the EU. For EU trade with the rest of the world, it depends on a balance of interests. Some politicians in some countries may be lobbied for protectionism in some cases by small business and labor interests, but in the UK at least, the dominant influence on the British Government (big business) is generally in favor of free trade.

3. What changes can you project vis-a-vis the EU's policies on off shoring? (specifically related to the pharmaceutical industry)

I'm not sure that the EU really has a policy on offshoring. Offshoring is accepted as a fact of life, and the decision is left to business to make on the grounds of what makes business sense. This does not deny that there are contrary interests (recall the US TV video we watched on resistance to offshoring in middle-American).

4. Will the European Union retain the policy of "no need for an across the board harmonization of the Member States' tax systems?"

Whether there is or is not a need, I see no prospect of this. Certainly, it is inconceivable that the present UK government would cooperate with an across the board harmonization.

5. What are your expectations with regard to the EU's future expansion/integration policies?

I'm sorry, but my opinions on this are not clear enough to give you any reliable advice.

6. What actions and/or trends can you forecast with respect to monetary policy within the EU? How likely is the prospect of the Euro being the only currency within the EU? Will the Euro survive or will countries revert to their previous national currencies?

If a Labour government in the UK (1997-2010) resisted membership of the Euro, I think it inconceivable that a Conservative government will agree to membership of the Euro. As to the survival of the Euro, I was amused that in the early days of the Euro, economists in

banks in the City of London confidently predicted that the Euro would be the weakest of currencies – and yet for long periods it was stronger than the US Dollar or the GB Pound! Granted, the Euro is in a mess now, but I still believe it will survive – though I suspect that the rules of membership will be mad a lot tougher.

7. How likely is the prospect of Fiscal policy integration within the EU?

No prospect of the UK agreeing to this.

8. What changes can you project vis-a-vis the EU's policies on import laws to support or hinder the flow of pharmaceutical products manufactured outside the EU?

In general, I see a project to harmonize EU standards with general international standards, and that should in most cases lower barriers faced by countries outside the EU to exporting into the EU. However, sometimes the standards are set very high – which does act as a barrier to exports from developing countries. I'm not sure how relevant that is to pharma, however.

9. In March 2010 the European Commission made a commitment to "renew the EU strategy to promote Corporate Social Responsibility as a key element in ensuring long term employee and consumer trust". How could this commitment possibly affect the pharmaceuticals/generics industry in the EU over the coming years?

I can't comment on the specific implications of this for Pharma.

10. In what ways do NGO's influence policy on pharmaceuticals within the European Union? Do NGO's have a stance/role on the sale and use of generics within the EU?

I can't comment on this in the specific context of Pharma.

11. What role will the movement towards sustainability have on the pharmaceuticals/generics industry over the coming years?

I can't comment on this in the specific context of Pharma. More generally, some commentators see rapid innovation as the solution to issues of sustainability. More controversially, perhaps, I see rapid innovation as one of the causes of problems with sustainability. These two different perspectives suggest very different policies towards sustainability.

12. What is the likelihood of a unified legal framework within the European Union on a community patent system?

There has been some progress in this direction already. There is a European Patent Office, and many companies view patenting as a European and/or international activity, and not just a domestic issue.

13. What are the projected trends with regards to benefits policies within European Union member states? Will there likely be a unified policy on benefits across the EU?

By benefits, do you mean unemployment benefits, disability benefits, etc? If so, I don't expect to see great progress towards a unified policy in the next 5-10 years.

14. What changes are likely to occur over the coming ten-twenty years within the European Commission's environmental legislation policies that could possibly affect the sale of generics in the EU?

I can't comment on this in the specific context of Pharma.

15. What is the likelihood of the EU adopting a unified pricing regulation structure in the pharmaceutical industry?
16.

I can't comment on this in the specific context of Pharma.

17. What trends can you forecast vis-à-vis the EU's favoured trading partner policies? Will the EU trend more towards free trade or protectionism? Which countries do you expect to be granted Most Favoured Nation (MFN) status by the EU over the coming years? Will India be granted MFN status? If yes, when do you anticipate this to occur? How will EU trade policies affect the pharmaceuticals industry over the coming years/decades?

Wow, these questions are big questions! I think I will have to 'pass' on these.

18. What technological advancements (disruptive and/or incremental) are most likely to have a significant impact on the future of the generics drug industry?

I can't comment on this in the specific context of Pharma. I simply know too little about the technology.

19. Over the coming years/decades, in which specific areas do you anticipate developments vis-à-vis pharmaceutical industry cost structures and value-chains?

I can't comment on this in the specific context of Pharma. I simply know too little about the technology.

20. Are there any current or forecasted factors/indicators that are likely to have a significant impact on GDP growth rates within the EU?

Yes, lots of them.

21. What are the expectations with regard to EU member states' discretionary income patterns and what specific EU policies/actions (current or future) are likely to have an impact on these patterns?

Pass.

22. What are your projections regarding business cycle volatility within the EU over the coming years and what policies/actions can the EU central bank adopt to ensure business cycle stability?

Pass.

23. Can you project any significant changes in immigration policy within the EU - with regard to migration within member states and migration from non-EU countries? What is the prospect of a harmonized immigration policy within the EU?

Opinions differ on this. I think it is likely that pressure from labor interests will grow for limits on migration from outside the EU. But many business interests are in favor of such immigration (lower wage rates).

24. What are the current and projected future trends (ten-twenty years) with regard to the life-styles of citizens within the EU? How will these trends specifically affect healthcare practices?

Pass.

25. In what ways do NGO's influence policy on pharmaceuticals within the European Union? Do NGO's have a stance/role on the sale and use of generics within the EU?

Same as question 10 above.

26. Will EU member state governments increase/decrease healthcare spending (as a proportion of overall budgets) over the coming years/decades?

I doubt they will do this. The demographic trends alone suggest otherwise – growing life expectancy.

27. What changes do you project with regard to the private healthcare sector in the EU over the coming years/decades?

Pass.

APPENDIX 4

1. PRESENTATION SLIDES

EU GENERIC DRUGS INDUSTRY

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PROJECT TITLE

Scenario Planning as a Tool for Long Term Strategic Planning - The Generics Drug Industry in the European Union.

OBJECTIVES

- Comprehensive Environmental Scan
- Identification of Key Factors/Drivers
- Projection of Key Trends with Implication
- Scenario Building
- Strategic Recommendation

SCOPE

- Environment – MACRO, PESTLE
- Market – EU Generic Drugs Industry
- Timeframe – 2030

SCENARIO PLANNING – EU GENERIC DRUGS INDUSTRY

SCENARIO DEFINITIONS

"…an **internally consistent** view of what the future might turn out to be – not a forecast, but one possible future outcome" (Porter, 1985)

"… **narratives** of alternative environments in which today's decisions may be played out. They are not predictions. Nor are they strategies. Instead they are more like hypotheses of different futures specifically designed to highlight the risks and opportunities involved in specific strategic issues" (Ogilvy & Schwartz, 1998)

Scenario Characteristics

Internally consistent	Time-limited
Coherent	Ordering perceptions
Plausible	Based on assumptions
Interconnected events	Different possibilities
Relevance	Based on past/present
Challenging	Based on pre-determined events
Representative	Trent outcomes
External	Imagined
Narrative	Decision-making tool
Boundaries/framework	Progressive

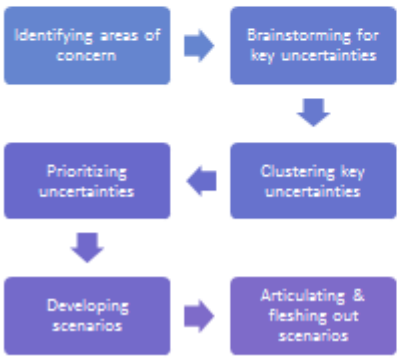
Scenario Elements

SCENARIO PLANNING

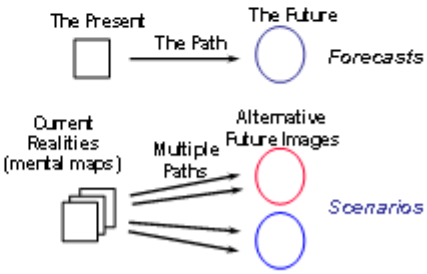
"… consists of **developing** plausible representations of a firm's possible future that make different assumptions about forces driving the market and include different uncertainties" (Kotler, 2003)

"… is a disciplined **method** for imagining possible futures that companies have applied to ao great range of issues." (Shoemaker, 1995)

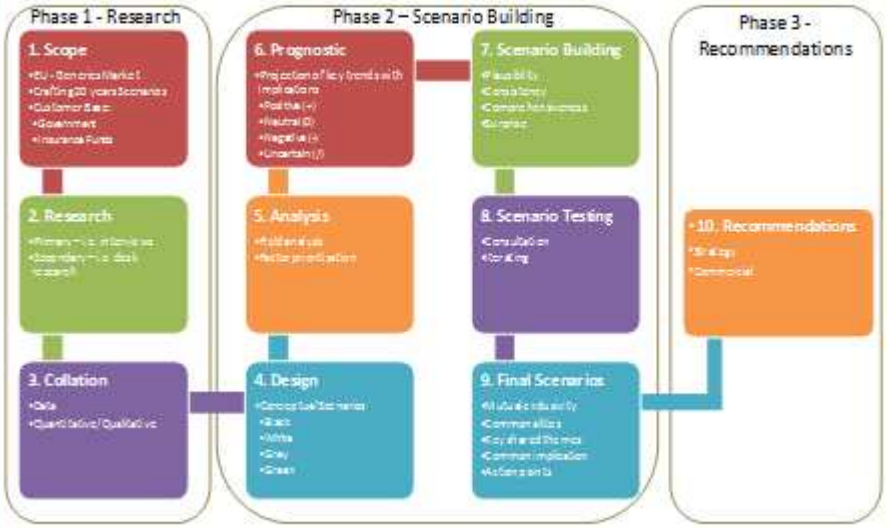
Generic Steps of Scenario Planning



Scenarios VS Forecasts



PROJECT PROCESS



RESEARCH

Process

- 45 Factors identified
- Assigned relevance to factor on a scale of 1 through 5
- Extensively researched each factor

Sources for Research

- Primary Resources
  Experts and Specialists
- Secondary Resources
  Journals
  Articles
  Data monitors

Tabulated PESTLE Factors

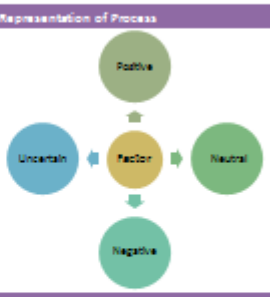
PESTLE	Factors Identified	Assigned Weight
Political		Low 1 - 5 High
1	Political Stability	2
2	War	2
3	Legislative Structure/Frameworks	4
4	Pricing Regulations	3
5	Tax policy	4
6	EU expansion	3
7	Govt. intervention in free market	4
8	EU integration	4
9	Intellectual property protection	4
10	Favoured trading partners	3
11	Monetary & Fiscal Policy	4
12	Trade Restrictions	4
13	Tariffs	4
Economics		
1	Economic Growth rate	4
2	Exchange Rates	3
3	Outsourcing	3
4	Inflation rates	2

ANALYSIS

Process

- Projected key trends from PESTLE factors 20 years into the future
- Possible impact on the Generics Drug Industry (+), (-), (neutral), (uncertain)
- Re-assigned the key trends relevance vis-à-vis scenario creation

Graphical Representation of Process



Tabulated Factor Prognostics and Relevance to EU Generic Drugs Industry

Factor Prognostics and Relevance to EU Generic Drugs Industry

Positive Projection	Relevance	Negative Projection	Relevance	Neutral Projection	Relevance	Uncertain Projection	Relevance
EU Regulation Framework	5	EU Regulatory Framework	5	EU Market Interventions	4	EU Monetary Policy	4
EU Expansion and Integration	4	EU expansion and integration	4	EU Demographics, immigration and fertility rate	3	EU Fiscal Policy	4
EU Monetary Policy	4	EU Monetary Policy	4	EU Health and Safety	3		
EU Fiscal Policy	4	EU Fiscal Policy	4	EU Intellectual Property Protection	2		
EU Pricing Regulations	4	EU Pricing Regulations	4	EU Infrastructure Quality	2		
EU Market Interventions	4	EU Preferential Trade Agreements (FTA's)	3	EU War & Conflict	2		

WHAT DOES THE FUTURE HOLD?

Scenarios 2030

· "Todo es Bueno!"

· "Nein, nicht gut!"

· "Deux Union Européenne!"

SCENARIOS

Scenario 1: Story Line

June 30th 2030: Nigel interviews Juan Cervantes, a member of the Spanish parliament for his views of the European economy. He is most interested to know how the EU macro environment will be as his employer, an Indian pharmaceutical company, has plans to penetrate the EU market. The EU has expanded with new members such as Turkey, Croatia, Bosnia and Herzegovina, Serbia, Montenegro, Macedonia, Kosovo, Albania. There is integration of all member states, harmonization on policy making, and strong unity and political will. Generic drugs uptake levels in the EU are at par with levels in the US. The EU's financial markets are stable and secure, and free market competition is thriving in the EU. Most member states boast a healthy GDP growth rate. EU citizens have the highest quality of life and longest life spans. New discoveries are being made in the fields of biotechnology, genomics and nanotechnology. Juan Cervantes is very pleased with all the progress within the European Union. Juan says: "Todo es Bueno!"

Key Macro Environmental Elements in 2030

- Expanded and expanding EU
- Strong Integration
- Increased Cooperation
- Harmonization on Policies
- Strong Political leadership
- Common currency across the EU
- Very high levels of competition
- Strong Economies across the EU
- Stable and secure business environment
- Uniform policy on Generics
- Strong cost-competition
- Reduced levels of Govt. debt and deficits
- High standards of living
- Vibrant Private Healthcare Industry
- Strong Focus on Preventive Care
- Minimal levels of Counterfeit drugs
- Advances in Genomics, Nanotechnology, Biotechnology
- Strong Corporate Social Responsibility
- Advances in Packaging Technology
- Radical improvements in Drug Delivery Systems
- Very bright future for Industries in the EU!

SCENARIO 1

SCENARIO 2

Scenario 2: Story Line

August 19th 2030: Hoba Aly of Bloomberg News interviews HSBC Chief Economist Jurgen Dolnich in Frankfurt. The EU has put the brakes on expansion having granted accession to only Turkey, Croatia, and Bosnia and Herzegovina in the past 3 decades. The euro zone collapsed in 2017 and all EU member states have reverted to their original currencies. There are stark disparities between the economies in the 'core' and 'periphery' member states. Integration is very weak, and there is no harmonization on policies. Unity within the EU is weak and there is a lack of political will. National interests have taken precedence over EU regional strategies. There are high levels of government debt and deficits due to exorbitant levels of public spending across most member states. There is volatility in business cycles and high levels of unemployment and inflation. Economies across the EU region are stagnant, and GDP growth rates are negative in most states. Protectionism is the dominant stance in most states and this environment has led to the exit of many businesses from the EU region. Governments are still providing generous benefits to citizens, and the private healthcare sector has shrunk considerably. Unemployment levels are high and there is increased social unrest. Inflation is out of control in numerous states. Attitudes towards immigrants are very negative, and industries cannot find skilled workers. Administrative controls have been implemented on pharmaceutical and generics products, and generic drugs uptake levels are low. In summary, Jurgen says: "Nein, nicht gut!"

Key Macro Environmental Elements in 2030

- EURO Zone has collapsed
- EU puts brakes on expansion
- Fragmentation on Policy
- Protectionism
- Weak economies in most of the EU
- Lack of Political Will and Leadership
- High levels of Govt. Debt and Deficits
- Volatile business environment
- High Inflation and Unemployment
- Industries are moving out of the EU
- Negative stance on Immigration
- High levels of Bureaucracy
- Low levels of efficiency and productivity
- Strong labor unions
- Social Unrest
- EU has a very weak global competitive position

SCENARIO 3

Scenario 3: Story Line

July 20th 2030: Ajay Bhakshi, who works for Vijay Pharmaceuticals interviews Monsieur François Girbaud, the EU's new trade commissioner. Mr. Girbaud relates to Ajay the existence of "Deux Union Europeenne." Unity within the EU has weakened, and there is a union of strong 'core' states and a separate union of weak 'periphery' states . Each of these two unions within the EU have formed alliances amongst themselves to look out for their own interests.

The union of strong 'core' states:

Are the only current 10 members of the Euro zone. These member states enjoy positive GDP growth, low unemployment, low inflation & stability in business cycles. 'Smart' immigration policies are adopted by these states to benefit their industries. Citizens in these states enjoy a high quality of life. The private healthcare sector is thriving in the strong states. Healthcare systems are efficient and provide a very high quality of care . Generics have a very bad reputation in the marketplace due to high levels of proliferation of counterfeits. The strong economies have a good record vis-à-vis protection of the environment as well as social responsibility and sustainability.

The union of weak 'periphery' states:

These countries suffer from negative economic growth rates, high unemployment, high inflation and volatility in business cycles. Transaction costs are high as these countries have reverted to their original currencies. Protectionism is high, and migration from outside the EU is at a very low level. Public spending levels are high, and these countries have massive debt and deficit levels. Health care systems are highly inefficient and very bureaucratic. Patient populations are high, and citizens have a very low quality of life. The private healthcare sector is almost non-existent. The reputation of Generic drugs is bad as counterfeit drugs have proliferated the marketplace. The weak 'periphery' states have a poor record on environmental, corporate social responsibility, and sustainability issues.

Key Macro Environmental Elements in 2030

Deux Union Européenne

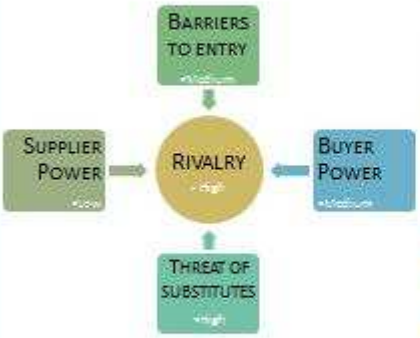
Union of Strong 'Core' States:

- Still part of the Euro Zone
- Strong economies
- Cooperation and integration
- Harmonization on Policies
- Stable Business Environment
- Globally competitive
- Low levels of Govt. debt and deficits
- Thriving private healthcare sector
- Good record on Environment, CSR and Sustainability
- High quality of life for citizens
- 'Smart' Immigration Policies
- Generics have a bad reputation

Union of Weak 'Periphery' States:

- Not part of the Euro Zone
- Weak economies
- Fragmentation on Policies
- Protectionism
- Unstable and volatile business environments
- Not competitive globally
- High levels of Govt. debt and deficits
- Weak private healthcare sector
- Poor record on Environment, CSR and Sustainability
- Poor quality of life for citizens
- Negative attitudes towards immigrants
- Strong labor unions
- Proliferation of Counterfeit drugs
- High patient populations

Porter's 5 Forces



Implication

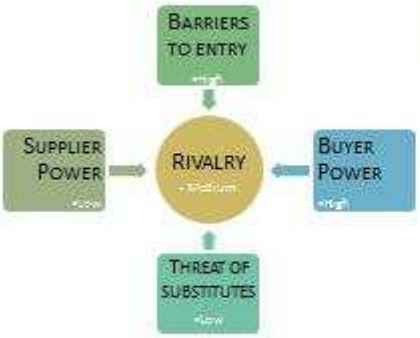
- Near - Perfect Competition – Price wars!?
- Decreasing public health spending!
- Low quality manufacturing is suffering – Brands offer better value propositions
- Strong Substitutes – Biotechnology, Genomics, Prophylactic medicine, etc.
- Increasing generic uptake – ageing population, EU expansion, etc.
- Green thinking – manufacturing, facilities, etc.

What's your differentiation?

SCENARIO 1: OPPORTUNITIES & THREATS

Opportunities	Threats
Integrated global markets	Disruptive technology
New technologies	Intense global competition
New Products	Substitute products
Affluent society	Increased buyer power
Ageing population	Increased due diligence and compliance standards
Less bureaucracy	Spreading prophylactic approaches
Harmonized policies	Price control
Expanding EU	
Growing attentions to health	
New therapies and delivery systems	
Increased use of generic drugs	
Positive attitude for soft medication (OTC drugs)	
Expanded health insurance sector	
New diagnosis and new social diseases	
Quality focus	
Environmental focus	
Differentiation focus	

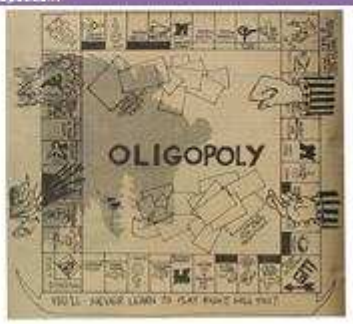
Porter's 5 Forces



Implication

- Oligopoly – Co-opetition!?
- Threat of foreign competition?
- Counterfeit drugs – Regulations?
- Price control – Buyers are powerful
- Transaction Costs – exchange rates?
- Increasing generic uptake – aging population, EU expansion, etc.

Co-opetition?



SCENARIO 2: OPPORTUNITIES & THREATS

Opportunities	Threats
Long-term contracts	Disruptive technology
Lobbying	Intense global competition
Secure large market share	Substitute products
Ageing population	Counterfeit drugs
Market knowledge	Increased buyer power
Hedging Finances	Increased due diligence and compliance standards
Multi-strategy	Spreading prophylactic approaches
Growing attention to healthcare	Price control
Government support	Parallel imports
Cost leadership	Transaction costs
New therapy and delivery systems	
Increased use of generic drugs	
Positive attitude for soft medication (OTC drugs)	
New diagnosis and new social diseases	

- Oligopoly or perfect competition!?
- Threat of foreign competition?
- Counterfeit drugs – Regulations?
- Price control – Buyers are powerful
- Transaction Costs – stakeholders?
- Substitutes?
- Increasing generic uptake – aging population, EU expansion, etc.
- Green thinking - manufacturing, facilities, etc.

SCENARIO 3: OPPORTUNITIES & THREATS

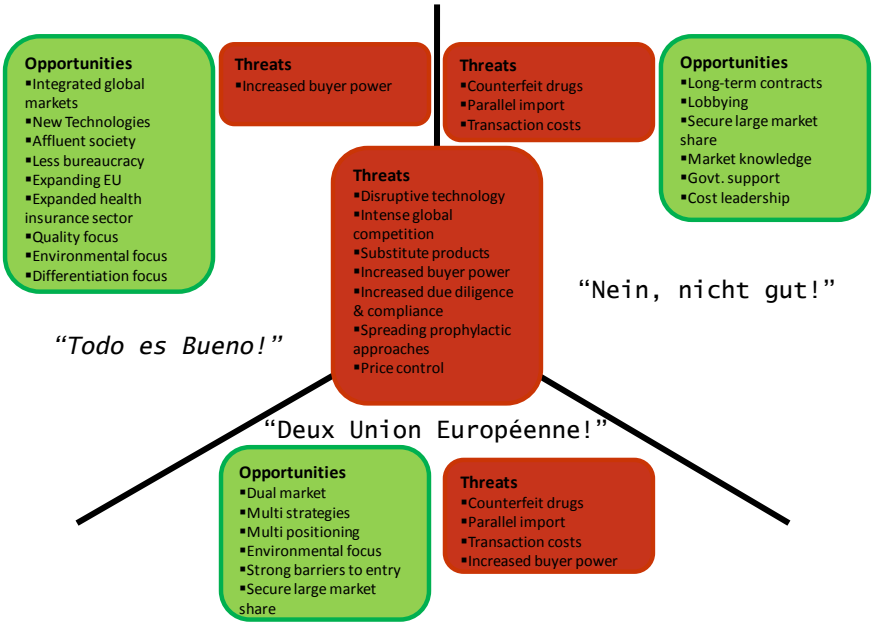
Opportunities	Threats
Dual markets	Disruptive technology
Multi-strategies	Intense global competition
Multi-positioning	Substitute products
Ageing population	Counterfeit drugs
Growing attention to healthcare	Increased due diligence and compliance standards
Quality focus	Spreading prophylactic approaches
New therapy and delivery systems	Price control
Increased scope for use of generic drugs	Parallel import
Positive attitude for soft medication (OTC drugs)	Transaction costs
New diagnosis and new social diseases	
Environmental focus	
Strong barriers to entry	
Secure large market share	

Scenarios 1, 2, & 3: Opportunities & Threats

Opportunities	Threats
Integrated global markets	Disruptive technology
New technologies	Intense global competition
New products	Substitute products
Ageing population	Increased due diligence and compliance standards
Less bureaucracy	Spreading prophylactic approaches
Harmonized policies	Price control
Growing attention to healthcare	
New therapies and deliver systems	
Increased scope for use of generic drugs	
Positive attitudes towards soft medication (OTC drugs)	
Expanding health insurance coverage	
New institutional purchases	
New diagnosis and new social diseases	
Focus (Quality, Sustainability & Differentiation)	

Scenario 1,2, & 3 Opportunities & Threats

Scenarios 1,2, & 3 Segmented Opportunities & Threats



Scenarios 1,2, & 3 Opportunities & Threats

SCENARIO CHALLENGE

- Use the scenarios to challenge implicit and explicit assumptions, stretch strategic thinking and foster organisational learning
- Organise workshops to expand and develop scenarios
- Use scenarios to test current strategies
- Identify robust strategies and risks
- Set up monitoring units to identify signs and indicators for each scenario

RECOMMENDATIONS

RECOMMENDATIONS

- ***Revisit your generic strategies***: Polar generic leadership (i.e. cost-leadership or differentiation-leadership) focused might not have a competitive advantage against mixed strategies.
- **The Key Ingredient**: customer value proposition – branding, marketing, quality? Growing counterfeit drugs, affluent society, etc.
- **Penny Wise with Research**: Invest in research – sudden technology breakthroughs, patent formulation, market niche, etc.
- **Stakeholder Management**: EU commission, pharmacists, etc. Enforce barriers to entry? – Allocate resources i.e. Marketing, PR, etc.

RECOMMENDATIONS

RECOMMENDATIONS

- ***Give in to the Green***: recycle drugs, reduce packaging, ethical supply chain, green manufacturing, etc. Defend from environmental regulation and improves stakeholder value proposition.
- ***Strategic Location***: Locate manufacturing facility thinking long-term, i.e. Turkey. These states offer proximity, growing infrastructure, and long-term transaction costs benefits i.e. logistics, free trade, etc.
- ***Face the Enemy***: Forming strategic alliance with players from foreign markets i.e. China, India by M&A, Joint Venture, etc. will promote organizational learning and develop economies of scale

THANK YOU