XRM: INTEGRATED CUSTOMER RELATIONSHIP MANAGEMENT FOR PHARMACEUTICAL INNOVATIONS

vorgelegt von

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Abstract

This thesis consists of four parts. The first part conducts a generic literature study on customer relationship management practices for innovations. It discusses management of innovations and the importance of marketing for the economic success of newly launched products. However, a closer look into marketing strategies reveals the evolving nature of marketing from transactional to relationship, opening opportunities to the broader concept of customer relationship management.

Subsequently, the second part describes the pharmaceutical industry to determine key factors and trends affecting the market and its dynamics. Based on an in-depth literature review, the author elaborates a comparative analysis between the U.S. and European markets and health care systems where the roles of the various health care players and their interdependencies encompass a wide spectrum of particularities and specific challenges.

As the pharmaceutical market becomes increasingly dependent on its innovations to maintain revenues, the market success of its new products is a critical factor that needs adequate innovation management support and above all, a sophisticated customer relationship management approach. Therefore, the third part investigates the status quo of marketing initiatives targeting physicians and patients. The aim is to understand generalized concepts of customer relationship management applied to the pharmaceutical industry. This analysis uncovers weaknesses of the current approaches due to the particular industry environment requiring an integrative, practical system.

Part four develops a marketing and communication process taking into consideration three determinant factors relative to the pharmaceutical market: customer diversity, processes, and disease segmentation. It is thereafter developed into an instrument for planning a comprehensive integrated customer relationship management for pharmaceutical innovations.

Keywords: customer relationship management, pharmaceutical marketing, pharmaceutical communication, integrated communication, direct-to-consumer.

Zusammenfassung

Die vorliegende Dissertation besteht aus 4 Kapiteln. Im ersten Kapitel wird eine allgemeine Literaturstudie über Kundenbeziehungsmanagement für Innovationen durchgeführt. Es diskutiert Innovationsmanagement und die Bedeutung von Marketing für den ökonomischen Erfolg neu eingeführter Produkte. Ein genauer Einblick in die Marketingstrategie jedoch deckt die derzeitige Entwicklung im Marketing auf: der Trend entfernt sich vom Transaktionsmarketing und nähert sich dem Beziehungsmarketing an, die Grundlage des Kundenbeziehungsmanagements.

Das zweite Kapitel beschreibt die pharmazeutische Industrie und untersucht Schlüsselfaktoren und Trends zum verbesserten Verständnis der Marktdynamik. Auf Grundlage einer Literaturrecherche erarbeitet die Autorin eine Vergleichsanalyse zwischen dem US-amerikanischen und dem europäischen Markt, bzw. Gesundheitswesen. Dabei wird besonderer Fokus auf das breitgefächerte Spektrum an Marktbesonderheiten und Herausforderungen für die unterschiedlichen Akteure der pharmazeutischen Industrie gelegt.

Da der pharmazeutische Markt zunehmend von Innovationen abhängt, ist der Markterfolg von neuen Produkten ein kritischer Faktor zur Erlösgenerierung. Hierzu ist ein adäquates Innovationsmanagement und, darüber hinaus, ein hoch entwickeltes Kundenbindungsmanagement erforderlich. Daher erforscht das dritte Kapitel gegenwärtige Marketinginitiativen für Mediziner und Patienten. Hierbei sollen allgemeine und auf die pharmazeutische Industrie angewendete Kundenbindungsmanagement-Konzepte verstanden werden. Die Analyse soll Schwächen der bisherigen Ansätze aufdecken und mögliche Lösungen durch integrative und praktische Systeme erarbeiten.

Kapitel vier erstellt einen Marketing und Kommunikations-Prozess für den pharmazeutischen Markt, der drei Faktoren besonders in Betracht zieht: Kundenvielfalt, Prozesse und Krankheitssegmente. Abschließend wird ein Instrument zur Planung eines umfassenden und integrierten Kundenbeziehungsmanagements entwickelt.

Schlagwörter: Kundenbeziehungsmanagement, pharmazeutisches Marketing, pharmazeutische Kommunikation, integrierte Kommunikation, Direct-to-Consumer.

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List of Abbreviations

ABPI	Association of British Pharmaceutical Industry
CDER	Center for Drug Evaluation and Research
CME	Continuing Medical Education
CPMP	Committee on Propriety Medicinal Products
CRM	Customer Relationship Management
DDMAC	Division of Drug Marketing, Advertising, and Communications
DMP	Disease Management Program
DTC	Direct-To-Consumer marketing
DTX	Integrated Direct-To-Consumer marketing
DUR	Drug Utilization Review
EEC	European Economic Community
EMEA	European Medicines Evaluation Agency
EPO	Exclusive Provider Organization
EU	European Union
FDA	Food and Drug Administration
HMO	Health Maintenance Organization
IMD	Incrementally Modified Drug
INN	International Nonproprietary Name
IR	Investor Relations
IT	Information Technology

NCE	New Chemical Entity
NIH	National Institute of Health
NME	New Molecular Entity
OTC	Over-The-Counter drugs
PBM	Pharmaceutical Benefit Manager
Phy. RM	Physician Relationship Management
PMCPA	Prescriptive Medicine Code of Practice Authority
PR	Public Relations
PRM	Patient Relationship Management
PTO	Patent and Trademark Office
R&D	Research and Development
TQM	Total Quality Management
US	United States
WHO	World Health Organization
XRM	Integrated Customer Relationship Management

Introduction

The pharmaceutical companies are counting increasingly on the success of their innovations to stay competitive in their markets.

The first part of this dissertation analyses generically the management and marketing of innovations in order to define more precisely the role of customer relationship management (CRM) in the management of innovations. Innovations are the motor of the economy and companies strive to introduce successful products into the market. The management of an innovation can be segmented in various stages relating to the product development process. The "Competitive Innovation Advantage" of a new product has been shown to be positively influenced by marketing measures adapted to this process and the concerned market environment (Trommsdorff 2004).

But marketing has been evolving in the last two decades from a transactional to a relationship science, switching the focus from the product to the customer. A consequence was the emergence of CRM, enclosing even a broader spectrum of corporate units including customer service and sales. The implementation of measures characteristic to CRM requires the support of new advances in information technology at different levels within the company to collect and analyze information, to share knowledge, and externally to enhance communication with customers. All industries have been applying this new type of approach to different degrees, and some have been capable of developing successful collaborations especially in fields such as consumer goods and financial services. The components of a CRM approach are hereby documented and clarified for the purpose of this particular study focusing on the pharmaceutical industry.

The innovation occupies a prime position in the pharmaceutical industry. This is first demonstrated by a thorough description of the current situation in order to draw an accurate overview especially in the context of the industry's requirements. The pharmaceutical company depends greatly on its innovative capacities. And the products brought onto the market are subject to an enormous pressure from all stakeholders to perform, whether it is concerning the efficiency of the product itself or by reaching optimal acceptance and sales. Pharmaceutical marketing has been crucial in supporting the innovation's success. Traditionally, it focused on the physician.

However in recent years, especially since 1997, the consumer has emerged as an essential target as the Food and Drug Administration (FDA) simplified the historically much regulated communication towards the patient in the United States. Indeed, there has been an ongoing change in the consumer's behavior, observed in parallel to the developments occurring in the health care system aiming at increasing the consumer's own health responsibility.

Naturally, in the pharmaceutical industry, CRM programs have been applied to the physicians and patient groups. But initiatives taken do not seem to be completely in line with the demands and structure of the pharmaceutical industry. This thesis aims at drawing a comprehensive reference instrument for CRM taking into consideration the requirements imposed by the particular context. The research described demonstrates a need to integrate all health care players into the marketing strategy of a pharmaceutical company, thus also specifying the traditional marketing fundaments to the particularities previously defined.

The analysis work concludes by presenting an integrated CRM (XRM) approach based on hypotheses to be validated in further empirical research.

PART I: LITERATURE ANALYSIS

1 Management of Innovations Focusing on the Success Probability Related to Relationship Marketing

Innovations first implicate specific corporate processes where the innovation and its context must be defined. This context includes the technological environment, and above all the corporate architecture allowing creativity to be marketed (Tanaszi 2002). The process of a new product development is therefore hereby exposed.

The managerial approach of product development can lead to the product's success. More specifically the predominant role of marketing will first be discussed. As marketing has evolved throughout the years into relationship marketing, this new aspect will then be tackled to introduce the current approach of customer relationship management. The pillar of these recent concepts, the "communication", is finally described to grasp an overview of the management approaches.

1.1. Framework of Innovations Revolving Around Corporate Processes

Innovations are generally successful on their markets when their development has been systematically prepared and carefully implemented. According to Pleschak and Sabisch (1996, 44), this development management includes planning, organization, and process controlling. It requires increased flexibility and capability for the application of organizational solutions, management concepts and analyses. The management of innovations is dependent on the corporate strategy and involves intensive operations often requiring change management to impose an innovation-orientation.

Strategy represents the bundling of resource applications for the defined goal of developing and securing future earning potential. Concrete measures derive from these general goal settings: specific products, their market, and the timeframe within which they are to be developed, produced and commercialized. Thereby, the corporate management settles the development goals of their business units and keeps the corporate unity (strategic corporate planning). In this planning approach, top management specifies growth, means and milestones. Single strategies are planned by business units but are interdependent (Bourgeois III et al. 1999, 16-7).

New businesses are also defined. These “new ventures” sometimes need 10 years, to provide return on investment for research, development and commercialization, and contribute to profitability. In the meantime, established and profitable market segments must produce the means necessary for the development of innovative products. These usually operate in markets, whose life cycles have passed their growth phase. The companies rely then on the contacts between sale representatives and their internal resources with the customer, and on fully developed distribution systems, involving mature products and production technologies. Therefore, economically viable business units are responsible within the company to provide the liquidity necessary to finance growth areas (portfolio management).

1.1.1. Breakdown of Innovativeness

The definition of the word "innovation" has evolved in the last three decades as described by Cumming (1998, 22). Forty years ago innovation designated a process introducing a change. The "newness" component was only later added through the practical use of the process, differentiating innovation from change. Also, a patent can only apply to an innovation and not to an invention. The description of an unknown scientific or technical phenomenon without giving the solution to the problem, does not entitle the right to a patent. According to Prastacos et al. (2001, 5) *"an invention is a new scientifically or technically relevant discovery concretizing new knowledge"*. An innovation needs a market validation and generates value to a customer (Schumpeter 1964, 57). An invention might turn into an innovation with further experimentation, development and refinement. This definition was refined by including the role of success, relating it to a successful commercialization, thus as a mean to create and maintain sustainable competitive advantage (Johannessen et al. 2001, 21).

The competitiveness of innovations is directly linked their problem solving issues. Theses issues can be differentiated either by:

- design;
- demand-fit;
- or novelty degree (change).

1/ Design

Design differentiation can be a product, process or social innovation depending on what the innovation refers to. Most authors only define innovations as a product or process offering new benefits (McDermott and Colarelli O´Connor 2002, 424; Cumming 1998, 22). A product or service innovation offers an improved or cheaper solution to the buyer. Thus, a product offer is often supplemented by service offers. On the contrary, there are process innovations of new technical policies for the service production. Product and process innovations can be differentiated logically, but are not completely separate since they are often related to one another. For the customer, the product innovation and the process innovation are often confounded.

Social innovations also called “market innovations”, unlike process and product innovations, depend on the behavior of people, groups and organizations. They are recognized as “socio-technical innovations”. They are involved in developing and serving the markets, and are closely associated with the goals of other innovations (Johne 1999, 7). These social innovations cover, for example, the implementation of strategic corporate planning or the design of a system for personnel and organization development.

2/ Demand-fit

The market orientation of all innovations is a basic strategic requirement of the innovation’s management and innovations are led by an increasing level of demand on quality, speed and operating efficiency by the buyer. Innovations can be differentiated by their demand-fit. On the one hand there are “pull-innovations”, or market-induced innovations, responding directly to the demand, or more clearly to customer’s needs. They are characterized by a relatively high success probability. On the other hand, there are the “push-innovations” or environment/technology-induced innovations stemming from the development of new technologies and organization forms for which new application fields must first be defined. The success probability is generally lower as for “pull-innovations”, even if they usually claim a higher novelty degree. Efficient success conditions are therefore set when the innovation is induced by both need and technology advances.

3/ Novelty degree or change

Innovations can also be differentiated according to their novelty degree and the following six categories were defined by Trommsdorff and Schneider (1990, 4):

- **Basic innovations** represent a breakthrough in technology or organizational principles and are the source of numerous following innovations.
- **Step-maker and key technologies** are referred to when leading a completely new generation of products, services or processes.
- **Modified innovations** result from the improvement of single or multiple parameters of an existing product.

- **Adapted innovations** are characterized by an adaptation to specific customer wishes or requirements.
- **Imitations** are post-developed or copycat products of already available solutions.
- **Pseudo-innovations** appear to be improved products, but bring no new benefits to the customer.

Innovation is, indeed, also subjective. For example, from a supplier's point of view, a new product-market combination must not be a worldwide novelty and must not have a high degree of novelty. Imitations and customer-specific adaptations can be innovative and furthermore, successful. From the customer's point of view it does not depend on objective technical business features, but rather on the perceived use through a competitive comparison.

Change, more precisely the "newness" representing a unidimensional construct incurred by the innovation can differentiate incremental and radical innovations, the two extremities of a continuum (Dewar and Dutton 1986; Damanpour 1996; Johannessen et al. 2001). The differences between incremental and radical innovations are also described by Henderson and Clark (1990, 9). Incremental innovations belong to a current market with known applications and do not include completely new technologies (step-maker technology). Most researchers consider that incremental innovations introduce relatively minor changes to existing products. They exploit the established perceptions and reinforce the position of established companies. Radical innovations are characterized by a high degree of novelty and are associated to broad, complex corporate changes. They are based on different engineering and scientific techniques allowing completely new potential applications in completely new markets or requiring dramatic behavior changes to existing markets. They provide the foundation on which future generations of products are built on. Roure (2001, 121) analyzed many studies supporting the fact that radical innovations can lead to a sustainable competitive advantage, thus they are positively associated to success. In general, it implicates higher investments (Park 1987) and economic risks due to technological uncertainty, cost, and technical and business inexperience (Green et al.

1995). Incremental and radical innovations also face fundamentally different challenges. These have been studied by McDermott and Colarelli O´Connor (2002).

In business, the innovation describes the use of new technical business, corporate and social concepts, which are recognized as novelty by society. This is a similar view to Zaltman (1973, 10) who defines innovation as "*any idea, practice, or material artifact perceived to be new by the relevant unit of adoption*".

1.1.2. Determination of the Major Role of Technology

The choice of technology development and application plays a crucial role in connection with the innovation process. The management of technology is involved at every level of the innovation management. According to Bullinger (1994, 97), it focuses on the development of technology concentrating on the technology-related corporate potential. When technology stands in the foreground of operating dispositions, technology management plays an independent function, whether through the marketing of technological knowledge (i.e. patent or license) or through a technology-oriented direction of the competitive strategy. Technology's advances open new perspectives and opportunities to concretizise ideas (Cumming 1998, 25). And the benefits are increasingly the result of the integration or fusion of multiple technologies instead of depending on one new technology (*British Food Journal* 1996, 26).

Various studies on technology levels concluded in three main approaches relying on either the contribution to the industries, the timing of the market entry or the transfer capacities between stakeholders.

a. The technologies depending on the contribution to the industries can be differentiated in five groups (Tschirky and Koruna 1998, 49):

1/ **Basic technologies** possess recognized technical principles. They are applicable in various branches and do not play a crucial competitive role in the specific business areas where they have been developed.

2/ **Key technologies** are at the forefront of technical development. Most of them are protected by patents and often offer a higher potential for improvements. They are

seldom used in multiple branches, even if within the concerned branch they induce strong competitive pressure.

3/ **Step-maker technologies** present great differences in their application possibilities which can be very restrained. They usually have an important competitive potential and may change the actual competitive structure.

4/ **Future technologies** are still in the research phase.

5/ **Killer technologies** can quickly reduce or render customer requirements obsolete. These are typically developed externally to the concerned enterprise.

b. The timing of the market entry is particularly important as Backhaus et al. (2000, 137) point out. The marketing strategy can depend on the technology's advance levels at the time of entry on the market:

1/ **Technological leading** or pioneer technologies have a high R&D orientation, high product technology standard, relevant novelty and complexity degree, high gains, high product and acceptance risk, and create entry barriers for competitors.

2/ **Early-following technology** has its own R&D, and is separated by a relatively short time gap from the pioneer. It offers similar service as the pioneer and enters attractive growth markets with reduced competitive intensity. It is characterized by the fact that the competitor is the pioneer and orients its sales results on the pioneer's experience. The competitive advantage is acquired through additional services, product improvement, higher quality, better marketing, etc. The introduction risks are low.

3/ **Late-following technology** is developed based on mature technologies or products, thus demanding low R&D costs. The competitive intensity is very high and focuses on service. There are also low introduction risks, no diversification in new markets, and low contribution of the new product on the total revenues. These are typical "me-too" products or product imitations (Ansoff and Steward 1967, 75).

c. The innovation relevant to benefit of external resources can take place in the context of technology transfers. Technology transfers support and enable the

generation and realization of innovations. Basically there are three established forms of technology transfer (Mayer and Blaas 2002, 286):

- **Agreement or contract research** is established between a private or public establishment for R&D work and a buyer (company, university, private or public research institute).
- **Research cooperation** of multiple companies, business associations or similar pre-competitive mergers can work together on a common research project. This is analyzed in depth by Meyer (1994).
- **Network R&D** is composed of independent companies within a research network where information, knowledge and personnel are transferable.

Clark and Fujimoto (1991) describe how innovation technological superiority offers the greatest interest and provides the greatest performance, features, quality, and value for money, therewith gaining the customers' preference.

1.1.3. Evolution from Recognizing a Problem to Commercialization

Innovations arise from a substantially, complex process which includes finding a solution to a newly defined problem, evaluating and successfully applying it. This is supported by Cumming's (1998, 23) analysis of the creative process resulting in three basic steps to be considered for the creation of an innovation. The innovation process is more extensive than just research and development activities. It is more of a diagonal corporate task, involving more or less intensively all of the company's functions. The development of new products is limited by the necessary finances. Thus, the requirement for a successful innovation management process depends on a good combination between profitable products and new developments at different maturity stages with well-balanced chances and risks. The number and limits of single phases of the innovation process are case-dependent, but generally look as described by Trommsdorff (1995, 4) in Figure 1.1.

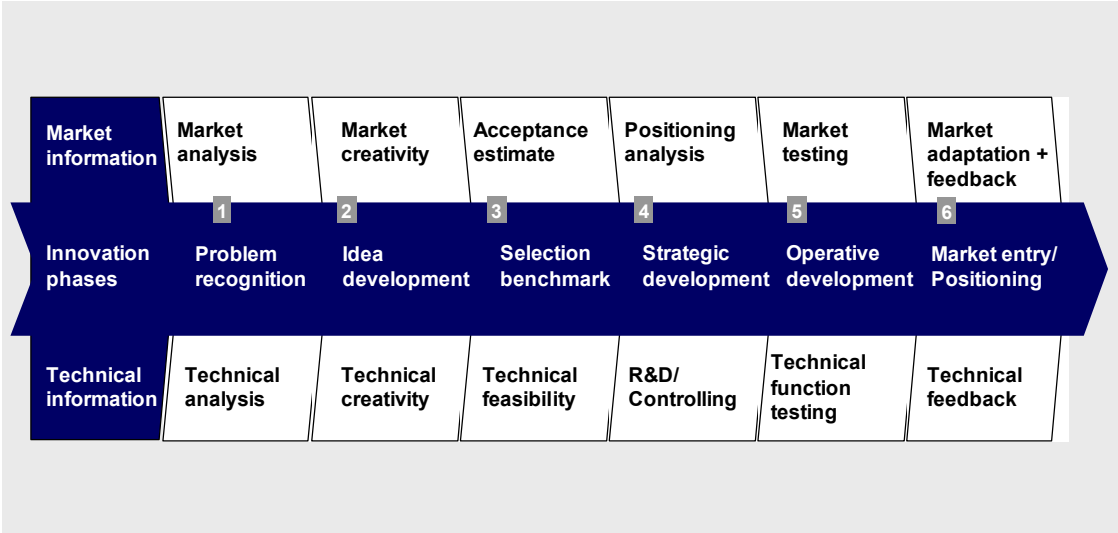

Figure 1.1. Innovation process described by Trommsdorff (1995, 4).

An innovative solution to a problem is first recognized in the starting phase of the innovation development. The solution can be a product, process or behavioral measure. This stage is characterized by a relax, participative, behavioral freedom between employees and superiors with decisive capacities.

Following the idea development phase is the internal business implementation phase. The less people influence the decision process, the shorter this phase is. But an intentional delay can raise the quality of the decisions since various aspects can be investigated and oppositions dismantled at the forefront. Therewith, advantages and disadvantages are weighed against each other during an extended decision and implementation phase. The innovation's tasks are determined in detail in the realization phase. The employees' negotiation freedom decreases as the project moves forward. The level of written guidelines and rules for the coordination of the innovation increases continuously. Throughout the process, the necessary creative tasks allow increasingly strong operative management of partly fewer complex sub-tasks. The more the innovation is important to the company, the more complex are the tasks to accomplish, thus the sooner the innovation process is released from the daily business organization.

Differences are established between “internal ventures”. They are relatively independent units built within the parent company, and “external ventures”, which are either legally or economically separated from the parent company.

- New product departments and project groups are typical internal ventures led by one responsible senior manager. Generally, this manager originates directly from the corporate management and is provided with advanced negotiation authority. All phases of the innovation project, up to the market entry run under his direction. High expertise competencies and especially, leadership and personal skills with the members of the innovation team are required for the success of the project.

- External ventures often follow advanced goals, exceeding the scope of single innovation. Rafiq and Saxon (2000, 4) find that innovation results in general from external specialist input or from bi-partite partnerships.

1.1.3.1. Generating an Idea: The Initial Phase

In order to guarantee a sustainable market success, a company must analyze its environment continuously. According to Vahs and Burmeister (1999, 89) a situation analysis pinpoints the relevant issues for the innovation process. Also researchers have put into light the importance of understanding exactly the end user’s needs at an early stage in the development process (Cumming 1998, 23). This results in the description of discrepancies existing between the actual situation analysis and the targeted situation. The initiative can then benefit from other corporate departments through improvement recommendations or controlling activities.

Most authors agree that the process of idea generation is “creativity”, and that it is an important precursor to innovation (Cumming 1998). Creativity, or the capacity of the people to find solutions to problems, is not only seen as an asset but also as a skill which can be learned and developed. Creativity leading measures are increasingly turned into core competencies within the innovation management process as shown by Geschka (1986). The idea of a new product, service, process or social innovation can be generated internally or externally (by customers or competitors) to the company. An external impulse implies that there exists a not-yet-measurable demand for the development of the product. The close collaboration between the creativity of the

R&D department and marketing takes on a strong importance for the generation of internal ideas.

Presently, internal ideas seldom lead to innovations. Most of the time, the initiative for improvements comes from operative marketing (sales force, product manager, marketing and sales representatives) dealing directly with customer problems. Next to the development of individual innovation awareness and the application of creativity-oriented conditions, only a constructive cooperation between strategic and operative units can lead to an effective innovation process.

The execution of an innovation process is impossible without the efficiency of a team work within the hierarchy (or matrix) whether internal or external. Only then, when all innovators are on the same wave length and all necessary information for generating ideas is available to the whole team, can the foundations be laid for the implementation of an innovation process.

1.1.3.2. Turning an Idea into a Product with Specific Value

The phases encompassing the evolution of the idea to the operative development depend greatly on the innovation itself. For example, the development of innovations with a high novelty degree frequently encounters oppositions within the company. In this phase, market data is collected, investment bills drawn and feasibility analysis carried out.

For Trommsdorff and Schneider (1990, 4, 9) the goal of a preliminary analysis of the considered innovation idea is to concentrate on the potential success of the project. It includes the planning and implementation of a clear project management taking into consideration the budget and the use of necessary human resources. The evaluation and selection of ideas are the management's task. The decision must stem from a team with expertise and leading competencies in various corporate areas.

Research and development (R&D) activities tend to be carried out in different units of the same organization, and often at different locations in order to access foreign sources of knowledge. The R&D corporate process includes activities of a different nature. According to Cavone et al. (2000, 3), one activity is "*related to exploration and experimentation and therefore the development of technical capabilities, the other*

one is the exploitation of such technological capabilities to generate and provide products and services". The two activities are linked by the technology integration as shown by Iansiti et al. (1997). But depending on the industry the two functions may be more or less separated due to the requirements of the structural organization.

1.1.3.3. Implementation of a Concept Followed Through

Project management allows new ideas which have not been developed. It can also decide to approach or not a new business, and allocate the necessary new resources. Project management is therefore a critical instrument for the successful realization of innovations. It includes four steps (Gannon 1994, 3; Czuchry and Yasin, 2003, 4; Calaveri and Fearon 2000, 5-6):

- preparation;
- planning;
- realization;
- and controlling.

The last phase of the innovation process is the market entry of the new product or process, for which the market maturity of the innovation must be determined. It includes multiple activities for the long-term preparation of the market and the implementation of tools such as the marketing-mix, which have often been underestimated in the scientific or technological company. For Trommsdorff (1991), marketing activities do not start just after the research and development phase, but in every phase of the innovation process market information must be collected and related marketing measures designed and implemented. Marketing is especially appropriate for market novelties, which have no comparable solutions. They should be the first to attain market acceptance considering that sustainable sales are fundamental to develop an idea into a successful innovation product.

1.1.4. Common Prerequisites for Establishing an Innovation-Driven Company

A number of authors (McGinnis and Ackelsberg 1983, 64; Johannessen et al. 2001, 27) put into light the importance of the organizational variables insuring good working relationships required for managing innovations effectively. In a nutshell, there are

three components supporting corporate innovative capacities. One is the corporate culture reflecting the value and standard structure, traditions and mentality of an organization. The second element is the organizational management network structure, and the third element is the internal marketing or release of information.

a. Corporate culture

An innovation process requires organizational development for the accomplishment of the innovation's tasks to be oriented towards the corporate mission. Schneck (1998, 726) puts an emphasis on corporate culture determining the behavior of the leading forces and of the employees towards each other. Martensen and Dahlgaard (1999, 744) recognize that corporate culture has a strong influence on the behavior of the working force. Its function lies in the value and reference system allowing a common understanding across the various business areas. It stabilizes the decentralized organization process through an orientation towards participative value. Therewith, the common value system encourages the employees' motivation and identification with the company.

b. Organizational management

An innovation-oriented organization model is characterized by flexibility, stimulation of employee creativity, teamwork and cooperation capacities. Macharzina (1995, 400, 609) refers to two alternative designs available to companies. The first involves team-oriented structures characterized by the fact that decisions in the innovation process do not depend on single people but rather on groups lead by a project leader. The participants are then released from daily business tasks (operative implementation of the venture management concept). Networks help to reduce interface problems in order to support cooperation. The organizational sense is a network, based on relationship structures of independent units (people, groups) tied by common values. The second organizational architecture of the innovation process is one that can be lead in various parts of the company, each with different structures and leading principles. In an innovative corporate organization, project management is applied through a network management to lead complex innovation steps. This can be part of an internal venture management with the creation of quasi-independent organization

units. The work is efficiently distributed and focused on specialization and coordination.

The basic organization problem is to find such an organizational structure which stimulates creativity and at the same time has efficient processes. The participative leading style and cooperative working form lead to structural and social requirements for innovative working habits for many positions within the company. A corporate culture supporting the innovation process has a business orientation focused on the innovation. It is characterized by an open communication and a matrix minimizing management, moving away from the matrix with numberless, often opaque single decisions. Communication involves different levels, different functional areas at different stages of the innovation process and must insure a common understanding among all internal parties concerned (Martensen and Dahlgaard 1999, 742). An information network is built to support idea management in order to collect improvement proposals. Employees have a creative working atmosphere with the implementation of an incentive system for creative work, ambitious working goals, and when they can rotate between various development areas. Responsibility is delegated through teamwork and a flat hierarchy as well as through top-management involvement. Career and promotion chances for innovators are also defined. Open communication applies also to external communication measures and support to the customer. The knowledge available is associated to the knowledge carriers. The participation degree characterizes the magnitude to which single employees take part in decisions. Information release act as an instrument to stimulate the innovation readiness. Above all, the information must be carefully selected and focused.

c. Internal marketing

The timing of the information is crucial. Innovation processes can be handicapped by complex, poorly structured, undefined informational statements just as much as ill-managed operational situations. Every concerned party wishes to be informed as early as possible in order to be able to apply some influence. Often the information is released too early, and therefore is still unstructured and unclear. However, when released to late, the concerned parties have no influence possibility anymore on the course of action. Employee oppositions are reinforced or provoked by broad

information. In addition, promoters within the company as described by Hauschildt and Gemünden (1999, 9-43) play an important role for creating a link with the corporate management. And in order to be able to estimate the possible reactions, it is essential to take into consideration the comments from the concerned parties in every phase of the planning and the implementation.

1.1.5. Creation of a Competitive Advantage for Innovations

Innovations permit companies to overtake competitors and build strong competitive entry barriers (Gubman 1998, 169). Not only is the success of an innovation crucial to the competitiveness and survival of businesses, but on a broader level it also affects the economic performance of countries and regions (European Commission 1991, 8).

The success of the innovation management, leading to the introduction of an innovation in the market can be steered in different directions and intensities by a range of influencing factors. Since the mid-1960s, theoretical quantifiable systematic models of the unlimited possible influences on the success and failure of innovations, such as analyzed by Schmalen and Wiedemann (1999), have been developed. According to Trommsdorff (1995, 4) the research for success factors often splits the innovations in successful and non-successful ones.

Success factors can be differentiated between controllable and non-controllable factors. The factors that are not controllable by the company are the market condition (Gatignon et al. 1990, 398), the number and intensity of competitors, customer-supplier relations, and external knowledge infrastructures (Johannessen et al. 2001, 27).

Controllable factors have been identified by numerous studies to be either core features of the product and the company, or to be related to marketing measures (Shepherd and Ahmed 2000, 102; Gatignon et al. 1990, 392).

a. Core features

According to Rafiq and Saxon (2000, 225), the core features include:

1/ the product competitiveness itself;

2/ the company's expertise;

3/ the production capacities;

4/ the available management resources;

5/ and the ability to manage external company resources.

The product can show uniqueness and superiority. Unique and superior products are new on the market and highly innovative. They are superior to the competitor's products considering quality and market need satisfaction, thus they posess a higher problem solving potential. The novelty degree or innovation potential determines largely the pricing leeway, since innovative products are subject to a lower competitive intensity than products already positioned on the market. In an extreme case, the product creates a market in which the manufacturer has a monopoly. Its market dominance depends on the competitors´ decision to take advantage of the potential gains through imitation.

A high level of expertise in the research corporate skills will have an impact on the product's quality and on the potential continuous development of the product (technical development potential). This implies an efficient cooperation between the various corporate departments. The innovation process is therefore efficient developing a product at lower cost and which can quickly enter the market (Brown and Eisenhardt 1995, 372). The aspect of actual technology use (i.e. experience in up-scaling) and the current access to resources play a prominent role for the future market success. Large companies are genrally superior at using synergies resulting in innovative technologies over a broader spectrum.

The production capacities play an important role on the innovation's presence on the market. A smooth production start and the suitability of the production capacities are particularly relevant.

The development and positioning of innovative products always request high management involvement to design strategically the innovation process within and outside the company efficiently. Management resources should be available to support the innovation's requirements. Product innovations often fail due to a lack of clear

mandates and financial resources leading to a poor implementation of the innovation process parallel to the daily business.

Regarding the company's external resources to provide innovation, it is key to be efficient at recognizing its potential partners and establishing a stable relationship with them.

b. Factors related to marketing

The factors which can be influenced by marketing measures include the company's knowledge of the market, understanding the end-user wants at an early stage in the development process, leading to appropriate measures concerning the innovation and the focused communication with the customers through promotions, image and branding (Cumming 1998, 23).

These factors are modeled by Trommsdorff (2004) and their influence made measurable with the Competitive Innovation Advantage (CIA) model. The model creates a link between theory and business, and aims at evaluating the future success of the innovation and the success factors. The higher the CIA is, the higher the success probability. Five factors are measured to determine the CIA:

1/ superior competitive benefits;

2/ response to a customer's important need;

3/ the recognition by the customer;

4/ difficulty to compete against;

5/ and the level to which important influences from the environment can be anticipated and proactively acted upon.

The first factor can not be influenced by marketing and refers to to the core features described above, whereas the other factors can.

Marketing not only includes the traditional marketing mix, but also market research which is particularly important in the early phases on the innovation process. Customer needs are analyzed in depth to develop the product adequately. Within this

approach, market research is not only a classical, quantitative analysis. This process is based above all on cooperation with the important customers and an exchange of qualitative information. Marketing has to work closely with the product development department to forward its customer knowledge resulting in products with a high degree of benefits to the customer.

Image and branding are key factors to face competition and market saturation especially for products conceived for markets in advanced phases of the product life cycle with high product saturation. Stahl (1964, 9) states that corporate and brand identifications are essential to attain product diferentiation. Often a high novelty degree is insufficient to build a new market. It must face the actual solutions, which may already have image and customer loyalty advantages. Communication strategies are crucial at promoting the product's advantages and influencing how the customer perceives the product.

To summarize the above success factors, an efficient innovation management is impossible without the adequate allowance of additional resources (financial, material, and personnel). Also, the more the product is innovative, the less there is to subdue in a current market with high competitive intensity. The innovation must be tied to clear customer benefits, resulting in a competitive-perceived product. And a professional marketing is especially important for the product's success in order to discern the customer needs and respond to them accordingly by offering the appropriate product under the right conditions (price, distribution and communication).

1.2. Implications of Marketing on Economical Development and Success

A closer look will be taken into the marketing approaches ensuring the success of the products on the market knowing that both, market success, economic success (Homburg and Stock 2001b) and customer satisfaction (Hallowell (1996) can be positively influenced by marketing in the case of innovations. These are interrelated as the role of marketing in the strategic management process of the company has been affirmed by opening entrepreneurial opportunities (Hutt et al. 1988, 16).

Historically, marketing was first concentrated on the numbers of transactions. It has move towards a deeper concept taking into consideration the humanistic side of the interaction. The relationship with the customer is especially crucial to build an appropriate frame to ensure the success of an innovation.

1.2.1. Evolution from a Product-Focused Science to a Relationship-Building Approach

The industrial revolution fostered product-centric marketing strategies with a focus on leveraging economies of scale for delivering mass-produced products and services to a large number of people. This is transaction marketing relying on the product itself and the traditional marketing mix composed by the "four Ps" model developed by McCarthy (1960). Kotler (1997, 92) defines marketing as the "set of marketing tools that the firm used to pursue its marketing objectives in the target market". The goal of the "four Ps" (product, price, place or distribution and promotion) is to grow the market share profitably. Basically, the main concern is to increase the volume of transactions between seller and buyer. Volume of transactions is considered a good measure of the performance of marketing strategies and tactics. In transaction marketing, the technical quality of the product is the major feature (Grönroos 1994, 12).

However, by organizing business units around assets, the various divisions will inevitably view customers from their own perspectives rather than from a shared, company-wide point of view due to a lack of explicit coordination. It also means that each division reaches ad hoc, often shortsighted decisions on pricing, investment,

capacity usage, and service levels – decisions that are based on each customer's importance to that division rather than to the organization as a whole. At a minimum, customers should be able to expect consistent interactions when dealing with different parts of an organization. Webster (1992, 10) denounces the increasing irrelevance of profit maximization focused on a series of transactions facing today's dominating role of relationships. But some authors such as Vence (2002) still defend the need of strong transaction marketing in order to establish a further concept of marketing. The whole picture could be seen as a continuum such as shown by Grönroos (1991), from transaction marketing involving the consumer packaged good to relationship marketing concerned with services.

Relationship marketing was first referred to in the beginning of the 1980s by Berry (1982). It is today an accepted concept, and has entered the world of basic marketing as interpreted by Kotler (1997, 36-61) and has induced a "*shift from a focus on transactions to a focus on relationship focus*" (Webster 1992, 14). The main notions implicated are those of building relationships with customers and enhancing lifetime value. The goal of marketing has turned into "*creating and maintaining exchanges by promoting products and services that satisfy the needs of consumers*" (Graeff 1995, 28). This is in accordance to Grönroos´ (1994, 9) and Morgan and Hunt's (1994, 35) definitions although these translate satisfaction into successful relational exchanges. It can also be enhanced by Webster's (1992, 14) definition of marketing as a "*management function responsible for making sure that every aspect of the business is focused on delivering superior value to customer in the competitive marketplace*". Different terms were used to relate aspects of this transition in the marketing philosophy: one-to-one marketing by Peppers and Rogers (1999), mass customization by Gilmore (1997), customer intimacy by Wiersema (1996) and permission marketing by Godin (1999) among others.

The concept of relationship marketing is built on three theoretical approaches according to Hennig-Thurau and Hansen (2000):

- **The behavioral perspective** is composed of trust and satisfaction. Payne and Ballantyne (1991) conclude that the goal of relationship marketing is to build satisfying relationships with other market players such as customers, suppliers,

distributors, in order to gain their preference and long-term trust. It is based on economical, technological, and social links between the different parties and reduces the transaction time.

- **The network approach** includes the business-to-business marketing interactive character of relationships and own inter-organizational perspective. The ultimate level of relationship marketing for Kotler and Dubois (2000, 653) is the construction of a network including all players involved in the company's business.

- **The new institutional economics approach** employs modern economic theories to explain the development and breakdown of relationships. Reichheld and Teal (1996) illustrated the economic superiority of the relationship marketing approach.

These three approaches include the transaction cost theory used by Backhaus et al. (1996) and Söllner (1994) and the agency theory discussed by Kleinaltenkamp (1994) and Mishra et al (1998). Hennig-Thurau and Hansen (2000) resume relationship marketing as an approach using the appropriate relationship dimensions with the overall goal of minimizing the costs of structuring and managing a relationship, thus giving way to the term "relationship management".

Based on the work from Diller (1991), Grönroos (1991), Glynn and Lehtinen (1995) and Hansen and Bode (1999), the key differences between the concepts of relationship marketing and transaction marketing can be summarize in table 1.1.

Criteria	Relationship marketing	Transaction marketing
Primary objective	Relationship	Single transaction
General approach	Interaction-related	Action-related
Perspective	Evolutionary-dynamic	Static
Basic orientation	Implementation-oriented	Decision-oriented
Long-term vs. short-term	Long-term	Short-term
Fundamental strategy	Maintenance of existing relationships	Acquisition of new customers
Focus in decision process	All phases focus on post-sales decisions and action	Pre-sales activities
Intensity of contact	High	Low
Degree of intra-organizational dependence	High	Low
Measurement of customer satisfaction	Managing the customer base (direct approach)	Monitoring market share (indirect approach)
Dominant quality dimension	Quality of interaction	Quality of output
Production of quality	Concern of all	Primary concern of production
Price elasticity	Customers less price sensitive	Customers price sensitive
Role of internal marketing	Substantial strategic importance	No or limited importance
Importance of employees for business success	High	Low
Production focus	Mass customization	Mass production

Table 1.1. Comparison between transactional and relationship marketing based on Diller (1991), Grönroos (1991), Glynn and Lehtinen (1995) and Hansen and Bode (1999).

1.2.2. Specific Application of Relationship Marketing on Innovations

For Drucker (1954), a business' goal is to "create a customer" through marketing and innovation.

Innovation is indeed a key to competitive advantage as many authors have shown such as Hamel and Prahalad (1991) and D´Aveni (1994). But in order to be successful, organizations must ascertain the customer's needs and wants and produce products

and services aiming at satisfying them. A company needs to focus on its customers, to innovate appropriately on the one hand and then diffuse its product or service back to the targeted customers on the other hand.

A customer-focused organization should know how its customers evaluate its performance, and possess internal measures reflecting its customers' performance assessment. It should perform superiorly to its competitors from the customer's perspective and understand how its customers are performing in the eyes of their own customers. It should take into consideration that the company is taking part in the performance of its customer (Andrew et al 2001, 5).

The goal of a marketing strategy is satisfying targeted customers. This consists of defining and analyzing the targeted market, and creating and implementing an appropriate marketing mix around this goal subsequently. It also traditionally includes the analysis of the marketing macro-environment which comprises political, legal, regulatory, social, technological and economic factors. The marketing strategic tasks focus on the selection of the targeted market, the positioning of the product or the brand, and the gain of a differential advantage or competitive edge. The marketing environment, marketing strategy, the marketing mix and customer satisfaction can be represented by figure 1.2. based on Kotler (1997, 95) and Dibb et al. (1997, 18).

The relationship marketing strategy starts by identifying a target and then defining a point of contact with the company, or more specifically the employee point of contact. A separate department led by responsible executives is then allocated to manage the task of building and caring for this relationship. According to Kotler and Dubois (2000, 652-653) a relationship marketing plan should include medium and short-term goals.

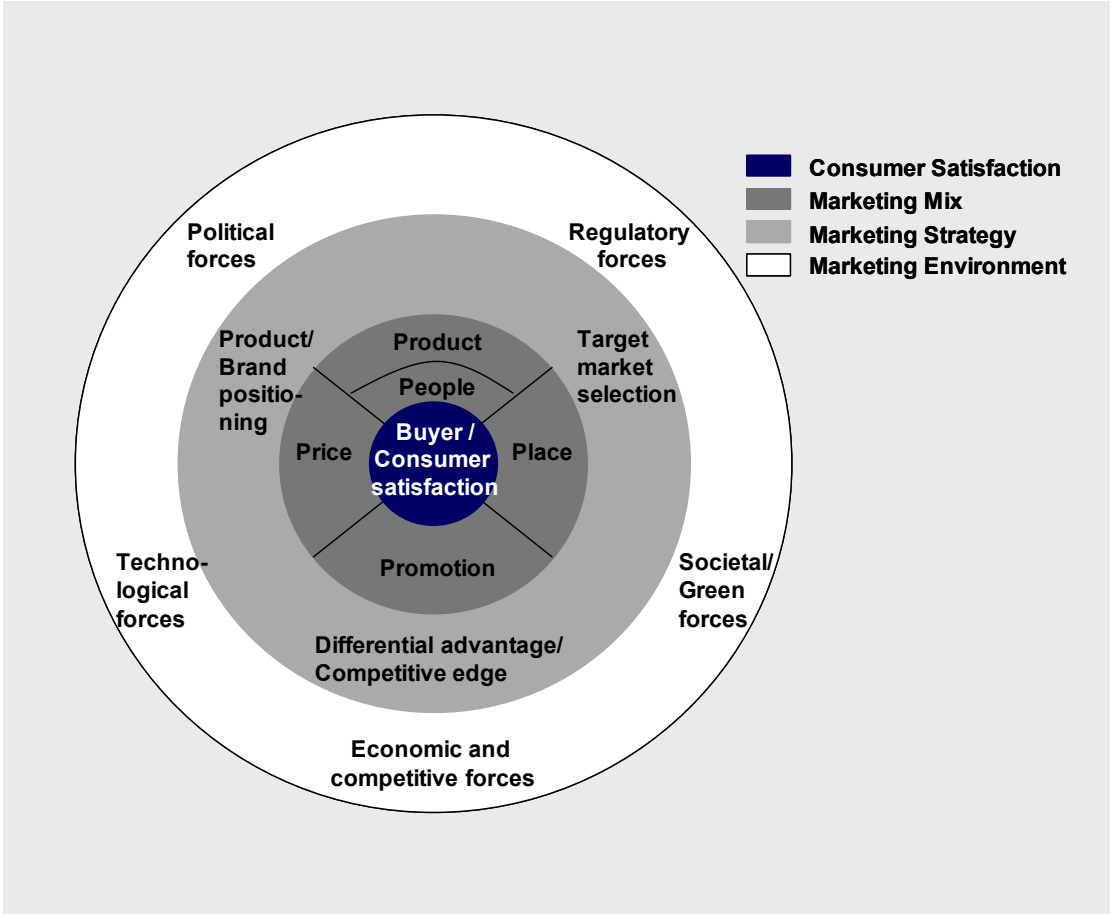

Figure 1.2. The marketing environment, marketing strategy, marketing mix and customer satisfaction based on Kotler (1997, 95) and Dibb et al. (1997, 18).

Relationship marketing focuses on customer satisfaction which plays, in turn, a positive role on customer loyalty (Homburg and Bucerius 2001, 57). And the market success of the company, or of the product, is strongly influenced by the level of customer loyalty as described by Rust and Zahorik (1993). The idea of economic superiority of the relationship marketing approach has been presented by Reichheld and Teal (1996). This approach has been complemented by other empirical research (Reinartz and Kumar 2003) concluding that the focus should not be on more relationship building, but on building the right type of relationship.

1.3. Development of the CRM Concept

Relationship marketing was a pure individual marketing. However, this concept is no longer sufficient for some authors such as Dutta et al. (2002, 4). While key ideas of one-to-one marketing remain valid, the value propositions have to be expanded to take into account active networking amongst customers and businesses.

Hansen (2000) elaborates two focus areas of relationship marketing: internal business processes and external customer communication. The design and management of transactional tasks bind the resources of the service and marketing departments. The data collected by communication is in turn used for product development, and general corporate management. All departments are working closely linked to one another, oriented towards the customer and his needs.

These corporate integrations can be analyzed by applying the three dimensions of marketing identified by Webster (1992, 10; 2002, 23). On a corporate level, the first dimension includes the company's culture focusing on customer orientation and the internal organization, completed by two dimensions belonging to the concrete application of theoretical concepts. One is a strategic dimension responsible for customer segmentation, targeting and positioning involving market research. The other one is the operating level taking into consideration the tactics appropriate to the developed strategy.

1.3.1. Corporate Involvement in Customer-Centered Strategies

According to Homburg and Sieben (2000, 7) CRM is the direct consequence of the transition from transaction to relationship orientation of marketing based on customer satisfaction. For Sieben (2001) customer satisfaction is a central value of customer relationship management.

Customer satisfaction was developed in the 1980s as part of the larger concept of customer loyalty. In the 1990s, the service and consumer goods industries discovered the strategic potential of satisfied customers tied to the company in the long-term (Christopher et al. 1991). Today, CRM appears as a systematic and individualized

customer management incorporating customer satisfaction and customer retention. The evolution of a focus on customer satisfaction to the development of a CRM initiative involves an increase in systematization, individualization, business orientation and IT applications.

Technology has been a key driver for CRM development, through the power and user-friendliness of computer-based systems. Also, the capability of storing large data volume, web-based systems led to the creation of user-friendly interfaces that could be used for customer self-service. In fact, the impact of technology has been so strong that the term CRM is often associated only to the implementation of a software package (Ferguson 2000; Xu et al. 2002, 442).

However, CRM concentrates on the relationship marketing strategy. It comprises the process of implementing this strategy. First, the corporate roles are redefined and assigned in order to make the implementation possible and efficient. Then the processes involving the rest of the company are designed. It consists of planning and enabling a dialog with the customer based on an exchange of information.

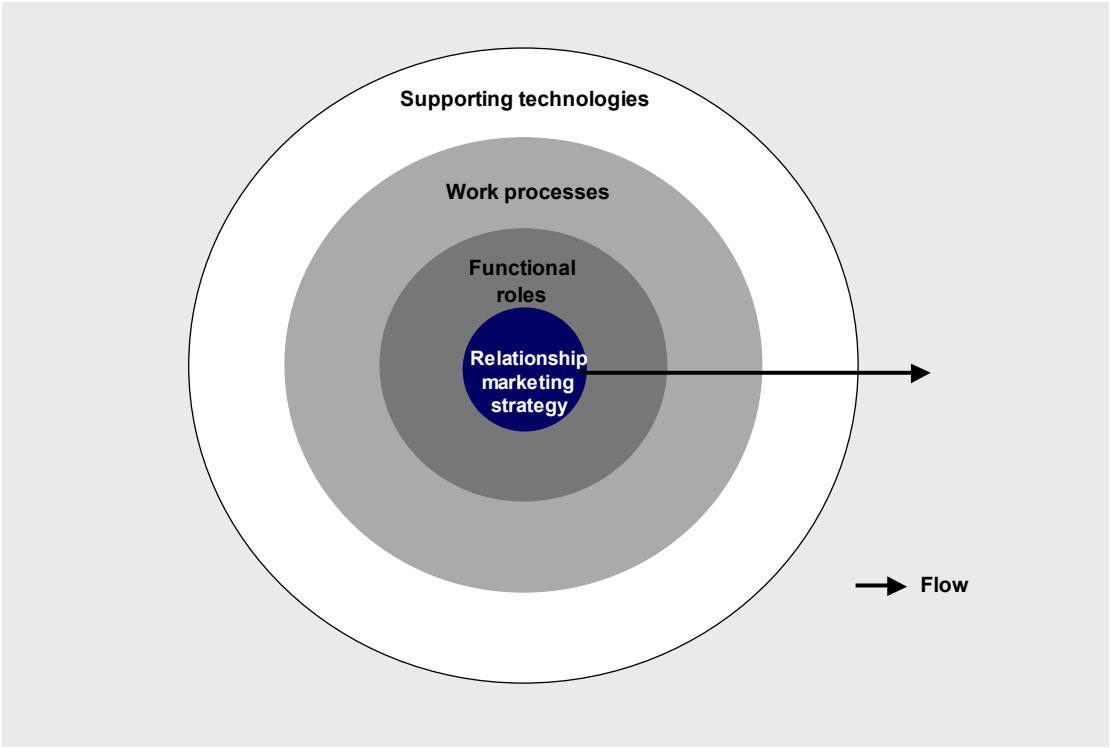

Figure 1.3. Effective CRM development follows a concentric pattern starting with relationship marketing strategies (Lee 2000, 15).

For Gray and Byun (2001), CRM is a broad concept covering marketing management, manufacturing management, human resource management, service management, sales management, and research and development management. Additionally, since relationship management deals with learning about customers' needs and requirements through ongoing transactions over time, one objective of relationship management described by Clark et al. (1994) is to achieve this learning on most, if not all, internal processes. For example, in the case of an innovation, product development uses this data to take into consideration customer needs and requirements concerning a product or a service. CRM is supported by technology enabling data gathering and its analysis and allows it to be shared throughout the whole company. Thus, CRM requires organizational and business level approaches impacting internal customer-centric configurations for conducting business rather than designing a simple marketing strategy.

Galbreath and Rogers (1999, 162) describe CRM as follows: "*activities a business performs to identify, qualify, acquire, develop and retain increasingly loyal and profitable customers by delivering the right product or service, to the right customer, through the right channel, at the right time and the right cost. CRM integrates sales, marketing, service, enterprise resource planning and supply-chain management functions through business process automation, technology solutions, and information resources to maximize each customer contact. CRM facilitates relationships among enterprises, their customers, business partners, suppliers, and employees. It is a strategy for competitive advantag*e". Gerecke (2001) also consider CRM to be increasingly a product's critical success factor.

1.3.1.1. Reorganization of the Corporate Entity

The knowledge gained through data collection must be optimized and shared with all internal processes such as new product development and supply chain management. Indeed, CRM does not only have an impact on external relationships but also on the internal architecture (Reinartz et al. 2003, 4).

1.3.1.1.1 Changes Affecting Human Resources

There are four components of a customer-oriented corporate culture according to a model developed by Homburg and Pflesser (1999, 14): values, behavior standards, artifacts (stories, languages, tradition and infrastructure), and customer-oriented

behaving. These can be in turn influenced by set principles, visions as well as behavior rules, leadership styles and tools forming the “symbolic management”.

In a customer-oriented organization turned towards innovations, the personnel management has to reflect these orientations. In order to stimulate the customer orientation, human resources also has to adapt accordingly. Homburg and Bucerius (2001, 67-68) describe five areas concerned:

1/ recruitment of employees comfortable in dealing appropriately with customers;

2/ training and continuing education to enhance employee knowledge at all levels, on the customer and its needs in order to provide the tools and information necessary to manage the customer and the front-line employees;

3/ personnel evaluation to set personal goals based on the interaction skills with the customer;

4/ advancement according to experience and personal achievements in customer skills especially in marketing and sales;

5/ compensation depending on the corporate business, it can include a variable or commission dependent on customer sales, thus influence capacities on retention and loyalty.

These actions are supported by internal marketing tightly aligned to external marketing. It is also crucial to acquire and maintain the support and motivation of all employees by communicating with them about the products and strategies (Grönroos 1994, 12-13; Galbreath and Rogers 1999, 168).

Homburg and Stock (2001b) have proven the direct positive effect of employee satisfaction on customer satisfaction and an indirect one on customer closeness. This correlation is linked to the level of innovativeness of the product or service.

1.3.1.1.2 Restructuring of the Relationship Between Corporate Functions

A customer-driven company has an organizational structure allowing information flow and cooperation between internal departments potentially leading to competitive

advantage (Powell et al. 1996, 142) mainly due to the consistency of the messages (Duncan and Moriarty 1998, 9). This strategic importance of intra-organizational collaboration has also been underlined by Grönroos (1994, 12) and the impact on the innovation success has been shown by a number of empirical studies (Cooper, 1979; Zirger and Maidique 1990). Based on their characteristics described by Kotler (1997, 762), an information flow scheme can be drawn reflecting the major role of relationship marketing within the organization leading to customer relationship management. In a customer centric organization the data flows from relationship managers to headquarters rather than from headquarters to relationship managers:

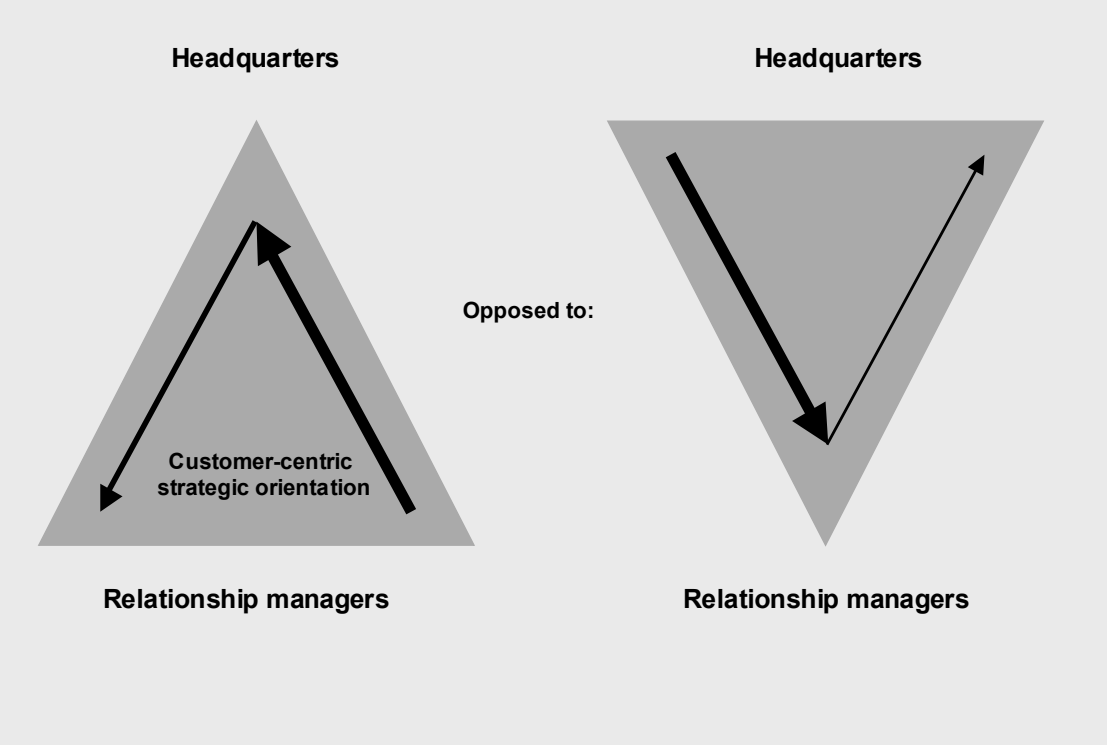

Figure 1.4. Data flow in a customer-centric strategic orientation (Lee 2000, 33).

Marketing is based on the customer. It is integrated with other businesses of the company, such as research and development (R&D), manufacturing, accounting, service, sales, and logistics. There is a two-way information flow between marketing and the other departments. The tasks of marketing as defined by Wehrmeister (2001, 271) are to carry out all market studies, focusing on customer satisfaction, image and competitor analyses in order to provide the information R&D requires to develop new products tailored to the customer's needs, that manufacturing requires in order to improve a product which will bring a concrete benefit to the customer, and that sales and service require to enhance knowledge about the customer and to support the

interaction and communication with the target group. The dialogue between the marketing and R&D functions is essential throughout the strategy formation process (Hunt et al. 1988, 14). As Moenaert and Souder (1996) have demonstrated, the novelty level of a product has an inferior impact on the success of the innovation compared to the perceived relevance and credibility attributed to the product. Thus, as shown by Gupta et al. (1986), the integration at the R&D and marketing interface is particularly relevant for the success of an innovation.

In return, the feedback collected by service, sales and logistics can be forwarded to marketing which will analyze the information and re-inject it into the corporate circuit where it is needed. Even accounting can contribute to the marketing knowledge by providing profitability reports by product, market segment, geographic areas (region, sales territories), order sizes, and individual customers. All this is supported by a workforce trained to think about the customer, and characterized by teamwork and its willingness to share knowledge.

In addition, a structure enabling such an information flow, needs strong and adapted IT solutions, and internal events such as seminars, and get-togethers to encourage and facilitate the exchange between departments.

1.3.1.2. Definition of the Ultimate Goal: Customer Satisfaction

Customer satisfaction is the result of a customer´s perception of the value received. The value is actually the perceived service or product quality. Satisfaction is obtained when the value is superior to the price and customer acquisition costs (Blanchard and Galloway 1994) and superior to the value expected for the transactions or relationships with competitors (Zeithaml et al. 1990; Oliver 1980).

By looking at the client development, figure 1.4., customer satisfaction supports the conversion of a potential client to a partner, the highest level of a customer-company relationship. In addition, it is important for Buchanan and Gillies (1990) that relationships are to be planned on a long-term basis with direct impact on the company's profitability. Hallowell's (1996) findings support this by arguing that customer satisfaction is related to customer loyalty, which in turn is related to profitability.

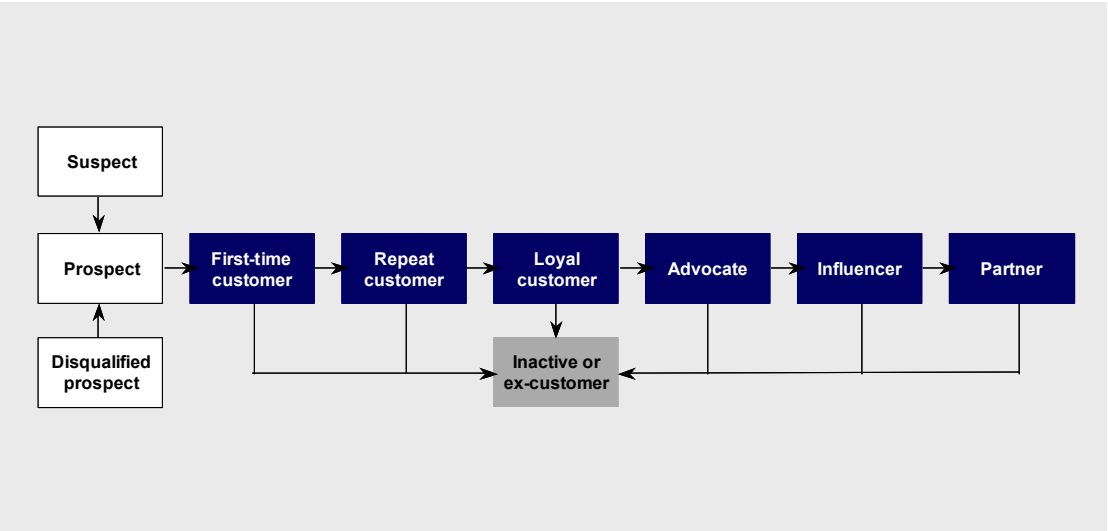

Figure 1.5. Process of customer development based on Kotler and Dubois (2000, 83), and Malaviya and Spargo (2002, 10)

Any business starts with the acquisition of customers. Acquisition is a vital stage in building customer relationship. For the purpose of acquiring customers, an organization is likely to focus its attention on the "suspects". These can include people with enquiries, lapsed customers, former customers, competitor's customer referrals, and existing buyers. From these, the organization needs to sort out the prospective customers and retain the most valuable ones. Reinartz et al. (2003, 4) stress on building the right type of relationship. A potential client is a "suspect" or a "disqualified prospect" who evolves into a "prospect".

When a "prospect" is convinced about the product or service, he can purchase it and become a "first-time customer". A "first-time customer" seeks the simple purchase of a product or a service. He expects a simple and efficient transaction. The relationship is impersonal and the strongest impact on the customer's experience is product quality.

When the product or service has corresponded or exceeded the "first-time customer's" expectations he might purchase it again becoming a "repeat customer". He purchases the same product of service because he is familiar with the experience and is willing to experience it again. He expects a reliable service provider, with the highest possible service quality. An easy access to the product or the service supports the relationship with him.

If the “repeat customer’s” expectations, thus satisfaction is sustained he will become a “loyal customer”. A “loyal customer” feels comfortable and welcomed in the environment offered by the organization. Purchasing is a nice experience and he engages in an affective relationship. The ambience has the most impact on him, and comfort makes this relationship stronger. The next stages are increased levels of loyalty.

An “advocate” expects recognition for his purchasing behavior such as special treatments that will enhance the inter-personal experience. He is seeking a personal relationship which can be provided e.g. through loyalty programs.

The “influencer” puts the importance on intra-personal factors. He feels honored for who he is and what he stands for. An “influencer” will increase sales by inciting non-customers to enter the customer loop. Product customization and personalization as well as brand extension are drivers of this type of relationship.

The “partner” feels the need to participate actively and seeks collaboration with the company. He can contribute to the management of the company by providing feedback and participating actively to the company’s business. Both internal and external factors have a great impact on him. He requires an interaction in a context which goes beyond one-self, by sharing a larger vision and social welfare.

At any moment a customer can become “inactive” and has to be reactivated through recovery programs. Rust and Zahorik (1993) and Sheth (1996) have shown customer retention to be crucial for the success of relationship marketing. According to Klee and Henning (1996) it differs from a repeat purchase by the fact that it implies an intentional component: the customer means to buy this product and not another.

Jacoby and Chesnut (1978) and Morgan et al. (2000) draw also a distinction between customer retention and customer loyalty. Although according to Reicheld and Sasser (1990), Reichheld (1996) and Hennig-Thurau and Hansen (2000), retention and loyalty are both closely related to economic success of relationship marketing. They can induce cost reduction such as amortization of sales, marketing and set-up costs over a longer time period, therefore reducing the costs to acquire customers, and the reduction of service costs resulting from the customer product expertise. Another

impact is sales increase and lower customer-price sensitivity. However, retention implies purely behavioral aspects and the marketer is the active party, whereas loyalty includes behavioral and attitudinal aspects and focuses more on a dialogue between the marketer and the customer (Jacoby and Kyner 1973). Increasing customer loyalty also means increasing the customer lifetime value.

Therefore, the higher the retention rate, the higher the market share. Thus, as Grönroos (1994, 12) indicates, an effective way to monitor customer satisfaction is by regularly measuring the market share. Market research can determine the quality of satisfaction reflecting the levels of loyalty.

According to Homburg and Stock (2001a, 35) customer satisfaction can be influenced by the following business elements: product, sales force support, documentation, order transaction, service, communication, and management of claims/complaints. Galbreath and Rogers (1999, 164) indicate three areas to focus on to satisfy customers: customization, personal relationships, and after sales service/support. Apart from the product, the main actions remain on establishing a dialogue between the company and the customer: the communication and the communication channels.

1.3.2. Construction of the Traditional Marketing Mix Approach

Numerous authors such as Hansen and Bode (1999) and Bruhn and Bunge (1994) have discussed the modifications resulting from changes in the “marketing mix” approach created by Borden (1964), giving an additional support to the traditional 4 Ps developed by McCarthy (1960, 41-50). The four Ps forming the marketing mix are “Product”, “Price”, “Place” and “Promotion”. This is the basic model of marketing dominating all other models and approaches and representing the undisputable paradigm in academic research (Grönroos 1994, 4). Each component can be adjusted to the customer orientation.

1/ Product

Modern information technology allows companies to individualize their products and services according to the varying needs of their customers as noted by Pine (1993). The customer becomes a co-producer in the value generation process and customized elements in previously standardized products for mass markets are integrated. For

services, research has identified the decisive service quality element (Parasuraman et al. 1988). Argyris (1998) describes the importance of social aspects of service quality as well as the importance and difficulties of empowering service employees.

2/ Pricing

Pricing varies according to the level of novelty. For a “me-too product”, the room to maneuver pricing is quite narrow. It is also a function of the maturity level of the market, whether it is new, underdeveloped or mature. Hennig-Thurau and Hansen (2000) place the application of price differentiation strategies at the center of relationship-oriented pricing. There are two approaches considered in relationship marketing. One promises customers immediate benefits by offering discounts. But as Morgan et al. (2000) have shown, this might lead to a loyalty based solely on prices and not a true customer commitment. Another approach, studied by Diller (1997) is to identify various price functions within the customer’s decision process. This focuses of the relevance of pricing for customer satisfaction and trust. As shown by Prasad Mishra et al. (1998) a price premium can be associated to quality and counteract adverse selection and moral hazard problems due to products with experience attributes. However, their quality can only be ascertained after purchase.

3/ Place or distribution

The strategic principle and concept lying behind the place or distribution location is the customization of business relationships in order to get closer to the customer. The distribution can be individualized for example through customer clubs. Wehmeister (2000, 123) describes numerous points of contact: through a network (internet, email, kiosk system), through direct means (letter, fax, telephone), or through personal contact (sales representative, broker, structures, stores). The more personal the contact, the more binding this contact is for the customer. The public space is the point of contact supporting most of the advertising. Due to the need for individualized information, distribution systems are also becoming data collecting points of contact (Vavra 1992). The network communication is also very efficient and reliable as well as a central point of data collection. A new form of contact was introduced under the term “interactive marketing” by Hagel et al. (1997) aiming at reducing the number of

access points for the convenience of the customers in concordance with the extension of choices.

4/ Promotion

Interaction is introduced according to Duncan and Moriarty (1998) in the form of individual dialogues with customers through promotional activities. Communication (rather than persuasion) is the central element providing the bridge between customers and the company. According to Kitchen (1994, 20), the whole marketing mix has a role in communication, but "(…) *only promotion is charged with informing, reminding, persuading and inducing action in consumers so that behavior is directed favorably towards a marketer's offering*". For example, Boulding et al. (1994) have shown that messages sent to the customers can even have an impact on price differentiation. Schultz et al. (1993, 46) state that "*marketing in the 1990s is communication and communication is marketing. The two are inseparable*." This reflects perhaps an extreme view, but there is no doubt that communication stands in the forefront of customer relationship management.

1.3.3. Definition of the Predominant Role of Communication

Communication strategies have in fact two sides according to Graeff (1995, 28). One is the information received by consumers revealing their goals and their needs. This exchange is carried out through market research, whose task is to collect and analyze customer data. The other one are the messages and information sent by the company. The promotional objectives are first determined and lead to the development of a promotional strategy. This strategy is implemented through defined means and forms of communication whose effects are evaluated through controlling.

1.3.3.1. Broadening View of Communication and its Role in Establishing Relationships

Communication can be described as the "(…) *human act of transferring a message to others and making it understood in a meaningful way*" (Andersen 2001, 168).

As described by Rowley (2001, 203), marketing communication focuses on directing the right message to a target audience through a specific channel. As Pathak et al. (1992, 1) put it, "*the major objectives of any promotional program are to inform and*

to persuade", thereby influencing the customer's perception of the product or the company positively. In a broader description of the goals pursued by communication, Mohr and Nevin (1990, 36) state that communication serves to: transmit persuasive information; allow participative decision making; coordinate programs; exercise power; and encourage commitment and loyalty. Rowley (2001, 206) and Graeff (1995, 28) list the marketing objectives in the context of external communication: increasing sales; maintaining or improving market share; creating or improving brand recognition; creating a favorable climate for future sales; informing and educating the market; creating a competitive advantage, relative to competing products or market positions; and improving promotional efficiency thus persuading consumers to behave in desired ways. Public relations are also interrelated with the total communication strategy as described by Ranchhod et al. (2002, 7). It is about controlling the external aspect presented to the general audience (government, employees, opinion leaders, suppliers, consumers, customers, financial institutions, trade associations, business partners, media, and pressure groups). Moreover, communication has become knowledge-based (Radford and Goldstein 2002, 256).

Duncan and Moriarty (1998) argue that the new generation of marketing is best characterized, understood, and carried out with a communication-based model of relationship marketing. In this model, communication is not just about persuasion, but has a role in informing, listening and answering, requiring an interaction supported by a two-way communication. For Andersen (2001, 169), the concept of communication activities may play a decisive role in the relationship marketing process, thus in CRM. Swift (2001, 12) even defines CRM as "*an enterprise approach to understanding and influencing customer behavior through meaningful communications in order to improve customer acquisition, customer retention, customer loyalty, and customer profitability*".

Therefore, CRM communication includes traditional marketing promotion as well as all other contact activity with the customer such as loyalty programs and support systems. Kotler (1984, 28-30) describes corresponding gradual goals which are cognitive, action, behavior and value changes. Reichheld (2001, 81-82) agrees in the fact that two-way communication and learning promotes trust, resulting in customer loyalty. Hallowell (1996, 28) describes loyalty attitude as being the attachment to a

product, service or organization, whereas a loyalty behavior is the relationship continuance, and increased scale or scope of relationship, and recommendation.

It is also important to differentiate the various types of corporate communications. Van Riel (1995, 1-27) has exposed three types: management communication targeting internal and external groups; marketing communication involved in advertising and selling; and organizational communication such as internal media and public relations. Indeed, CRM involves communication not only between the company and its customers, but as well internal organizational communication (Xu et al. 2002, 446). The use of all three types of communications implies an integration which is then found in the application of CRM strategies due to their interdependency. According to arguments by Phelps et al. (1996), this integration requires a consensus decision-making approach for developing communication strategies.

1.3.3.2. Analysis of Parameters for a Communication Strategy

The first step to a communication strategy for a company is to understand its customers´ and stakeholders´ decision making process in order to position a product, a service, or an organization in the minds of customers and stakeholders through segmentation and the strategic and implementation choices (Proctor and Kitchen 2002, 152; Kroeber-Riel 1992, 378). In this light, the communication strategy takes into consideration the purchasing flow involving a cognitive, an affective and a behavioral stage.

Lavidge and Steiner (1961, 61) have describe a purchasing model moving from awareness, to knowledge, to liking, to preference, to conviction, to purchase. The behavioral dimension between awareness and knowledge is cognitive, requiring therefore a communication based on information and facts. The transfer between liking and preference is characterized by an affective stage, where a communication focusing on attitude and feelings is more appropriate. In order to turn a conviction into a purchase, communication can influence by inducing motives and desires. The purpose of Lavidge and Steiner's model is to determine how consumers use advertising in their purchase processes. These steps can be grouped in three general processes: gaining awareness and knowledge about the product; developing an attitude towards the product; and making the purchase decision. Whereas Kotler et al. (1994,

165) define the decision process in five phases: problem recognition, information search, alternative evaluation, decision and consequences.

These concepts are similar to the model described by Roger (1962) developed for innovations. But all of these models are based on and relate to the best-known communication model developed by Strong (1925, 9), the AIDA model:

3/ Attention: the customer must notice the communication.

4/ Interest: the consumer must be drawn to take in the communicated message.

5/ Desire: the consumer must want to acquire the product or service related to the communication.

6/ Action: the consumer must make the purchase.

According to Kitchen (1994, 23), the biggest challenge of communication is first to get the attention of the consumer.

The communication strategy model developed by Mohr and Nevin (1990) is based on the following four characteristics: the frequency, the direction, the modality and the content of the message.

1/ The frequency of the communication describes the amount and the duration of the messages.

2/ The direction of the message can be either horizontal or vertical indicating a hierarchy in the relationship with the customers. Communication is a constant activity and should target the customer at every stage of its relationship with the company. Therefore the communication strategy should be based on the evolving relationship with the customer. Andersen (2001, 172), describes three corresponding phases involving a pre-relationship phase, a negotiation phase and a relationship development phase. Specific measures are appropriate for the acquisition of a customer, but may not be optimal for retaining the same customer. The actions can be interpreted as product/service introduction through awareness for the acquisition stage, as reminder for the retention stage and as creation of identification or branding for the loyalty stage. All communication

measures should be carried out in parallel since all customers are not at the same stage of their development towards their relationship with the company.

3/ The modality is the mean by which the exchange is supported such as the traditional points of contact. In the last decade, the internet has been discovered as an efficient communication platform. First, as reported by *The Marketing Health Services* (1999, 30), new approaches and alternatives were developed. It allowed a global twenty-four hour reach, a high interactivity for one-to-one marketing, the use of multimedia, and the integration of marketing communication into business operations. It has also enabled opportunities for the communication strategies as it is effective for creating a brand, product and corporate awareness and image, providing information, and facilitating a dialogue with the customer by handling customer complaints, queries and suggestions, thus constituting an important support for CRM implementation. It also makes it possible to enhance success measurements (Rowley 2001, 210) by recording traffic, visit duration, sales on a systematic basis and repeat purchases. The internet has also been a support for the globalization of communication strategies (Rowley 2001, 204). Indeed, a communication strategy can be global, but therefore needs to be strategically integrated at the corporate and strategic business unit level (Kitchen and Eagle 2002, 182). But the same authors concede that sometimes the needs defined by the global corporate entity are not necessarily the needs actually identified in the specific marketplaces.

4/ The content of the communicated message depends on the corporate strategy and the level of CRM development. Two types of messages can be sent according to Schenk et al. (1990, 123): experience-related and information-oriented messages for new customers with experience knowledge but little product knowledge. These messages refer to the consumer's mental representations of communicated information as consumers understand and interpret information individually taking into consideration the comprehension process described by Graeff (1995, 31). Information-oriented messages are directed to consumers with product knowledge. Also, the communication of services differs from the communication for products and depends on the tangibility of the service, the link that the service will establish between the

supplier and the customer, the consistancy of the service and the specificity of the context (Hill and Gandhi 1992, 68-9). For example, Pieters et al. (2002) describe a model for highly competitive markets, where the communication strategy consists in increasing the message originality's or outspending the competition for more frequent messages.

Another variable related to the content of the message is branding. Branding can be related to many concepts according to several authors. De Chernatony and Dali'Olmo Riley (1997) for example outline a brand as: a legal instrument; a logo; a company; an identity system; an image; a personality; a relationship; an added value; an existing entity. Branding for Prasad Mishra et al. (1998, 277) is a bond serving a specific purpose for the end-consumers by providing evidence of commitment. A brand can be used to protect the investment, franchise and reputation of the product (Blackett 1992, 22) as it can be associated to quality and reliability providing buyers with choices (Blackett and Harrison 2001, 33). In fact, there is no doubt that branding can lead to a competitive advantage in general (Dichtl and Thiess 1989, 380; Wenzel 1986, 237).

Another approach is corporate branding allowing the company name to drive the brand. According to Stahl (1964, 9) and Proctor and Kitchen (2002, 45), it can help reduce the payout periods for new products and amortize costs throughout the company's whole portfolio. When a company has a strong recognition, it has a larger playing field for introducing new products as it uses its established identification to push successfully for a greater market share with a maximum return on investment. The better a company is perceived the higher its chances of getting a favorable first hearing for a new product among customer prospects and at getting an early adoption of that product (Levitt 1967, 17). Sometimes the overall corporate identity is more important than the single brands (PWC 1999, 23). Corporate branding is particularly adequate when the product has a short life expectancy and when the end-consumer has no influence on the product choice.

Communication strategies for innovations carry some particularities variable to the context. For example, Lee and O'Connor (2003) have studied the correlation between communication strategy and new product performance. The connection was made between the level and type of innovation with the communication strategy. It includes

pre-announcement messages aiming at customer education, anticipation setup and market preparation. It also includes the direction whether the messages are emotional or functional.

The investments in communication can be a function of the manufacturer's resources, thus manufacturer's size (Gatignon et al. 1990, 398) and the market's growth and size (Balasubramanian and Kumar 1990, 64).

1.3.3.3. Understanding the Customer: Market Research and Analysis Framework

One perspective offered by Hamilton (2001, T4) interprets CRM as: "*the process of storing and analyzing the vast amount of data produced by sales calls, customer service centers and actual purchases, supposedly yielding greater insight into customer behavior*". The knowledge of the customer is central to the success of CRM since it is about orienting the interaction means to fulfill the customer's expectations. But to do so, the company has to first define those expectations by developing a deep understanding of customers and markets: what they value, what types of services are important to them, how and when they like to interact, what they want to buy, and how much they want to invest. For example Hofstede (1999), has offered a methodology to estimate the consumer-product ties to focus new product development and communication strategies. Market research's goal is to develop general principles and concepts based on empirical data (Greenberg 1967, 50). It differs from the physical sciences by the fact that it is subject to human perceptions and interaction, time and conditions in which data was collected.

Market research is particularly important for innovations as demand is high for strategic innovation market research to support future-oriented basic decisions with information (Radford and Goldstein 2002, 255). Even if measuring quantitatively, mid-term prognosis of complex systems are almost impossible, the innovator must be sensitive to long-term and short-term impacts.

Primary research is conducted to capture needs, attitudes, and satisfaction levels. There are many ways of collecting the data needed for market research analyses. Activities can include interviews, group discussions, surveys but also automatic data collection systems retrieved from customer service for example. Based on Homburg

and Sieben (2000, 8), the data needed in order to understand the customer revolves around the customer's profile, buying interactions, service interactions and contacts. This external data is then associated to internal data reflecting the resources tied to establishing and maintaining a relationship with the customer, the stability of the relationship and the customer's profitability (Mitchell 2003, 228).

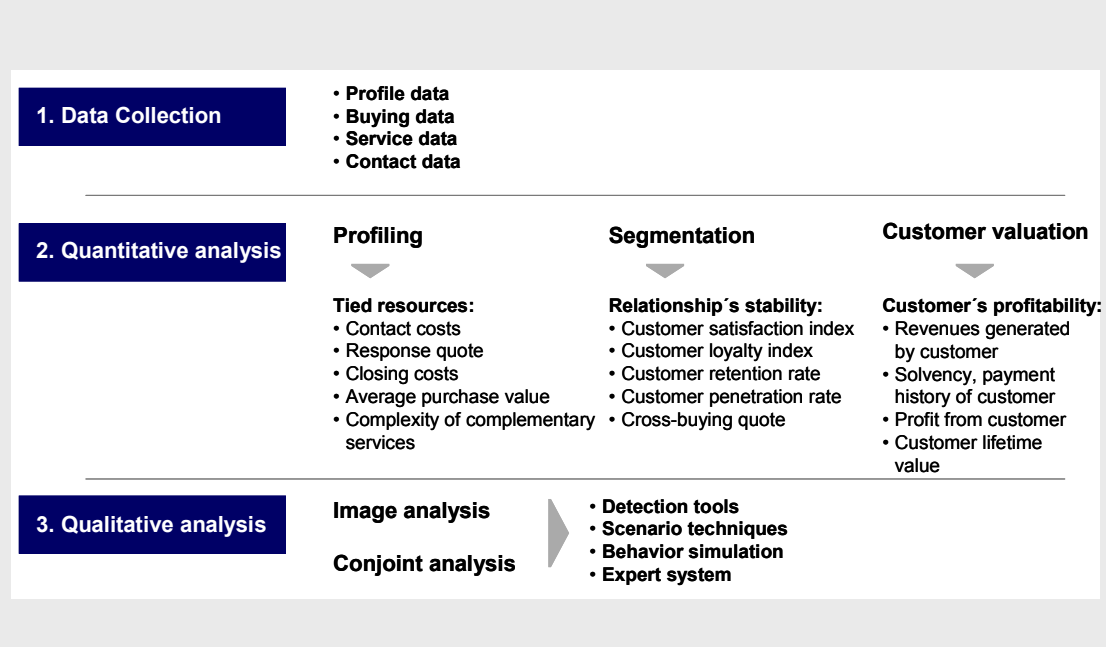

Figure 1.6. Overview of market research and analysis construct based on Homburg and Sieben (2000, 8), Suresh (2002, 4), Mitchell (2003, 228), Montgomery et al. (1989, 193) and Wittink et al. (1994, 42).

As described by Suresh (2002, 4), the quantitative approaches include customer profiling, segmentation, and customer valuation.

1/ Profiling customers helps understanding demographics, purchase patterns and channel preferences. Loyalty profiles vary from company to company, but each industry has an average behavior pattern that influences the customers' loyalty. Customers may have very different requirements depending on the industry. According to Coyles and Gokey (2002), these patterns are generally determined by five structural factors: how often purchases are made; the frequency of other types of interactions, such as service calls; the emotional or financial importance of a purchase; the degree of differentiation among competitors' offering; and the ease of switching. First, profiling produces new insights. Second, it highlights the different tactics required to manage each of the segments and a company's

need to carry out a range of actions to reach all of them. Third, when combined with standard customer-value analysis, the profile helps a company base its loyalty-building priorities on the size of each opportunity and maintain the control over the tied-up resources.

2/ Segmentation such as hyper-segmentation is behavior-based. It identifies logical unique groups of customers that tend to look alike and behave in a similar fashion. One-to-one marketing, through the determination of service types and grading within the segments translates the value to the clients in monetary value and the level of service to deliver. The stability of the relationship can therefore be directed and sustained.

3/ Customer valuation such as lifetime value, or long-term potential helps understanding profitability. Value may also be based on the customer's ability or inclination to refer other profitable customers.

Low and Mohr (2001, 83) argue that the use of the data collected depends on the information type and the decision context. New analyses such as image analyses and conjoint analyses are increasingly used in order to determine the customer needs and behavior. As described by Wittink et al. (1994, 45), the conjoint analysis is a multivariable process to quantify the benefit structure of the target customer. For innovations with medium to high novelty degree, the conjoint analysis offers recommendations on product characteristics and pricing. Other qualitative approaches reflect the complex interactivity and can help recognizing the obvious with a certain precision. Methodical support enhances the strategy content research (Montgomery et al. 1989, 193) by delivering means such as strategic early detection tools, scenario techniques, future simulations of the target customer's behavior and expert systems.

Moreover, Law et al. (2003) stress the fact that companies need to perform continuous reviews with customers in order to detect any changes or further improvement.

1.3.3.4. Elaboration of Activities Supporting Communication Campaigns

The promotional activities include the "push" activities such as advertising and direct marketing, as well as "pull" activities such as support initiatives and loyalty programs.

Customer relationship promotional activities include the activities of the marketing promotional mix described by Kotler (1997, 605) and Wehrmeister (2001, 133) using the common communication platforms of advertising, sales promotion, public relations, personal selling and direct marketing.

Advertising	Sales Promotion	Public Relations	Personal Selling	Direct Marketing
• Internet, print and broadcast ads • Packaging – outer • Packaging inserts • Motion pictures • Brochures and booklets • Posters and leaflets • Directories • Reprints of ads • Billboards • Display signs • Point-of-purchase displays • Audio-visual material • Symbols and logos • Videotapes	• Contests, games, sweepstakes, lotteries • Premium and gifts • Sampling • Fairs and trade shows • Exhibits • Demonstrations • Coupons • Rebates • Low-interest financing • Entertainment • Trade-in allowances • Continuity programs • Tie-ins	• Press kits • Speeches • Seminars • Annual reports • Charitable donations • Sponsorships • Publications • Community relations • Lobbying • Identity media • Company media • Company magazine • Events • Educational information • External links	• Sales presentations • Sales meetings • Incentive programs • Samples • Fairs and trade shows	• Catalogs • Mailings • Telemarketing • Electronic shopping • TV shopping • Fax mail • E-mail • Voice mail

Table 1.2. Common communication platforms (Kotler 1997, 605; Wehrmeister 2001, 133).

All these activities are applied at different levels during the product-client relationship evolution. For example, the usage of print and electronic sources are dependant of the complexity of decisions in maling information available (Rowley 2001, 211). The different stages can be differentiated between pre-launch (targeting suspects), acquisition (targeting first-time customers), retention (targeting repeat customers), loyalty (targeting loyal customers, advocates and partners) and recovery (targeting ex-customers).

Advertising is important all along but especially for the acquisition of new customers. It also includes labeling and packaging related to the product's correct use. Drake (2002) has points out the human factors to consider ensuring optimal communication reach. Sales promotions will incite customers to repeat their experience with the product if they were satisfied the first time. Direct marketing acts on all levels facilitating the interaction.

These one-way oriented communications can support the development of an attractive personality profile for the product, service, and supplier. This has been the most significant development related to relationship marketing as it is supported by advances in segmentation (through the availability of census) and databases (Evans 1998, 9).

A stronger bound can be developed through personal selling (Webster 1968, 13). It can influence positively on the loyalty profile as there is no substitute for one-on-one communication affecting positively the perception of the organization and reinforcing the lifetime relationship (*Marketing Health Services* 1999, 26). Public relations are particularly crucial in the pre-launch phase, and continuous activities are beneficial for boosting customer's loyalty.

The more the relationship strategy evolves, the more the company needs to offer and manage service elements of its market offer since they become increasingly the competitive ground (Grönroos 1994, 13). A study by Treacy and Wiersema (1995) concludes that the enhancement of core product features by an appropriate level of support is key to achieve an intimate relationship with the customer. Support activities such as contact centers, field services, web service, front-line service delivery, technical support & service, recovery activities, hotlines, or new service offerings, provide information and address service failures. These can be considered as complementary services composing the relational aspect of the product. Herewith, satisfaction can be boosted and a dialogue can be encouraged. The company can support the customer in using its products appropriately and in turn, receive direct feedback.

Loyalty programs have been discussed and recognized in the scientific analysis of management and economics (see Borenstein 1996 and Kim et al. 2001). They are also referred to as reward programs and are directly associated to the repeat purchase (Kim et al. 2001, 100). There are two types of loyalty programs: one giving immediate benefits or privileges and one turning the product into a user-friendly commodity. The type of program applied depends on the size and the relative price sensitivity of the targeted heavy-user segment.

The first type of loyalty program includes financial, material and social benefits. Financial benefits can take the form of frequency programs, club programs, and rebate systems. Material benefits include newsletters, insider's tips, and gifts. Social benefits can be privileges, customer networks, and an individualized contact between the customer and the company's personnel.

The second type of loyalty program increases the ease of customer use, and lets switching appear to be more inconvenient or costly, therefore weakening price competition as shown by Kim et al. (2001, 113). The measures include automated key interactions, such as bill payments and subscription renewals, storing information needed repeatedly (for instance, addresses or credit card numbers) as many online stores do, offering bundled services, and supplying the customer with equipment and tools facilitating the product use such as software or ordering processes. Building loyalty isn't just about preventing defections and encouraging extra spending. It is about understanding and managing all customers with the goal to build emotional ties (Allen and Meyer 1990, 15).

All these communication actions are comprehensively planned providing understandable and flexible messages without saturating the target (Stainer and Stainer 1997, 73).

1.3.3.5. Explicit Implication of Information Technology as Enabling Tool

The first generation of CRM IT solutions appeared in the 1980s and early 1990s. They were concentrated on automation and internal process standardization. In the mid-1990s, the web came into play and allowed a more intense interaction between the customer and the company (Xu et al. 2002, 444). The ultimate stage of these tools is the integration of supply chain management, by combining these last developed solutions with enterprise resource planning (ERP) systems (Ebner et al. 2002, 51).

Traditional transactional marketing does not require information technologies extensively due to the absence of need to distinguish, differentiate, interact, and customize. Although some argue that IT has a small role in CRM, all key CRM tasks depend on information technologies and systems. CRM is system-oriented, and so is relationship marketing (Grönroos 1994, 13).

Marketing, sales, media, distribution, shipping, and customer service departments are affected by the technology application of CRM. Usually CRM is described as being composed of three technology segments described by Wardley and Shiang (2000) focusing on the front-line of CRM (sales, marketing and external communications):

- dialogue systems;
- marketing automation;
- and sales automation.

According to Werhmeister (2001, 148), there is a fourth segment supporting the CRM activities and insuring the information flow within the company: internal support systems.

1/ Description of dialogue systems for customer interaction

Dialogue systems enable the interaction with the customer. These can include personal or digital points of contact:

- **Experiential marketing** represents concrete situations where there is a direct contact between the consumer and product.
- **Help desk management** solves problems based on actual knowledge. It allows following the problem through up to monitoring results and developing solutions.
- **Call centers** automate inbound and outbound calls connecting corporation and customers. Automated telephone systems are used. This is particularly relevant for high traffic such as for banking and administrationwith. Due to emerging technologies, more interaction is integrated such as global telephone-based call centers and the internet.
- **Communication by e-mail** includes outgoing and incoming communication. Outgoing e-mail provides available, targeted, useful and unobtrusive information to clients. Incoming e-mail is at the initiation of the customer. E-mail queries, complaints, or compliments can be used as an opportunity to cross-sell, up-sell, or ask for more information to build the customer’s profile.

- **Virtual communities** of common interests such as platforms for information networking are places where information is seeked, ideas echanged, opinions shared and buying decisions influenced.

- **Collaborative filtering software** automatically gathers the opinions of like-minded users and provides useful individual recommendations right away, therefore increasing cross-selling opportunities. These can also be defined as agents.

- **Individualized web portals** and **wireless data services** are applications where customers can create personalized web pages based on a standard web page with a company's or client's name on it. Each customer edits and selects their features, thus providing customer-specific information. Customized information is transposed to cell phone, pagers, PDAs, etc. Cookies support these individualize services as they register the users´ configurations.

- **Web page format** (HTML) can have designated places for the user to type information. This can be used for purposes such as site registration and survey research.

2/ Determination of marketing automation supporting customer analysis

Marketing automation is composed of tools to manage, analyze and process customer information to adapt the current services and products according to the target group's features and requirements (Suresh 2002, 7-8

- **Electronic point of sale** (EPOS) and **retail scanner systems** allow collecting buying data such as sales, price, margin, transactions but also more specific data on the customers (social characteristics and habits).

- **Website logs** keep track of the internet page's visit (pages, duration, sales result). Customization results on the customer knowledge acquired through this tool.

- **Real-time profiling** tracks the click stream immediately. It supports the online behavior investigation and allows momentarily adaptation for internet promotion and internet presentation.

- **Data warehousing** stores information and makes it organization-wide available. It comprises transaction records and external market information sorted out by subject.

- **Data mining** permits the analysis of extensive data for the identification of patterns in customer behavior to respond appropriately.

- **Online Analytical Processing** (OLAP) or multi-dimensional data analysis, allows the retrieval and analysis of the data warehouse. It is particularly appropriate for secondary analyses and monitoring models.

- **Web-based decision support and reporting tools** for communicating the results of analyses to the whole organization as individual messages

3/ Sales automation for efficient sales forces

Sales automation software is designed to manage the entire spectrum of the sales function, encompassing account, contact and list management. It helps in automating and optimizing sales processes by shortening the sales cycle and increasing sales productivity. It enables the company to track and manage all qualified leads, contacts and opportunities throughout the sales cycle including customer support. It improves the effectiveness of marketing communication programs for generating quality leads as well as greater accuracy in sales forecasting. The internet can be used by the company in imparting proper training to its sales forces. In depth product information, specialized databases of solutions, sales force support queries, and a set of internal information on the internet can improve the productivity of the sales force (Fetterman 2002, 2).

It can be supported by field service management applications used to allocate, schedule, and dispatch the right people, with the right parts, at the right time, log materials, expenses, and time associated with service orders, view customer history, or search for proven solutions.

4/ Internal support systems insuring a complete internal integration

Support systems back the company's internal business. These are management information systems, call management systems, controlling systems, computer

telephony integration, capacity planning tools, purchasing management, and telephone systems (ACD, IVR, Voicebox, etc.). Programs such as XML-based CPExchange facilitate the exchange of customer information across units within the company (Cheng 2001, 3).

1.3.4. Measurements Necessary to Monitor and Control the Implementation of a CRM Initiative

Controlling the CRM implementation, as any marketing and communication audit, is necessary to follow the progress and the adaptation of the strategies to the customer. According to Stone (1995) and Stewart and Pavlou (2002), this monitoring provides the constant measurements of results, the identification of priorities, the adaptation requirements to the structural context and goal, and reveals internal issues relevant with the increasingly interactive new media. A constant measure of the CRM benefits can provide such information. Although some authors such as Hayman and Schultz (1999) concede that measuring a return on investment (ROI) in marketing is very difficult to master, they propose another approach measuring the return on customer investment (ROCI). This approach allows taking into consideration an integrated communication strategy by considering total financial timeframes and more realistic means for measuring CRM returns.

Wehrmeister (2001, 151) has exposed a comprehensive controlling structure for monitoring the CRM benefits by measuring the direct impact of the CRM implementation. The point of contact quality, process quality, customer cost, customer satisfaction, customer loyalty, customer return (lifetime value) and sales success are the immediate, quantifiable effects of the actions taken in order to build and care for the interaction between company and customer.

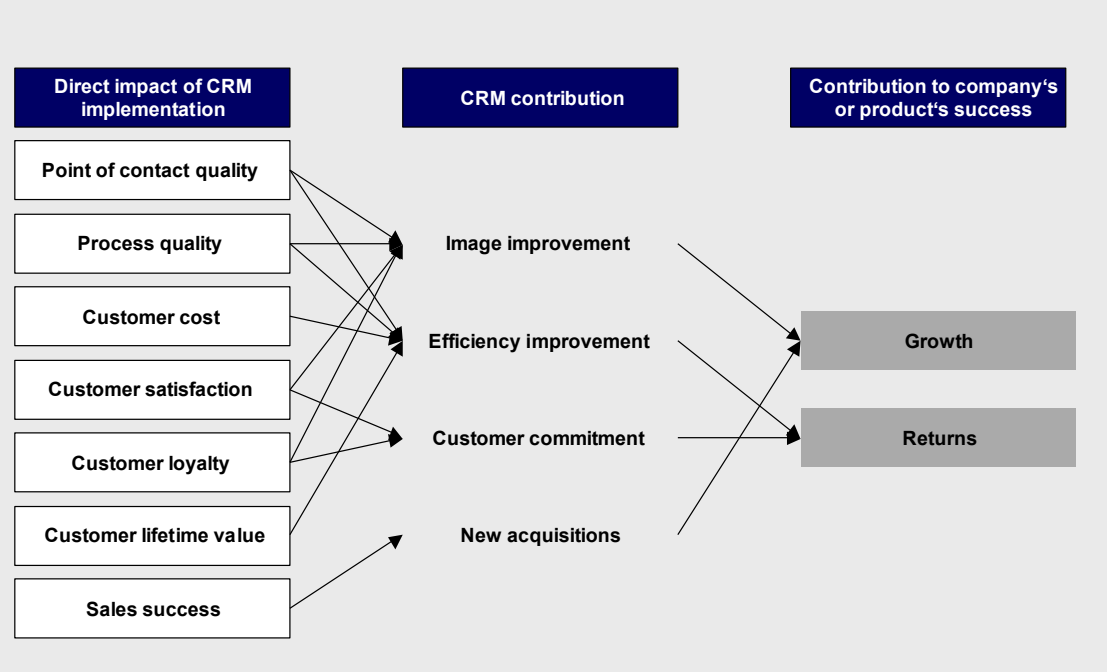

Figure 1.7. Controlling of CRM benefits by Wehrmeister (2001, 151).

These elements can then be transformed into direct CRM benefits.

- The image improvement results from the point of contact quality, process quality, customer satisfaction and customer loyalty.
- The efficiency improvement is a combination of the point of contact quality, process quality, customer cost and customer return.
- The customer commitment is measurable through customer satisfaction and customer loyalty.
- The new acquisitions are directly related to the sales success.

The CRM benefits can be directly associated to the company's or product's success considering that image improvement and new acquisitions have a positive effect on the company's growth, and the efficiency and customer commitment influences the increase of returns. Reinartz et al. (2003) have shown that a CRM implementation has a positive impact on a firm's market performance which in turn, is associated with better economic performance.

1.3.5. Evolution of a CRM Business Process

A properly implemented CRM allows a company to gather customer data swiftly, identify the most valuable customers over time, and increase customer loyalty by providing customized products and services. Wehrmeister (2001, 61) finds that it also reduces the costs of serving these customers and facilitates the acquisition of similar customers.

The communication activities should be constantly carried out adapting to the changing structural guidelines. Communication supports the CRM goals. Table 1.3., based on findings of CGEY and INSEAD (2002), Berthon et al. (1999) and Gray and Byun (2001), describes the CRM structural evolution according to three CRM strategic maturity stages related to the clients' development. This evolution corresponds as well to the characteristics of marketing shareholder value delivery described by Gerecke (2001, 237).

1/ The first task of CRM is to identify its customers and implement a process which will collect the necessary information efficiently. The goal is to achieve operational effectiveness. To serve or provide value to the customer, the company must know and identify the customer through marketing channels, transactions, and interactions over time.

2/ The second task consists of data analysis and segmenting the customers to develop targeted communication measures. The differentiation of customers is based on the fact that each customer has its own lifetime value from the company's point of view and each customer imposes unique demands and requirements to the company.

3/ The third task involves developing a direct relationship with the customer establishing a dialogue beneficial to all parties. This interaction is characterized by a collaborative relationship between the customer and the company adapting to changes in customer demand over time. From a CRM perspective, the customer's long-term profitability and relationship to the company is essential. Therefore, the company needs to learn continously about the customer. Keeping track of customer needs and behavior is an important task of a CRM program.

Additionally, an ongoing update of data collection and analysis can guide an ongoing improvement and a deepened customization. It is an ongoing improvement to "treat each customer uniquely". This will ensure adaptations to changes occurring on the market. And through the personalization process, the company can increase customer loyalty.

	Identification: building operational effectiveness	Differentiation: analytical insight	Interaction: collaborative relationship	Customization: ongoing improvement
Goal focus	• Basic customer knowledge • Single customer view	• Deep and individualized customer understanding	• Cost effective multi-customer dialog	• Customer satisfaction and loyalty
Benefit	• Cross-selling	• Cost effective marketing campaign	• Cost effective customer service	• Lower cost of acquisition and retention • Maximize share of wallet
Organization	• Adjust organizational layers to productivity levels • Install segment focus in selected functions (e.g. sales)	• Install segment focus in marketing and customer service • Set up single-point CRM accountability and capability development	• Establish codified, cross-functional processes • Reinforce cross-functional teams (e.g. sales, product launch, etc.)	• Stand ready to manage change and adapt to new parameters • Employee involvement and training on customer management skills
Channels	• Increase sales, marketing and customer service efficiency • Pilot new channels in selected business areas	• Define key customer groups and segments • Roll out new channels organization wide	• Establish fully integrated, dynamic channel mixes for all key customer groups and segments	• Seek out new channels
Analytics	• Produce data strategy and set of robust, clean data for customer	• Produce data strategy and set of robust, and clean data for all players (customers, suppliers, distributors, ...)	• Drive use of segmentation models across business units and functions • Produce segmentation models incorporating interaction between all players	• Constant update of collected data and appropriate adjustments
IT	• Marketing automation • Dialogue systems	• Marketing automation • Dialogue systems • Corporate support systems	• Marketing automation • Dialogue systems • Corporate support systems • Sales automation	• Sales automations • Marketing automation • Integration in Enterprise Resource Planning (ERP)

Table 1.3. Stages of CRM evolution with structural guidelines (CGEY and INSEAD 2002; Berthon et al. 1999; Gray and Byun 2001).

All of the above can not be pursued all at once. A company has to start with data collection and subsequently work its way through the process. The speed at which the CRM evolution proceeds is different for every company. It depends on the company's capacities, and on the complexity and support of the industry.

Other issues remain regarding the implementation of CRM, requiring further development such as customer privacy and technology maturity. The personalization process in CRM involves the collection of demographic and behavioral data from each single customer. However, this information is what most customers consider personal and private. There are major customer concerns, legal regulations and global public policies. The borders of customer privacy remain blurry.

Most of the CRM technologies are immature and implementation costs are high. A CRM solution can be expensive (€100 000 million) and time consuming (up to three years). Since the users see the returns only on a long-term basis, it can be a source of frustration. In addition, there are little standardized technologies and protocols for CRM implementation in the market. The industry of CRM technical solution suppliers is experiencing a period of consolidation hampering stable technical support.

According to Rigby et al. (2002) and Gray and Byun (2001), the CRM success factors can be clustered in four areas:

- building relationship with the right customer implying the knowledge about the real targeted customer (definition, requirements and lifetime value);
- creating a customer strategy before implementing a CRM strategy;
- changing the organization before implementing CRM;
- and using appropriate technology suited to the company's CRM requirements.

In summary, personalization, loyalty, and lifetime value are the main principles of a CRM implementation. However, another dimension is added by Galbreath and Rogers (1999, 162): "*CRM facilitates relationships among enterprises, their customers, business partners, suppliers and employees*". This implies that CRM should be coherent and consistent by taking into consideration all players.

2 An Analysis of the Current Pharmaceutical Environment

2.1. Description of the pharmaceutical markets focusing on the United States and Europe

In 2002, the global pharmaceutical market was worth €510 billion. The United States led the pharmaceutical market growth between 1998 and 2002 with 70 percent, whereas the growth of the European pharmaceutical markets during the same period varied between 25 and 48 percent. In 2002, the U.S. market was dominating, representing 51 percent of worldwide drug revenues, followed by Europe with 22 percent and Japan with 12 percent (VFA 2003, 55-56; IMS 2003, 1).

In Korea, Thailand and Indonesia, the revenues sank by more than 10 percent in 1998, and are still recovering today. However, the historically unattractive Asian markets have a promising growth perspective within the next ten years, especially the Chinese market, due to its population and its strong growth in 2002 with a volume of €7.4 billion. Even if the pharmaceutical emerging nations are developing positively, the North American, European and Japanese markets remain the largest, representing three-fourth of the pharmaceutical market for the next 10 years. The worldwide growth between 2002 and 2007 is expected to reach 9.3 percent (Pajot 2003, 14).

Total expenditures on pharmaceuticals represent between 0.7 and 2.2 percent of GDP across all OECD countries, with an average of about 2.1 percent (Gambardella et al. 2000, 11). Pharmaceutical expenditures are higher in the United States and Japan than in Europe (VFA 2003, 57). The driving forces of the expenditures are: an aging population being more dependent on multiple medications for treatment; the introduction of new drug therapies for conditions that had less effective previous treatments; higher third-party drug coverage; the substitution of higher-priced new drugs for lower-priced existing drugs or other forms of healthcare; more attention to prevention and improved diagnosis; an increasing number of patients diagnosed with conditions for which new pharmaceutical treatments are available; and the more aggressive marketing by manufacturers through direct-to-consumer advertising (GAO 2000, 2; GOA 2002, 9; PhRMA 2002, 8; KFF 2003, 2; Busse et al. 2003, 18).

2.1.1. Characteristics of the U.S. Pharmaceutical Market

The important annual growth rates of the U.S. pharmaceutical market has been driven by the growth of the internal market and by the control of a larger share of the European market. The 14 percent annual growth of the American drug market results from the demand of patent-protected compounds. In comparison to Europe, innovative medicines are considerably more common. A positive development of this tendency is foreseen until at least 2010. The American pharmaceutical market has been booming in the past 5 years due to substantial successful market entries. The use of prescription drugs by Medicare and Medicaid patients has also boosted demand. A particularity of the U.S. market is the volume and quality increase of prescription drugs. U.S. exports are directed in a much larger proportion towards developed markets and the share of pharmaceutical value added in total manufacturing has increased from 2.3 to 3.4 percent in the last decade (VFA 2003, 55-6).

The United States support larger-sized pharmaceutical firms due to the 1962 Amendments to the "Food, Drug, and Comestic Act" from the FDA, while smaller firms have suffered reductions in research productivity (Lacy Glenn 1990, 501). American pharmaceutical companies focus on core competencies and are today called "life science companies". Supported by high revenues, they are leaders in the development and commercialization of innovative therapy approaches. The relative position of the United States as a locus of innovation has increased over the past decade. The share, in terms of sales of New Chemical Entities (NCEs) launched by U.S. corporations over the total sales generated by the top 50 NCEs on the market, rose dramatically in the 1990s to reach almost 70 percent. In 1999, more than 80 percent of the total sales of the world's top 15 drugs were originated by U.S. companies (IMS 2000, 1). This trend is also characteristic of the upcoming years: the American leadership seems to derive from the presence of a larger number of innovative companies mainly due to better in-house capabilities (with a greater reliance on licenses), and more effective use of the market for technology.

Beside the high "innovation will", the liberal conditions favor growth. Direct sales, as well as direct promotion, support the use of prescription drugs. The majority of drugs are distributed from wholesalers to retail dealers. Unlike in Europe, independent pharmacies distribute only 19 percent of drugs. The end-consumer brings 30 percent

of all prescription receipts to drug store chains. Distance selling accounts for 8 percent of prescription compounds' sales (PhRMA 2001, 53). Although a significant number of prescription drugs have lost, or will lose in the next 5 years their patent protection, the future is promising. And the consumption of medical drugs is increasing mainly due to the demographical evolution. In addition, certain Health Maintenance Organizations (HMOs) and various Managed Care Organizations have accepted that they could prevent or reduce costs of stationary care by encouraging innovative treatments (Lichtenberg 2001, 248).

Price competition is very strong in this liberal environment. However, due to pressure applied by the HMOs' Pharmaceutical Benefit Managers (PMB) on the reduction of drug prices, prices have remained fairly stable since the mid-1990s.

The share of pharmaceutical employment in total manufacturing in the United States has increased from 0.94 percent in 1985 to 1.3 percent in 1997. U.S. employment in the pharmaceutical industry represents half of Europe's (Gambardella et al. 2000, 15).

The U.S. pharmaceutical market is characterized by an uptake of new products relying on price premium and marketing access; generics and therapeutic substitution; an expansion of access and usage; consumerism; and an emerging parallel trade (Pajot 2003, 16). It is foreseen that the United States represent the market of the future by staying the growth motor of the world's pharmaceutical market for the next 10 years. The gap with Europe and Japan will seem to widen continuously.

2.1.2. Characteristics of the European Pharmaceutical Market

Europe's pharmaceutical market share represented 27 percent of the total world market for ethical pharmaceuticals in 2003 (Pajot 2003, 14). The pharmaceutical industry is the fifth largest industrial sector in the European Union (E.U.) amounting to 3.5 percent of the total manufacturing production.

Since the 1990s, significant differences and increasing divergences across European countries are observed. There are a number of reasons for these unequal developments. First of all, Europe is composed of countries with different health care systems, and different laws for controlling pharmaceutical production, logistic, distribution and sales. Various socio-political influences, the diversity of languages

and cultural habits also lead to an additional segmentation of the market. These significant variations can be sectioned in the level of consumption, pricing and growth outlook (Kucher 2000, 4).

1/ **Level of consumption**: Germany and France represent half of the European market. Together with Italy and the United Kingdom, they represent 75 percent of the European market (VFA 2003, 57). The extremes in relation to the gross domestic product (GDP) are the over-average consumption in France and the under-average use in the United Kingdom, Portugal, Greece and Italy. The high French expenses can be related to history. Until the mid-1990s, the French health care system had reimbursed all drug expenses. Despite more extensive exception rules, which were introduced in the last 5 years, the majority of expenditures are still being reimbursed (Kucher 2000, 3-4). Switzerland and Sweden invest an over-average share of their GDP in the purchase of medication. Together with the Netherlands, Belgium, Austria and Luxemburg, Germany have average drug consumption.

   There is an intensified cost-containment policy in Europe and the pharmaceutical industry is a target for savings. This leads to an active encouragement of generics and a slow uptake of products even though there is a growing consumerism (Pajot 2003, 18).

2/ **Pricing**: the medical drug prices differ due to the different approaches used by the E.U. member states for regulating pharmaceutical prices (Mrazek and Mossialos 2004, 114). The cheapest medicines are found in the poorer countries such as Portugal and Greece. The prices in the Netherlands, Denmark, Ireland, the United Kingdom and Belgium are the highest. This has result in increasing re-imports within the European Union since 1995. The size of these re-imports is estimated to reach several hundred of millions of Euros (Kotzian 2002, 9-10).

3/ **Growth**: between 1995 and 2000, the total pharmaceutical spending as a percentage of total health expenditure increased in the E.U. member states (Mossialos et al. 2004, 3). The French industry shows a steady and considerable growth and the pharmaceutical industry in Sweden, Ireland, the Netherlands and Denmark is booming. However, Italy declined significantly in the early 1990s

and Germany has been slowing down in the past five years (VFA 2003, 64). As a whole, the 10 largest European pharmaceutical companies have increased their yearly revenues by 5 percent. Medium enterprises were able to establish themselves in the market next to the big companies due to the willingness of an important amount of the population's revenues invested in health care. And there is the presence of a relatively large amount of companies that are specialized in low value added activities, like manufacturing and commercialization of products licensed from other companies, or simply using medical-like substances or low amounts of medical substance. European regulated and fragmented environments allow for the survival of these businesses (BPI 2000, 39). All European companies appearing in the top 10 ranking in 1999 have had to go through significant mergers or acquisitions to maintain their competitive position. The strategic corporate decisions are often unfocused and do not concentrate on core competencies. An example is the large chemical conglomerates regrouping everything from polymers to pesticides. These companies have had difficulties adapting to their diversified and changing markets. The ten biggest European pharmaceutical companies only reach half of their revenues with the sales of pharmaceutical products. As specialization continues imposing itself, the companies will increasingly have to refocus.

The share of pharmaceutical value added in total manufacturing has increased between 1985 and 1997 from 2.2 to 3.4 percent. Germany, the UK, France, Italy and especially Switzerland are the main producers. The European Union is a net exporter of pharmaceutical products and has been so for the last ten years (Gambardella 2000, 15).

However, the pharmaceutical business growth relies on its innovative capacities. In 1995, Europe ranked second in Research and Development (R&D) spending after the United States and is followed by Japan. But since success always starts in the local market, the increasing cost amortization measures are repressing innovations. Twenty years ago, the European pharmaceutical industry was the hub of innovative drugs. Today, the management of innovation is developed rudimentarily even though it is still producing 40 percent of the worldwide medical drugs. Due to increasing state interferences, the pressure on the European Community leads to a national

presentation of a whole-European base. This results in a flattening of the pharmaceutical market dynamics. Thus, Europe is losing its attractiveness for the positioning of innovative drugs. And even European companies invent in the United States when they do not invent in their home countries, particularly the German, Swiss, British and French companies. Europe is characterized by a majority of low R&D intensive, local, small pharmaceutical companies operating in protected domestic markets. These are poor innovators (European Commission 2002, 6).

2.1.3. Discrepancies Highlighted Between the Studied Markets

The main differences between the Unites States and Europe are reflected in the growth of the pharmaceutical industry. The European industry grew faster than the United States and Japan in the 1980s. In the 1990s, it then grew less than the U.S. industry. The U.S. pharmaceutical market had a growth roughly equal to the European's at the beginning of the 1990s, whereas it is twice as much today. This is due to the deceleration of growth in Europe and an acceleration of the U.S. industry growth.

As a whole the United States are more attractive for R&D investment than Europe due to the economic and health care environment, the science base, the investment conditions, the regulatory framework, and societal attitudes towards new technologies (Van Arnum 2002).

The industry in Europe invests less in R&D than the United States. In 1998, the United States and Europe were both spending around €20.5 billion on R&D. In 2001, while Europe's R&D expenditures remained constant, the U.S. R&D expenditures jumped to €27.7 billion (VFA 2003, 62). And the industry growth in the United States mainly stems from the growth of its non-labor inputs which include specific investments in R&D. In Europe, the growth of the industry is likely to depend on factors other than R&D, capital or labor: the growth in capital translates less obviously into sales growth due to the effects of regulatory regimes on industry structure, with the larger presence of firms and activities less dependent on internal R&D and innovation, and more dependent on external inputs, such as international licenses, pricing policies, peculiarities of the public regulatory and health care systems or demands in individual European countries.

U.S. organizations base their R&D on innovations which are cost extensive to bring to market. They have substantially devanced their European counterparts in the sales of major innovative products based on New Chemical Entities (NCEs) in the last decade. Companies based in the United States are responsible for almost 50 percent of the global drug development (Schweitzer 1997, 28). However, the number of top selling NCEs developed by companies of either region does not differ significantly. This would suggest that the European multinationals are facing a comparative disadvantage in selling their new drugs. This is reflected in the fact that the top five European countries (France, the United Kingdom, Germany, Italy, and Spain) represented 12 percent of blockbuster sales worldwide, whereas the United States reached 72 percent of these sales in 2002 (Pajot 2003, 26).

The U.S. has become the pharmaceutical innovation leader Van Arnum (2002) reports. Unlike Europe, they have encouraged research in the life sciences and pursued vertical integration of the drug development processes resulting in specialized research companies and suppliers. The balance between the different players is based on partnerships and exchange of resources. Innovation opportunities are investigated and aimed at the production of an end-product which has a determined market. They have been capable of developing new tools for for drug discovery and testing (combinatorial chemistry techniques, genomics, high-throughput screening, etc.) that can strongly increase the efficiency of the research process

Facing the availability of resources offered in the U.S., Europe has taken avantage of them without developing the local research opportunities. This explains the lack of technology and innovation specialists on the old continent.

The United States have recently faced a restructuring of their pharmaceutical and health care systems resulting in demand growth. The percentage of U.S. sales of pharmaceuticals is dominant which has been an avantage for the U.S. based pharmaceutical companies as they could primarily target their own local market. The sales are also due to the research and production efficiency. The cost and the amount of human resources due to lower value added activities such as routine testing are higher in the European pharmaceutical industry bringing the production costs up.

In some European countries insufficient market-based competition is observed. The market players are therefore encouraging inefficient positions within the industry. This is depictured by the fact that in countries relying on administered prices, the prices and market shares do not vary substantially after a patent expires, whereas in competitive drug markets, when a patent expires, generally prices drop due to the entry of generics leading to a significant market share turnover. Although Europe aims at the general usage of innovative drugs, the U.S. price competition stays stronger.

Due to the preponderance of the American market, large pharmaceutical companies must be present in the American market in order to reach a continuous growth (Javalgi and Wright 2003, 284). It has been shown that products launched first in the United States penetrate the global market better and that blockbusters launched first in the United States achieve twice the sales (Pajot 2003, 24). However, it is increasingly difficult for European companies to master perfectly the rules of the U.S. market and to take into consideration the important market penetration costs. It is almost impossible for less important companies, which have not had the experience in Europe of free-pricing, liberal sales and marketing opportunities, to be competitive on the American market without any local support. It will be even more complicated for European companies to develop a U.S. pillar due to the increasing competitive situation.

2.2. Impact of the Different Health Care Systems

The development of innovations in the pharmaceutical area makes an important contribution to the medical progress in our society. And with it, the permanent and generalized access to medicines builds the basic standard of medical care. Unfortunately, the health care systems are constantly under pressure due to increased costs, drawing the limit between health care responsibility and financial restrictions.

The important factors contributing to the rapidly increasing health care costs are delimited by Mehta and Mehta (1997, 109) as follows: increase in life expectancy; inflation and higher wages; advances in medical technology and treatment procedures; spiraling R&D costs and shortening life-span of new drugs; changing disease patterns; growing affluence that provides incentives to artificially prolong life; urban living and life style; liability issues and stricter drug approval procedures; managed health care; and budget cuts in the public sector. Krämer (1989) and Seewald (1987) expect the change in the demographical pyramid to become the biggest challenge of the occidental health care system as the population is aging. In order to be able to deal with the cost burden, there is a general tendency to reorganize and save, even if the structure in each country, as well as political parties and legislations differ.

The financing of a high medical health care level for the whole population at the current cost contribution is not sustainable. Parallel to the state health care, the private individual health care must provide important accessible means. And in the next 20 years, the demand for additional services depends strongly on the readiness of individual financial participation: the co-payment possibility of a patient will determine the quality of his medical care. Measures to return costs to the individual are illustrated by the World Health Organization (WHO) campaign focusing on prevention, thus aiming at making the individual responsible for his health.

2.2.1. Characteristics of the U.S. Health Care Based on Managed Care

24 percent of the U.S. population has no coverage for medical care. Those covered by plans through their employer represent 30 percent, thus the majority of the population is privately insured in the United States. There is only a publicly financed system for

seniors (Medicare) covering 15 percent of the population. Additionally to this social establishment, there is another institution insuring medical basic health care for 11 percent of the population living in poverty (Medicaid) (Pajot 2003, 16). Although, those public institutions are also looking for saving strategies, the system is not regulated. They are rather optimized through Health Maintenance Organizations (HMOs) introduced at the beginning of the 1980s (Liberman and Rubinstein 2002, 24). These insurance companies guarantee an adequate and cost beneficial health care. The organizations negotiate the health care contracts with the medical services on behalf of the insured party. As a result, entire hospitals including personnel and inventory can be listed under contract. If the patient needs a particular physician, the medical office or clinic is selected depending on the contract (Beam and Tacchino 1995, 18). The luxury of freedom to consult a physician of own choice is exchanged against a reasonably-priced basic care. The managed care concept has been developed to ensure not only quality, but also financial feasibility of the medical interventions (Elzinga and Mills 1997, 289-90). In contrast, another system called Exclusive Provider Organization (EPO), has no capitation or gatekeepers. As described by Wheat (2001), the patients are allowed to self-refer to specialists and EPO doctors are paid on a fee-for-service basis.

All organizations work with positive and negative lists in order to design a cost efficient drug reimbursement. Therefore contracted physicians have access to a set of drugs they can prescribe, which will be reimbursed. The patients are gradually cared for with cost efficient therapies through a “step care” concept. Only in case of unsuccessful therapy, another therapeutic approach can be implemented. The physicians’ prescription habits are regularly controlled by Drug Utilization Reviews (DURs). The use of generics by medical personnel is also encouraged by HMOs.

Since the mid-1990s, Pharmaceutical Benefit Managers (PBM) have been hired to further reduce costs. Their main task is to negotiate discounts from list prices for branded products with the pharmaceutical companies. This form of direct contact resulted in reduced drug expenses (Danzon and Chao 2000, 321). American health care experts estimate that a fourth of all Americans were insured through HMOs at the beginning of the year 2002 (Mills and Bandhari 2003, 1).

2.2.2. Characteristics of the Fragmented European Health Care

European national healthcare systems are highly diversified in their organization and financing. There are national health concepts ranging from general tax funds (U.K., Spain, and Italy) to personal insurances with multiple providers (Germany, France and the Netherlands) (Saltman and Figueras 1998, 92). This results in serious differences in the services offered reflecting the different social values, ethics, and levels of wealth across Europe (EUI 1999), thus promoting inconsistencies, inefficient use of resources, uneven standards of medical care, and distortions in the functioning markets constituting an impediment to the creation of a unified European market, with all its implied consequences (i.e. economies of scale, higher competition).

Presently, all big European economies seem to be at the limit of their social service possibilities. Since the mid-1990s, the European health care systems are fighting against budget limitations, and the member states of the European Union are trying to limit the disbursement growth to 2 percent. In 2025, 15 percent of the European population will be over 65 (Brooks 2003, 206) increasing the pressure on the health care spending as older people consume a large share of medical care. And even if the expenses for medicines are only a limited part of the entire budget, they are often in the center of political discussions resulting in single measures taken by different countries to absorb the costs or other directives such as the Price Transparency Directive adopted in 1990 (Burstall 1991). Example of measures taken are the positive and negative lists, the increase of co-payments, the intensive price regulation, the strong use of generic drugs and the limitations of the reimbursable drugs' spectrum (Milmo 1992, SR29).

In some countries, such as France and Germany, all medically relevant drugs are reimbursed. On the contrary, in the U.K., an important amount of international standard drugs are not covered by public health care. Thus, the savings are directed towards the restrictive use of innovative therapy concepts (Huttin 1999, 247). The favorite practice of many European countries of reimbursing only prescriptive medications offers an important savings potential, e.g. in Belgium, Portugal and Finland, where only compounds prescribed by physicians are reimbursed by the public health insurance. In Germany, more than 25 percent of all prescribed drugs can also be obtained without prescription and therefore are not reimbursed. An increase of private

co-payments has also been observed to support the cost containment policies. In some countries, the amount of co-payments depends on the social status: the higher the revenues, the less the state reimburses. Other countries prefer the graduated co-payment. Here the amount of reimbursement is correlated with the gravity of the illness or with the therapeutic benefit of the medication. Drugs for a life-threatening disease therapy are completely reimbursed. The patient is to take in charge all supportive means not directly indicated for his condition.

2.3. Determination of the Particularities and Challenges Affecting the Pharmaceutical Industry

Gambardella et al. (2000) and Butler (2002) have analyzed the elements of the pharmaceutical industry and distinguished it from other industries. A number of these particularities explain the complexity of the involved product and therefore economies involved.

The pharmaceutical industry plays in an environment involving numerous players and strict rules set by the community. The considerable differences between the American and the European pharmaceutical industry are justified by globalization, the individual approach to science, labor and financial markets, and the consideration of intellectual property rights and marketing through pricing and branding approaches.

In this industry environment, pharmaceutical companies attempt to stay competitive facing external and internal challenges. The external pressure includes a general globalization tendency resulting in waves of mergers and acquisitions, the disparities still found among European countries struggling to establish a single market as well as a global standardization and an increasing pressure from shareholders expecting the companies to sustain past growth in very intense R&D competition for every therapeutic area. The structure of the scientific community plays a decisive role on the innovative capacities of the pharmaceutical companies as well as the different incentives offered to scientists carrying the knowledge of the industry.

Pharmaceutical companies are facing many internal challenges. First, the productivity level has difficulties to deliver corporate demands. Second, R&D has to take into consideration the rapid advances in technologies becoming increasingly complex and expensive, thus more difficult to manage. In addition, quality management sets the standards quite high. And last, the expected patent expiry of blockbusters announces a substantial loss of revenues and the high non-compliance rate of patients is also a concern for the industry.

2.3.1. Effects of Globalization on the Pharmaceutical Industry

There are numerous developments accelerating the trend towards global market unity (Hofstede et al. 1999, 1). These include rapidly falling national boundaries; regional unification at various levels(e.g., the European Union, North American Free Trade Agreement, Association of Southeast Asian Nations, Mercosur); standardization of manufacturing techniques; global investment and production strategies; expansion of world travel; rapid increase in education and literacy levels; growing urbanization among developing countries; free flow of information; labor, money, and technology crossing borders; increased consumer sophistication and purchasing power; advances in telecommunication technologies; and the emergence of global media. Globalization offers new perspectives for innovations (Roure 2001, 116). However, the main observed impacts on the industry are the increasing international consolidation, the harmonization of the regulatory framework and the competitive structure's disparities of the regions.

2.3.1.1. View of the Growing Importance and Frequency of International Market Entry Strategies

Historically, pharmaceutical companies approached to introduce older products without patent protection or which was about to expire to tap on unused market opportunities (Yaguan and Song, 1999). Today, pharmaceutical companies have to enter foreign markets to sustain growth. Meffert and Bolz (1994, 119), Nakata and Sivakumar (1996, 70), Smith B. (2001, 83), and Javalgi and Wright (2003, 280), discuss the available entry methods including mergers and acquisitions, subsidiary establishments, import/export, licensing and joint ventures. The solution depends mainly on the foreign market, the consumer and governmental framework.

To date, smaller companies were protected by the particularities of the national market. However, due to the increasing pressure of globalization, their survival is now jeopardized. Medium-sized pharmaceutical companies face existential difficulties, if they do not possess access to key technologies for the development of innovative medical drugs.

The competitive potential can be defined by the size of a company. The R&D and marketing resources can be considered a competitive advantage as the amount of communication effort correlates to the availability of the manufacturer's resources

(Gatignon et al. 1990, 398). Therefore, merging with other companies is often the last resort for growth (Blackett and Harrison 2001, 38). In 2002, the pharmaceutical industry registered 374 mergers and acquisitions deals (PWC 2003b, 4). Further consolidation is expected in the next few years, until a few global conglomerates remain with a market share of between 10 to 15 percent each. Since the mergers in 1999 between Astra and Zeneca to AstraZeneca, and Hoechst and Rhone-Poulenc to Aventis, and in 2000 of Glaxo-Wellcome and SmithKlineBeecham to GlaxoSmithKline, five of the ten biggest pharmaceutical companies worldwide are headquartered in Europe.

So far, none of the companies have reached higher revenues than €17 billion, and have more than 5 percent market share. As a result, none dominate the international market through medical drug sales. Unlike the automotive and electronic industry, market shares are broadly spread. General Motors possesses a market share of over 15 percent and chip manufacturer Intel produces 82 percent of worldwide manufactured computer chips. Due to their low market share, single pharmaceutical companies try to compensate, or rather minimize the risk of high development costs for innovative products (15 to 20 percent of revenues) leading to an increasing number of research cooperations (Green 2003, 1; *China View* 2003, 1)

2.3.1.2. Observation of the Urgency for a Harmonized Framework

Product development and marketing have been affected by a worldwide globalization. This results in regulatory difficulties as well as obstacles for product design, manufacturing processes and labeling. Even the existence of different medical schools has established regional and national therapy methods producing an impact on the demand and use of certain compounds furthermore resulting in price differences.

Unlike in the United States, in Europe every step from R&D to production and sales of a pharmaceutical product is regulated by the government. Even manufacturing authorizations are given by respective regulation authorities on a national level. The pharmaceutical market is regulated at two levels: first by regulatory mechanisms of the Single Market and second by single actions of member state at a national level. This results in significant differences between member states, in terms of price, reimbursement thus consumption, classification of products and their advertising

(Hancher 2004, 56). The European Commission (1998) explains those differences by a number of factors: divergent medical cultures and prescribing patterns, price discrimination, as well as conjunctural factors such as inflation and currency fluctuation. Price fixing policies in some European countries cause widely divergent prices, leading to conflicts between the operation of price fixing mechanisms and a lack of a single medecines market (Permanand and Altenstetter 2004, 51).

Even if, since the 1980s, the European Union is working on the improvement of the framework, little development was observed (Steinert 1998, 69). The wide range of liberal, but also restrictive measures, have each a different impact on the health care system and the European pharmaceutical industry. Due to the national responsibility of health care politics, the country-adapted tendencies are not leaning towards a harmonization of the pharmaceutical market where it is important to recognize the various motivations and policies of every country.

Actions taken to build the Single Market in pharmaceuticals include medicine licensing through the creation of first the Committee on Propriety Medicinal Products (CPMP) and later the European Medicines Evaluation Agency (EMEA) to offer fast access to the whole European market. The European Commission authorizes the commercialization of new drugs based on recommendations by the EMEA (Garattini and Bertele' 2004, 80). Since 1995, mutual recognition has been achieved between member states. But the EMEA and the CPMP lack the power to bind the national authorities to their decisions. The result is conflicting standards from the different regulating authorities. On the contrary, the FDA has congressional authority to reinforce national regulations (Moore and Cullen 1999, 104).

The introduction of a centralized authorization procedure already represents great improvement. In case the E.U. does not succeed in harmonizing local markets, the European pharmaceutical industry will continue to lose pace in comparison to the American rivals. The European Commission has nonetheless recognized the problem and has recently issued proposals intending to reduce the gap between the U.S. and E.U. regulatory conditions to improve E.U. competitiveness. These proposals concern the pre-patent expiration testing, direct-to-consumer advertising, the elimination of the five-year renewal rule, and reinforced pharmaco-vigilance monitoring (Smith B. 2001,

86). In 1989, the Price Transparency Directive was the last measure taken by the European Union to harmonize pricing and reimbursement (Hancher 2004, 60).

In addition to the harmonization of the European framework, there is the harmonization of the international regulations. The International Conference on Harmonization (ICH) was established by regulating authorities and drug industry associates in Europe, Japan and the United States in 1991. Its goal is to find a common ground for testing requirements and manufacturing standards of pharmaceutical products. The ICH includes four areas: quality; safety; efficacy; and multi-disciplinary topics. It aims at achieving a common format and content of a single international registration dossier for new drugs and good manufacturing practices for active pharmaceutical compounds (Steinert 1998, 69-70; Moore and Cullen 1999, 107). There is already a U.S.–E.U. mutual recognition agreement (MRA) for accepting plant inspection reports by other governments (Javalgi and Wright 2003, 276).

2.3.1.3. Variations, Levels and Forms of Competition Resulting from the Consumer Market Structure

According to Grabowski (1989, 31-2), pharmaceutical competitiveness is affected by different factors: national health insurance programs constraining drug prices, driving down profit margins; national policies influencing technological and economic opportunities for drug innovation; health sector cost-containment measures impacting on pharmaceutical sales including generics, and innovation incentives; and stringent economic environments.

The introduction of the Kefauver-Harris Amendments in 1962 in the United States had a great consequence. The U.S. pharmaceutical industry has transformed itself, particularly raising the cost and complexity of R&D (Liberman and Rubinstein 2002, 28). Many U.S. firms were forced to upgrade their scientific capability. The use of definite scientific requirements for clinical trials has contributed to establishing early relationships with the biomedical community.

When the rising costs of prescription drug benefits drove employers, insurers and managed care plans to adopt new measures of cost containment (U.S. Senate 1993), a differentiated set of techniques was developed by the buyer groups (HMOs, PBMs, insurance companies). They relied extensively on private funds and market-based

techniques, allowing processes of corporate adaptation, restructuring in marketing and distribution channels, stimulation of competition and, indirectly, innovation.

In Europe, Britain has nurtured a fierce competitive environment. It has invited skilled competitors and adopted regulatory concepts allowing a competition similar to that of the U.S., such as free-pricing, exchanges between academics and the industry as well as aggressive marketing activities. This has resulted in the imposition of British firms on the global market.

At the same time, in other European countries, regulatory schemes have been leaning towards an increasing dependance on market-based mechanisms (European Report 2001, 1). However, the firms' strategic orientations and organizational attitudes are changing slowly and tend to persist for long periods of time. Equally, the development of competencies and innovative capabilities is a long cumulative and difficult process that does not respond immediately and smoothly to economic incentives.

Over the past decade, significant progress has been made at the national and European level towards the introduction of stronger competition, the strengthening and the re-organization of the research base, the creation of capital markets, etc (Tancer and Mosseri-Marlio 2002, 264). And in more recent years, an encouraging dynamism is observed in countries like Germany, France, the Netherlands, Sweden and Denmark, as the rate of new biotechnology firms increases.

The competiveness of pharmaceutical and biotechnology companies is heterogene in Europe. The fragmented regulatory framework has also contributed decline in creating gaps in the innovation incentives and usage. The attractiveness of more developed market has equally draining the European innovative entrepreneurship (Hancher 2003, 3).

2.3.2. Analysis of the Financial Environment and Funding Structure

The available financial architecture differs greatly according to regions. Some as opposed to others do not support risk, therefore inhibite the development of new ventures. In this context, it is important to note the pressure applied by the stakeholders on the industry to sustain the growth experienced so far. And this is a growing challenge.

2.3.2.1. Description of Financial Markets and Pharmaceutical Investments

The development of biotechnology is supported by specific financial structures. There is no doubt that venture capital supports start-up activities. In the United States, the definition of ownership encourages venture capital as the legal framework allow for high-risk ventures and the attractive incentives for entrepreneurs and scientists. The ownership of firms is primarily financial in structure, and rooted in large capital markets (e.g. NASDAQ, NYSE). Collaborations between new firms and larger established corporations also play a decisive role in providing capital.

In Europe the capital markets are not favorable to high-tech ventures. This has affected the investment in start-up biotechnology companies. The focus was turned rather towards governmental programs. There were simply very little incentives to invest locally in science when the knowledge is readily available across the Atlantic.

2.3.2.2. Effects Due to an Increasing Pressure From Investors

Pharmaceutical companies need to maximize their return on investment in order to respond to the particularly high expectations of investors and to fund future development work, including withstanding potential failures (Butler 2002, 67; Barak and Wilson 2003, 245). Therefore all globally active pharmaceutical companies have continuously raised their R&D budget. Today, American companies are investing three times as much in R&D as in the 1980s. According to PWC (1998, 2), large pharmaceutical companies will need to launch 22 to 31 blockbusters within the next seven years to reach revenue forecasts.

Because of this impressive investment activity, the highest priority is an efficient organization and the completion of all research projects. The companies are increasingly evaluated by their pipeline rather than by their size (Best Practices Benchmarking 2000). The pipeline should present a certain potential by having prescription drugs in every clinical development stage as well as diversified by including products that could potentially be developed for various indications. It should respond to real needs concerning compounds solving relevant clinical problems and for which actual therapy exists and include at least one potential blockbuster generating alone annual revenues of at least €600 million (Grabowski and Vernon 1990, 816). This seems realistic as today, a third of all blockbusters achieve

over €2,4 billion in sales each (Pajot 2003, 22). However, it is to keep in mind that the traditional, highly successful blockbuster model is being put into question as it seems to be unsustainable in the longer run (A.T. Kearny 2002, 2).

2.3.3. Report on the Working Force Sustainability

In any industry relying on advanced knowledge, issues arise with the acquisition and management of information vectors. Scientists represent the knowledge resources of the pharmaceutical company. But as the benefits offered differ according to regions, there has been a flow towards the most attractive packages especially those offering high personal development.

2.3.3.1. Importance of Education and Research in Biomedical Innovation Systems

There are three factors playing a crucial role in scientific research. These affect the industry's level of knowledge, thus its innovative capacities: research funding, life sciences education and the position of academic research in the economy.

1/ Research funding

The Unites States has become leaders in life sciences due to the investment dedicated to this industry for the last twenty years, especially in biomedical research. European states have also been contributing to the development of this scientif area but the investments remained considerably under their American counterparts. The consequences are to be seen on the level of development, and the lack of research possibilities in Europe. Of course, investment and labor have been turned towards the U.S. in the light of higher returns and benefits contributing to the further advance of American science and the enlarging gap with Europe.

The difference can be traced to the fact that Europe has a very fragmented funding structure based on national entities. Science depends mainly on a multitude of small laboratories and large research center.

It is very different in the United States where the National Institute of Health (NIH) provides public funding. Other funding sources are as well very active. Academics and the industry work closely together and benefit from the principle of "open

science" for the sharing of knowledge. Competition is a great driver and scientists are given an important field of play (Geuna 2001, 609-15).

2/ Life science education

Due to the nature of the Europe, biomedical education is as well fragmented in Europe and has focused on patient care as opposed to research. They have just started incorporating molecular biology into the main cursus of pharmacy, and medicine studies. They were more concentrated on the structure imposed by the chemistry-based pharmaceutical science. University laboratories and large public research organizations were isolated and sole responsible for biomedical research. This resulted in the late apparition of biotechnology startups which formation rate has been linked to the strength of university and public research institutes in the related science (Trim 2003, 67).

In addition the new enterprises did not have the cooperation advantage with the large pharmaceutical companies due to their lack of developed competences. Moreover, large European companies addressed primarily the American scientific and technological specialists to take advantage of their well-developed skills (Archibugi and Coco 2001, 254; Madhok and Osegowitsch 2000, 328; Voelker and Stead 1999, 205). And because of the fast progress rates of the scientific and technical knowledge of American companies, the competent European start-ups ended up being acquired by the American leader.

3/ Position of academic research in the economy

The U.S. industry has developed and exploited the results delivered by public research. In the late 1970s, the Bayh-Dole Act has encouraged this transfer of knowledge and the academics turned into the core of new ventures (Stevens 2004, 93). The U.S. environment is characterized by the strong link between academy and industry (i.e. free exchange of personnel between the academy and industry) where the "open science" approach has always been prevalent. Results are published in scientifique journals available to all. The "open science" approach is important for sharing knowledge with the industry. It supports and encourages industrial growth (Hagen 2002, 215-6). Lately the academic system is increasingly keeping its

knowledge for itself. This is a serious issue in the scientific information exchange circle in the United States.

2.3.3.2. Differences and Evolution of Labor Markets for Skilled Researchers

There is an active labor market for scientist, technicians, and science specialized managers in the United States. The exchange of human resources is facilitated and encouraged without many risks for the employees. These can take place between academic research centers, pharmaceutical companies and the biotechnology firms through common project and partnerships.

Benefits and compensations usually ensure a steady and reliable position and personal development throughout one's career. Often entrepreneurs originate from large corporation, and are willing to take the risk of being responsible for a new venture because the personal responsibility is diminished, ensuring a safety net.

In Europe, regulations limit the exchange of personal between the players in the pharmaceutical industry. Personel unions make it difficult to reshuffle and dispose of human resources to gain efficiency and to adapt to the changing needs. One's career is often confined to a single institution, constraining the exchange of knowledge and skills. This organization is profitable for long-term and established entities, but for a fast changing and highly skill-intensive business, this can create a handicap (Gambardella et al. 2000, 74-5).

Casper and Kettler (2000) have shown that successful research in high-technology firms requires the recruitment of scientists with highly specialized knowledge. A study from the National Science Foundation (2003) concluded that a growing percentage of scientists and engineers in the United States come from other countries: "*Foreign-born workers with bachelor's degrees represented 17 percent of all science and engineering positions held by people with bachelor's degrees, 29 percent of master's degree positions and 38 percent of PhDs. Global competition for scientific and engineering expertise is becoming more intense while the number of U.S. born graduates choosing science, engineering or technology careers is declining.*"

Concordantly, according to a report from the European Commission (2003), European Union researchers use more the American competencies than the ones available

locally. About 75 percent of Europeans citizens who obtained doctorates in the United States in the 1990s did not foresee returning to Europe. E.U. firms invested one-third more in the United States in 2000 than U.S. firms did in the European Union. The United States' main attractiveness for young scientist is greater opportunities for career development, and not due to compensation. The main draw is the liberal environment around science ensuring a certain work quality. Broader scope in position and activities and better access to leading technologies are the key and deciding factors (PWC 2003a, 5). Also in the United States, there is a market-based system of financial institutions and very strong financial incentives such as stock options. In Europe, things have been changing since the late 1990s, but for example, during the 1980s the organization of the European financial markets and property rights law made stock-based financial systems difficult to implement.

Since September 11, 2001, there are divergences of opinion between the U.S. government and the scientific community, as pertaining to the free circulation of knowledge and the reductions of visas for foreign scientists and students. This could have an impact on the U.S. research environment (Foucart 2004).

2.3.4. Description of the Legal Issues Focusing on Patents and Liability

The protection of intellectual property rights is a prerequisite for supporting the innovativeness of an industry as opposed to process protection encouraging imitation activities. With the changing R&D environment and the growing importance of generics, the patent-related regulation put into place for already a few decades seems to be less efficient at protecting the innovation as well as the “innovator”. Also, with the increasing demand on standards and expectations, the pharmaceutical companies have been made entirely liable for their products and sometimes have to face the harsh consequences related to the complexity of drugs and their versatility.

2.3.4.1. Importance of Delimited Intellectual Property Rights

Innovations are the blood and veins of the economy. In the electronic industry, 70 percent of the revenues are due to products not older than 5 years. The telecommunications reach 90 percent of its revenues with offers brought on market within the last 24 months. Also, in the pharmaceutical industry, growth and future safety has to be secured by new product development. For this reason, the protection

by patents contributes to the strategic success position and to the positive development of a company as it allows the innovator to have exclusivity on its product until the patent expires.

Trade mark rights are supposed to protect creative activities from illegal use and forgery. The patent is the most important industrial protection law for discoveries, which are, in turn, the basis of technical innovations. The economical use of trade mark rights, especially of patents result in an exclusive economical situation. They guarantee the inventor a time-limited monopolistic competitive advantage and are independent in form of licensed tradable business objects. However, the advantages of a patent protection should be carefully weighed against the disadvantages. These include the time and cost of the authorization process (especially for a worldwide registration) and the danger of imitation or alternative development through the publication of know-how. To reduce the costs of patenting, large companies have their own patent departments. They have the necessary infrastructure to register their product for foreign trademark rights with the help of international databanks taking into consideration the different laws.

The importance of clear definition of patent protection has supported the biotechnology ventures during the last decade and has allowed them to develop profitably. The framework of property rights in Europe is limited and encourage rather processed rather than products.

According to McMillan et al. (2000) and to Grabowski (2002), patents are an essential to the creation of innovation in the pharmaceutical and biotechnological industry. Although it is not because large property claims is not the incentive to produce knowledge, but it is rather that is supports the markets created and allow a quicker and controlled transfer of knowledge as described by Merges and Nelson (1994). Indeed, strong systems of patent protection exist in all countries with strong innovative pharmaceutical industries as opposed to locations with only a process protection as in Japan before 1976.

Next to the in-house R&D, transfer of technology or information import from the scientific world is important for the pharmaceutical industry. This transfer can on the one hand be the informal exchange of single employees with external institutions

(personnel transfer), or on the other hand be a contract agreement on know-how licenses. Owned or acquired patents can prevent unwanted use of scientific content from foreign companies.

Grabowski (2002, 851) lists the reasons why patents are so important in the pharmaceutical industry compared to other research-intensive industries: high R&D costs; extremely low relative imitation costs; high failure rate of new drug candidates; and high new product approval cost, both time-wise and financially. Although, the patent-protected drugs may, nevertheless, face competition from therapeutic substitutes (Danzon and Chao 2000, 312).

The patent's legal validity of 20 years is not the most important part for the commercialization of a drug; it is rather the effective time in which a product can be exclusively marketed. In the pharmaceutical industry, patenting takes place a long time before the authorization to market the product. It takes up to five years for the approval process (*Regulation* 2002, 6) and between 11,6 to 14,9 years between the invention and the market readiness of a product. If the company only applies for the patent shortly before the market entry, it would take the chance that a competitor applies for this exclusivity before. Due to the high investments in innovative compounds averaging at $500 million (Louie 2001, 104), there is no other way but to apply for a patent as early as possible. Therefore, the objective in the industry today is to launch to market in an average of just seven years in a trend to reduce the pre-launch period to enable a greater return on investment (Butler 2002, 66). As Blackett (1992, 22) writes it, a drug is currently usually commercialized only five to seven years with patent protection. And it generally takes a pharmaceutical company four to five years to recoup its investment in that product, leaving a maximum of two to three years to generate profits on the drug (Grabowki and Vernon 1996, 196). Although it is important to note that most countries with innovative industries have passed patent term restoration laws providing a partial restoration of patent time lost during clinical trials and the authorization process (Grabowski 2002, 852)

Europe offers the longest market exclusivity which can reach more than 20 years whereas it is limited to 14 years in the United States) (Van Arnum 2002). Unfortunately the recognition of a European patent on a national level can be

problematic. The difficulties stem from the fact that the recognition process is linked to significant costs. The European community is only partly capable to hold a national grip and binding legal practices, even if this problem has been openly discussed for years. Since 1989, the agreement on the recognition of community patents has been adopted, but the structural problems were not sufficiently removed. As long as the territorial laws still bind the recognition of the centralized processes, the positive development of an innovative medicine on the European local market is jeopardized (Castellion 2001). Clarity would also be required in other areas such as the development and positioning of follow-up products, or the issue of generic manufacturers being allowed to start the development of me-too products during the patent validity. According to the American law, this practice is legal and is gaining importance in a number of Middle and Eastern European countries (Sharlin 2000).

Between 2002 and 2007, the U.S. patents for thirty-five drugs with global sales of more than €60 billion will expire involving 30 of the current 57 blockbusters (Van Arnum 2003, FR4). When a drug loses its patent, sales drop sharply in unregulated price markets. And these drugs will be difficult to replace. In a report published in 2003, IMS Health (Pajot 2003, 30) estimated nine potential blockbusters in the industry's pipeline in 2002, and another 17 such drugs in the pipeline from 2003 onwards. However, none of these new medicines is expected to generate similar profits as the current stars in the industry. In any case, Mehta and Mehta (1997) agree that an approach regarding the commercialization of the product after patent expiry should by defined three to five years before. These can include pricing policies depending on the product's and market's characteristics (Barak and Wilson 2003, 246), or switching to OTC status (Maynard and Bloor 2003, 35)

2.3.4.2. Correlation Between Increasing Quality Management Demands and Liability

Despite the impressive R&D costs for new products, more than 11 000 compounds were developed since the mid-1980s. Generally, the compounds were focused on diseases with high medical needs. In 2000, more than 340 research projects were initiated in the area of neurology, cardiology, HIV and oncology. As the developed pharmaceutical drugs are therefore becoming increasingly complex, so are the demands for safety and effectiveness standards as the product has to respond to the

optimal quality standards set. In addition, the expectations of patients have increased regarding the range of treatments and the quality on not only the products but also of the health care services (Busse et al. 2003, 21).

These factors lead to an increase of product liability exposure (Moore and Cullen 1999, 102) for which the manufacturer is held responsible for any drug defects as well as for the outcome of the therapy. A patient's adverse reaction could result in a negative contribution to the perception of the company depending on how the community reacts to it.

2.3.5. Dependency of the Pharmaceutical Industry on Research and Development

There is an intense R&D competition and the products available are offering a spectrum of choices, each fighting for a share of the market. The timing of a market entry is anessential success factor (Cavone et al. 2000, 7).

It is also increasingly difficult to generate high revenues with me-too products or products without clinically relevant advantages, leading to a growing demand of innovative newly approved products. And since the product life cycle is continuously shortened, the pharmaceutical companies must renew their portfolio every 8-10 years. To reach this goal, according to PWC (1998, 2), the pharmaceutical industry should position every year, 22 to 31 compounds. Presently there are only 50-60 New Chemical Entities (NCE the precursor of a chemical drug) through the authorization process, in the United States as well as in Europe, of which 60-70% will be approved. IMS Health (Pajot 2003, 13) reports a decline of the number of launched NCEs from 1994 to 2002. In addition, post-marketing product withdrawals and late-stage failures in the pipeline are common. One in 5000 drugs has potential and fewer than three in ten drugs make it through clinical trials (Louie 2001, 104). Between 1997 and 2001, 12 drugs with combined peak sales potential of more than €9 billion were removed from the market. Late-stage failures cost even more: in the three years to 2001, the industry leaders terminated 28 products with potential peak sales of more than €17 billion (Arlington et al. 2003, 6).

Numerous blockbusters are losing their patent protection opening the door for generics. In addition, the number of branded drugs has multiplied, and some of those

drugs have very similar medical properties (Arlington et al. 2003, 6). This will be increasing since up to 20 companies can be working towards exactly the same therapeutic indication.

Pharmaceutical companies rely on their capacities to innovate, thus on the productivity of their R&D even if developing a full-fledge commercialized drug is a real challenge in a highly competitive environment.

2.3.5.1. Observation of a Relative Lack of Productivity in the Laboratory

In 1998, the biggest drug producers clamed that they were aiming to develop three NCEs per year (Butler 2002, 66). Today some companies claiming the production of three or more billion-dollar blockbuster a year are required just to maintain their sales growth. Yet they are far away from reaching this goal, and shareholders´ expectations have put the bar even higher.

It was estimated that in 2001 the industry leaders spent about €30 billion on R&D or 16 percent of sales (IMS 2003), doubling the 1997 R&D expenditures and trippling the ones of 1992. However, the output of new drugs has declined ever since. In 2001 the FDA has approved only 24 new molecular entities, fewer than any of the previous six years. Also, as seen previously with the increasing demands on R&D for quality and standards, project failures are increasingly frequent and costly, binding unnecessary resources.

In addition to this lack of productivity, there is still a gap in the synchronization of the product development between product design, industrial design and the scientific teams resulting in time loss (Strategic Direction 2002, 25-6).

2.3.5.2. Consequences of Dynamic Scientific Advances on Technology

The technology and processes used for drug discovery are becoming increasingly complex, especially since the shift from chemistry to molecular biology which involves high-technologies. For example, in 2003, biotechnology projects accounted for 24 percent of the active pipeline (Pajot 2003, 28).

Alliances and outsourcing are useful for filling out some lack of skills or competences by offering access to state-of-the-art technology and knowledge. It considerably

reduces the complexity of the innovation process (Schweitzer 1997, 118-9). In addition, these services are often at a lower cost and higher standard than in-house resources. According to Meyer (1994), these alliances based on R&D will depend on the company's size, its efficiency, the scope of the research, the timing advantages and the standards set. According to Coles et al. (2002, 21), some companies have mastered the forces in play and follow a complex outsourcing approach such as R&D cooperations. For example, drug discovery companies offer expertise and are focused on particular indications. Their goal is to carry out the innovation process to establish licensing partnership for a drug with pharmaceutical companies. Platform technology companies are specialized in cutting edge technology focused on specific developments of the drug discovery process. Through these partnerships, the pharmaceutical company reduces R&D costs considerably and has direct access to the new technologies and skills without have to invest in them.

Furthermore, these companies impact the pharmaceutical company's technical level and its use of synergies through the understanding of the clinical relevance of the innovative drug's application and the scientific know-how for the development and manufacture of innovative pharmaceutical drugs (i.e. production of therapeutic antibodies, merger proteins and vaccines in industrial measures) as well as new managerial necessities. They also contribute to the globalization of R&D to access new sources of knowledge (Cavone et al. 2000, 2, 9).

2.3.6. Determination of the Specific Role of Marketing

For the pharmaceutical products, marketing takes on a different dimension as prescription drugs differ from other consumer products in two important aspects (Elzinga and Mills 1997, 288):

- consumers are only allowed to buy drugs prescribed by physicians;
- and insurances pay for them most of the time.

Thus the ethical pharmaceutical product prices are not regulated by the usual market laws of demand and supply, and the communication influence opportunities on the consumer are currently limited as these have just emerged in an era where the consumer is starting to take on responsibility for his health. The compliance of the

consumer has been recognized to be an important issue in the flow of the pharmaceutical market.

2.3.6.1. Impact of Pricing and Resulting Price Differences

As previously described, generally the prices increase throughout the years due to the increasing costs of R&D (Grabowski and Vernon 1990, 817). In addition, price changes are also triggered due to differences in generic penetration and competition intensity between the various countries.

According to the VFA (2003, 58) when the U.S. drug prices averages 209, the English prices lie by 102, the German prices by 84, the Dutch prices by 78, and the French prices by 79. Historically, drug prices were relatively high in countries that did not have strong government intervention in prices. Regulatory systems as in France and Italy drive down prices over the life cycle of the pharmaceutical products (Danzon and Chao 2000, 319).

However, one has to differentiate between two systems. One relies on free or semi-free prices and on competition-based mechanisms. This system is prevalent in the U.S., the U.K. and Germany since the exclusion of patented drugs from the reference pricing system in 1996. There an important degree of competition and shift of market shares after patent expiry can be observed. This system relies primarily on competition as it uses low-price products. It promotes a clear distinction between firms that act as innovators and firms that act as imitators after patent expiry. Innovative drugs enjoy premium prices and profit exclusivity when under patent protection. But as soon as the patent expires, competition is harsh.

The second system relying on price fixing such as in Italy and France experience a significant degree of stability of the firms´ market shares over time (Danzon and Chao 2000, 318, 350-1). It is a systems relying on administered prices. It is, however, unable to replicate the performance of private markets in the introduction of appropriate selective mechanisms and pressures on price levels. This system encourages brand proliferation and horizontal differentiation by the means of “me-too” branded products well before patent expiry.

In many European countries, distribution margins for wholesalers and pharmacists are still fixed by law, in general as a fraction of the final price. The same branded medication, possibly manufactured in the same plant, can have a different price tag according to markets. The cause of this lies in the variations of legislations. The price is not based on the business capacities but on the financial setting of health insurances. Normally the pharmaceutical industry can not align their prices to those from the countries with the lowest prices because of cost recovery. This results in great variations in prices (VFA 2003, 58) and in product to product reimbursement contributions. Pharmaceutical drugs that have the same sales price in all countries can have various consumer prices. This is due to the state-fixed gross margin of pharmacies and wholesalers as well as the diverging taxation. As a matter of fact, even for relatively cheap drugs, the price difference can vary up to 100 percent. In addition, the added value tax also differs according to the country. In certain countries, there are tax reductions whereas in others, the whole tax charge is applicable (BPI 2000, 27). Pharmaceutical companies can accept these price concessions as long as the whole product line allows balanced business results and that the costs are covered as well as the interest of invested capital.

All European countries regulate pricing somehow. They can rely on therapeutic comparators, which are the prices of products in other E.U. countries. Reference pricing is increasingly referred to, based on reimbursing only the average price within a therapeutic category. Price variation is therefore lower across the E.U. countries, but this method contributes to the inflation of generic prices. It dissuades as well competition. It has been shown by Ioannides-Demos (2002) that reference pricing only achieves short-term savings for the state as it discourages physicians from prescribing expensive new products. It leads to increase expenses for older drugs and generic drugs (Wechsler 1999) due to volume inflation determined by prescribing and marketing influence (Maynard and Bloor 2003, 38). It is an important determinant of the price paths as has been shown by Aronsson et al. (2001). In addition, physicians may no have any personal incentives to know prices or be price sensitive unless they have a prescribing budget (Danzon and Chao 2000, 316).

In the recent past, under the pressure of increasing fiscal constraints, the European Federation of Pharmaceutical Industries and Associations (EFPIA) is seeking to

liberalize pricing policies (Van Arnum 2002). Some European countries complemented their price fixing procedures with interventions on levels of reimbursement, de-listings, and price cuts. While, according to the available evidences, these measures tend to realize, at best, short-term savings for the health care systems and, in any case, they have not affected growth rates of pharmaceutical expenditures, these measures have introduced new distortions on the final markets (Jacobzone 2000, 37).

2.3.6.2. Newly Defined Importance of Pharmaceutical Branding

It is important for pharmaceutical companies to present a comprehensive and single image of their product on a global scale and branding plays an increasing role in the promotion of ethical drugs. Because of restrictions, branding was traditionally confined to safe OTC products. The industry has noted that the experience from consumer goods is not transferable to the pharmaceutical industry since the end-consumer does not have the complete freedom of choosing the product himself and pharmaceutical products do not have the life expectancy of true brands. But since the patient is becoming increasingly emancipated, and exercising a more defined influence, this issue is becoming a new opportunity for pharmaceutical manufacturer.

Success can be enhanced through branding creating benefits for all health care players at the same time (Blackett and Harrison 2001, 39). These benefits include the relationship with the customers; a competitive differentiation; a global reach; influence on behaviors and attitudes; and encouragement of customer loyalty.

Branding is mainly communicated through the name, logo, colors, packaging and positioning contributing mainly to the advertising profile defined by Vanderwalle (1992, 76). But it can also be reinforced by providing knowledge such as accurate information, expert advice, discussion forums and links to other reputable sources. These are called “value-added-packages” or services offered by the pharmaceutical company supporting the brand, and trying to emphasize identification with the brand. The name, logo and presentation derive from the positioning of the product. But the visual effects are hindered for ethical drugs as most prescription medicines do not have a proper packaging and are dispensed in packaging provided by the pharmacy.

Branding is an early process (PWC 1999, 22) taking place already during clinical studies aiming at increased name recognition. According to Liebman (1999, 2) and Baur et al. (2002, 52), marketing and R&D have to start collaborating already during the clinical trials to develop a brand based on findings from prescription influence analyses.

Wick (2004, 13) reports that drug companies spend up to €1,75 million to find a name and has identified more than 33,000 trademarked brand names and some 9,000 generic drug names. For pharmaceutical innovations, the name must not suggest efficacy and usually has nothing to do with the active compound, but may refer to the disease it is indicated for (Blackett 1992, 23) (e.g. a patient-friendly branding would appear to have a greater appeal to physicians than scientific-sounding name). In Europe, the Committee for Proprietary Medicinal Products (CPMP) is specifically charged with the determination of whether or not a proposed trade name could create public health concerns and risks to public safety. A trade name is defined by the CPMP as the invented name of the medicinal product without reference to the pharmaceutical form and strength. While the Patent and Trademark Office (PTO) focuses on the trademark registration process to identify and distinguish the source of the goods of one party from those of the others, the focus of the FDA review is to safeguard public health by preventing medication errors due to confusingly similar proprietary names. The disparity in timing, and the differing criteria used by the European Union to assess the confusion potential of a proposed proprietary name, can result in disparate outcomes for the sponsor. However, neither the FDA nor the CPMP process allows for consideration of whether a particular proprietary name will or may constitute an infringement of another entity's intellectual property rights. Significant differences also exist in the time frames and criteria used by the FDA and the CPMP to evaluate the impact of a new proprietary name on public health. The proprietary name may be approved or rejected in the United States on the basis of name confusion while the opposite result can occur in the European Union countries, resulting in two different proprietary names for the same drug product.

Branding is equally important according to findings from Laitin (2000) for ethical and OTC drugs, but differs from ethical drugs due to the time pressure due to patent and due to market preparation component. For pharmaceutical innovations, branding

allows the product to stand out against the competition and survive generic substitution as loyalty to a brand can outweigh the price (Blackett 1992, 21). This is due to the fact that branding relates to physicians and patients in the same way and acts on the perception of the product created by the pharmaceutical company. Brand name drugs have been shown to be viewed as more effective, having less adverse effects, and giving greater value for money especially for higher risk medications (Tootelian et al. 1988, 28). It can also play a substantial role if the ethical drug is destined to switch to an OTC status.

Branding can be extended to a global branding (Baur et al. 2002, 44-46) as long as the positioning and communication are consistent, supporting identical creative marketing campaigns. Global branding allows a product to enter a market with an already recognized name and an accepted pattern of effectiveness (Javalgi and Wright 2003, 284). According to Liebman (1999) it also creates economies of scale for distribution, packaging and promotion. But it is difficult for pharmaceutical companies to develop global brands due to trademark, legal obstacle and internal problems in the corporate culture (Blackett 1992, 23).

Since the lifecycle of a pharmaceutical product can be quite short, line extensions play an important role, the branding image transfer between the parent brand and the extension can be a source of reduced marketing costs, and a better positioning (Blackett and Harrison 2001, 39). As for consumer goods, Bridges et al. (2000, 4) point out that effective communication strategies can help focus on the relevant associations providing an explanatory link between the parent brand and the extension, thus a favorable perception transfer. This association can be attribute-based, relying on physical characteristics, or non-attribute-based, making use of similar imagery and usage situation.

2.3.6.3. Recognition of Compliance's Influence on Health Care Costs and Economical Success

Compliance is defined in the medical literature as "*the extent to which a person's behavior coincides with medical or health advice*" (Bentley et al. 1999, 59). A more detailed definition is formulated by Ellickson et al. (2000, 4) considering a patient to be non-compliant with his doctor's prescription if either he does not buy the drug (purchase non-compliance), or he does not consume the drug in accordance to the

doctor's prescription (use non-compliance). Recently non-compliance is referred to as "non-adherence" (Bradley et al. 2004, 164).

Compliance works at another level as it has also been shown that doctors anticipate non-compliance when they prescribe a drug (Armantier and Daw Namoro 2003, 4). They will have a tendency to prescribe a drug they think their patient is more likely to take.

Non-compliance is a recognized issue and according to a recent study by Dezii (2000, 9), up to 70 percent of patients do not comply with drug prescriptions. Ellickson et al. (2000, 5) also report an average rate of non-compliance with drug prescription of 70 percent with 20 percent of purchase non-compliance and 50 percent of use noncompliance. This results in annual costs of $170 billion in the United States exceeding the expenses in prescription medications.

Non-compliance has also serious health implications. According to Col et al. (1990, 841), up to 11.4 percent of admissions to hospital resulted from failure to comply with a drug therapy. Another study by Sullivan et al. (1990, 21) suggests that 125,000 cardiovascular deaths in the United States annually could be related to non-compliance. A lack of therapy trust puts in jeopardy the success of the therapy and is an important cost driver. In the five biggest European markets alone, these costs reach €36 billion.

Compliance has a strong impact on the treatment of chronic diseases. It is primarily linked to the information available to the patients and their motivation (Drake 2002, 10). The patients need to understand their illness and how they can actively participate in the disease management and take the responsibility for it (Bradley et al. 2004, 166). This conflicts with the pharmaceutical companies facing an increasingly complex set of challenges as they strive to meet investors' higher expectations for earnings stability and superior shareholder returns.

2.4. Understanding the Pharmaceutical Product Spectrum

Pharmaceutical products include either drugs bought freely in a store or pharmacy or those whose access is subject to a prescription. The prescription-only medicine contributes to about 90 percent of global pharmaceutical revenues, with a highly regulated market, facing government and political interventions (Blackett and Harrison 2001, 37). They can be branded (ethical drugs) or not (generics), they can be innovative compounds or copies. They can also be part of the "alternative" drugs not officially recognized by traditional medicine. The range is indeed broad and is hereby described. However, the present study will focus subsequently on the segment implicating R&D and the most complex regulations which reflects the particularities of the industry and is at the center of the challenges faced by pharmaceutical companies: prescription innovative drugs.

2.4.1. Analysis of the Predominant Role Played by Pharmaceutical Innovations

European companies have historically been quite innovative, especially the important German and Swiss firms. But today, the United States followed by Great Britain have imposed their innovative leadership in the pharmaceutical industry and have overtaken Continental Europe.

The post-war era has been characterized by the emergence of molecular biology. Until the mid-seventies, pharmaceutical was based on chemistry and on incremental drug modifications. It profited to large organizations, whose size was a definite adavantage for the introduction of new compounds. The revolution brought by molecular biology allowed the emergence of new technologies opening new perspectives for the discovery and production of pharmaceutical drugs. These skills became the base for competitive advantage and required a structured innovation process. The specificity and the complexity of the new knowledge introduced specialized suppliers into the market such as biotechnology firms. But the high costs have been the main barriers to entry. As argued by Gambardella et al. (2000, 36), the organization of the industry into new high-technologies suppliers and the extensive vertical specialization of the

industry, focused on the "exploration" of new technologies. An industry specialized in their "exploitation" can be highly conducive to innovative performance.

The increase of health care expenditures has lately encouraged the appearance of imitators and generic companies offering the innovation at reduced costs. This has put the innovation into a new perspective. Major innovative breakthroughs bring along first-mover advantages with extremely high rates of market growth (Danzon and Chao 2000, 326). However, as Bottazzi et al. (2001, 9) point out, the innovation will have an impact on the competitiveness of the firm but will not insure a sustained competitive advantage and a "*systematic above-average growth to the individual innovators*". Sustainable growth within international competition implies innovative products and services as well as an efficient organization of production workflow.

Only innovations can respond to the increasing individual and social demands on quality and efficiency. In the global competition, the research companies are increasingly forced to develop better solutions in order to obtain a potential competitive advantage. The intensity of competition is illustrated by the example that up to 20 companies conduct research on the same therapeutic indication. This competition for innovation creates an enormous time pressure. For this reason, the development and commercialization of a pharmaceutical product is dependent on the competitive conditions. The ultimate goal is to reach a more efficient care through concepts such as disease management, networking and evidence-based therapy.

Lichtenberg (2001) has shown that newer drugs reduce substantially the total cost of treating a given condition. Thus, due to the demand of all health care players, the industry is increasingly developing integrated concepts to optimize the care process. E.g. patients and physicians for asthma and diabetes are being integrated in a common therapy plan through education, guidelines or online communication systems. The modalities are standardized, the compliance and therefore the medical care quality rises. Moreover, the living quality of the patient and the central problem themes of the public health insurance systems are therewith improved (Harms et al. 2001a).

2.4.1.1. Differentiation of Pharmaceutical Innovations

Innovative drugs can be classified into three groups recognized by the regulating authorities (NIHCM 2002a, 4): New Molecular Entity (NME), Incrementally Modified Drug (IMD) and "Other".

1/ **NME**s represent drugs with a completely new active ingredient. These have the highest level of innovativeness. They offer a clear advantage in the medical treatment and have a positive impact of the patient's life quality and expectancy.

2/ **IMD**s are based on an existing active ingredient. They are characterized by offering an improvement to the corresponding NME (safety, efficacy, secondary effects, and delivery). These include new formulations (including combinations with other active compounds), new salts or esters, and new indications.

3/ "**Other**" drugs are existing compounds which have entered the market before 1938 and fall under 1962 Kefauver-Harris Drug Amendments. They present the lowest level of innovativeness.

Another segmentation of the drugs differentiates them by their relevance. Some drugs may be qualified as priority drugs because they appear to offer clinical improvement over available products and therapies in efficacy, safety, compliance, or use in a new sub-population. The other remaining drugs are standard drugs as they do not offer significant improvement over marketed products.

2.4.1.2. Development of a Pharmaceutical Innovation Process Based on Research and Development

The innovative product development is generalized under the term R&D. According to Brockdorff (2001), it is the process of planning and systematically gaining new knowledge through the combination of relevant emerging product factors. R&D must orientate itself according to the targeted corporate strategy. It allows a high proportion of creative activity, which is less subject to management and organizational principles. From the point of view of an innovative company, there is a difference between internal and external R&D.

In the internal pharmaceutical R&D, there are specific departments with special organizational characteristics. The technology know-how, the available resources, the

relevant market segments and the changes in the market environment are the components considered for the corporate R&D strategy development. These determine if the focus of the R&D activities should revolve around their own innovative capacities, based on integrated external knowledge or around imitated innovation.

Powell et al. (1996) do not believe that an individual firm is capable, nowadays, to control and master internally all the knowledge required to discover and develop a new drug. Especially since the explosion of technological opportunities due to the molecular biology revolution, the ability to access and make efficient use of such collaborative networks with technology suppliers has become a crucial source of competitiveness. For this reason, pharmaceutical companies have had to make use of external R&D.

Universities and other research entities are increasingly being integrated into the whole concept on a national and international level. Besides academic institutions, also highly specialized companies are being tied through cooperations. These technology centers dominate scientific knowledge. Thus, classical pharmaceutical companies dedicate an increasing amount of their R&D budget in these partnerships and on the construction of networks for the development of innovative products (Razvi and Bolten 2001).

Collaborations have increased in the last decade. But the U.S. firms act early in the innovation process at the pre-clinical phase. In Europe, the tendance is rather towards co-marketing 1990s. Furthermore, U.S. firms act more frequently as licensors (originators) of new R&D projects as compared to the other European countries, which are typically licensees (developers). The “originators” role of U.S. companies is linked to the disproportionate share of licenses which involve – largely as licensors – biotechnology companies, universities and other research centers as compared to most European countries.

The development of new pharmaceutical drugs goes through a very long process which can be separated in different phases:

1/ pre-clinical;

2/ pharmacology and toxicology;

3/ clinical (phase I-III);

4/ authorization;

5/ market entry.

Each of these phases implies a clear strategic orientation, budgeting, regulations, and marketing.

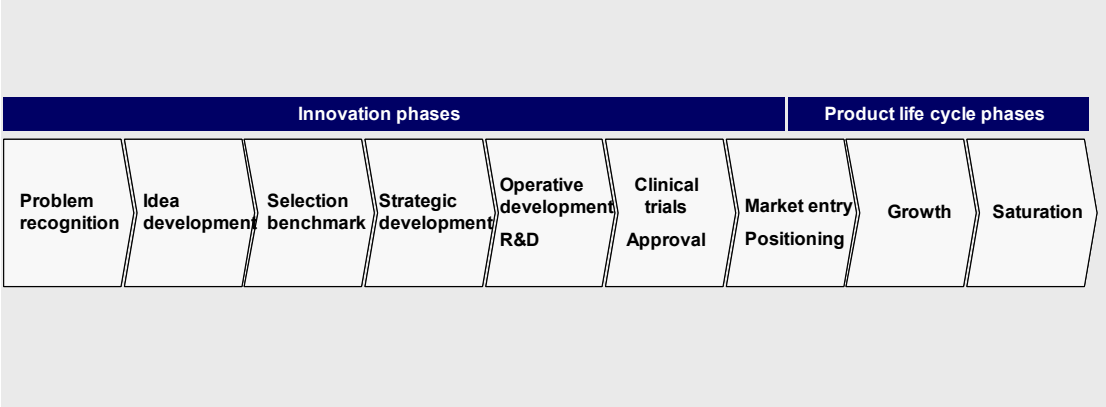

Figure 2.1. The pharmaceutical innovation process includes the innovation phases supplemented with a stage for the clinical trials and is followed directly by the product's life cycle.

The pharmaceutical innovation process is based on the general innovation process described in 1.1.1. But the component R&D must be supplemented with the pre-clinical and clinical trial stages leading to the approval of the pharmaceutical product on the market by the regulators (FDA in the United States and EMEA in Europe). Through the portfolio management of the pharmaceutical company, ideas expected to encounter failure are brought to an end before or latest after the first clinical phase I in order to limit the cost of development and leave the resources available for other research projects (Pilot 2000).

Rafiq and Saxon (2000) discuss the fact that the pharmaceutical innovation process involving collaborative input from R&D and marketing is a major factor for supporting the success of the new developed product.The traditional product life cycle follows the innovation phases. These are composed of the market entry, growth, and saturation stages which lead to a decline.

1/ At **market entry** or introduction stage, market size and growth is slight. Substantial R&D costs have often been incurred in getting the product to this

stage. In addition, marketing costs may be high to test the market, undergo launch promotion and set up distribution channels. Companies seldom make profits on products at this stage where products must be carefully monitored to ensure growth.

2/ The **growth** stage is characterized by a rapid growth in sales and profits. Profits arise due to an increase in output (economies of scale) and possibly better prices. At this stage, businesses usually invest in increasing market shares as well as enjoy the overall growth of the market. Accordingly, significant promotional resources are traditionally invested in products that are firmly in the growth stage.

3/ The **saturation** or is also referred to as the maturity stage. Competitive advantage relies on marketing and financial activities. The competition is at this stage the strongest and the product is often confronted to "me-toos". R&D focuses on extending the product's life through feature modifications, or improving manufacturing processes.

These stages lead to a decline where the market shrinks, reducing the overall amount of profit that can be shared amongst the remaining competitors. At this stage, great care has to be taken to manage the product carefully. It may be possible to take out some production cost, to transfer production to a cheaper facility, sell the product into other, more profitable markets. Ultimately, depending on whether the product remains profitable, a company may decide to end the product or to modify it.

2.4.1.3. Identification of Changing Patterns Affecting Pharmaceutical Innovations

Between 1989 and 1994, the FDA approved 350 new drugs. In the following five years, between 1995 and 1999, 569 new drugs were approved. This is an increase of 219, although only 7 of the 219 additional new drugs were priority NMEs. In 2002, 16 priority NMEs were launched in the United States compared to 8 in 1992. Europe is lagging behind with only 4 priority NMEs launched in 2002, opposed to 15 in 1992 (VFA 2003, 61). Thus the rate of innovation is not increasing for the most innovative class of products.

The NIHCM (2002a) describes some changes in the drug approvals distinguishable between 1989 and 2000:

- "*Priority NMEs, the most innovative drugs, contributed little to the increase in new products.*
- *IMDs contributed more than NMEs to the increase in priority drugs.*
- *Most growth came from products that did not provide significant clinical improvement, especially modified versions of older drugs.*
- *Standard-rated drugs increased their dominance of prescription spending*."

In a nutshell, pharmaceutical companies are turning to incremental changes for existing products in an effort to extend the life of their innovations. Through this method, they reduce investments in R&D, authorization processes to market a new product, extend patent exclusivitiy, make use of the new technology available and can take advantage of the brand positioning achieved by the older product.

2.4.2. Rise of Generic Drugs

Generic drugs are medical compounds that bring the active substance on the market under a generic name, the INN (international nonproprietary). According to the World Health Organization (WHO), an INN "*identifies a pharmaceutical substance by a unique name that is globally recognized and is public property. Generic names are intended to be used in pharmacopoeias, labeling advertising, drug regulation and scientific literature*" (WHO 2002, 39). There are about 8000 INNs growing every year by some 120-150 new INNs. The INN system is a result of the World Health Assembly resolution WHA3.11 presided by the WHO in collaboration with national nomenclature commissions such as the British Approved Name BAN, Dénomination Commune Française DCF, Denominazione Comune Italiana DCIt, Japanese Accepted Name JAN, or the United States Adopted Name USAN.

Before 1984, generic pharmaceuticals were uncommon, due to the fact that a company wanting to manufacture a drug whose patent had expired, had to conduct the same tests as those required from the original innovator for efficiency and safety. In 1984, in the United States, the Waxman-Hatch Act was passed requiring from the generic

manufacturers to prove that the generic drug was identical to the original product except in inert ingredients, shape, packaging, labeling, and shelf life. Grabowski and Vernon (1992) have shown that since then generic drugs have increase on the market.

Due to the current economical issues, generic medicines have become the center of attention and are increasingly prescribed (Davis 1985). The decline of product exclusivity and the increasing cost awareness of the western health care system, supports this approach. The market for generics differs depending on the country. Some might be more open to generics than others such as the United Kingdom, Germany and Holland, as opposed to France, Spain and Italy (Barak and Wilson 2003, 246-247). The measured pharmaceutical revenue's spectrum due to generic drugs varies from 5 percent in Italy to 40 percent in Germany in 2000.

Presently, the amount of generic medicine compared to the total prescription medecines is highest in the United States followed by the United Kingdom and The Netherlands (Mrazek and Frank 2004, 246). The prescription of generic drugs is expected to grow more than the total worldwide pharmaceutical market with 10-15 percent in the next 5 years. This growth is mainly due to the expiration of patents for a high number of high revenue compounds. According to IMS (2000) more than 100 compounds will lose their patent protection until 2005, and a dozen blockbuster compounds will lose their exclusivity. This means, that the actual worldwide market volume of €25 billion will increase to €40 billion. Even if the manufacturer of the original compound finds efficient legal ways to extend the period of exclusivity, the generic market segment is experiencing an unprecedented boom, particularly in North American and Western Europe (IMS 2003, 1). The forecast for the global generic market is a Compound Annual Growth Rate (CAGR) of 9,3 percent between 2002 and 2007, with North America gaining 52,7 percent of the world market. Growth is expected to be more intensive in North America compared to Europe (Pajot 2003, 14). Although, it is foreseeable that the role of generics in France, Spain and Italy, where the use of generics is presently insignificant, will increase drastically in the near future as the growth of the generics market penetration are respectively 49, 42 and 21 percent (Pajot 2003, 10).

Barak and Wilson (2003, 245) note the effect of patent loss and the entry of generics on the health care players. Generics are a mean to reduce health care expenditures for governments and payers. Pharmacists are therefore encouraged to switch prescriptions to a generic alternative. Generic substitution is allowed in six of the fifteen E.U. Member States (Maynard and Bloor 2003, 38). The incentives, however, differ from country to country as for example in the United Kingdom and in the United States, the pharmacist retains the margin between the reimbursement price and the acquisition cost of the product dispensed (Danzon and Chao 2000, 317). Preferential margins are offered in Spain, France, The Netherlands, and Norway, and fixed prescription funds are applied in Denmark (Mrazek and Frank 2004, 249). For prescribers, it allows them to free up limited funding (cash-limited prescription) for the prescription of more expensive prescription medication only when necessary or free up prescriptions when subject to indicative amounts. The efforts to develop a physician awareness to use cheaper alternative compounds has had quite some success. Patients have lower co-payments. The combination of these benefits results in a more cost-effective healthcare and a wider access to more medicines.

It is and will always be more difficult for innovative medication to stand up to the generic market competition. When the patent expires, the research pharmaceutical companies must reduce their prices to avoid losing prescriptions. For the health insurances, generics are a decisive factor for general cost reductions as their price is 30 to 60 percent lower than the original drug (Grabowski and Vernon 1992) since there are no R&D costs and minimal marketing activities but the active compound remains the same with the same effect. However, in some countries (e.g. Germany), generics are branded (Mrazek and Frank 2004, 247). Whereas in other countries (e.g. U.S.), the generics are non-branded and compete on price. Today, generic products target generally drugs easy to manufacture, with high potential volume, price and margin, and accessible and price sensitive markets.

2.4.3. A Parallel Design of the Interdependent OTC Market

The group of over-the-counter (OTC) medicines includes all drugs that can be obtained without a prescription. Unlike the generic market and the field of innovative drugs, the trade of OTC compounds is considerably more complex.

This area includes:

1/ all prescription-free drugs (even if these have been prescribed by physicians);

2/ all prescription-free drugs for self-medication that are available in pharmacies;

3/ all drugs, available anywhere, not necessarily in pharmacies, but in drug stores and other retail stores;

4/ and all natural and herbal drugs, as long as they are prescription-free.

The political acceptance of self-medication is increasing in the E.U.. regardless of various successes, there are a number of different problems associated with the mutual recognition of national authorization decisions. This is why there is no single European market for self-medications. The delays are due to the fact that in certain countries the authorization requests for these products are not processed unless under tremendous pressure.

This leads to an unclear definition of the OTC market throughout the different countries and therewith the size of the OTC market depending on the statistical data collection of the different product groups (Padhi et al. 2003, 21-5). For example, there is a large amount of OTC products prescribed and reimbursed by health insurances in some countries as Germany. Because of this, only half of the OTC medicines are considered self-medication and not even 20 percent of all OTC products are freely available. The size of the self-medication market is estimated at 18 percent of the total global pharmaceutical market (*OTC Bulletin* 2002, 23). It can be assumed, that the trend to self-treatments will grow due to the increasing health awareness.

Self-medication through the use of OTC drugs is described by Ho et al. (1997, 104) as a cost-effective way of treating minor illnesses without the need for expensive medical attention. According to finding from Rassat (1991), Fargel (1991), and Gehrig (1992), the use of self-medications is increasing and the pharmaceutical industry's advertising measures are creating a "self-medication lifestyle" need. Therefore the OTC market differentiates itself from the prescription market not only by its context but also by its product spectrum. The attitude towards medicine at the beginning of the 21st century has changed. An important number of drugs were not anymore taken for an actual

disease, but taken for health preserving reasons. Indeed, according to many American surveys, self-medication is often associated to prophylactic measures. Prescription drugs are associated to the treatment of a "real" disease. Thus, the therapies for light diseases lead the OTC market revenues with more than €75 billion, followed by light pain relievers with revenues of €0,5 billion (James 1998). It is health and not the disease seen as the growth market of the future.

Global players often consider the option to switch prescription status. There are numerous advantages for pharmaceutical companies to target the OTC status due to reduced development and distribution costs and shorter times to access the market because of relaxed regulations. The demand for cheaper OTC compounds increases since fewer drugs are being reimbursed. In the U.K. alone, the transfer of three high-revenues drugs from the prescription drugs to non-prescription drugs have seen their market volume double in five years.

OTC consists of various segments including pharmaceutical drugs, vitamins and dietary supplements, homeopathy and phytotherapeutics (Bond et al. 2004, 261).

The market segment of vitamins and supplements itself has considerably grown in the last few years. Hill (1997) mentions growth rates for the supplement industry of 25 to 30 percent annually (Patton 2004). The definition of OTC products varies from country to country. According to Mason (1998, 297), the reason for the blurred boundaries between drugs and supplements lies in the ambiguities of government texts such as the Dietary Supplement Health and Education Act of 1994. It allows drug-like products to be classified as supplements and have suggestive health claims on the labeling. In addition, supplements are not required by the FDA to have pre-market approval or safety testing.

The use of homeopathy and phytotherapeutics is also rising, and not only in Germany, where these traditional areas are well-developed. Unlike vitamins and mineral preparations, the use is indeed subject to a special licensing system for the health authorities to control quality and use. But these regulations are highly variable (Ernst and Dixon 2004, 312-9). Since their action is often not proven, their use is being observed with skepticism. Nevertheless, it is not rare to find phytopharmaceuticals in market segments of traditional medications. Some of these drugs have been in use

now for decades and the companies have no incentives to conduct a thorough financial analysis. Despite the increasing acceptance of alternative therapy possibilities, the pharmaceutical industry was not able to position these medicines successfully until now. The United States have shown that this area can develop positively when new introductions stimulate the market. Especially the close cooperation between companies and media can create an awareness of these approaches.

Another characteristic of the OTC drug segment is the variation of the distribution channels in the various countries. While distribution channels are virtually unlimited in the United States, OTCs are exclusively sold in pharmacies in most European countries (Bond et al. 2004, 267). France, Spain and Portugal are classical example of this concept. A mixed-system has been established in Germany in the last 20 years. Even if the majority of products are available through pharmacies, the wholesaler's and retailers' sales are rising. Basically, the sales depend on the pharmaceutical drug laws. Some products are only to be sold by pharmacies, and dietary supplements can be also carried by other distribution channels. Despite liberal conditions, self-medication drugs are predominantly sold in pharmacies. For compounds, which are also available at other sales points, pharmacies carry 40 percent of the market share. Because of increasing competition from drug stores, discounters and food stores, this situation is expected to change drastically and resemble more the American one. With the consumption rise, the "population dietary means" are bought where the other goods for the daily needs are available. The pharmacies have developed the primary core competency in "disease", whereas the discounter and supermarkets have focused on "wellness and health".

Above all, the web-based distance shopping has opened new channels. The internet is gaining a more important role as communication and business platform (Bradley et al. 2004, 172). The sales of OTC through e-business transactions have a three digit growth rate every year, and are particularly well-developed in the United States.

The OTC drug segment relates much more to a consumer goods market than ethical drugs. Thus, the dynamics are very different. Nevertheless, as the regulations on the commercialization of ethical drugs are evolving and becoming increasingly liberal, the

pharmaceutical industry can inspire itself on the OTC example and learn from its experiences.

3 Application of CRM to Pharmaceutical Innovations

The success of a pharmaceutical product is not only dependent on new product features but also on a number of external factors. Although 50 percent of the pharmaceutical company's revenues are due to new compounds, only 3 out of 10 compounds generate the expected returns (BMBF 2000, 77). Customer orientation and interaction are becoming central factors in pharmaceutical innovation marketing, taking place during the whole development process, from the research through the clinical phases to the market entry. The customer is becoming the central element around who product development strives to satisfy the needs of the market. Various communication and cooperation strategies are developed to gain the market's seal of approval. This leads to the definition of a comprehensive communication concept for the innovation's early phases, the clinical phases, and the market launch in order to prepare the targeted market parallel to the product development. Dichtl and Thiess (1989, 386-388) include the role of services, clinical studies, sales force, data collection and analysis to the classical element of pharmaceutical communication reinforcing the role of a customer relationship approach.

First a general look at the existing CRM programs in the pharmaceutical industry will be exposed and will be supported by the definition of specific industry related maturity stages to understand to the current and future goals of pharmaceutical CRM. Then concrete CRM activities available to the two main targeted customers, the physician and the patient, will be closely analyzed to understand the status quo.

3.1. Relevance of Current CRM programs in the pharmaceutical industry

Some trends are driving changes in the way pharmaceutical companies interact with their customers. One of these is a shift in perception of the healthcare industry "*from a hallowed and deeply respected privilege of society to a service industry comparable to financial services or consumer goods*" (Coles et al. 2002, 9). According to Stone (1995, 54), health care is now aiming at "*enrolling and retaining lives*". Pharmaceutical marketers are turning their focus from new product launches to efforts aimed at attracting new customers towards increasing retention levels among existing markets and cross-selling drugs across related diseases. Muttalib (2003) has discussed that medium and long-term success can result from relationship-building activities driven by both the marketer and the healthcare customer. Also, according to Sommer (2002, 9), the causes of inefficiency in the healthcare system, next to the development and manufacturing of pharmaceutical drugs are due to wrong prescribing behavior, wrong medical drug intake and abandonment of therapy. This reveals a lack of information for the prescribers and the patients, thus, a non-existing or inefficient CRM.

The new challenges of the pharmaceutical industry is, after the development of innovative products, building a customer relationship management. These two issues are and are expected to stay, by far the most important on the priority list of the pharmaceutical marketing and sales departments according to two studies conducted by CGEY (2001b, 11; 2002b, 15).

Customer relationship management is not a new concept in this industry. It is not anymore an option but a necessity in order to remain competitive. Another worldwide study by CGEY and INSEAD (2002, 6) showed that 76 percent of life sciences companies have already made some kind of CRM investment and 57 percent of executives interviewed expect CRM initiatives to increase over the next five years. An April 2002 survey by Forrester Research (2002), found that 60 percent of the world's top pharmaceutical companies already had CRM projects under way, a comparatively high percentage to the average 38 percent for all global corporations. CRM measures are mainly applied by large pharmaceutical organizations as shown in a

pharmaceutical market study by Prof. Homburg and Partner (2001). Despite a lack of productivity in the pipelines and stagnating marketing budgets, pharmaceutical CRM programs have not been evolving as fast as in other industries. And pharmaceutical marketers are expressing uncertainty about the return on investment. According to Forrester Research (2002), 16 percent believed that measuring value was a barrier to implementation and 26 percent thought the cost of infrastructure and integration has slowed down the development of CRM.

Until today, life sciences CRM has focused on IT-driven single point solutions such as sales force and call-center automation. These often did not meet all expectations revolving around reporting or operational improvement, cost reduction, increased productivity, and customer satisfaction. In addition to the cost induced by adopting such systems, communication activities used to maintain or increase sales are typically 8-9 percent of the sales revenues (Cearnal 1992, 23). And the money and efforts have not been yet reflected in the results released by the pharmaceutical companies.

Currently, life sciences CRM concentrated on two target groups: physicians and patients. Forrester Research (2002) found that 37 percent of companies consider the physician as their primary customer for their CRM strategy, 21 percent of companies think of the consumer as the primary customer and only 11 percent primarily target both, physicians and consumers.

Pharmaceutical marketing has experienced an increasing interest on the patient. The small and medium-sized pharmaceutical companies have not invested much time and money in CRM and are generally solely focused on physicians. Indeed, in the United States, about 86 percent of promotional spending is directed to prescribers, mainly physicians (80 percent of promotional spending), and only 14 percent to patients (Henry J. Kaiser Family Foundation 2003b, 3-4; GOA 2002b 3, 10; NIHCM 2001, 4).

Also, two systems have to be differentiated. The first one is represented in the United States and New Zealand accepting to consider the patient as a customer of the pharmaceutical company allowing a dialogue between the two parties. The other system is represented by the rest of the world prohibiting pharmaceutical companies to communicate directly to the patient. For the purpose of this thesis, the first system will mainly be analyzed in order to draw a broad picture of the pharmaceutical customer

relationship management. A chapter at the end will be dedicated to the impact of the regulations imposed by the other type of health care system.

3.2. Maturity Stage of Life Sciences Customer Relationship Management

Based on a survey, Coles et al. (2002, 12) found that "*71 percent of pharmaceutical companies did not have an executive in charge of customer relationship management, 75 percent implemented CRM in separate departments or channels and 53 percent said that IT was only somewhat aligned with their CRM efforts*." They have also demonstrated that most pharmaceutical current marketing practices are still based on behavioral data such as sales and prescriptions. This reflects the inconsistency of CRM application in the pharmaceutical industry and the disparities compared to other industries (CGEY and INSEAD 2001, 12).

Another study by CGEY and INSEAD (2002, 9) has analyzed the different components of CRM:

1/ The **channels** are being personalized, moving from a single channel, the sales force, to a multiple channel system targeting the various physician segments.

2/ Very few companies understand the prescribing behaviors. They are trying to integrate the data gathered from all sources. The improvement of the data quality is part of making the existing models more operational. Their goal is to develop a more detailed and predictive segmentation model using **data analyses**.

3/ The **IT** for life sciences CRM is focused on integrating a number of single point solutions and improving user training to increase the use of the current systems. The next step would be to introduce more sophisticated analytical capabilities.

4/ In the **organizational architecture**, there seems to be an increase of basic level of marketing and sales performance as well as an increase of data transparency and visibility. The entire organization is focusing and aligning itself through segmentation models and strategies, and at the same time introducing a stronger process focus.

According to this study, the CRM strategy of life sciences companies lies between operational and analytical CRM. The main focus is still trying to coordinate data

collection, and personalizing the relationship with their current main customer: the physician.

3.3. Application of CRM Targeting Physicians

For a long time, since physicians have the prescribing power, it was considered that they automatically had the purchasing decision of pharmaceutical prescription products and were therefore considered as the most important target group of the pharmaceutical manufacturer (Becker 1992, 13-14; Wehking 1985, 35). Butler (2002, 67) concedes that, traditionally, the physician was the customer and sometimes some hospital specialist and a few nurses. The important role of the physician in the prescription decision has been demonstrated by Hellerstein (1998). Customer relationship management for the physician, or physician relationship management, has relied on the pharmaceutical company's sales force. Pharmaceutical companies have always had a close relationship with physicians through the personalized contact established by sales representatives. This target group has been segmented at length according to their specialty, geography, prescribing behaviors, medical offices, and other socio-demographic factors, resulting in a more focused and appropriate communication.

However, the environment changed and the strategy of building larger and larger sales teams to interact more intensively with the physician is being questioned. According to Mooney (2001), the physician has been going through behavioral changes. The result is a physician more serious and more selective about his medical education. For Ross (2002), there is a tendency to put a stop to the "push" strategy from sales representatives to encourage the "pull" from physicians. In addition, facing the increasing demands of patients on physicians, the role of the sales force is also shifting to a more supportive role of the doctor-patient relationship.

The relationship between the physician and the pharmaceutical company can also evolve to create a partnership. Physicians can transmit their knowledge, interest, experience, trust in a product or a company to their peers, therefore influencing prescription habits positively in favor of the concerned product or manufacturer.

Also, the relationship does not only stop at the product's commercialization as the physicians also participate during the whole innovation process. They are involved in

product development and participate actively in clinical trials. They are kept up to date by specialty journals and magazines transmitting scientific advances. It is a target group putting emphasis on educational marketing versus promotional marketing.

However, pharmaceutical companies are finding it increasingly hard for their sales forces to get face time with physicians and have been turning to e-detailing and other emerging electronic techniques to reach doctors. And indeed, the conversation has to lean towards the scientific information such as the nature of the disease, the patient type involved, and the epidemiology. This requires having scientifically competent points of contact, the sales force, and call centers.

3.3.1. Description of the Current and Emerging Pharmaceutical Activities Focusing on Physicians

The main activity areas directed towards the physician include market research, and sales force contact intertwining with the marketing and educational campaigns. In addition, technological advances have allowed developing tools which contribute to facilitating the dialog between the pharmaceutical company and the physician.

Pharmaceutical company	Relationship Management Programs	Technical Tools	
Marketing	**Educational programs** Scientific publications Continuing medical education (CME) courses Continuing health care programs Conferences/conventions/symposia Audiovisual presentations **Promotional programs** Journal advertisements Internet advertisements Clinical trial advertising	**Marketing Automation** **Interactive computer programs** **Web portals** **E-prescription**	Focus on segmentation and analysis of physician market
Campaign management **Market research**	Segmentation Group discussions/Interviews		
Sales force	**Educational programs** Detailing Information material **Promotional programs** Samples Gifts Direct mail advertising **Retention programs** Call centers Speaker programs (Study clubs/semi-seminars) Clinical trial recruitment	**Sales Force Automation** **Call centers** **E-detailing** **Support contact activities** Professional meetings Telephone E-mail Fax	Focus on team selling
Physician contact			

Table 3.1. Physician relationship management today: marketing and sales are responsible for the educational and promotional programs.

3.3.1.1. The Importance of Market Research for Analyzing Physicians

Market research takes place prior to market entry in order to be able to segment physicians. It helps focus on their specific needs. A specialist will receive more in-depth and targeted information. The measurement of physician's satisfaction levels and needs during the product's life cycle as these evolve is also key and can be useful for product extensions plans or innovation modification.

Market research activities are composed mainly of physician interviews, expert workshops, group discussions, surveys, conjoint and image analyses (trommsdorff + drüner, 2003). Currently, marketing departments are focusing especially on segmenting and analyzing the physician market.

Research has shown that in the pharmaceutical industry, the essential sources of information for physicians are journals, continuing medical education (CME) courses, conferences and conventions, colleagues, directories and reference books, pharmaceutical representatives, dealers and wholesalers, government bulletins and literature, direct mail from pharmaceutical companies, videotapes and films, radio networks, cable television, study clubs and discussion groups (Reynolds 1992, 6). Top sources of information cited in a U.K. study in March 1991 (*SCRIP World Pharma News* 1991) were self-training and experience, including CME-type courses, scientific papers, colleagues and patient preference. Today, the internet can be added to this list as it takes on an increasingly important role in the transfer of information between pharmaceutical companies and physicians (Coles et al. 2002, 29).

3.3.1.2. Directly Linking the Company to the Physician Through the Sales Force

The number of sales people has been growing exponentially in the United States, Europe and Japan based on the proven correlation between sales force size and market share (Coles et al. 2002, 26). And today the activities of the sales force is the single most expensive part of the marketing mix (Butler 2002, 66).

But the primary care market is approaching saturation says IBM Business Consulting Services (2003, 13) and further expansion of the sales force could mean decreasing cost-effectiveness of the existing sales force, therefore diminishing the returns from incremental salespeople. According to CGEY and INSEAD (2002, 15) only

companies with a small sales force or with new therapeutic areas are to invest in the sales force. In addition, CGEY (2002, 11) has surveyed pharmaceutical companies conceding that the optimization of the sales force is an actual challenge.

The sales force is the personal and main contact to physicians. They play an early role in clinical trial recruitment since they are the more adept at reaching out and pulling physicians into participating. They also have to communicate intensively with the physicians when a new product enters the market based on detailing. Detailing is the direct promotion of the pharmaceutical drug to the physician by a sales representative. It has been shown by the Henry J. Kaiser Family Foundation (2003a, 3-4) to have a significant impact on the number of prescriptions written for the drug by the physician.

Detailing has been shown to be associated to a particularly high ROI for large and more recently launched brands (Neslin 2001, 20). The sales representatives have the possibility to discern and develop influencers resulting in greater marketing efficiency as described by Gladwell (2002). The supporting activities are mostly insured by sales representatives who can act personally at the physician's request. Scharitzer and Kollarits (2000) have conducted a study which has shown that there is a significant correlation between the satisfaction ratings from physicians concerning pharmaceutical representatives and their prescription behavior. In turn, this has had a positive influence on the success of a pharmaceutical product according to trommsdorff + drüner (2003).

Heutschi et al. (2003, 264-5) describe the challenges faced by conventional detailing. These include the limited opportunities for personal calls; the large intervals between sales calls; the short call duration; the high costs involved; the inadequate availability of on-the-spot information; the lack of differentiation from the competitors; the standardization in communication; and the often incorrect classification of the physician.

In addition, direct and telephone access is highly restricted and limited. Considering that the delivery of a product message can last at least five times the duration of an average medical consultation, the time barrier is also a great disadvantage. According to Elling (2002, 86), the number of sales calls to doctors has risen by only 10 percent

since 1993, whereas the number of sales representatives has doubled in the same period. The cost of detailing to a doctor face-to-face is expensive including the salesperson's time, travel, expenses, samples, and literature. In order to optimize the sales forces, pharmaceutical companies have been integrating sales force automation (SFA) components of customer relationship management for more than ten years. These IT applications allow an exchange of information regarding the physicians, experiences, and solutions to encountered problems within the sales force.

The main concern of the sales force is to implement a team selling approach that provides synergies and therefore a more efficient system to carry out daily business as well as to transfer knowledge throughout the department. It will also have to redefine its role due to the increasing importance of technology in the interactive relationship being developed between the pharmaceutical company and the physician. Team selling enables a shared view of the targeted physicians across the selling team consisting of traditional sales representatives, clinical medical liaisons, channel partners and third-party or contract sales organizations (CSOs). The CSO task is to reach physicians who are too remote or have a low prescription-writing activity to justify a visit from the pharmaceutical company's sales representative. The team is supported by other service and marketing channels due to their additional visibility into physician interactions with contact centers, physician participation in clinical trials, and marketing campaign activities. This multifaceted approach is necessary to respond to the needs of each physician and situation (Chapman et al. 2004, 153) and it creates a single view of the physician. The goal is to segment the physicians more effectively based on profitability, cost to serve them through the sales force, and cost to serve them through a CSO.

3.3.1.3. Differences Between Educational and Promotional Programs

U.S. pharmaceutical companies invested 82 percent of all promotional spending in 2000 on physicians of which 45 percent was spent for samples, 23 percent for detailing, 11 percent for educational meetings and 3 percent for journal advertisement (NIHCM 2001, 4).

Carlton-Perloff (1994, 603) suggests that promoters of tangible products are more inclined to use informational advertising, while intangible product promoters focus on

persuasive advertising. There are indeed two types of communication programs directed to physicians for whom the FDA issued guidelines (FDA 1997): educational and promotion programs. This difference is due to the important role of scientific knowledge involved in the use of pharmaceutical products.

1/ **Educational programs** are axed towards scientific facts, the product's characteristics and use. They are aimed at providing the physician with the knowledge necessary to be able to make a sound choice as to the product's benefits for the patient. The educational components such as journal publications, continuing medical education (CME) courses, continuing health care programs, conferences/conventions/symposia, and audiovisual presentations, are included in the marketing campaign (Pathak 1992, 2). It is to be noted that product managers can not conduct their own CME programs and have to establish a partnership with a provider. The scientific aspect is very important to gain credibility, and already at the early stage of R&D, research results can be published and communicated to inform the medical community of advances in that particular field. Also, this prepares the clinical trial physician recruitment which is a growing issue for pharmaceutical companies. The most recent introduced educational programs are reflecting the need in being effective in communicating more complex messages as the mechanisms of pharmaceutical innovations become much more targeted and involve increasingly more complex working mechanisms and technologies. Physician meetings and events represent the second highest ROI although underutilized compared to the other marketing activities (Neslin 2001, 21).

2/ **Promotional activities** are aimed at building a brand and communicating the availability of the product. The promotional activities revolve around advertising whether print or online. They play a supportive role, attract attention and create an awareness of the product. It can also contribute in building the brand. According to Neslin (2001, 16, 21), at most, 50 percent of the total ROI occurs in the first month of the promotional activities, with up to one or two years for most of the impact to settle in. Medical journal advertising has the higher ROI among marketing activities especially for larger and older brands. It is also unfortunately underutilized.

A highlight of the promotional initiatives is the distribution of free product samples provided to the physician. It has the advantages of being available when the physician is about to prescribe a drug to the patient, the patient, in turn is more likely to take a free sample than to fill out a prescription. And free samples endear patients to doctors. Therefore, it plays a multifaceted role: promotion material, compliance booster, and doctor-patient relationship support.

Physicians can also receive gifts from pharmaceutical companies; however, these follow strict regulations by the FDA and the EMEA according to guidelines adopted by associations such as the American Medical Association or the Pharmaceutical Manufacturers Association to prevent abuse (Cearnal 1992, 29). Direct mail advertising solicits an immediate response such as calling a hotline, completing and mailing a coupon. The current form of promotional marketing practiced by the pharmaceutical industry has been qualified of "interruption marketing" focusing on extending the reach and the frequency of messages (Godin 1999). This can result in a saturation effect of the customer who becomes unwilling to listen to the sent messages.

Marketing and sales are responsible to provide communication to physicians and this specific task includes educational and promotional programs.

It is also important to note that even if the public and political forces associated to educational programs are completely separate from promotional programs, and, although they sometimes integrate advertising into conventions and other type of medical meetings not subject to regulations as strict as for CME, it is a great way to boost the awareness of a pharmaceutical innovation.

3.3.1.4. Addition of Services and Tools to Support the Physician

Extending additional support to the physicians allows them to choose how they wish to interact with the pharmaceutical company (e.g. phone call, fax, e-mail). Physicians can utilize contact centers to request samples, request a sales or medical scientific liaison visit, direct a technical question, request product information or obtain any other related support. Call centers are also made available in order to have a direct referral with the pharmaceutical company. Many companies already have an organization that takes calls on adverse events. The goal is to provide an additional

level of service to physicians to better meet their needs and to increase loyalty. It also has the ability to reduce the cost of serving the entire physician base, as contact centers are a more-cost effective way to meet basic physician needs than an equivalent number of field sales representatives. Coverage can be made 24 hours a day, 7 days a week, be staffed with customer service as well as medical personnel, and be tied into a web portal for online coaching or assistance. This unique contact center solution can be tied to other departments such as legal, packaging, technical and also patient relationship management through reminder services.

The internet allows physicians to reach out to the pharmaceutical company when and where they choose. The enabling technology includes portals with personalization and content delivery capabilities. Approximately 15 percent of physicians have expressed a desire to be detailed via the internet. The goal is to facilitate a better flow of information (e.g., product-related data or other information normally delivered as a detail visit), which can be enhanced by personalized and easy to use interfaces. Providing web support increases not only convenience for the physician but also the reach and frequency of the relationship.

Apart from the traditional CRM tools, there are two additional and somewhat revolutionary applications: e-detailing and e-prescription systems (Smith B. 2001, 85).

E-prescribing is a support system involving other healthcare players to their benefit. Point-of-care e-prescribing systems allow the use of computers or hand-held devices to submit prescriptions to pharmacies electronically. In the United States, the National Council for Prescription Drug Programs, Inc (NCPDP) has established standards for transmitting electronically prescription information between the prescribers and drug suppliers. According to Tercha and Gleason (2002), through e-prescribing, physicians can particularly "*reduce medication errors, improve patient satisfaction and reduce practice costs*". It also allows reaching the physician at the prescribing moment informing him about the latest news and driving physician brand awareness. Physicians can be directly educated on prescription guidelines such as indication, benefits, efficacy, dosing and recommended refills. News or additional clinical information can serve to increase the doctor's awareness in relation to compliance,

scientific information concerning the drug. This information is instantly communicated and reached.

E-detailing is a complementary IT application which can be used for the sales force to deliver a message at the doctor's convenience. It can also support the district representative as a door opener, by offering samples, information or patient education material. Liebman (2000, 1) has described e-detailing by mentioning two examples:

- iPhysicianNet, is a live detailing through a videoconference. The IT component is provided to the physicians. The pharmaceutical company can also organize "peer influence group conferences" and send various programs to the physician.

- Physicians Interactive, focuses on prerecorded interactive detailing.

It has been shown that detailing with the aid of visual material increases significantly physician prescribing. However, the use of visuals requires time and is difficult to expose within the available two minutes (Arnold 2003, 12). E-detailing offers a spectrum of actions involving a range of human-human-machine interactions including the internet, mobile devices, interactive systems, telephone and personal visits (Heutschi et al. 2003, 266). Therefore the solution brought by e-detailing greatly supports the sales force as it lowers detail costs, has a greater reach and interaction frequency, more customer information and better segmentation possibilities, has synergy effects for conventional detailing, a higher customer acceptance, greater depth and speed of information (Liebman 2000). Nevertheless, its implementation is still facing the following challenges: reduction of absolute marketing costs; provider situation and market structure to offer competitive solutions; legal restrictions; internal skepticism and resistance; mistrust and objectivity of the information; and the establishment and acceptance of new communication channels (Heutschi et al. 2003, 268-271).

It is important for the technology to be compatible with and to be able to integrate the office systems already in place. This is often the barrier to the application of these systems along with the resistance to change.

3.3.2. Planning Physician Relationship Aligned with the Innovation and Life Cycle Process Evolving into a Multi-Channel Concept

Figure 3.2. puts into perspective the above described CRM activities. The relationship between the pharmaceutical company and the physician is continuous from the R&D stage onwards, but the focuses are different for the marketing department and the sales force along the innovation process and the product's life cycle. At first, the scientific aspect of the innovation is very important to be communicated and will develop into a strong educational program such as continuing medical education courses. Market research before market entry is as well essential to give all required knowledge to the sales force for them to approach physicians with the new product. The sales force's task is to introduce the product and facilitate the interaction between the product and the physician. The sales force has another task: recruiting the right physicians for clinical trials as well as influencers who can, in turn, contribute to the product's promotion within the medical community on a broader scale.

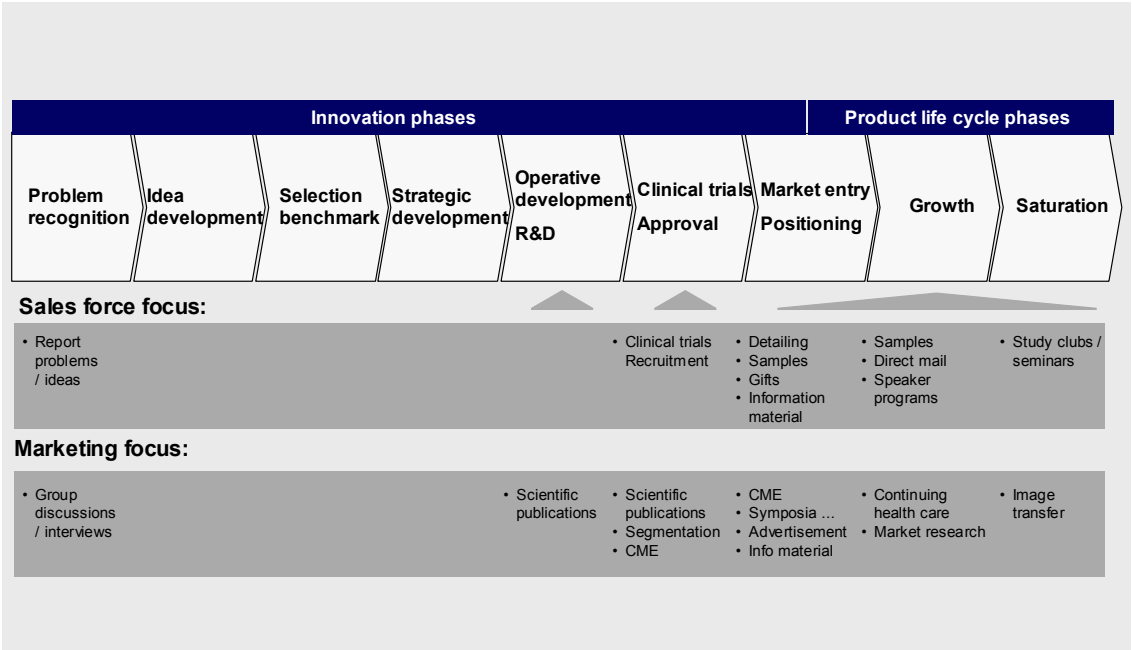

Figure 3.1. Physician participation in the innovation process and the product life cycle phases: the physician becomes an important marketing target already in the R&D phase.

A synchronized campaign management provides the extended sales team and the physician with a set of information and activities that strengthens and reinforces the campaign such as ensuring the physician's knowledge of the timing and nature of

marketing campaigns, providing campaign-related collateral materials to the physician, and supplying physicians with samples. The goal is maximum effectiveness of the campaign.

Visibility into clinical trial participation and speaker programs enables the extended sales team to have a better view of physician participation in clinical trials and speaker programs. Shared information includes past and present clinical trial participations by product and trial phase, dates, topics, and evaluations of past speaking engagements, and lists of prospective speakers by topic area. This helps utilizing sales in recruiting physicians for clinical trials and speaker programs and to better manage relationships as trial physicians become opinion leaders and product advocates. Recruiting costs go down, and the utilization of opinion leaders as influencers increases.

The physicians' expectations and needs have changed in the last decade and they require an adaptation from the sales force's behavior to provide a broader support in their patient-doctor interaction and allow them time and convenience of contact. A shift occurred from a product "push" strategy towards a more consultative approach (Coles et al. 2002, 28), dealing less with the rational aspect of the product and more with the emotional one. This has evolved into an integration need of the information from all touch points: contact centers, websites, kiosks and sharing data between sales representatives.

The trend is leaning towards a multi-channel customer relationship management at the physician level. The combination of these channels and capabilities provides a more flexible, intimate and complete physician relationship allowing the physician to choose the time and manner of the interaction with the pharmaceutical company. In turn, the company presents a consistent message to the physician and can ensure a rapid follow-through on inbound physician requests or outbound campaign/communications, as the channels are integrated and the views of the physician are shared. The five components of such a system are described by Hagemeyer (2002) as:

- team selling;
- synchronized campaign management;

- visibility into clinical trial participation and speaker programs;
- contact centers;
- and leveraging the internet.

Pharmaceutical companies seem to be in the second maturity stage described in 3.2 for their relationship management with physicians since they are still trying to fully understand this customer but have collected sufficient information to be comprehensively analyzed.

3.4. Application of CRM Targeting the Patient

The patient is becoming more and more a central target of the pharmaceutical company. However, building a relationship with him is fairly complex due to the prescribing process and the many influences involved. It is also a difficult task as pharmaceutical products are subject to regulations either allowing promotional programs for the consumer but applying restrictions or prohibiting it completely. In order to first grasp the concept of patient relationship management (PRM), the patient and the purchasing, alias the prescribing process must be understood.

The health care market has been changing and one of the most important issues is the position of the patient as a customer. The population has been growing older and this will be even more emphasized as the baby boomer generation ages. However, these will bring a new view of healthcare by believing in individuals taking on more responsibility for their health. This complies with the WHO campaign and government efforts focusing on making people responsible for their health through information to enable them to take appropriate decisions and choices (Stuart 1999, 788). In Europe, data sheets, copies of patient information leaflet and factual, non-promotional information can already be provided to a patient upon enquiry (Jaderberg 2002, 180).

According to a report from Coles et al. (2002, 7), the use on the drug is becoming increasing dependant on the patient. In 1988, Thiess (1988, 424-426) already mentioned a communication politic for the patient next to the physician and pharmacies, predicting an increasing importance of the patient's opinion. Another study from CGEY (2001b, 9) conducted in Germany and Switzerland shows an expected increase of the patient's importance in comparison with physicians and clinics/hospitals. Hohensohn (1998, 125) finds the patient involved and intending to take part in the prescription decision, through "active and information-oriented doctor-patient discussions". The physician and patient, therefore, negotiate an action plan for the management of the disease and a therapy acceptable for both parties (Bradley et al. 2004, 162). Ten Kate (1998, 34) states that consumers take responsibility for treating their health problems most of the time. Most doctors expect the consultation style in

the future to be doctor and patient led. In the same study, the patient is shown to be able to differentiate a therapy decision and product choice. Another study shows that over 50 percent of prescribed drugs are not well accepted by patients (CGEY and NBCH 2002, 2).

In the United States, there has been a clear shift towards the patient as pharmaceutical companies are allowed to communicate directly to the end-consumer. In Europe, this shift is also existent, although more discreetly as regulations do not allow direct advertising of prescription medicine to patients according to the Directive 92/28/EEC of the Council of the European Communities (1992).

The patient is becoming increasingly a target for marketing and is also pulled into product development, since pharmaceutical companies are directing their innovation process towards customer, or more precisely, consumer needs.

Badenhoop (2001, 15) has defined patient relationship management (PRM) as an innovative business concept for building and retaining long-term, profitable business relationships with the patient as end-consumer of medical products.

PRM is, at the moment, focused especially on chronic diseases where it is easier for the pharmaceutical company to build a life-long relationship with the patient, even though other therapeutic conditions such as "lifestyle" diseases[1] are argued to be also appropriate to this approach (CGEY 2001b, 5). Marketing can take on a preventive role in order to create an awareness effect for conditions usually not openly recognized or untreated.

3.4.1. Additional Consideration of the Patient Flow and Prescribing Process

To defined PRM activities, the purchasing flow of the patient has to first be drawn. In this case the purchasing flow is based on the prescribing process. However, the typical general processes of purchasing and communication models can hereby be applied. Côté and Stein (2000) have designed the theoretical model of a patient flow to sort out

[1] This is subjective to the definition given to "lifestyle" diseases, which varies according to marketing and medical use. A clearer description will be introduced further in this work depending on the disease's positioning.

the needs, progress and capacity planning. But for the purpose of drawing a communication strategy, the particular situation of decision taking for the choice of pharmaceutical prescriptions has to be considered.

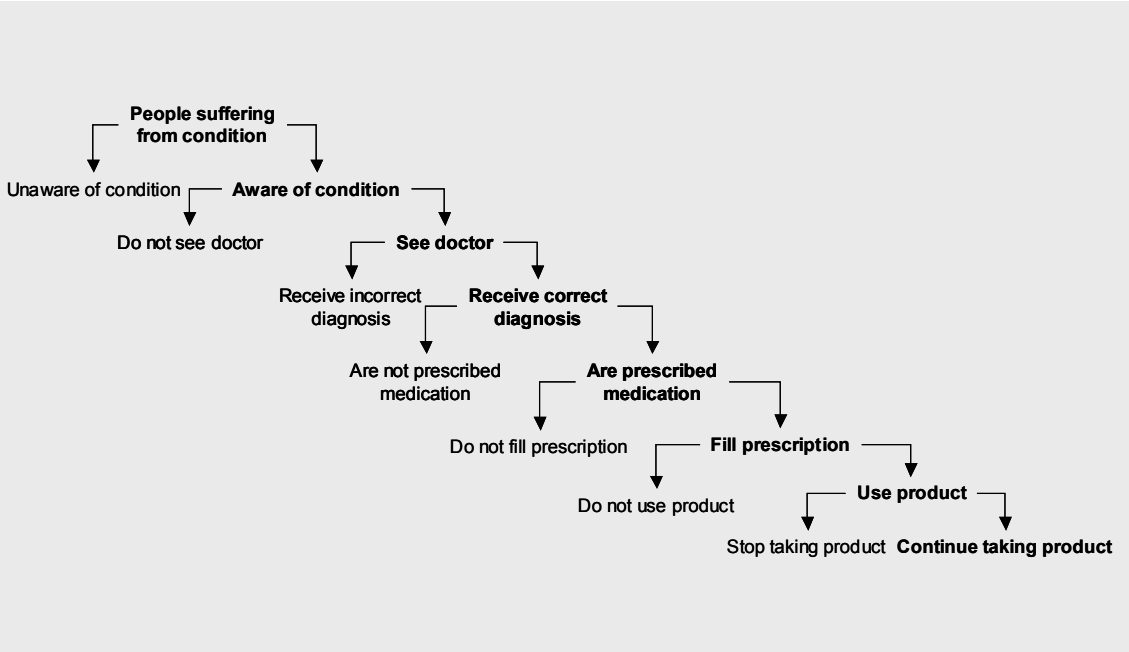

Figure 3.2. A summary of the patient flow has been presented by Sugahara (2003, 24).

The physician's influence and the time pressure during the actual decision alter the whole process. The events before and after the doctor's visit also have to be included. The prescription as part of the decision process has been described by Hilleke-Daniel (1989, 123). Boerkamp (1995, 44) has described the actual prescription process starting from the decision to visit a doctor, to accept the diagnosis, to follow a therapy, up to the choice of the medicine. The patient can thereafter decide whether to comply with this prescription, taking the purchase decision. The patient's choice is assumed to be a rational trade-off between health benefits, and monetary as well as non-monetary costs associated with drug consumption such as side effects, dosage and schedule. Indeed, the patient may not blindly follow the doctor's choice regarding the treatment of the disease as it is assumed that the doctor may not know precisely some of the patient's characteristics such as aspects of health history, anti-drug attitude, and exposure to drug advertising. In addition, the doctor may not know how much the patient trusts his competence. Different components relative to the patient can be therefore defined revolving around the patient's satisfaction. Ley (1980, 71-73) describes them in a model including understanding, retaining and compliance.

The current factors influencing the consumer's prescription drug knowledge and requests are described by Peyrot et al. (1998, 30-1). These include demographics (income, occupational status, origin, gender, and education), media exposure, attitudes towards direct-to-consumer advertising (DTCA), and the medical experience.

3.4.2. Description of the Actual and Emerging Pharmaceutical PRM Activities

According to Badenhoop (2001, 15), the central PRM components are:

- **market research** for a critical customer segmentation;
- **data-based marketing** leading to educational communication and advertising;
- and **customer service** aiming at customer retention with customer loyalty program and disease management programs (DPM).

The summary of PRM activities are reported in table 3.2.

Pharmaceutical company	Relationship Management Programs	Technical Tools	
Marketing **Data-cased marketing or Campaign management** **Market research**	**Educational programs** Publications Information material Conferences/conventions/symposia Websites **Promotional programs** Print, mass media and internet advertising. (disease awareness, product claim, reminder, manufacturer) **Clinical trial recruitment** **Advertising** Segmentation Group discussions/Interviews	**Communication** Internet system: e-mail, websites Wireless Application Protocol (WAP) Short Messaging System (SMS) **Data collection and analysis** Online risk-assessment questionnaires Marketing automation: advanced data analysis Data warehousing: storage applications and platform allowing integration of data from different IT systems Data mining: decision-modeling software OLAP for ongoing analysis Website log records	Focus on Advertising product directly to the patient
Customer service **Patient contact**	**Retention programs** **•Loyalty programs** Call centers Web portals Interactive systems E-prescription E-health **•Disease management programs (DMP)** **Clinical trial recruitment** Advertising	**Customer retention** Call centers Help desk management Sales automation Web portals (virtual communities, agents) Web-based interactive systems (reminders, automatic refills) E-prescription systems Electronic records Monitoring devices	Focus on Answering Questions and complaints

Table 3.2. Patient relationship management today: marketing is responsible for the educational and promotional programs; customer service focuses on support and direct interaction with the patient (Frederiksen et al. 1984; Kotler and Clarke 1987; Koberstein 1993).

1/ Market research

Market research can focus on customer segmentation to understand the patient and his needs. This activity can already take place during the actual product development phase resulting in an innovation corresponding to the requirements of the end-consumer concerning for example side-effects, compatibility with other drugs and presentation form. Market research can also be useful during clinical trials in order to segment the patients, providing the information necessary to establish a focused and targeted marketing campaign and ensure a trustworthy market entry of the innovation. After market entry, the satisfaction level can be measured by evaluating patients directly, or through physicians or patient support groups. This can lead to changes in the marketing mix and to further product developments necessary once the drug's patent expires.

2/ Data-based marketing

Frederiksen et al. (1984) as well as Kotler and Clarke (1987) have each given a wide overview of communication mix tools and the strategic relevance in the marketing of health care. Also Koberstein (1993) draws a detailed picture of the different tools and gives examples of patient communication. He supports, as Paul (1988, 36-38) does, relationship marketing for health care.

Patient-oriented communication is more commonly referred to as direct-to-consumer marketing or DTC. In order to have a better overview of the different approaches DTC material can be separated according to educational communication and advertising (Boerkamp 1995, 241-245; Henry J. Kaiser Family Foundation 2003a, 4). These are two main marketing directions covered by the pharmaceutical manufacturer according to Baudot (1991, 24-27) and to Hohensohn (1998, 151): the product-related marketing and the health behavior-related marketing taking into consideration the socio-economic aspects. These two types of marketing are interrelated. Also Hohensohn (1998, 148) has tempted to map out the many concrete goals of patient marketing.

- **Educational communication** plays a crucial role as medical drugs are not pure rational products. They can persuade through service promises and not through emotional associations alone. This type of communication includes

disease awareness, prevention and therapy support, and product-related training: print articles (newspapers, magazines, and specialty magazines), radio and television series, reports or documentary, internet, brochures, pamphlets, videos, literature, package inserts, and sales force. The communicated information can be about the therapy, the product, the disease and environmental factors such as sports and nutrition for a certain condition.

- **Advertising** includes disease awareness and product advertising: print (newspapers, magazines, specialty magazines), radio, television, internet, billboards and other outdoor advertising, brochures, pamphlets, posters, direct mail, gifts (health passes, blood pressure passes, emergency ID, dosage and appointment writing pads, note pads, therapy book and agendas). Emotional print ads have been described in depth by Girardi (1987, 216).

Patients usually search for information in four types of sources according to Kotler (1987, 265-266) adjusting to the health care market and supported by the empirical approach of Fritz (1981, 120):

1/ "*personal, non commercial sources such as friends, family and doctors;*

2/ personal, commercial sources such as a sales representative;

3/ impersonal, non-commercial sources such as the mass media (television, radio, internet);

4/ impersonal, commercial sources such as advertisements, catalogues, and packaging."

The increased importance of the internet as a source of information is supported by the fact that customer research their symptoms online more than 40 percent of the time (Yarmoff, 2001, 4).

In 2000 in the United States, 57 percent of the direct-to-consumer spending was invested in television ads, 31.8 percent on print ads and 11 percent on radio, billboards and other (NIHCM Foundation 2000, 4). DTC has mainly been confined to advertising, even though is does involve the complete communication campaign directed to the consumer. The FDA has defined three types of DTC advertisements

(GOA 2002, 6-8). The first type is product claim advertisement which mentions a drug's name and the corresponding condition and describes the risks and benefits of the product. This type of advertisement is strongly regulated. The second type of advertisement is reminder advertisement disclosing the name of the product and dosage form or cost, but it is not allowed to present the use foreseen or to promote it. The third type of publicity allowed is help-seeking advertisements. These are not regulated. The drug is not refered to by its brand. Only descriptions of the disease are mentioned, advising to request additional information from the medical community.

Mass media play a particularly important role in DTC especially for health education (Bradley et al. 2004, 168). Trigt (1995) describes the importance of medical information through mass media due to the increasing interest in medicine and pharmaceutics influencing individual health behaviors and health politics. Compared to the other types of mass media, the internet is taking on an increasing role in the health and product communication. According to Coles et al. (2002, 6) the patient is researching increasingly for health information online. According to an American study by Miller and Reents (1998), among those seeking medical data online, 52 percent are looking for information on diseases and 33 percent on pharmaceuticals. This is supported by the fact that the number of websites with health information for consumers is increasing and that e-pharmacies are becoming increasingly common in countries allowing them. DTC is adapting to the new technologies available to establish contact between the pharmaceutical company and its patients.

A study by Neslin (2001, 16) has shown that ROI on DTC is only of 10 percent in the first month of the activity and 72 percent in the first year of the marketing campaign. DTC is best for large and recently launched brands. Although, comparatively, the ROI for DTC is lower than for medical detailing.

In the United States, where the dialogue is open between pharmaceutical companies and patients, promotional spending on consumer for prescription drugs has grown nearly tenfold since 1994 according to the Henry J. Kaiser Family Foundation (2000, 1, 8) to approximately €2 billion in 2000 or almost 16 percent of total promotional expenditures (Weissman et al. 2003, 82). The spending has especially increased following the relaxation of regulations by the U.S. FDA in 1997. Promoting to the

patient has spurred many discussions and is implicated in many controversies including health insurances and physicians. Indeed, promoting to the patient implies a more complicated and intense relationship between doctors and patients, requiring a broader reach, more information and a change in the dialogues according to a study carried out for the FDA (Aikin 2003). Drugs benefiting from DTC are often best sellers in their category and are characterize by an increased growth compared to other less promoted alternatives (GAO 2002, 3). Promotion has been accused of driving the costs of health insurances up and misleading the consumer[2].

Direct-to-consumer marketing can have many effects. Studies (Calfee 2002, 23; Henry J. Kaiser Family Foundation 2003a, 5) have shown that DTC encouraged patients to approach their physician about problems they would not have mentioned without the awareness campaign. Surveys from the FDA and private organizations show that DTC advertisements encourage consumers to ask their physicians for brand-name drugs (GOA 2002, 16). It extends the pharmaceutical company's product impact by involving hard-to-reach patients. In turn, consumers can gain extra benefits not only limited to the advertised drug by obtaining supplementary information about their health. Such spill-over effects can include awareness of a new condition or new diagnoses especially for under-diagnosed and under-treated conditions such as high cholesterol, hypertension, diabetes and depression. Other examples are attentiveness to side effects, increased information search, and education about alternative, non-medical treatments as described by Weissman et al. (2003, 91). DTC also plays a role in increasing the patient's compliance as it has been shown to comforts the patient and make him feel comfortable about the drug (Marinker 1997). Aikin (2003) reports that patients exposed to DTC are more likely to use the drug properly and to comply with the treatment. Another effect described by Peyrot et al. (1998, 31) is the increase of consumer requests for a prescription drug to be included on a formulary to be reimbursed. This could even lead to a re-classification of the medication to an OTC status. But it is to be noted, that even if conventional marketing focuses on increasing market share, it has been shown that this type of promotion increases sales for the

[2] But in this study, those issues will not be taken into consideration as an overview of PRM is to be described.

advertised drug and for its competitors alike. Especially non-branded DTC marketing focuses on increasing the market size. It does not boost the market share of the advertised drug in relation to its competitors.

Although, the benefits of DTC have been put into light, Avorn (2003) refute their arguments by questioning the relevance of pharmaceutical promotions directed to the consumer favoring a more public, non-commercialized approach of health care communication.

3/ Customer service

Based on Sattlegger (2001, 71) service and customer retention programs can include the following components: direct response campaigns, availability of the company through call centers, extensive information intended for the patient which can include brochures but also more complex and detailed literature, save and process complaints and reclamations through a care of customer relationship with follow-ups, support of patient emergency situations, facilitating orders with automatic refills, appointment reminders through web-based interactive systems. Another component is e-prescription which has been discussed for the physician. It is also of great benefit for the patients as they can gain more time with their physicians, greater convenience in the prescription process and improved medication safety. Customer retention can take the form of customer loyalty programs and disease management programs.

5/ Customer loyalty

Customer loyalty is a new concept and concern for pharmaceutical companies which are currently focusing on generating prescriptions rather than keeping patients according to experts in management consulting (Arlington et al. 2002, 42). Customer loyalty in this industry implies not only that the customer is satisfied with the product, but also that he trusts it for its efficiency and safety benefits. CGEY (2001b, 10) has shown that in 2000, 29 percent of companies used customer and consumer retention programs and 58 percent of them were planning them for 2003. Customer loyalty programs have recently taken a new turn by providing free products for loyal customers (Biospace News 2004).

Customer loyalty can imply building a brand especially for pharmaceutical products. Friesewinkel (1992, 45-48) shows that an established brand represents quality, safety and therapy benefits. Not only does it imply a stronger customer loyalty that a no-name product, it can also be extended to other products from the same manufacturer. For example, this plays an important role for the market entry of modified innovations and for the communication strategy after patent expiry.

6/ Disease management programs

Therapy support and compliance encouragement measures provide the following: an access outcome statistics on drugs, hospitals and individual physicians; information on disease patterns, product and concrete therapies; support of general lifestyle; information on disease environments such as sport and nutrition; support for living with the disease. All of this can be regrouped under the term "support communication". It traditionally involves four types of communication according to Brüderl (1988, 153): emotional, informative, instrumental support and support of self-evaluation. It focuses on disease management programs and e-health.

Patient support can be represented by simple direct response measures in pharmacies and on packages. But as more technology is available for health care, patients are becoming more demanding and expectant of support therapy systems. Indeed, the product offer is not enough anymore for the innovation to be competitive. Especially for chronic disease, there is a demand for a whole system offer for which disease management program (DMP) concepts have been developed, often in cooperation with service providers and health insurances. These concepts are integrated care management of the disease process with the goal of concentrating medical data and exchanging information quickly to insure an appropriate and timely quality therapy.

According to a study by CGEY (2002, 13), DMP concepts have the following effects:

- "*better treatment of chronic diseases especially diabetes and cardiac diseases;*
- *establishment of consistent therapy guidelines;*
- *improvement of patient compliance;*
- *standardization of therapy protocols;*

- *increase of customer satisfaction;*
- *and reduction of therapy costs (cost savings of 15-20 percent on the whole therapy for diabetes and cardiac diseases in the United States).*"

The DMP tools involve three components. The first is education (information material on disease and therapy, education courses for physicians and patients, websites). The second component is process management (compliance management, customer databank and Total Quality Management (TQM) measures). The last component of DMP is patient interfaces through call centers, sales force and telemedical patient monitoring systems. The leading implementations until now are call centers and sales force directed to the patient. The sales force is an expensive, personal and delicate tool which is only appropriate for certain long-term conditions requiring a high patient involvement. Adomeit et al. (2001, 100) have described an e-disease management process emphasizing patient selection and the integration of e-technologies. Disease management programs require the use of emerging IT applications such as monitoring medical devices, systems storing electronic records, software analyzing medical data and e-prescribing systems.

Today, the main contact pharmaceutical companies have with their consumer is a one-way information flow especially through websites focusing on disease and treatments. There is a need for developing interactive sites to build a two-way relationship.

3.4.3. Planning Patient Relationship According to the Product Process and Patient Flow to Establish a Dialogue

Based on the above analysis and referring to the "intervention opportunities in the consumer purchase continuum" described by Bach et al. (2001, 82), planning a PRM implementation follows the product process and the patient flow. The focus on patient requirements and satisfaction implies involving him at the beginning of the project where initially his needs are to be defined to justify the end-product.

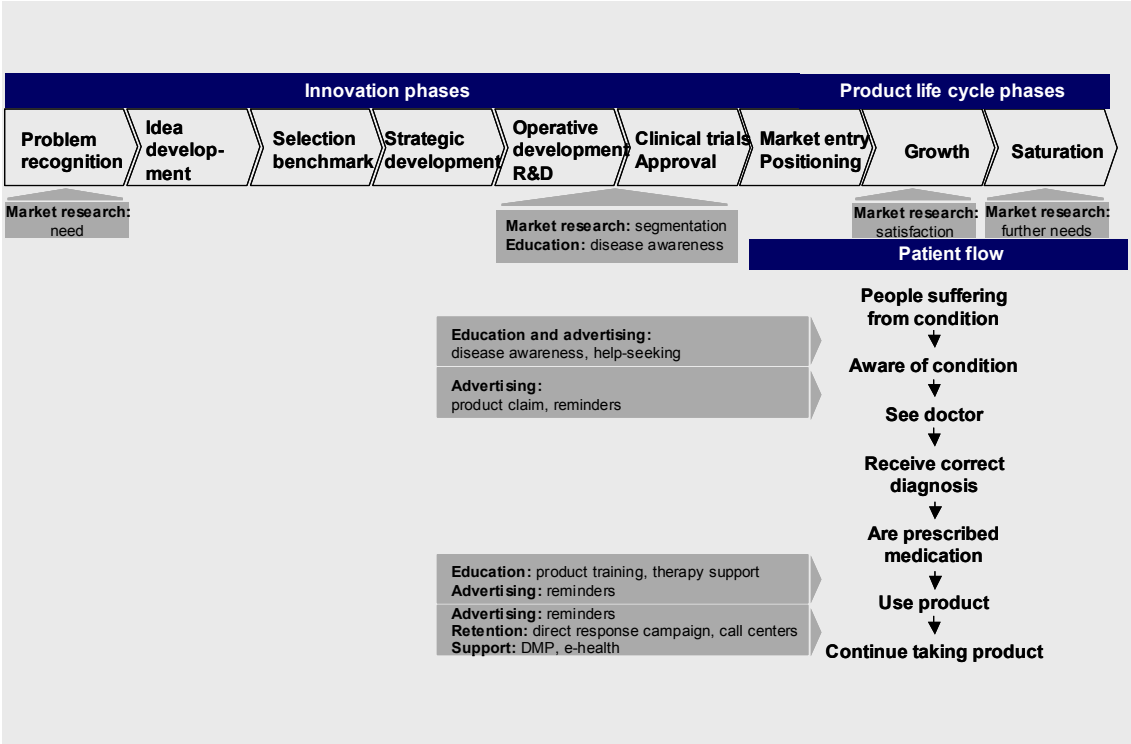

Figure 3.3. PRM planning must take into consideration the innovation process, life cycle and the patient flow in order to cover the whole spectrum of patient interface.

During product development and the clinical trials, the concordance between the product offer and the consumer must be established for target groups to be defined. Market research is carried on during the product's life cycle, measuring consumer satisfaction and developing requirements. This is the base for adjustments and the initiation of new projects.

Already during the clinical trials, pre-marketing activities can be initiated to prepare the market for the upcoming product. This means creating awareness for an unknown disease, or simply informing the public about scientific breakthroughs for a known disease. This awareness campaign is especially important during market entry and the growth phase to increase the market size. At the same time, product-related advertising campaigns are to increase market share by giving the potential consumer a particular product or brand to associate to the disease he was briefed on by disease awareness. He will need this information before entering the doctor's office because it is difficult to add new external information once he has received a diagnosis. The doctor and the patient will have to agree on a therapy and medical drugs. Reminder

advertising can give the patient confidence about filling out his prescription and other educational material can comfort him in the choice of the medicine therefore acting on patient compliance. It is important for the pharmaceutical company to ensure the patient's understanding and appropriate use of the drug to increase its success rate, thus increasing consumer satisfaction. Retention programs are aimed at facilitating the use of the product and creating a brand which in turn, can support other products of the same manufacturer. Support programs such as disease management programs can accompany the patient throughout his whole therapy, thus in some cases, lifelong.

A consolidation of success factors resulting from studies and research on patient relationship management by CGEY (2001b, 19-20), Lesser et al. (2001, 1-3), Homburg et al. (2002a, 103-105; 2002b, 126-129) and Harms and Grosse-Wichtrup (2000, 154a) lead to the following pharmaceutical CRM success factors: the customer focus, the position of PRM within the corporate strategy, the right organizational structure and IT architecture, supplemented by alliances with strategic partners.

1/ The **customer focus**: the first success factor is building a relationship with the right consumer. The patient's needs and behaviors have to be analyzed to develop a sound knowledge to anticipate changes. Patients must be segmented in order to focus on specific indications and patient life-cycles and to individualize and broaden the offer of products and services such as support programs. The market is to be tested before the innovation's launch and communication strategies are to be evaluated beforehand as well. However, a real dialogue must be established such as direct response campaigns allowing the patient to reach out to the pharmaceutical company.

2/ The **position of PRM within the corporate strategy**: the development of a patient relationship management approach should be incorporated into the overall business corporate strategy with the goals and expectations of PRM and its activities to be defined in monetary terms.

3/ The **right organizational structure**: the organization should be structured to support PRM activities through appropriate distribution of resources and professional, efficient sales and customer service. According to Sattlegger (2001, 77), it has to have especially skilled and competent customer-oriented

employees and provided with the tools, knowledge and infrastructure to solve consumer's problems.

4/ The **IT achitechture**: IT is to support PRM by establishing platforms and processes for databases, continuous analysis, communication, devices exchange for information and prescribing.

For pharmaceutical companies, gaining the trust of patients is not as easy and transparent as for consumer good companies. Information provided by the pharmaceutical industry is often regarded as suspicious if it is not supported by a renown scientific or community source. Alliances with strategic partners such as an early involvement of opinion leaders or the integration of patient groups in communication measures are desirable. The dialogue established between the pharmaceutical company and the patient must be, in any case, supported by the treating physician (Badenhoop 2001, 21, CGEY and Gartner 2001), either for the use of education websites or the application of disease management programs.

3.5. Determining Pharmaceutical CRM'S Return on Investment

As mentioned above, the means to measure the investment in CRM programs have been a barrier to the development of this initiative in the pharmaceutical industry. According to a study carried out by Forrester Research (2002), 42 percent of companies use internal utilization as a reference, 37 percent use increased revenues, 26 percent improve customer relationship, 21 percent increase market research intelligence, 21 percent a positive ROI, and 16 percent correlate it with reduced costs. Nevertheless, CRM controlling remains a difficult task to perform, and to quantify but could inspire itself on the traditional methods of CRM controlling described in 1.3.2.5.

The advent of new technologies can make it easier to measure the results. For example e-prescriptions could offer real time data for ROI estimates and facilitate tracking changes in prescribing behavior. Therefore, allowing measuring the overall effectiveness in terms of achieving a brand's strategic objectives.

3.6. Identification of Issues Concluding a Need for Adaptation

But the so-far-described CRM approach does not yet seem adapted to the complexity of the health care industry as many players are involved in the health care process, not just the physician and the patient. And each are having an increasingly defined role. They influence either financially or psychologically the end-consumer, the patient. Their actions can either pressure or support the prescribers. The relationship between them and the pharmaceutical company should not be underestimated and a clear strategy should be defined to cultivate this network. This leads to the fact that the pharmaceutical company already has contact with all of its customers, but the information is coming from different corporate sources and is not shared throughout the organization. This would require an integration of multiple point solutions in order to present a consistent and comprehensive message. Integrated communication is the goal of all communication campaign and communication for the physician should be coherent with the DTC activities for example. Thus, the physician relationship management approach should be coordinated with the PRM approach. It seems like a comprehensive communication concept and a real patient-orientation could be reinforced by an instrumental method adapted to the industry.

PART II: INTEGRATIVE DISCUSSION

4 Convergence of the Analysis in a Comprehensive Pharmaceutical CRM Approach

Butler (2002, 67-68) points out the current trends affecting the pharmaceutical marketing. One is consumer insight as the patient is increasingly recognized as a customer group. Another one is a consistent quality, caliber and motivation of the sales force having to rely more on team selling. There is also a clear focus on developing opinion leaders and influencers as their role in the health care network is taking on importance. In this network, investor relations (IR) and public relations (PR) are crucial since the image and transparency of the pharmaceutical corporation is often in the center of expectations. All these issues are related to good communication and a consistency of key messages targeted to the complete health care network. The solution to the challenges faced by the pharmaceutical industry could be alleviated by formulating an integrated customer relationship management.

The goal of this research is to define an approach for CRM responding to the important issues relevant to the pharmaceutical industry, integrating all health care players and taking into consideration the purchasing process specifically according to the involvement level of the end-consumer.

4.1. Extension the Marketing Values

The influence of political and social forces is introducing new conditions to be considered for the communication process of a pharmaceutical innovation marketing strategy. The open discussion about the sense, purpose and success of the application of a particular medicine and therapy, opens the door to new physician and patient awareness.

Evidence-based medicine finds therapeutic costs and targeted results worth the financial investment. Value for money becomes a decisive benchmark for the being and survival capacities of medical and pharmaceutical drug candidates. Unlike in the 1970s and 1980s, the health care system as a whole can not anymore support medical advances at any cost. In the past the issue was related to the costs of the new medicine. Today the issue is whether or not the social system is ready to invest in a new type of therapy, therewith building a new barrier for the introduction of innovative pharmaceutical products.

To analyze the feasibility and to ensure a profitable commercialization of a pharmaceutical innovation, companies are relying increasingly on a marketing strategy aiming at building relationships. However, marketing strategy is changing constantly its tools and instruments. Sometimes these require refinement and adaptation to the relevant industry. MacStravic (2000, 18-20) and English (2000, 21-23) emphasize the abandonment or breakdown of the borders between single elements of the classical “4 Ps” approach in general. This would not mean to consider the pillars of marketing, the four Ps “Product”, “Price”, “Place” and “Promotion” obsolete, however, they are perhaps not specific enough today for the pharmaceutical industry and as Grönroos (1994, 14) suggests, there may be a need for new perspectives to be more market-oriented.

The industry differs considerably from the consumer goods industry by three main aspects:

- One of them is the number of health care players, each having an influence on the product's purchase.

- The "purchasing" process is also far from conventional as it implicates the provider, the consumer, and other customers holding determinant and influential roles on access to the product and payment transaction. It is a complex market trading process.

- The last difference is the fact that pharmaceutical products can themselves be segmented depending on the disease they are targeting. The opportunities of establishing relationships between the customers and the pharmaceutical company are very different and positioned accordingly within a CRM strategy. These not only involve the products, but the services related to a therapy and the appropriate interactions with the customer, as well.

Traditional marketing is therefore affected and is suggested to be changed in order to respond to the pharmaceutical industry's requirements. The traditional marketing mix can include a particular focus on three internal factors: people, process, and positioning.

Harms et al. (2001b, 1-3) have described an enhanced marketing approach taking into consideration these issues. The traditional marketing mix has been actualized and broadened by three new factors:

- **player**: considering the expectations and needs of all health care parties;

- **processes**: understanding the purchasing/prescribing and communication process of the health care parties;

- **positioning**: positioning of health care services according to the player and process considerations based on the differences of targeted diseases or patient involvement.

4.1.1. Incorporation of the Complexity and Interdependencies of Pharmaceutical Customers

People are a very important element for marketers as they reflect the level of exchange between customers and internal human resources. Some authors such as Dibb et al. (1997, 18) will include people as part of the augmented product element in basic marketing.

In 2002, the majority of the pharmaceutical industry marketing activities targeted the following "people" group: patients, physicians, pharmacies, hospitals and wholesalers. This spectrum is slowly widening to include patient groups, national and international authorities, insurance companies, social associations, political parties and medical interest associations. Authors Dichtl and Thiess (1989, 382) emphasize the need for a stronger consideration of all market partners. Indeed, when analyzing the marketing budget of American pharmaceutical companies such as CGEY (2001b, 16) did, the expenses for prescribers are considerably decreasing for the profit of patients, opinion leaders, and insurances. It is essential to understand the health care system and its value perceived by its market.

A few authors such as Spickschen (1971, 49-52) have described the interaction of the pharmaceutical company with the patient through physicians, hospitals and pharmacies. However, in these models, there is no direct communication with the end-consumer, the patient. James (1992, 29) has broadly defined the pharmaceutical company's customer base. It is a pyramid based on the patient, topped with the prescribers, the opinion leaders, the insurers, and the regulators. For the purpose of this study, the simplified version of James will be taken as reference as it includes all the players mentioned by other authors.

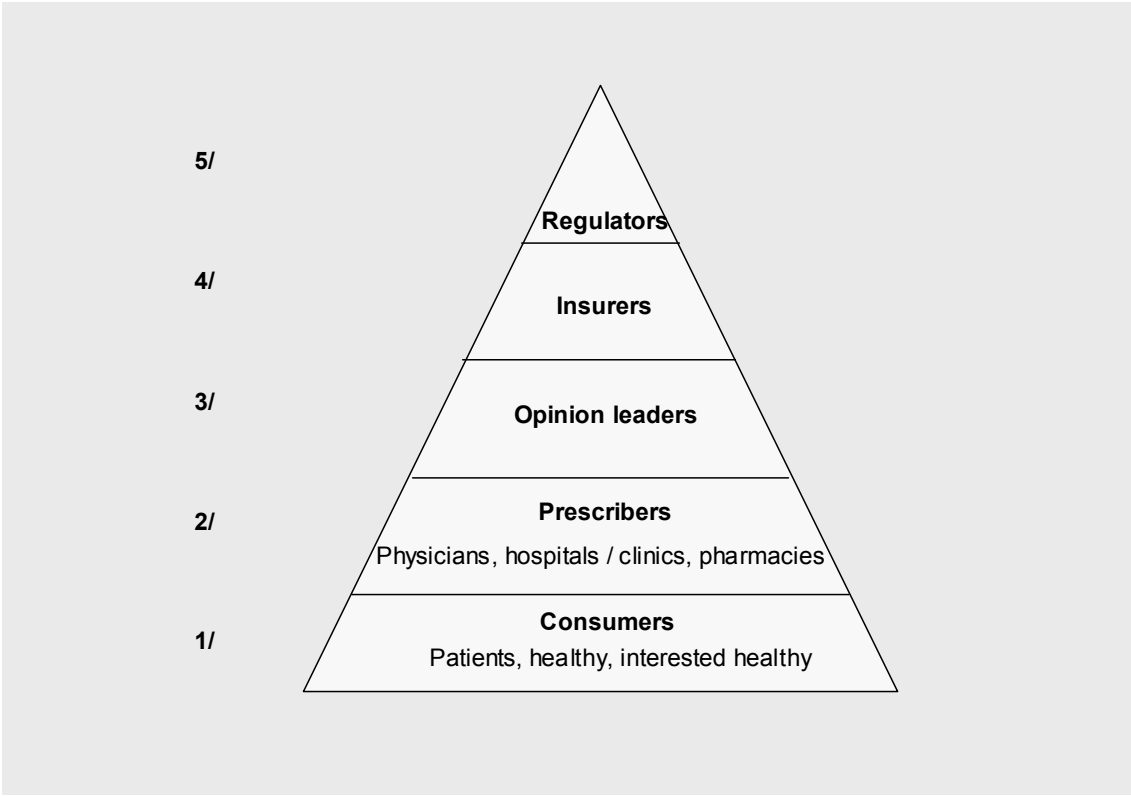

Figure 4.1. Pharmaceutical customer base based on James (1992, 29).

1/ Consumers

Ryf (2001, 31) has shown that patients are becoming a central target group of marketing at the beginning of the 21st century. This can be partly explained by the fact that people are becoming more conscious about their health and taking increasingly responsibility for it. According to Arlington et al. (2002, 43), their co-payments are dominating for very expensive drugs and they are increasingly aware of the drug's costs. As a consequence they expect much better and faster results. It might go as far as a gap between the perceptions, preferences and behavior of the patient in relationship to those of their doctors (Ellickson et al. 1999, 4). This has an impact on the compliance to the prescribed treatment, therefore affecting the success of the drug. As a result, the patient participation in the prescribing decision is rising (CGEY and INSEAD 2002, 12).

2/ Prescribers

The prescribers include the physicians, the clinics and hospitals, and the pharmacies. The physician is the most decisive contact person for drug prescriptions, even though clinics and hospitals must also be taken into consideration as their purchase departments are influencing the use of medicines (Wolf and Mothes 2002, 120), to cut cost and increase efficiency.

Physicians have to be capable of diagnosing the disease in the first place and they will have to support the consumer with information about the condition and prevention means, for those at high risk or who have recovered from the disease. The influence of the physician is crucial and must be coordinated with the patient's demands. For example, the mentioning of a brand or the name of a manufacturer by the patient can be supported by samples and material provided by physicians. The focus is solely on the product when the patient has a low involvement in the decision making. Compliance can be boosted when the patient recognizes the manufacturer's name. Several models of information asymmetry between doctors and patients have been developed. The model of Ellis and McGuire (1990) describes the interaction prescriber-patients as a non-cooperative conflict solved through the bargaining theory. For the purpose of this study, we will consider Rochaix's (1988) model where doctors and patients agree on the diagnostic of the illness, but hold different views of its severity.

The role of the hospitals and clinics is mainly to provide information to the consumer about the disease and available therapies. Direct marketing to the purchasing departments of these institutions results in imposing the products to the physicians within these organizations.

The role of the pharmacists has been evolving. Initially, they were responsible for the preparation of the drug. Today, they are seen as experts for drug information and are involved in selecting the drugs, monitoring their use, and counseling the patient (Reynolds 1992, 19). Pharmacists play a crucial role in the patient's compliance and directing them to the right use of the product. Also, building loyalty between the pharmacist and the manufacturer through services can have positive repercussions

later once the patent expires by hindering generic substitutions. Substitution policies do not affect innovations at their early product cycle stage, but become crucial after patent expiry. Marketing has been focusing on this segment for a long time already (Kassen 1987; Fiethen 1989). The pharmacist's role is especially important for the emerging e-pharmacies, where a large amount of information can be transferred at everyone's convenience. Another type of business model is chain-pharmacies to which the wholesalers are turning to.

3/ Opinion leaders

Opinion leaders influence the consumer by recognizing the disease, making him aware of it and supporting his actions taken (prevention and treatment). They will emotionally influence not only the customer but all the prescribers and insurances as well. Opinion leaders play a role in supporting the product and the therapy which will encourage the insurance to reimburse the drug. They play a gatekeeper's role and endorse a type of clearing function. They can include highly recognized physicians, politicians, academics, and patient groups (Bradley et al. 2004, 172).

Indeed, the patient is not anymore an individual patient but part of well-informed and organized associations. New activities are arising such as support groups and advocacy groups for patient or relatives. Moss (2002) has, through his article, concretely described the need of pharmaceutical companies to build long-term relationships with patient organizations, benefiting both customers.

Specialists and the academic environment have a strong credibility as they are at the forefront of pharmaceutical knowledge and technology advances. Health organizations, research institutes and e-health providers transmit objective information well perceived by the other health care customers who in turn search for their support.

4/ Insurers

The insurer emerged in the early 1990s as an influencer in the prescribing decision. Welzel (1989, 290-291) considers the insurances to have a strong influence on the prescription behavior of physicians especially for public health insurances. Insurances can apply pressure for certain prescription behaviors and the compliance of the patient can be affected by the fact that a prescription medicine is reimbursed or not. The main

goal of the pharmaceutical company is for insurances to reimburse their drug and therapy programs. Not having this reimbursement causes a barrier further down the chain, where prescribers are reluctant to recommend the product and the consumer has financial costs to add to the emotional and physical costs. Payers are expected to gain influence on the prescribing decision especially due to the fact that the United States and Europe are tightening cost-containment policies by using restricted formularies and tiered co-payment schemes. Payers have forced the introduction of a compelling health economic argument into the selling message. Adomeit (2002, 20) also suggests that insurers are to play an active role in the implementation of disease management programs, by being capable of overlooking their costs, success or failure, and therefore setting quality controls. Until now pharmaceutical companies have responded to this change of the payer's role by vertically integrating down the value chain such as Merck did by acquiring Medco in the United States.

5/ Regulators

According to Friesewinkel (1992, 48), the state sets the strongest environemental factor for the economical success of physicians, pharmacies and pharmaceutical companies. First of all, regulators have to allow the commercialization and marketing of the product, in a timely matter due to competition and patent expiry. Their decisions and opinions on the condition, the product and the manufacturer is the basis for the rest of the network of health care players. Maier (1993, 50-53) describes their influence on price regulation and allocations, therefore their crucial role on the innovative capacity of the pharmaceutical company. The whole process of patent application, approval to market and commercialization of an innovative drug must go through authorization authorities therefore also affecting the success of the product. The market is called upon to integrate social currents in its development plans. Since the politics of drug exchange and therewith the propagation of related costs minimization, the notion of value has moved to the central criteria of political decisions. The state can also influence through its health care politics encouraging or not certain medical application and use. Therefore a closer contact to all politically active lobbies is increasingly important for the commercialization of innovative products.

The goal of building relationships with the market players is to gain their preference and long-term trust. These relationships rely on economic, technological and social links between the parties. Thus, as put by Kotler and Dubois (2000, 47), the ultimate stage is the construction of a network between all these market players.

4.1.2. Consideration of the Specific Purchasing/Prescribing Process

Danzon and Chao (2000, 314) concede that demand for prescription drugs is quite complex as it depends on the interaction between the consumer's demand for medical care, and the choices of physicians and to a lesser extend of pharmacists. Regulation and competition also define the incentives and constraints on these choices along with the consumer health insurance coverage.

This attempt of creating an overview of the prescribing process considers two steps. First, the patient flow and the physician prescribing process are integrated in relation with the innovation and product phases. Second, the other customers are represented considering their role, which might be secondary or influential as opposed to active. Based on a concept drawn by Leutenegger (1994, 250-252), the pharmaceutical customer can act at two different levels: decision and influence (primary and secondary). A brief summary of the roles played by the other customers should be analyzed.

Figure 4.2. draws the link between decision makers and influencers at every phase of the innovation development and product prescribing flow. It takes into consideration the following facts:

Clinics and hospitals influence the choice of medicine available for their doctors to prescribe through formularies. Pharmacies provide information, counseling on ailments and diseases, use of medicine, compliance, ease of ordering (having the medicine available right away), substitution policies, and discounts (where permitted). Opinion leaders also provide information. They can boost the patient's compliance and loyalty by supporting the patient in his therapy not only with information but psychologically. Their role is also to increase the product's and company's credibility by providing an objective and trustworthy opinion as perceived economically uninvolved. Insurers reimburse the product or not, modulating the accessibility to the

drug and patient compliance. Finally, regulators allow the product to be marketed and commercialized. A good relationship with them helps smoothing the application process which is mainly based on scientific information and proof of the product's efficiency. According to studies conducted by trommsdorff + drüner (2003), governmental institutions as well as opinion leaders are well perceived sources of information by patients, toning down the lucrative venues of the pharmaceutical company.

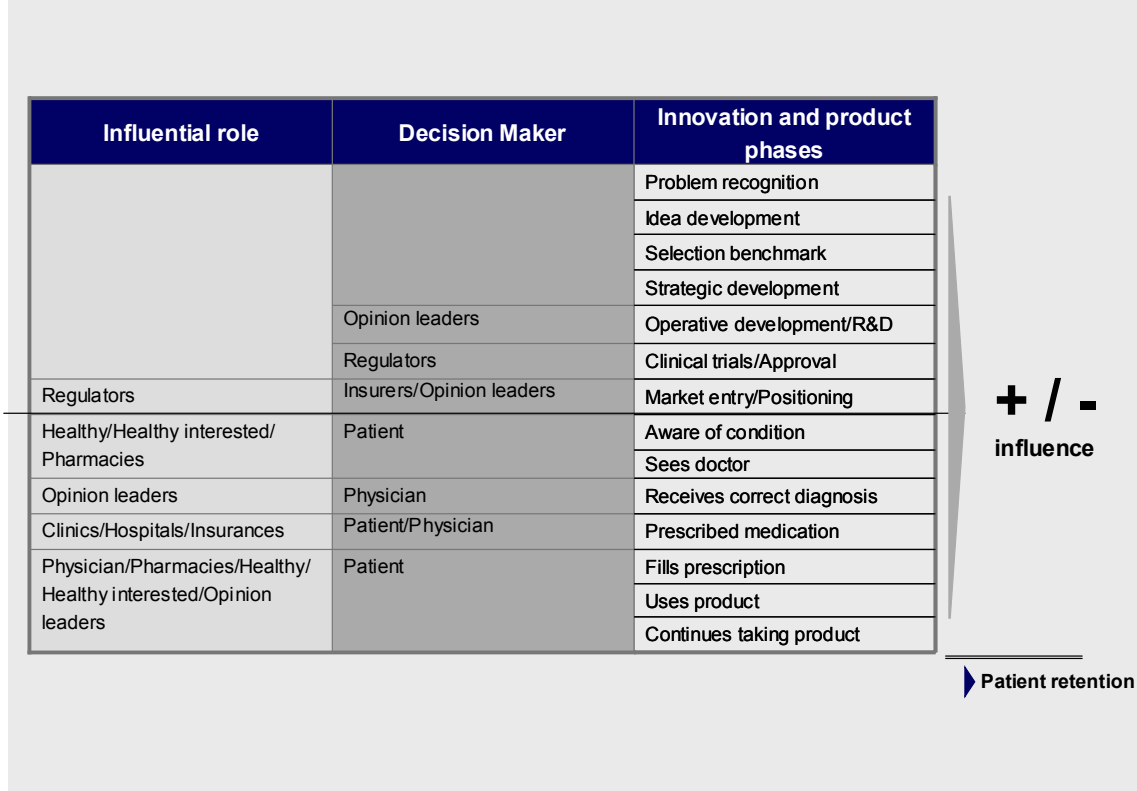

Figure 4.2. The pharmaceutical marketing can act at two different levels: decision makers, influencers.

4.1.3. Differentiation According to a Disease-Type Segmentation

The players and processes described above do not relate to one situation. It has been recognized that there are circumstances when it is difficult to empower the patient (Goodyear-Smith and Buetow 2001). The customer's involvement within the process can differ greatly on the basis of the type of disease, drug and therapy. A disease can include agonizing pain to active lifestyle elements. Palumbo and Mullins (2002, 439) and even the American Medical Association (2000) have already suggested that prescription drug advertising should be disease-specific to enhance consumer education. Even regulation authorities such as the FDA (GOA 2002, 12-14) establish a

difference in advertising for chronic diseases and for acute conditions. On a broader scale, management consulting companies such as CGEY (2001b, 17) and authors such as Ryf (2001, 40) define conditions for a patient relationship management based on the type of disease.

Fournier (1996) has shown that the consumer's relationship with the product (or the company) is linked to the expression of his identity. For Kotler (1997, 610), the communication objectives differ depending on the buyer's involvement with the product category and the level of differentiation perceived in the category.

Also as Mitchell (2003, 228) points out, customer relationships cannot be assumed to always be a natural or profitable solution as it depends on the level of involvement of the customer. The degree of consumer involvement in a product category has widely been recognized as major variable relevant to an advertising strategy (Laurent and Kapferer 1985, Rothschild 1979, Vaughn 1980). Howard and Sheth (1969) have emitted the hypothesis that the involvement with products leads to a greater perception of attribute differences, greater product importance, and greater commitment to brand choice. They conclude that a high degree of consumer involvement correlates with a high advertising effect. Laurent and Kapferer (1985, 43) recommend the use of an involvement profile relevant to market segmentation. This involvement profile must include the perceived importance of the product; the perceived risks associated with the product; the symbolic or sign value attributed by the consumer; and the hedonic value of the product. These are also the three factors recognized by Ho et al. (1997, 105), that may influence consumer satisfaction in a health care environment. Low and Mohr (2001) support these findings by presenting evidence that the group involvement is positively related to the information used. This is not only valid for the consumer but also for other customer as physicians and specialists will have less influence on the prescribing decision depending on the type of therapy followed (CGEY and INSEAD 2002, 13). Thus another factor needs to be considered for pharmaceutical products: the complexity and urgency of the treatment.

Based on Kotler and Clarke (1987, 238), Walther (1988, 190) and Vollert (1991, 88-89), and incorporating the complexity and urgency factors from Ryf (2001, 40), the following segmentation can be drawn with the related goals of each segment based on

the nature of the relationship between the consumer and the pharmaceutical product. The segmentation is based on the disease itself as it corresponds to the involvement profile (PWC 2003a, 1; PWC 1999, 17):

Consumer segmentation	Acute understandable	Acute urgent or complicated	Chronic understandable	Chronic urgent or complicated
Patient	Corporate loyalty		Product loyalty Highest involvement	Corporate loyalty
Healthy	Disease awareness and support, prevention			
Interested healthy	Prevention		Prevention and patient support	
Physician	Patient compliance	Decision maker	Patient compliance Support involvement	Decision maker Strong support involvement
Hospitals/ Clinics	Purchase and encourage product and therapy			
Pharmacies	Disease counseling		Support involvement	
Opinion leaders	Support disease, product and manufacturer			
Insurances	Reimburse product and therapy			
Regulators	Allow product to be marketed			

Table 4.1. The integration of all customer strategies implies setting goals for different segments and different customers.

- **Healthy people**: the healthy segment has a mild or no interest in the product, but could be interested in the disease. Their goal is to remain healthy, but they have to feel enough concern for the disease in order to adopt preventive measures then becoming interested healthy people. Their involvement with the product is low and the only sources of influence are opinion leaders and are affected by the regulators´ actions and point of view.

- **Interested healthy people**: they have either recovered from the disease or feel particularly concerned about it because of high risks of contracting it, or because they have relatives or friends affected by it. They are more open and often seek prevention and information. Their goal is also to remain healthy and they feel much more involved with the actual pharmaceutical solutions. Their main external influencers are opinion leaders and insurances.

- Patients:

  - The **understandable acute condition** is a condition requiring the episodic intake of a medical drug (i.e. flu). It is also a condition easy to grasp without any scientific background. The patient with an acute but understandable disease will seek information and demand functionality from the product, thus if not satisfied with it he will not comply easily with the therapy. Additionally, he measures the quality of the product mainly based on price and the manufacturer. He only wants to recover as fast as possible and will mainly trust the experts without seeking additional information. This patient is guided by physicians and pharmacies that are in turn influenced by hospitals or clinics and opinion leaders.

  - The **complicated and urgent acute condition** differs from the understandable acute condition by the fact that it is either too complicated for the general public to fully comprehend or that it falls in emergency situations where the sole decision maker is the physician (i.e. pneumonia). Patients affected by an urgent or complicated acute condition will express even less interest in seeking information than a patient with an understandable acute condition. Their goal is to reach a stable condition. They leave the product choice entirely to the physician who is often influenced by the medical organization he belongs to and opinion leaders.

  - The **understandable chronic condition** is characterized by the repetitive need of a medical drug (e.g. allergy), it can also be a recurrent acute condition (e.g. cystitis). The long-term aspects are very important to the patient such as therapy costs. He relates to his own experience and has access to a broad spectrum of information sources. His health is twice as important for him as for the other segments and he often belongs to the older population. The relationship with his physician is strongly established and their goal is to reach an

acceptable living standard coping with the disease. The insurances and opinion leaders are very influential for this segment.

- A **complicated disease or urgent chronic condition** is either a long-term, difficult to fully grasp condition or one that requires immediate long-term therapy (e.g. cancer). The patient hands all decisions over to the physician whose goal is to stabilize the condition.

The targeted disease and the therapy imposed by the pharmaceutical product will dictate the marketing strategy to pursue, focusing on the consumer/patient/people and adapt the appropriate measures to the other customers.

4.2. The XRM Approach: Integrated CRM

The model "Pharmaceutical Innovation Management" (PIM) developed by Mayer (2004) provides a solution to the Competitive Innovation Advantage (CIA) factors described by Trommsdorff (2001): the higher the CIA, the higher the probability of success for the innovation. As explained in 1.1.5., factors 2 through 5 can be influenced by marketing. These are again:

2/ response to a customer's important need;

3/ the recognition from the customer;

4/ difficulty to compete against;

5/ the level to which important influences from the environment can be anticipated and proactively acted upon.

A marketing approach for the pharmaceutical industry influencing these four factors positively is structured in four components forming the PIM:

- **Segmentation Evolution**: an exact customer understanding to support the development of innovative communication and customer retention concepts.
- **Influencer screening**: to identify the important actors and to involve them optimally in the marketing strategy.
- **Competition monitoring**: to analyze the critical competitive factors and enable the development of sustainable competitive advantages.
- **Integrated communication**: to insure the complete integration of the relevant health care partner.

Mayer (2004) has shown through his studies that the most influential factor is integrated communication focusing on CIA factors 3 and 5: the recognition from the customer and the level to which important influences from the environment can be anticipated and proactively acted upon. These findings support the market analyses

and the need of integrating all pharmaceutical customers into one strategy. As seen in 1.3.3.1. communication implies customer relationship management, therefore integrated communication refers to an integrated customer relationship management.

The need for an integrated CRM has been expressed by many authors. Wosinska (2001) results show the DTCA impact on the whole therapeutic category sales. Althought its particularly increases the sales of the brand with the preferred status on the payer's formulary. This shows that it is important to coordinate the marketing campaign for the drug and the reimbursement status with insurers. According to industry analyst IMS health (2002) half of the ten drugs with the highest DTC spending were also among the ten drugs with the greatest volume of samples distributed to physicians in 2000. In another study by Henderson (2002), over 70 percent of physicians are inclined to prescribe the drug for which they have a sample readily available. Several studies focused on the joint effects of direct-to-consumer advertising and promotion to physicians have all found that one is supported by the other (Rosenthal et al. 2002; Neslin 2001; and Wosinska 2002). Palumbo and Mullins (2002, 439) also point out that advertisements should be part of a manufacturer's education program targeting both physicians and consumers.

In a broader context, Wolf and Mothes (2002, 120) also conclude that prescribing and purchasing of a medical drug is not just dependent on physicians and clinics. Pharmacies, patients, wholesalers and insurances are gaining influence as well. There is no doubt that the consideration of all players of the prescribing and purchasing process of a pharmaceutical drug within an integrated communication strategy is essential (Becker 1992, 89-91; Gehrig 1992, 1258-1260). The integration of the other pharmaceutical customers has also been discussed as early as in 1991 in the *Arztneimittelzeitung* (1991, 10). This customer integration in a CRM approach should be carried out by a corporate organization capable of using all information and communicating one message to all of its customers. This can only be supported by an integrated information architecture.

Integrated customer relationship management is translated into the term XRM: targeting all the customers involved in the industry and managing the relationship between them and the pharmaceutical company interdependently.

4.2.1. Convergence of all CRM Strategies into One Extensible Concept

To have a clear picture of the XRM concept, a three-variable graph can be draw. The three variables are processes, players and positioning:

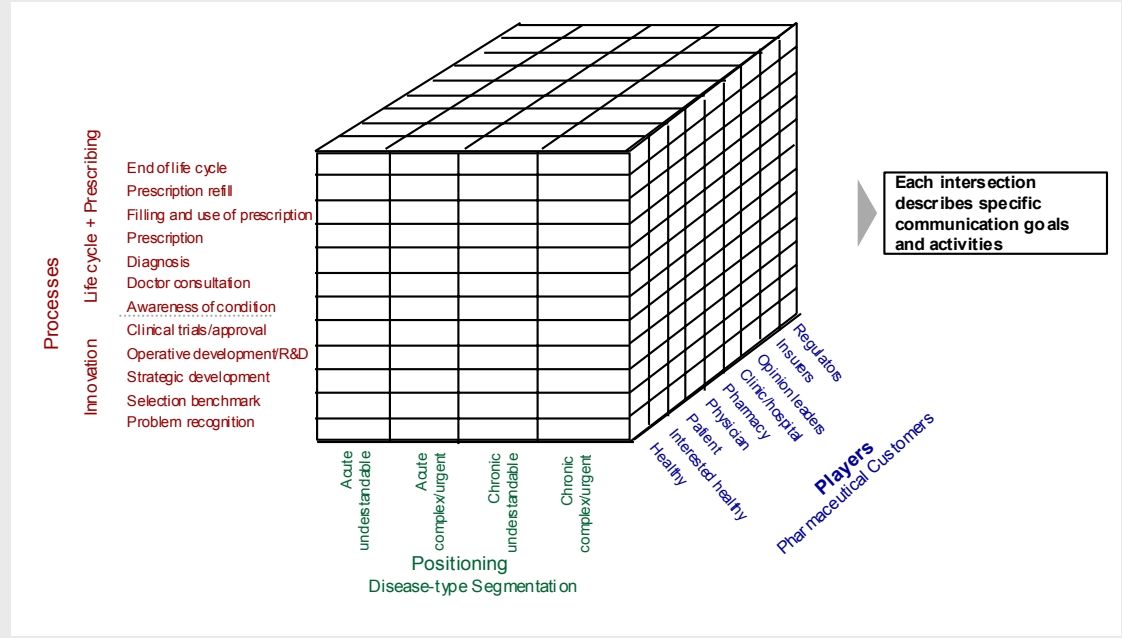

Figure 4.3. The XRM approach allows a holistic communication strategy appropriate for the pharmaceutical product involved. It includes the explicit consideration of processes, players and positioning.

Each intersection between the product's phase (processes), the disease type (positioning) and the targeted customer (players) demand a specific attention and developed entries. It represents one CRM strategy. The combination of all these intersections is the cube itself, see figure 4.3. illustrating the XRM approach. These single CRM components are interdependent and some will either be prerequisites or have repercussions for others.

In general, all products will engage in a disease awareness campaign in order to grow new markets or increase the size of the existing one. The level of intensity depends on the disease's occurrence, public recognition and acceptance. A sense of urgency can be introduced along with familiarity to create a present problem that can be remedied. Once the disease is an accepted and recognized condition, the focus of marketing can shift to the product and the manufacturer.

The XRM strategy revolves around the end-consumer. Thus, the primary segmentation will be that of the positioning of the pharmaceutical product which depends on the end-consumer's involvement with the drug. The strategy to develop will depend on the type of indication the product is meant for, directly related to the nature of the disease associated with the product.

First, the differentiation has to be made between high and low involvement diseases and then the particularities between acute and chronic diseases are to be defined. It is important to notice that for conditions that are complicated and urgent, the level of involvement is blurred as the influence of the consumer on the prescribing process is lower or non-existent.

- For a high involvement profile, Laurent and Kapferer (1985, 47) have summarized the characteristics of the customers: they seek to maximize expected satisfaction from their brand choice through an extensive choice process; they seek information; they are more likely to be influenced by reference groups; they are more likely to express their lifestyle and personality characteristics in their brand choice; and they process communication cognitively by going through stages of awareness, comprehension, attitude, and behavior. These customers are typically in the understandable chronic disease segment.

- Lower involvement products such as for understandable acute diseases, a conditioning technique is more to recommend by inciting the consumer to sample the product and built their own experience in order to influence the purchasing decision. Indeed, for low involvement products, Trommsdorff (1998, 87) suggests communication based on product claims and applications.

- For acute conditions, the manufacturer's recognition is more important than the product's as its use is punctual. There is an effect of image transfer which can be imported and exported to other brands owned by the same manufacturer. This is even reinforced when the condition is difficult for the end-consumer to understand or when the situation is so urgent that he lacks time to investigate information material or choose the preferred treatment.

- For chronic conditions, the goal of the marketer is to establish a long-term therapy use. Loyalty to the product and the support services offered by the manufacturer are key for this segment. In case the disease and the product's working processes are too complicated for the patient to grasp, trust in the manufacturer and service supporting the therapy plays a more important role than product recognition.

Table 4.2. describes the XRM components. These are based on the classic components described in chapter 1.3.5. of this work (goal focus, benefit, organization structure, channels, analytics and IT applications) supplemented with DTX, the concrete communication activities for an integrated customer relationship management. The disease-type segmentation mentioned above imposes a positioning on which depends the network of pharmaceutical customers supported by all of the XRM components. The goals are varying for each segment and so are the channels, the analytics, the IT applications and the organizational and cultural properties of the pharmaceutical company. The activities proper to each of the segments can be clearly defined. As a closer contact has historically already been established between companies and chronic patients, their XRM scenario is closer to the analytical stage than the operational i.e. second maturity stage. Acute-disease-focused companies are still in the operational stage of their relationship management maturity. And since the contact with end-consumers is hereby the first reference, a closer relationship will also have already been established rather for an understandable-disease-type than a complex-and-urgent-type. This means that understandable chronic disease-focused companies are further developed in the analytical stage than complex/urgent chronic disease-focused companies.

XRM maturity stage	Operational			Analytical
XRM Components	**Acute Complex/urgent**	**Acute Understandable**	**Chronic Complex/urgent**	**Chronic Understandable**
Goal focus	• Basic customer knowledge • Single customer view	• Basic customer knowledge • Single customer view	• Deep and individualized customer understanding	• Deep and individualized customer understanding
Benefit	• Cross-selling	• Cross-selling	• Cost effective marketing campaign	• Cost effective marketing campaign
Organization	• Team selling	• Install segment focus in marketing, sales and customer service	• Knowledge management throughout organization • Team selling	• Knowledge management throughout organization • Cross-functional teams
Channels	• Focus on prescribers	• Focus on all prescribers and consumers	• Focus on prescribers	• Focus on all customers
Analytics	• Accurate contact and sales data • Segmentation	• Accurate contact and sales data • Segmentation	• Data mining • Decision models	• Data mining • Decision models
IT	• Marketing automation • Sales automation	• Marketing automation • Sales automation • Dialogue system	• Corporate support systems	• Corporate support systems • Customer support activities
Activities = DTX	• Disease and manufacturer awareness	• Disease, product and manufacturer awareness	• Disease, therapy and manufacturer awareness	• Disease, therapy and product awareness

Table 4.2. XRM strategy components and their individual goals.

Currently customer relationship management seems to be less developed for acute diseases than for chronic diseases as the nature of chronic diseases implies a close follow-up of the patient through a long period of time. Information has already been retrieved from the end-consumer and is in the analysis process, as has been the cooperation with prescribers and opinion leaders.

Pharmaceutical companies focusing on understandable diseases are more inclined to address the end-consumer intensively than those focusing on complex or urgent conditions. The latter will require a stronger concentration on the prescribers, who are, in these cases, the only decision makers.

Thus the acute disease XRM leans more towards an operational system, aiming at basic customer knowledge and developing a single customer view than chronic disease XRM rather focusing on developing a deep and individualized customer understanding, not only according to the various customers but also customer

segments within the different customer groups. Therefore the benefit searched is cross-selling for acute diseases to make use of synergies and a cost effective marketing campaign for the chronic diseases to increase the efficiency. Companies focusing on acute diseases are still collecting accurate data on their customers and are starting to segment them in order to gain clear visibility. Companies focusing on chronic diseases are in an analytical phase where models can be developed to indicate methods and means taken to respond to the needs expressed by the customers. These models are also predictive and sensitive to the changes affecting the market.

Ideally all pharmaceutical organizations are customer-focused and strive for team selling for complex or urgent acute diseases. Whereas for the understandable acute diseases, the organization should already at this stage impose a customer group focus as well as a segment focus in the market, sales and customer service departments. The knowledge collected and acquired can be share throughout the organization with a knowledge management system for chronic-disease-focused companies. But complex and urgent products will require perhaps a stronger team selling and the understandable chronic disease product will benefit from cross-functional teams capable of tying the customer more strongly to one product.

When developing the XRM strategy for the acute complex and urgent conditions, the focus is mainly prescribers. This focus on prescribers can be already broaden to the segments for complex-and-urgent-chronic-diseases-focused companies as they are a step ahead in the XRM strategy. The companies producing products for acute understandable diseases must not only focus on the prescribers but on the consumers. This focus is widened to all customers for organizations targeting understandable chronic diseases.

The IT architecture supports the goals set for each positioning to faciliate and develop the relationship with the customers. In this context, marketing and sales automation are first steps for companies targeting acute diseases for them to be capable of collecting a large amount of data, start sorting it out and sharing the information within the directly concerned department. The applications supporting the dialog with the customer are essential for understandable acute diseases as more customers will be approached using means with a larger reach. These are developed into support

systems requiring various technologies and more complex technical material for conditions to be followed for a long period of time. At this stage, the organization should also be equipped with the necessary support IT tools allowing and encouraging an exchange of information between departments.

The above translates into integrated communication activities or DTX, investing mainly in disease and product awareness for understandable conditions, giving the customers a transparent view on the health issue. For complex or urgent conditions, it is more important for customers to recognize the manufacturer and its expertise in the concerned therapeutic area. All must include disease awareness campaigns aimed at all customers to create a sense of necessity and grow new markets.

These component-specific goals are set for today's situation and will develop further along the maturity curve with time, leaning towards a more collaborative situation. There is an ongoing customization that starts gaining importance in the analytical phase thus for chronic disease focused organizations. They have to carefully monitor the market for any changes which they will have to adapt to.

4.2.2. Determination of an Organizational Architecture Appropriate for XRM

An integrated customer relationship strategy also implies an organizational structure allowing a coordination of all strategies. This strategy is based on knowledge management supporting a strong information exchange. First, the corporate management must be customer-oriented itself. Second, the employees must be open to exchanging knowledge and accept transparency within the company. Third, the IT structure must support this data collection, sharing and analyses. Finally, marketing, sales and customer service must be customer-focused by segments. Figure 4.4. outlines the interdependency of the XRM organizational structure.

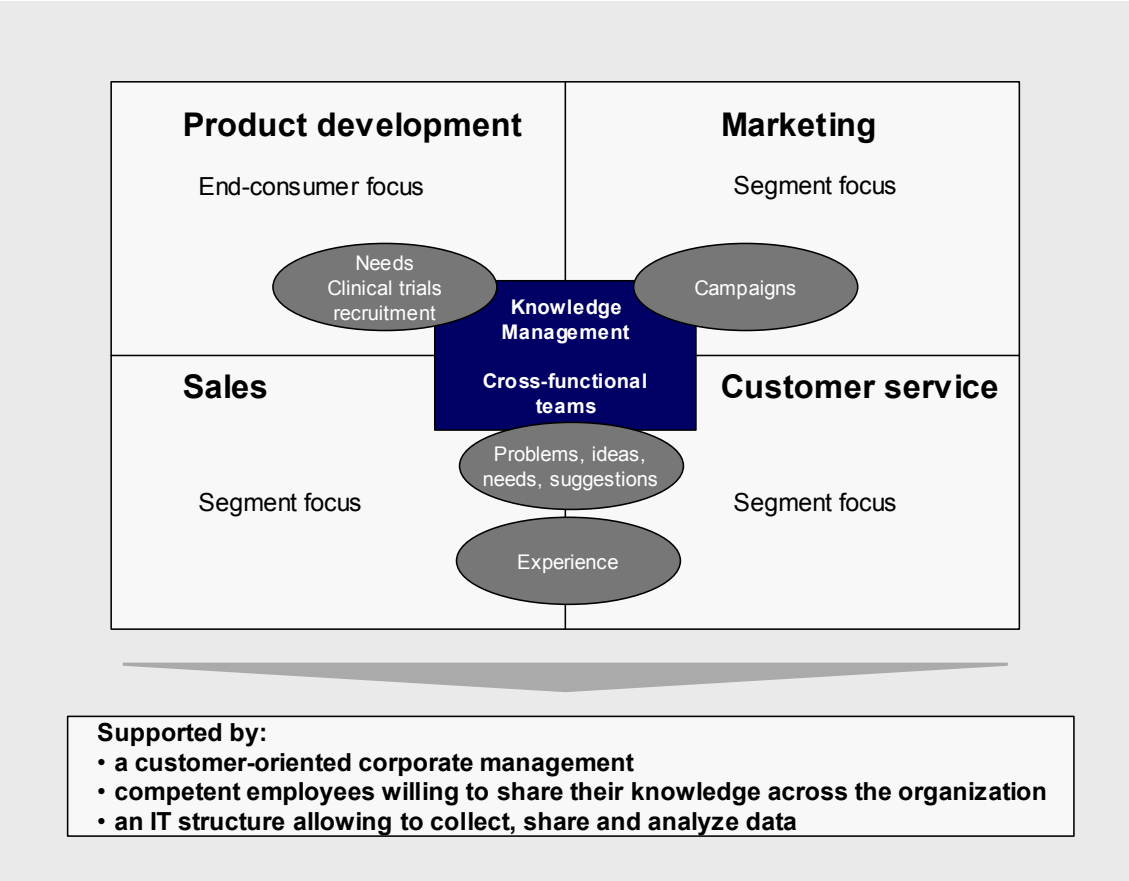

Figure 4.4. Interdependency of XRM organizational architecture.

The focus on the customer is supported by thorough segmentation.

- The sales forces would be divided in five: the traditional detailers focused on physicians and pharmacies, the healthcare advisors focused on the patient, the key account managers taking care of opinion leaders and high-priority customers, the relationship builders responsible for the insurances and the regulators, and the negotiators which have to deal with the purchase departments of hospitals and clinics. These groups have to share information among them and make available their problems, ideas, suggestions and customer needs in a corporate knowledge pool. The communication can be encouraged by a co-location of the business units.

- Customer service would follow the same process and exchange ideas with sales as both have direct contact with the customer. Roche has implemented an example of this concept under its “Roche One” initiative where four account

management divisions were formed. The four teams access a shared database pooling data across all channels.

- Marketing needs to consider the information relayed by the sales and customer service in order to target their marketing campaign successfully. These campaigns must also be promoted internally to gain support which, in turn, will improve the productivity and efficiency of other departments.

- For product development it is essential to have access and understand the needs of the future consumer. They must also be open to problems, suggestions and ideas from the departments who have direct contact with the customers and require input when recruiting patient and physicians for clinical trials. For example, Pharmacia implemented the "target product profile" tool which is initiated by marketing for the development and commercialization of a product (Smith P. 2001, 38).

In the end, the implementation of cross-functional teams will simplify, encourage and support this exchange of information throughout the organization.

4.2.3. Implication of Concrete Activities Supporting XRM

It is to be kept in mind as exposed by Dichtl and Thiess (1989, 375), that pharmaceutical communication has an activating and informational role. This is valid for all involved customer groups.

4.2.3.1. Continuous Use of Market Research for a Customer Database and Data Management

According to industry analysts CGEY (2001b, 15; 2002, 18) and Coles et al. (2002, 7), it seems that today the pharmaceutical industry understands its existing physician customer base but not the highly fragmented end-consumer. Customer insight used to be defined as an understanding of safety and efficiency (Butler 2002, 68). However, this view is no longer sufficient. In 2000, 50 percent of life science companies involved patients in product development. This percentage was expected to increase (CGEY 2001b, 15). However, investigations should not be limited to the end-consumer; other health care players must also be analyzed to understand their perception of the disease, the product and the manufacturer. PWC (1999, 20)

describes an individualized market intelligence support decision-making in the innovation and the product life cycle phases. This is essential for the manufacturer in order to design successful approaches.

At the early product development stage, market research concentrates on the market's needs involving patients and physicians. For clinical studies, other customers can also be approached to have an overview of the disease's recognition, acceptance and level of perception. The image of the manufacturer can become important in a broader context (as specialist of the condition). The product might be appreciated by the health care community, but it might also be found useless, not relevant or redundant. All these facts will help the pharmaceutical company to position itself towards these customers and provide them with the information necessary to ensure full support at market entry.

Another important wave of market research is during the growing phase of the product's life cycle to test satisfaction and to control the effect of the marketing and sales campaign. If necessary, it might also help changing strategies with the current product and help in positioning a new modified version of the innovation.

Market research is supported by various tools more are less appropriate to the goal of the study. Interviews, group discussions and automated data collections are very relevant when searching for new ideas and requirements. Other type of tools such as surveys used for conjoint analysis or image analysis are the ideal means for defining benefits, preferences and pricing. Surveys and group discussions are also useful tools to measure customer satisfaction, as is automated data collection being necessary for an ongoing monitoring of XRM implementation.

4.2.3.2. Definition of DTX: an Integrated Communication

Integrated communication evaluates the roles of each communication mean and combines them to obtain coherence and efficiency. For Kotler and Dubois (2000, 575), an integrated management of communication efforts reinforces the coherence of the corporate image for customers and employees like-wise.

The needs for integration results from the following fact: "E*verything a company does (and sometimes does not do) sends a message that can strengthen or weaken*

relationships" (Duncan and Moriarty 1998, 8) between the company and its customers, and is applicable to different organizational entities as well as to the marketing activities.

The goals of the pharmaceutical communication can be economical (Dichtl and Thiess 1989, 379-80). The former involves increased revenues, sales, market share and diffusion rate even though these are indirect results depending on the latter goals including recognition, the image and the perception. These translate into the following: reinforcing the competitive situation through the positioning of products; getting closer to all interaction partners of the pharmaceutical industry; improvement of the pharmaceutical industry in general; winning the trust of patients, physicians, pharmacies and opinion leaders; defense against generics entry; winning prescription and securing compound trust; avoid public interference through credible and competent information politics; and justify pricing.

These goals are supported by specific tools which should be packaged together. If the market receives contradictory or inconsistent messages, it will not respond and could harm the brand. The communication activities should be consistent for all players the company is dealing with, not just for the end-consumer. The strategy and positioning should be clear to all employees who will, in turn have to share it to customers.

As Rothstein (2001, 344) points out, in the modern health care environment, sharing information is important for many aspects on a larger scale. These include facilitating patient diagnosis and treatment; insurance and benefit claim evaluation and payment; public health monitoring; research; and health care education and training. Also the trend in health care is moving from simply communicating and sharing the information to executing transactions, customer service and disease management (*Marketing Health Services* 1999, 26).

Shared information is the basis of the XRM concept. The communication activities supporting XRM are summarized under the term "integrated communication" or DTX in this work. There are three main guidelines to follow to draw a DTX strategy.

- The first one is the integration of all health care customers into the established strategies for the physicians and the patients.

- The second one is the consistency of the time plan from the time of conception of the innovation to the market saturation considering the evolution of the patient flow during the commercialization phase.

- The third one is the focus differences due to the positioning of the pharmaceutical drug within the disease market.

4.2.3.2.1 Integration of the Influential Health Care Customers

According to Pathak et al. (1992, 1) the informational effects of promotional programs are achieved by providing decision makers and/or consumers with key information above all regarding the availability of pharmaceutical products, to allow a product choice reflecting their preferences. However, this description disregards the influential role played by the other health care players. They require additional information, and material to provide physical and emotional support to the end-consumer and the decision-maker.

- **Clinics and hospitals** influence the choice of medicine available for their doctors to prescribe by having purchased the product beforehand.

- **Pharmacies** provide information, counseling on ailments and diseases, use of medicine, compliance, ease of ordering, substitution policies, and discounts (where permitted).

- **Opinion leaders** can boost the patient's compliance and loyalty by supporting the patient in his therapy with information and psychologically if they are convinced he is following the best therapy possible. Their role is also to increase the product and company's credibility by providing an objective opinion that can be trusted by patients and physicians as they are perceived as economically uninvolved. Other programs can also be promoted to the health care institutions whose support increases the company's credibility. This kind of source is well perceived by patients.

- **Insurers** will support the product by reimbursing it. The marketing campaign is different for a product for which the end-consumer has to pay entirely.

- **Regulators** allow the product to be marketed and commercialized. A good relationship with them helps smooth the application process mainly based on scientific studies and proof of the product's efficiency.

The marketing for these groups is similar to that of the physician with a sales force and ample scientific information about clinical trials, products, services, and the company. Some material is available to the patient to support the activities of the institutions and promote the product, services and company.

The way all of these players perceive the pharmaceutical product will have an influence on the prescribing/purchasing process. This influence can be steered by integrating these targets in the customer relationship management program of the company.

4.2.3.2.2 Gradual Involvement of All Customers

Based on an article from Frerker et al (2002, 39), the main tasks of communication before the marketing launch is the preparation of the organization and the market.

- The preparation of the organization involves briefing reports for national branches, education and information for the organization about the condition, product and planned campaigns.

- Preparing the market implies a more complex communication program. The regulators and the insurances are the main targets before market launch as they have to respectively allow the product on the market and include it on reimbursement formularies. Just prior to market introduction, the communication programs turn to opinion leaders aiming at rising interest in expert groups through e.g. physician information, CME, or key accounts. In some cases such as unknown or taboo conditions, it is important to sensitize the general market to the disease. Medical marketing includes local programs in the last stage of the clinical trials and a press release plan.

When the drug enters the market, it starts a life cycle. The product's life cycle is separated in three phases in which each has its own patient flow with its strategy and related activities. Just at market entry, the entire focus is on consumers and physicians as the goal is to build a new market. If the situation permits it, investments are also

placed in educational promotion for the consumer and the physician. As the market grows, the communicational activities become increasingly promotional to support market growth. Once the market is saturated, the goal is to transfer the image either to other products carried by the company or to modified initial innovations.

4.2.3.2.3 Positioning Factors Resulting in Different Disease Foci

The differences between understandable and complex/urgent conditions are the consumer's little influence on the treatment choice, thus pharmaceutical drug. The situation is either too complicated taking too much time to educate the consumer, therefore not allowing contributing constructively to the decisions or the situation is an emergency and the patient lacks time or is not in a state to discuss the physician's decisions.

Chronic conditions require most importantly further support from prescribers and insurances. It is a segment where PRM plays an important role, requiring promotion of the whole therapy as a package rather than just a single product, therefore implying more educational measures particularly for the patient following the much extended therapy.

4.2.3.2.4 Tailoring DTX Communication Activity Levels

As for a traditional communication strategy, the activities supporting the information flow from the company to the customers are characterized by messages that can be purely promotional or educative (Dichtl and Thiess 1989, 379). As the importance of a dialogue rises, support programs are developed to facilitate the contact the customer has with the product and the company. These programs are very close and associated to retention and loyalty initiatives.

Based on the strategy for integrated communication, the communication activities for each of the remaining customers (i.e. pharmacy, hospitals/clinics, opinion leaders, insurances and regulators) should be defined.

There are two types of communication: a direct one and an indirect one. The direct one consists of the contact the pharmaceutical company has with its customer. It uses indirect communication to provide information via one customer to address another one such as the information pamphlets provided to physicians for their waiting room

or contracting e-health portals to develop awareness to a condition and its therapy. This material is actually intended for consumers. Each customer responds to particular communication means whether directly or indirectly, depending on the message to be transmitted by the pharmaceutical company.

	Customer	Current communication basis	Integrated communication DTX additional communication emphasis	New and emerging activites for integrated customer relationship management XRM
Traditional marketing focus	Physician	• Scientific publications on disease, research, therapy and product • Symposia/Conferences/Conventions • Sales force: recruitement for clinical trials, detailing, samples, gifts, direct mail • DMP material • Recommendation of websites, web portals • Advertising and information material for waiting room on disease, therapy and product Information material (disease, therapy and product) • Information for supporting the patient • Call center • Study clubs • Seminars • CME/Continuing health care program • Speaker programs		• Disease management programs • Interactive systems • E-detailing • E-prescription • E-health
	Patient	• Publications on disease, therapy, product and manufacturer in general print • Manufacturer, disease and product websites • Package insert • Disease awareness, product claims, reminders, clinical trials and manufacturer ad. (mass media, print) • Call centers • Web portal		
New customers integrated into marketing focus	Healthy	• Disease awareness advertisement • Disease awareness, product claim, reminder and manufacturer ad. (mass media, print) • Manufacturer and disease website	• Publications on disease, prevention (life style, sport, nutrition), therapy, product and manufacturer in general print	
	Interested healthy			
	Pharmacy	• Scientific publications on disease, research, therapy and product • Company contact (sales force): detailing and negotiation	• Scientific publications on disease, research, therapy and product • Disease awareness publications • Symposia/ Conferences/ Conventions • Product advertisement in specialty print • Information material on disease, product and manufacturer for physicians and patients • Public relations	
	Clinic/ hospital			
	Opinion leader			
	Insurance			
	Regulator			

Table 4.3. Current and emerging DTX activities according to the health care customer.

- The communication aimed at **healthy people** basically consists of disease awareness. The goal is for them to support the patients.

- The people who have a particular **interest** in the condition may be approached with preventive measures and information as they are looking actively for it.

- **Patient** communication is composed of publications on the disease, the therapy, the product and the manufacturer and is to be found in general print media. The different advertisements (disease awareness, product claim, reminder, clinical trial and manufacturer advertisement) are also available in mass media and print. Another mean of direct communication are package inserts providing detailed information about the product and its use. Websites are another effective way to transmit information about the disease, the product and the manufacturer.

- **Physicians** require scientific publications on the disease, therapy and product, as well as educational programs such as continuous medical education (CME) courses. Symposia, conferences and conventions are highly appreciated ways of exchanging views and transferring knowledge. The sales force is also an important communication mean through detailing. It allows building a personal relationship between the physician and the company. Advertising follows the same pattern as for consumers although focused on specialized prints. A large amount of material can reach the patient through the physicians, such as samples, gifts and information material on the disease and the product in form of pamphlets, books, or website recommendations. Physicians can become influencers for a pharmaceutical company. They are the ones promoting the pharmaceutical's product in their own way and within their community. Speaker programs are organized to transmit their expertise to others. The educational benefit for the community can be reinforced by other initiatives such as CMEs and continuous health care programs directed to physicians and pharmacists.

- Communicating with **pharmacies** follows a similar approach. The main difference lies in the restraints concerning gifts and the reduction of secondary

communication material directed to the patient to information material on the disease or the product. Pharmacies especially need this communicative support, as in certain countries, 50 percent of their product line is competing on price with wholesalers, discounters, drug stores and consumer markets. Their role as consultants for the product can be supported by the pharmaceutical company.

- **Clinics and hospitals** rely on scientific publications on the disease and the product, and the contact with the sales force responsible for detailing the product and negotiating purchase contracts.

- The same strategy is pursued for **insurances** and **opinion leaders**. However, it might be important to have further disease awareness publication in general prints to emphasize the relevance of the product once it has entered the market. Press releases are a supplementary mean of communicating the product's evolution and development within the market. Results of a survey by the VHA (2000) revealed that, the best way to gain loyalty from consumers is through sources recommended by doctors e.g. websites. This implies a significant effort towards marketing health portals in the same way drugs are marketed to doctors.

- Pharmaceutical companies already have a tight relationship to **regulators** cared for by company representatives reporting directly to them and ensuring the authorization process of the product. Scientific publications add support as well as disease awareness general publication to create a sense of need and urgency.

Clinics/hospitals, opinion leaders, insurances and regulators are very subjective to IR and PR that act on the company's credibility and trustworthiness. The opinion these customers have of the organization is influential and can be transmitted to the end-consumer. Information material about the disease, the therapy and the product can be provided to the consumer via these channels.

In addition, the DTX actvities include support activities not always focused on only one customer. The service is usually segmented according to the different customers.

- The most obvious support tool is **contact centers** involving a call center and a field service management. These aim to support the consumers, whether they are patients are not, and prescribers including physicians, pharmacies, clinics and hospitals. They must respond to questions, process complains and deal with reclamations. Employees of a contact center should be scientifically competent and trained to solve problems. They are supported by the whole organization by having access to a knowledge pool.

- **Web portals** are another way of supporting especially consumer sharing experiences and seeking for another type of help and support. It is also a source of information, however with a low implication degree for the consumer.

- A broader source of information is **e-health** suitable for prescribers, as well. Usually this service differentiates between the information transmitted to the consumer and the one available for prescribers which is generally scientifically richer and less suitable for the untrained person to understand.

- Another tool introduced by the internet is the **e-prescription** model. It simplifies the processing a prescription by allowing through the internet and subsequent product delivery. This concept still lacks acceptance and is fairly controversial as it faces opposition from traditional pharmacists and regulators. However, it offers benefits to consumers, and the prescribers, making the purchasing of a pharmaceutical product more efficient, more appropriate and more compliant with established rules. Also, it reduces medical errors and time loss associated to conventional written prescriptions.

- Physicians can particularly be supported by the pharmaceutical company through **study clubs** and **seminars** allowing an exchange of experiences, and support in dealing with the patient. The industry can also provide information regarding the patient-physician relationship. As this relationship is often dependent on the patient's condition, optimizing the dialogue and understanding between these two pharmaceutical customers could result in leveling compliance and retention rates from both sides.

- **Sponsoring events** and **reports** for opinion leaders and regulators create ties between them and the pharmaceutical company. It is a way for the pharmaceutical company to get involved in the community revealing a non-profit aspect.

A great part of the support activities provided by the pharmaceutical company aim at improving its customers´ relationship with their own customers. The rationale remains the fact that pharmaceutical customers are interdependent.

Besides the activities mentioned above, there are others means for binding a patient to the pharmaceutical company. On a first level, interactive systems can be established consisting of reminders for drug intake, or appointments with the physician and automatic prescription refills to facilitate the therapy's continuity and product compliance. This action is focused on incorporating the use of the drug smoothly into a life style with low adaptation efforts and demands on the patient. These systems are more appropriate for chronic conditions requiring a long-term drug intake and a constant medical monitoring. A broader application of these systems is included in disease management programs. These are a more complete support around the disease and can involve monitoring devices connecting the medical community and the patient on a permanent basis. The therapy can be easily tailored to the patient who has a strict frame for his therapy. He is more likely to follow it through due to the supporting link with his physician and his pharmacist. Patient relationship management programs are more adapted to chronic diseases containing a high product involvement.

4.2.4. Application of the Information Technology Supporting XRM

The IT tools appropriate to the implementation of an XRM strategy depend on the DTX activities. There are characterized by data management and analysis systems within the automated marketing sales, dialogue and internal support systems. They mostly involve the IT tools already applicable to a CRM strategy supplemented by applications for disease management programs such as electronic records, monitoring devices, e-detailing and e-prescription systems. Another important feature is the complexity of contact centers including call centers, field service management and

help desk management. These are regrouped under customer service which is itself segmented according to customers.

The IT structure for the internal organization must also support such an exchange of information within and between the business units of a pharmaceutical company. Table 4.5. gives an overview of the applicable possibilities for such a management of information required by the integration of customers for the pharmaceutical industry.

Activity	IT tools
Market research	• Online risk-assessment questionnaires • Marketing automation: advanced data analysis • Data warehousing: storage applications and platform allowing integration of data from different IT systems • Data mining: decision-modeling software • OLAP for ongoing analysis • Website log records
Sales force	• Field Service Management • Decision support and reporting tools • E-detailing systems • E-mail • Wireless Application Protocol (WAP) • Short Messaging System (SMS)
Contact centers	• Call centers • Field Service Management • Help desk management
Web portals, e-health	• Internet • Virtual communities
Interactive services	• Internet • Wireless Application Protocol (WAP) • Short Messaging System (SMS)
E-prescription	• E-prescription systems
Disease management programs	• Electronic records • Monitoring devices: video links, radio frequency devices, chips and sensors
Educational programs	• Interactive computer programs

Table 4.4. IT tools appropriate for the implementation of XRM.

4.2.5. Design of the XRM Process

A process can be drawn according to the time plan defined by the innovation process and the product's life cycle. It reflects the goals of pharmaceutical marketing for each of the customers at each stage of the evolution, the means to reach them through direct communication and how to take advantage of the interaction between the customers by providing indirect communication.

The XRM process depends on the disease. However, the acute understandable condition involves the basic promotion opportunities and will be described according to the players:

1/ Healthy consumers

The pharmaceutical marketing to the healthy community must create awareness of the disease before market entry through general publications. After market entry and during the whole product life cycle, healthy people must be aware of the disease and the product to influence and support positively a patient's choice. Here again, publications on the disease and the product as well as disease awareness and all product advertisement (product claim, reminder) create a presence of the disease, product and market.

2/ Interested consumers

The healthy community which is already interested in the disease or the product also needs some disease awareness during clinical trials and the product life cycle. The goal is similar as for the healthy community, additionally focusing on preventive measures especially in the growth phase of the product when the product and disease have been well recognized by other parties. Manufacturer, disease and product websites as well as e-health portals are important tools to provide information. Web portals come into play when patients have sufficient experience to share and communicate, influencing potential users.

3/ Patients

During the innovation process it is important to assess the patient's needs at the very first stage when the problem the innovation is supposed to resolve is defined. This information can be retrieved through interviews and group discussions. Throughout the R&D stage the patient's preferences can be selected by market research using conjoint analyses or image analyses. Patients also need to be recruited to participate in clinical trials. This can be done by advertising the clinical trial recruitment. A disease awareness campaign can already start in order to sensitize the public to the disease by, for example, publishing articles about the disease and its incidence. The task of market research is also

segmenting the customer to target appropriately the marketing campaign at market entry.

During the three stages of the product life cycle (i.e. market introduction, growth and saturation), the activities are quite similar. Disease awareness is a common activity throughout the patient flow in all phases of the life cycle. Publications in general prints as well as advertisement in the mass media and print can support this. Disease websites are a mean to transmit more detailed information about the disease, as well as medical websites available to the general public under the e-health concept. However, before entering the doctor's office, the patient must have the specific product in mind. This would be supported by publications about the product and product claim advertisements. A product website would also set the ground for a deeper knowledge of the product. For the patient to actually fill its prescription and use the product, he must trust the product and the manufacturer. Reminder and manufacturer advertising support building positive perceptions. Package inserts are necessary to communicate all information needed by the patient about the product and can provide a further link to contact centers which the patient might use when in need for more information, reassurance or to report unforeseen issues. But package inserts also play a decisive role on the correct application of the treatment and therefore the success of the drug. Market research should already measure the satisfaction level, contributing in assessing the product's success and helping in adapting the market strategy if necessary. Web portals can be used by patients to exchange experiences and take part in a larger community, influencing others consumers. The use of web portals increases with the experience patients have with the product even contributing to the product awareness in the next stage of the life cycle.

The growth stage of the life cycle is marked by the search for further patient's needs. For example, the use of web portals can broaden due to the increasing experience patients have acquired and can share. Also, the product can be adapted or modified to suit these new requirements pointed out by interviews and group discussions. Customer service will certainly have a role in communicating suggestions, problems, and ideas which arose during the first

phase of the life cycle. The introduction to e-prescription can also be done at this stage when the product has already positioned itself on the market and when trust has been established between the market, the product and the manufacturer.

4/ Physicians

XRM directed to the physician involves market research, the sales force, scientific and promotional marketing. As for the patient, the physician's needs should be defined at the early stage of the innovation's problem finding. Market research can conduct interviews and group discussions and is supported by the sales force which can report ideas and problems mentioned during their previous contact with the medical community. During the R&D phase, the physician's preferences are researched as for the patient through conjoint and image analyses. With the results, market research can focus on segmenting the physician group in order to design an appropriate marketing strategy for the market entry. Awareness of the product is at this stage important to ensure through scientific publications about the product.

The DTX activities for the physicians are the following:

- The focus of marketing activities is the awareness of the disease within the medical community especially during the early innovation phases. This revolves mainly around **scientific publications** about the disease and perhaps the research involved. These publications can also raise awareness, preparing the medical community for the clinical trial physician recruitement by sales representatives and advertisement in specialized print. This recruitment can be financially and time wise costly if not prepared carefully and not having all the contacts available when required.

- **CME programs** should be supported on a long-term basis, since directing the content is prohibited for pharmaceutical companies which can nevertheless support the providers.

- For the market entry, education programs such as **symposia, conferences and conventions** focus on an exchange of scientific information which can

be directed especially towards the pharmaceutical innovation and the medical advances implicated in its market entry.

- **Detailing** by the sales force creates a more personal relationship with the pharmaceutical manufacturer and product advertisements in the specialized print create further product awareness. But e-detailing could be very useful here, by creating a first, non-binding contact. Other means of creating ties with the physician is through small gifts such as agendas, pens, writing pads, etc. It is to be noted that the size of gifts is regulated. The relationship built with the sales representative will contribute to the positive perception of the pharmaceutical company, but is supported by manufacturer advertising in specialized prints.

- **E-health** is a mean for physicians to have access to further information. It also allows a reliable update of novelties concerning the condition, therapy, treatment and manufacturer.

- The **contact center** provides another source of information for the physician which can rely on the manufacturer for supporting his own work and relationship with the patient.

- **Support information** for the patient-doctor relationship can help the physician deal according to the given condition and maybe the emotional and physical implications demanding the physician to adapt to the situation. At the first stage of the product life cycle, market research measures the physician's satisfaction with the product through surveys and group discussions. Later on, during the growth phase, the evolving demands and needs should be researched in view of a product development or necessary adaptations.

- **Continuing health care programs** can keep the theme actual and **speaker programs** can also encourage and develop influencers within the medical community.

- The direct relationship with the sales representative can be carried out through **direct mails** in order to keep updates on both sides.

- At the end of the life cycle, **study clubs** and **seminars** can be organized to share experiences.

- Throughout the whole life cycle, **secondary communication material** directed to the consumers can be provided to physicians. These include advertising information material on disease and product for the waiting rooms; educational information about the disease, therapy and product along with samples which build a tie between doctor and patient, and also facilitate the first use of the product. A parallel activity to providing samples to physicians, is the creation of the patient's awareness that samples are available from their treating physician by advertising it through the mass media. Physicians can recommend further information sources such as websites and online portals.

5/ Pharmacies

Pharmacies need to be aware of the disease during the R&D phase of the innovation process and gradually understand the research and the product. They will consider scientific publications reporting the advances, disease awareness ads and product advertising in specialized prints. Educational programs are quite important such as continuing education and continuing health care programs. At the time of market entry, the sales force will focus on detailing. Later on, the contact center will provide any further information and further support to pharmacies. E-health is a source of non-binding information. The secondary communication provided to the patient through the pharmacies is information material on the disease before the patient visits his doctor and on the product when he fills in his prescription. Integration of e-prescription systems can facilitate the transaction with the patient once the product has gained recognition on the market.

6/ Hospitals and clinics

Hospitals and clinics need to gradually understand the disease, the research and the product before market entry through scientific publications. The goal of the sales force is to negotiate contracts with the purchasing departments at market

entry. The further support is ensured by the contact center. E-health access can provide continuous additional information. Information material on the disease and product can be further distributed to patients.

7/ Opinion leaders

Opinion leaders rely on scientific publication before market entry for disease and product awareness. Detailing is necessary to gain their support for the manufacturer and the product. Press releases will reinforce the trust in the product and manufacturer by encouraging transparency and honesty. By sponsoring events or other activities organized by the opinion leaders, pharmaceutical companies are showing their involvement in the community which is well perceived by all the other health care players. Speaker programs involving opinion leaders contribute to binding them to the pharmaceutical company. Providing information material to the opinion leaders on the disease for the consumers and the prescribers can support their role within the medical community.

8/ Insurers

The main goal of the relationship with health insurances is for them to include the drug on the reimbursement formularies. The reimbursement of the product will make the physicians more likely to prescribe it and the patient more likely to comply with the therapy. The insurances are to be made aware of the disease and the product before market entry. It is important for them to see the benefits of the product in relation to the urgency of the disease and its actual costs to them and to society. Not only scientific publications, but also reports and articles in general prints and mass media will actualize the theme. They can also be provided with information on the disease and product status to distribute to consumers and prescribers.

9/ Regulators

The relationship with the regulators is very intense before the market entry as they will be the ones allowing the product’s commercialization and marketing. They should be aware of the disease and should receive regular updates on

research and clinical trials directly by the company representatives which should aim for a fast and smooth authorization process. Sponsoring activities for the regulators show the pharmaceutical company's involvement in the community reinforced by transparency through regular press releases. Here again, information material on the disease can be at the disposal of pharmaceutical customers.

All of these activities for the different players are in relation to one another. And to these, other particularities are to be added depending on the disease. For acute conditions, one particular goal of pharmaceutical companies is the transfer of the image acquired through one product to the other products at the end of each patient flow. Next to the acute understandable condition, there is the acute condition which is either too complicated or which requires an emergency treatment. The latter will involve less product recognition than manufacturer recognition.

A chronic understandable condition is suitable for disease management programs and enhanced support activities. These can also include recurrent acute understandable conditions. It has been said that DTC advertising finds a broader use for chronic conditions than for acute conditions. However, this depends on the set marketing goal. The chronic condition which is complicated for the patient to fully grasp or which requires emergency treatment leaves less leeway for promotion directed to the patient. A more intense effort is turned towards the medical community which is then, most of the time, the sole decision maker.

It is recommended to put a strong controlling tool into place involving the participation of already existing market research and tools to measure the effects of communication politics such as those described by Dichtl and Thiess (1989, 393) based on the communication strategy pursued.

4.2.6. Developed Case Studies to Illustrate the XRM Concept

In order to illustrate concretely the XRM approach, a selection of five case studies is hereby discussed. Each one develops a specific CRM situation in referral to figure 4.5. The situations described take into consideration the five most differential variable combination defined by the processes, the positioning and the players and aim at an exclusive coverage of the product's phases.

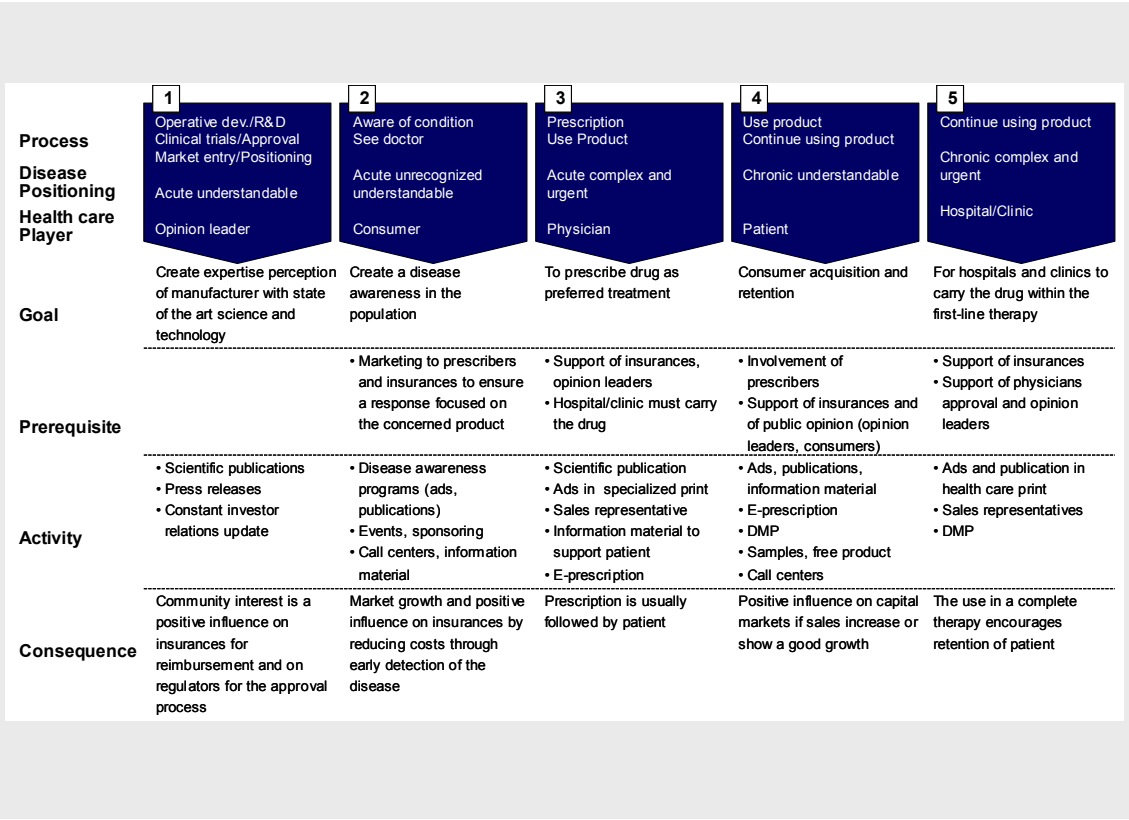

Figure 4.5. Each case study focuses on a specific phase for a determined condition and a target customer.

4.2.6.1. Case 1: Creating a Specialist Perception Through Opinion Leaders

Approaching opinion leaders as early as in the operative development R&D stage of the innovation can be particularly crucial, especially for an understandable acute condition. The actions implemented and carried out during the clinical trials up to the market entry reinforce the goal of creating the external perception of the pharmaceutical company being a specialist in the respective therapeutic area.

The focus on opinion leaders at this innovation phase is particularly appropriate to understandable acute situations as it requires the secondary influence power of opinion leaders on the rest of the health care players, all having different level of scientific knowledge. The information concerning an easy to grasp condition would be more likely to be intercepted and registered.

The opinion leaders can be academics, influencers directly from the medical community and from health care organizations such as e-health portals and patient groups. These players can be reached through scientific publications and events emphasizing on the research conducted by the pharmaceutical company. They rely on knowledge supported by proven material and facts accepted by the scientific community.

Other opinion leaders can be involved in capital markets. They should be constantly updated through press releases and investor relation activities demanding a more personal contact. Such a relationship has not only repercussions on the financial stance and valuation of the company, but also on the general perception of the company's stability, growth and therefore trustworthiness.

During these phases of the pharmaceutical drugs, the repercussions of maintaining a constant and transparent relationship with the opinion leaders can yield positive decisions with insurances and regulators. A positive perception of the innovation by the concerned community may influence the approval process which could be sped up if a need and relevance is demonstrated and supported. Once on the market, a supporting community may encourage insurance companies to allow the reimbursement of the drug once on the market.

4.2.6.2. Case 2: Making the Patient Aware of his Unrecognized Condition

In the case of an acute understandable but unrecognized or even taboo condition, the first priority is to create consumer awareness of the condition in order to bring the patient into the doctor's office. The goal is therefore to create disease awareness among the population along with ensuring its acceptance.

However, before implementing specific actions targeting the consumers, a corresponding marketing campaign should have been carried out for prescribers and

insurances to direct a positive response towards the concerned product and not towards a competing product in the same therapeutic area.

The disease awareness programs are composed of, beside the classical advertising published articles, reports and documentaries centered on the condition. These campaigns can also involve opinion leaders, even celebrities in events, and sponsoring actions to influence the acceptance of the disease within the general population. Other sources of information can be provided such as hotlines and material available in health centers, waiting rooms and pharmacies.

The direct consequence of these actions is market growth. It is creating a specific and recognized need for the pharmaceutical drug. At first, health care costs will increase. However, they can decrease again by an early detection of a condition and avoidance complications. This is seen as a positive influence on insurances in the long run.

4.2.6.3. Case 3: Influencing the Physician's Prescription Behavior for a Complex or Urgent Acute Condition

Physicians are the sole decision makers in a complex or emergency situation. They are the ones who orchestrated the use of the drug by prescribing the drug to the patient and directing the use of it. The behavior of the physician may also affect the patient's compliance to first start the treatment and adhere to it.

Physicians working in hospitals and clinics will be dependent on the drugs negotiated and carried by the organizations. They are encouraged to use the drug when available as first-line treatment. Also, the support of insurances and opinion leaders will be determinant in the physician's behavior.

The actions implemented by the pharmaceutical company will include all the traditional educational and promotional campaigns presently in place, as well as the predominant role of the sales representative. This role is supported by e-detailing, allowing the physician access additional information. Information material directed to the patient can support the physician's role as informant and reinforces the patient-physician relationship. E-prescribing is a tool that can facilitate the prescribing transaction and helps reducing medical errors. However, it only plays a role in complex conditions. As the availability of the drug plays a determinant role in patient compliance.

An efficient CRM strategy directed to physicians is an essential component in making the drug available to patients leading to the sales of the pharmaceutical innovation.

4.2.6.4. Case 4: Increasing the Chronic Patient's Compliance

The goal for a patient with an understandable chronic disease is to use a product on a long-term basis. The pharmaceutical company aims at acquiring this consumer and retaining him as a secure source of revenues.

However, this constellation involves other players and requires the active participation of prescribers as well as the support of insurances which have to reimburse the long-term treatment. The support of the public opinion will play a role on the patient's compliance, as the user may be influenceable by his environment including the opinion leaders and the healthy community surrounding him.

The promotional and educational activities carried out by the pharmaceutical companies include the usual advertisement, publications and information material such as brochures and pamphlets. These are strongly supplemented by samples to encourage the first use. Free products also support patient loyalty in case the product is completely reimbursed by the insurances. Call centers offer additional personal information and support. E-prescriptions allow a simplified access to the drug. Disease management programs directly accompany the patient through his therapy and offer monitoring and controlling tools supporting the patient and connecting him with medical units.

This helps boosting the sales as well as reducing acquisition costs contributing to the drug's success. The impact of a successful drug has repercussions on the capital markets which in turn will show positive valuation for the company, therefore affecting the other businesses of the corporation.

4.2.6.5. Case 5: Involving Hospitals and Clinics in Chronic Patient Retention for Complex and Urgent Situations

Hospitals and clinics play a decisive role for chronic complex or urgent conditions especially during the retention phase of the pharmaceutical product. The goal of the relationship between the pharmaceutical company and this customer is to carry the drug within the first-line therapy. The decision to adopt a drug within a first-line

therapy will depend on the negotiators sent by the pharmaceutical company as well as the existing support by insurances, physicians and opinion leaders.

The pharmaceutical negotiators are the direct contact with the pharmaceutical company and will bargain the purchase of the drug with the health organization. The buyers are likely to seek medical information available in specialized publications and other scientific sources. To support the hospital and clinic's business, information material can be provided to pass on to the patients as well as the full implementation of a disease management program thereby facilitating the contact between health organizations and the consumer.

If the health organization supports the therapy including the marketed pharmaceutical innovation, the patient with a chronic condition requiring a close monitoring is more likely to adhere to the treatment, less by choice than by necessity.

4.2.7. Expected Challenges Based on Change Management

The XRM concept involves adaptation from the consumers. And as with any change, resistance will be encountered. A working system might encounter four challenges in the market:

- IT use;
- the change of habits;
- privacy;
- and power relationship between the health care players.

1/ Information technology

The XRM concept relies heavily on IT. The aging population is less willing to learn and use interactive technology and would rather have a personal contact. They also do not have the necessary infrastructure to implement new technological tools (Xu et al. 2002, 446). This will not be an issue when the more IT-friendly generation starts needing more medical care. This is also valid for physicians and pharmacists who have to adapt to new systems using this technology. The latter also have to involve

themselves with the patient more deeply than today, establishing a real dialogue between them. This takes more time and energy.

2/ Change of habits

Although preventive measures and compliance programs integrated into disease management programs have been proven to reduce the cost of health care, increase the speed of recovery and encourage better integration of the disease in the patient's life style (Ellickson et al. 1999, 14), only a minority of patients are willing to accept the necessary changes involved, such as switching to a better diet or quit smoking. The insurances would have to be involved by giving the patients incentives for complying with a program or penalties for not following it.

3/ Privacy

Privacy issues are in the center of ongoing controversies (Rothstein 2001, 346-351; Evans 1998, 7). On December 28, 2000, the Department of Health and Human Services in the United States regulated medical privacy for the patients to hold control over their medical data, although these laws were not applied until April 14, 2003. This has an implication for the pharmaceutical promotional programs targeting specific patients on the basis of personal healthcare information, such as data on the prescription drugs being dispensed.. Levan Halpern and Grymes (2002) describe this issue at length with the implicated definitions.

4/ Power struggle between health care players

Another resistance center can be the power struggle between all health care players. The equilibrium of the physician-patient relationship has been analyzed by Good-Smith and Buetow (2001). Patients are increasingly seeking to take more responsibility for their health. But the medical community has trouble releasing their omnipotence and judges them often unfit to take such decisions as they might be more influenced by marketing actions than by scientific arguments. There is a balance still to be defined, depending on the condition, the customer and the product.

4.2.8. Prediction of the Success Factors Underlying XRM

Building on the CRM success factors, the XRM success factors can be extrapolated. The three following factors constitute the core of the XRM implementation for pharmaceutical innovations:

- first around the internal organization of the pharmaceutical company;
- second around a constant assessment of the taken measures;
- and third, around the complete integration of customers in order to optimize the synergies.

1/ Internal organization of the pharmaceutical company

A transparent organization is essential for having the involved business units to work together. The exchange of information through a knowledge management pool supported by the appropriate IT applications forms the basis. Cross-functional teams are the physical implementation of this structural change.

2/ Constant assessment

As with any strategy implementation, the measures taken must be regularly monitored and controlled in order to adapt quickly and detect gaps before problems arise. It is also a mean to predict the evolution of the strategy and allow for adaptation of the initial planning.

3/ Complete integration

Opinion leaders, insurances and regulators are to be actively included in the marketing targets. Tying a close relationship with them helps gaining credibility within the health care market. A less profit-oriented side can be presented, more focused on the community and the efforts invested for the meaningful benefit of society.

4.3. Involvement of the Regulatory Conditions Affecting XRM

The XRM model described above does not take into consideration the numerous regulations surrounding pharmaceutical marketing, particularly the laws concerning the communication directed to the consumer. In this regard DTC advertising is either allowed or prohibited. The United States have allowed it under certain regulations, whereas it is prohibited in Europe although regulations are expected to relax.

4.3.1. Analysis of the Differences Between a Liberal and Restrictive Environment

For many years, pharmaceutical manufacturers were reluctant to advertise their products directly to the consumer due to the requirements set by the food and drug law and regulations. Reeves (1998) provides a comprehensive review of the major steps in the evolution of DTC advertising regulations. Advertising must include a "brief summary" about the drug's effectiveness but also with the side effects, contraindications (FDA 1979). Advertisements for prescription drugs were directed towards the ultimate decision-makers, the prescribers. Recent changes in the Food and Drug Administration's (FDA) guidance, introduced in 1997 and finalized in 1999, have introduce opportunities to address the new roles played by patients and physicians.

For the agency, DTCA should show balancing information in the primary text of the promotional message comprehensible by consumers, to allow them to evaluate the drug benefit claims and form their own opinion about it (FDA 1995a; 1995b). It has also prohibited false or misleading labeling in the advertisements, such as falsely reporting scientific data or declaring clinical superiority for a drug without the support of scientific data. Additionally, only information consistent with the approved labeling can generally be used in advertising or represent a drug as a treatment only for a disease approved by the FDA.

The FDA recognizes three broad categories of prescription drug advertising, regulated in different ways (FDA 1995a; 1995b).

- **Reminder advertisements** focus on the brand name with any information about the drug. Sources are mentioned for obtaining further details.

- **Disease awareness or help-seeking advertisements** detail the symptoms of the indication, aiming at briging propective patients in the medical office. No brand name is referred to. This type of advertisement as reminder advertisement do not require the brief summary and fair balance requirements since no information on the benefit of the drug is communicated (FDA 1979).

- **Product claim advertisements** show the brand name and indication targeted. These include the brief summary requirements and include benefits and risk information.

Although the brief summary requirement is easily satisfied in print advertising, it is quite impractical for a thirty-second television commercial. Hence, FDA regulations allow sponsors of broadcast advertisements (televisions and radio) to make “adequate provision” of approved product labeling instead of the brief summary. The FDA released the “Guidance for Industry, Consumer-Directed Broadcast Advertisements” in August 1999, drafted in 1997 (FDA 1999), facilitating manufacturer dissemination of DTC promotions through broadcast media. It draws the guildelines for the broadcasting of DTCA, aiming at establishing a balance between the health care players. It includes the description of benefits, risks and sources of additional information.

As of April 2001, a new version of DTC broadcast advertisements has emerged. In fact, these advertisements are two complementary advertisements: a disease awareness advertisement and a reminder advertisement, separated by another sponsor’s spot for an unrelated product. Each spot runs less than thirty seconds and, standing alone, would not require a major statement or adequate provision as reported by Adams (2001). These practices are challenging the FDA, but rather than attempting to deter DTC advertising, the FDA appears to be concentrating on ensuring that the advertising is informative and well balanced, and that it adheres to the current Guidance. Following a 2002 FDA consumer survey which found that 73% of respondents read little or none of the "brief summary" containing risk information in print advertisements, the FDA has recently proposed to let drug manufacturers offer

less detail in print ads about the risks of prescription medicines. However, they would have to explain the most serious problems applying consumer-friendly language. According to Matthews et al. (2003), this is to encourage clearer communication of drugs' risks.

Within the FDA, drug advertising is regulated by the Division of Drug Marketing, Advertising, and Communications (DDMAC), under the Center for Drug Evaluation and Research (CDER). The FDA has recognized the different pharmaceutical customers as marketing targets, with a nuance based on the medical and scientific expertise, and the involvement with the communicated messages. Although their approval is not required before the launch of the marketing campaign, it is highly recommended (FDA 2002).

To ensure compliance with prescription drug advertising laws and regulations in general, the DDMAC utilizes a controlling program. The general population and industry players are encouraged to report questionable practices against which the agency may act against.

Europe has been awaiting the results from the Americans. The directive 92/28/EEC issued March 31, 1992 by the European Economic Community (EEC) prohibits DTCA for medical prescription drugs to the general public (Council of the European Communities 1992). Vaccination campaigns are exempted. Even the promotional information targeting prescribers is highly controlled. The goal is to set neutral grounds for prescription.

Although the flow seems to be going in the opposite direction as the British Medical Association declared in September 2000 plans to cooperate with the pharmaceutical industry to develop the actual status of DTC prescription drug advertising (*The Pink Sheet* 2000). These regulations are also facing pressure from the industry, the globalization of the digital information and the development of patient demand. The European Agency for the Evaluation of Medicinal Products (EMEA) take into consideration the fact that "*contribution of patients in the management and rational use of medicinal products is becoming increasingly common and therefore information to patients and participation to regulatory activities should be improved*" (EMEA 2002, 1). The European Union is currently debating a recommendation to EU

member states to allow DTC advertising for drugs according to certain indications (asthma, AIDS and diabetes) (Bradley 2004, 170). In fact, it is discussed whether to completely lift the ban on DTC advertising (Medawar 2001; Fuhrmans and Naik 2002).

4.3.2. Identification of Direct Consequences on XRM

Liberal regulations such as those in the United States allow a broader playground for pharmaceutical companies. DTCA has become a decisive factor for the sale of prescription drugs. In order to maximize the acceptance and efficiency of DTCA, according to Carroll (1991), Castagnoli (1996), Peyrot et al. (1998) and Perri (2000), the specific measures are to be undertaken within the frame of an integrated concept. First a careful evaluation of the strategic and operative aspects of the communication should be carried out from different perspectives. The inclusion of decisive opinion leaders and influencers at an early stage is essential in order to avoid possible negative influences and prepare the market for the reception of advertising campaigns. Furthermore, the close contact established with them allows a continuous discussion of the obvious changes within the market to judge customer needs and the dynamic of the systems. Another point is the support of marketing statements by the scientific community. And at last, the pharmaceutical company is to focus on enabling the communication dialogue with all health care players. In Europe, the pharmaceutical industry can play an important role in supplying information provided the regulations will be changed (Jaderberg 2002, 183).

Waiting for an expected change in regulations, the focus is turned towards a stronger economical marketing, leading to cooperating with political business institutions. Currently, pharmaceutical companies are required to be more active with the community, regulators, insurances, and opinion leaders to prepare the terrain once regulations change. The communication oriented towards the end-consumer therefore remains indirect or focused on disease education in cooperation with opinion leaders such as medical institutions and information providers. This type of campaign must carefully be planned jointly with other marketing programs especially the ones involving physicians to allow a positive reaction and in favor of the concerned pharmaceutical company or companies.

4.4. Summary and Formulation of Hypotheses Supporting XRM

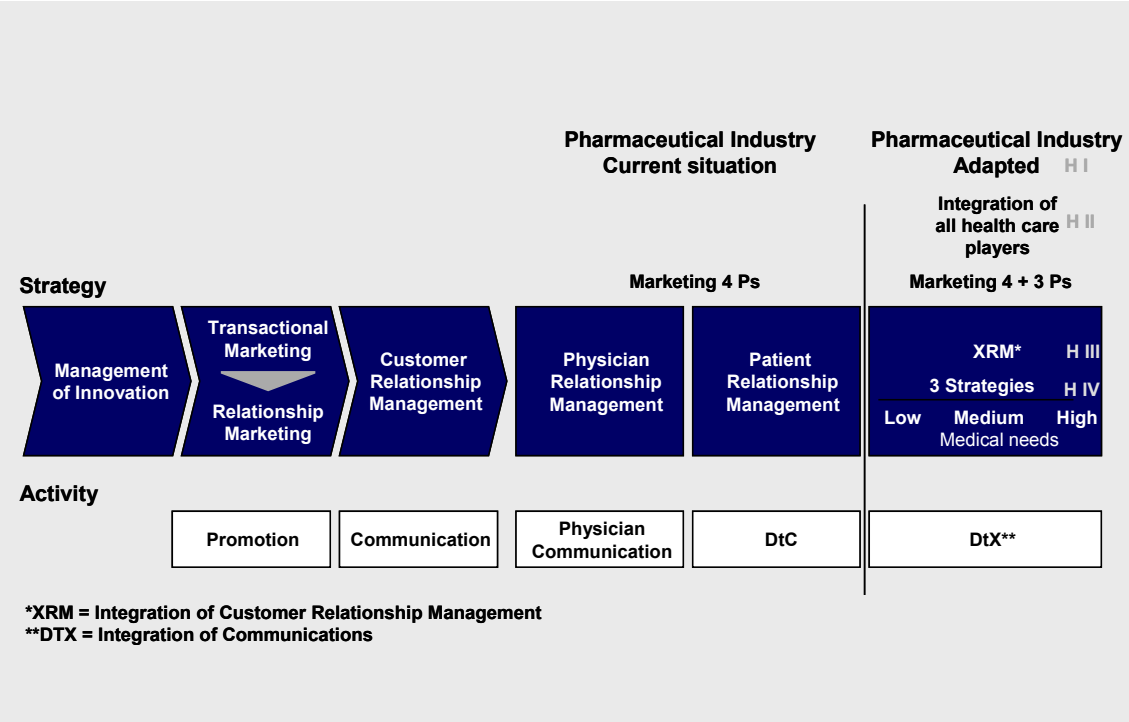

Figure 4.6. Structure and flow of dissertation.

This thesis has analyzed the importance of the management of innovation, whereby the dominant position of innovation in the economy and the necessity to insure its success on the market are described. Marketing is an essential component of the management of innovation and has itself evolved from a purely transactional science to a relational science encompassing the entire concept of customer relationship management. Its concern is not anymore only advertisement, but a communication dialogue established with the customer and supported by other measures centered on retaining the customer and gaining his loyalty.

Pharmaceutical marketing has been focusing on the physician and recently turned its attention towards the patient resulting in a physician relationship management and a patient relationship management approach.

However, the complexity of the pharmaceutical market needs to be brought forward as the end-consumer, the patient, is not necessarily the one deciding on the product's choice and the one assuming the financial costs. Other influences affect the market as

well, such as distributors (the other prescribers), opinion leaders, insurances, and regulators. The latter actually allow the product to be commercialized or not, forming a potential barrier to the product's commercialization and success.

The summary of this work includes an introduction of a new approach focusing on the integration of all health care players in the marketing strategy, or more broadly in the customer relationship management, for the pharmaceutical industry. These implicate four hypotheses challenging the current CRM situation and the marketing adaptation factors of the pharmaceutical industry.

4.4.1. Overview of the Discussion

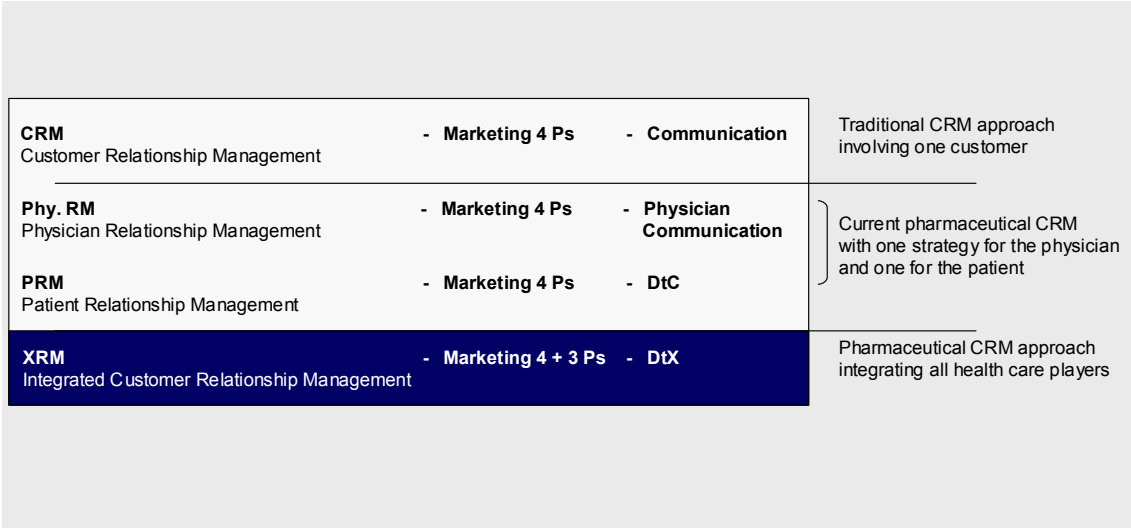

Figure 4.7. The summary of the dissertation reflects the development of the XRM approach and its relation to the resulting DTX actions.

The traditional CRM approach involves only one customer. The marketing mix is complete with the 4 Ps and the promotional activities revolve around the communication measures taken by the company.

The current pharmaceutical CRM approach is either directed towards the physician or the patient. Both use the traditional marketing 4 Ps mix. Physician relationship management results in a physician communication and the patient relationship management in direct-to-consumer communication.

An integrated approach taking into consideration all health care players is translated into the expression "XRM" indicating an integrated customer relationship

management. It relies on the focused marketing mix 4 + 3 Ps. The 3 Ps are the players, the process and the positioning. The communication strategy intertwining measures taken for every single customer is therefore resumed as “DTX”.

4.4.2. Development of Four Hypotheses to Further Validate

It seems that until now the pharmaceutical industry has been trying to adapt the CRM approached from other industries. However, the differences are enormous especially in relation with the customers, the process and the product. These are extended values which must be focused on particularly for the pharmaceutical industry.

This literature study has emitted four main hypotheses.

- The first one refers to the need of adapting particularities of the pharmaceutical industry to the whole marketing concept requiring the consideration of the players, processes and positioning as focus of the marketing mix.
- The second hypothesis describes the player component not as a static configuration, but as a network of independent players. The only possible optimization of the activities is the integration of all pharmaceutical customers into one strategy.
- The third hypothesis involves the CRM maturity stage of the pharmaceutical industry. Different industries will have different goals and tasks when establishing a relationship with their customer. This will evolve over time.
- The last hypothesis refers to the different needs depending on a disease-type-focus segmentation of the pharmaceutical drug.

H I: CRM needs to be adapted to the pharmaceutical industry.

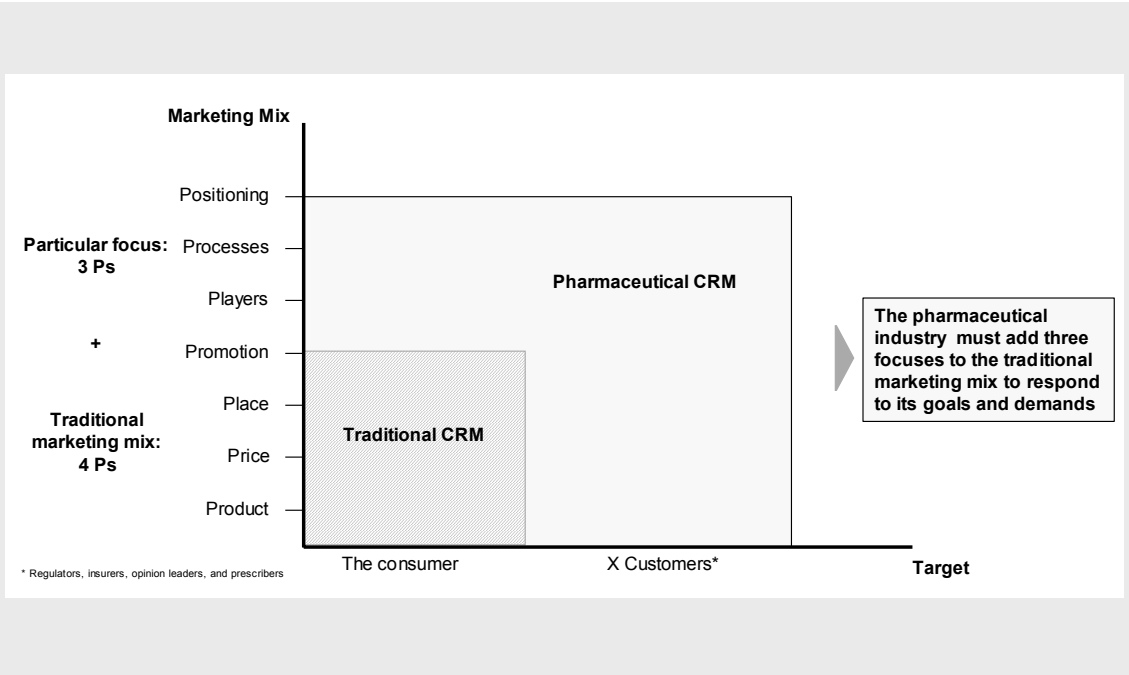

Figure 4.8. Hypothesis I.

The diversity of decision makers, payers and influencers is particular to this industry. CRM for the pharmaceutical industry needs to take into consideration all health care players and coordinate all actions taken when establishing contact with them.

The more the different customer relationship management approaches are integrated, the higher the probability of a high CIA or success probability of the pharmaceutical innovation.

H II: An appropriate CRM approach for the pharmaceutical industry is an integrated one.

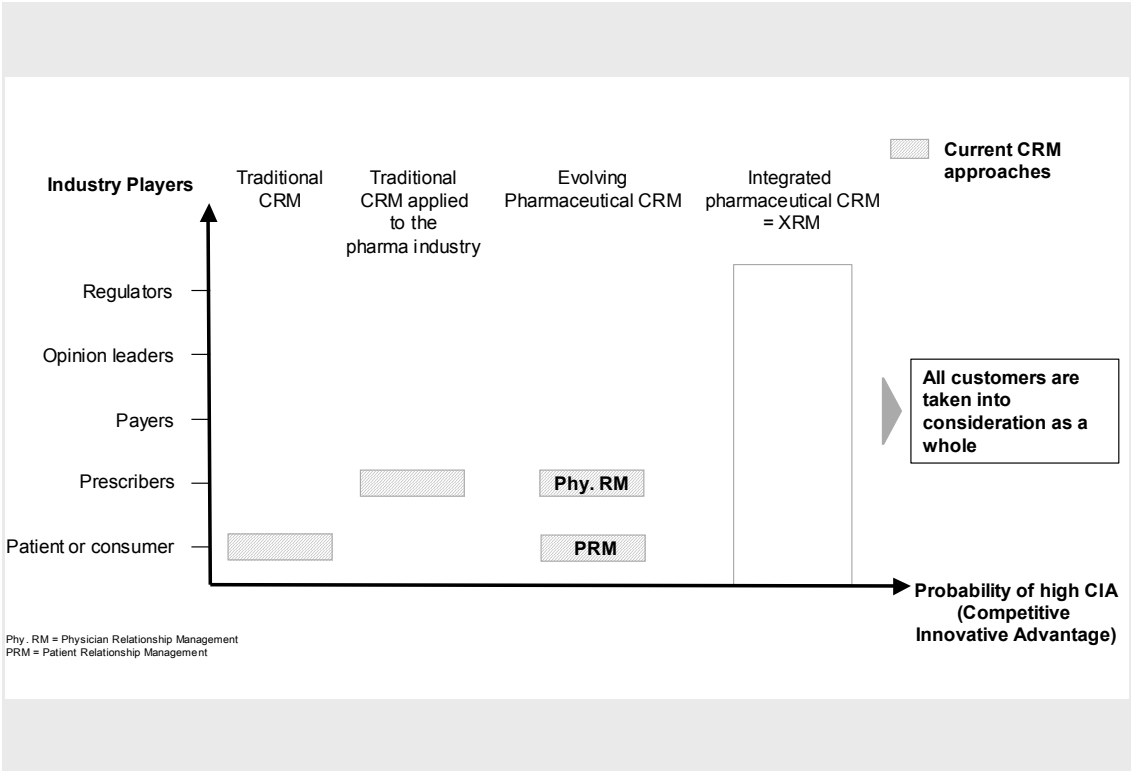

Figure 4.9. Hypothesis II.

Integrated CRM becomes "XRM". The more the different players are taken into consideration for a unified customer relationship management, the higher the success probability of the pharmaceutical innovation, thus the higher the Competitive Innovation Advantage (CIA) quote.

To achieve this, pharmaceutical companies are starting to develop a deep and personalized customer understanding.

H III: XRM or integrated customer relationship management is entering the second stage of the industry CRM maturity

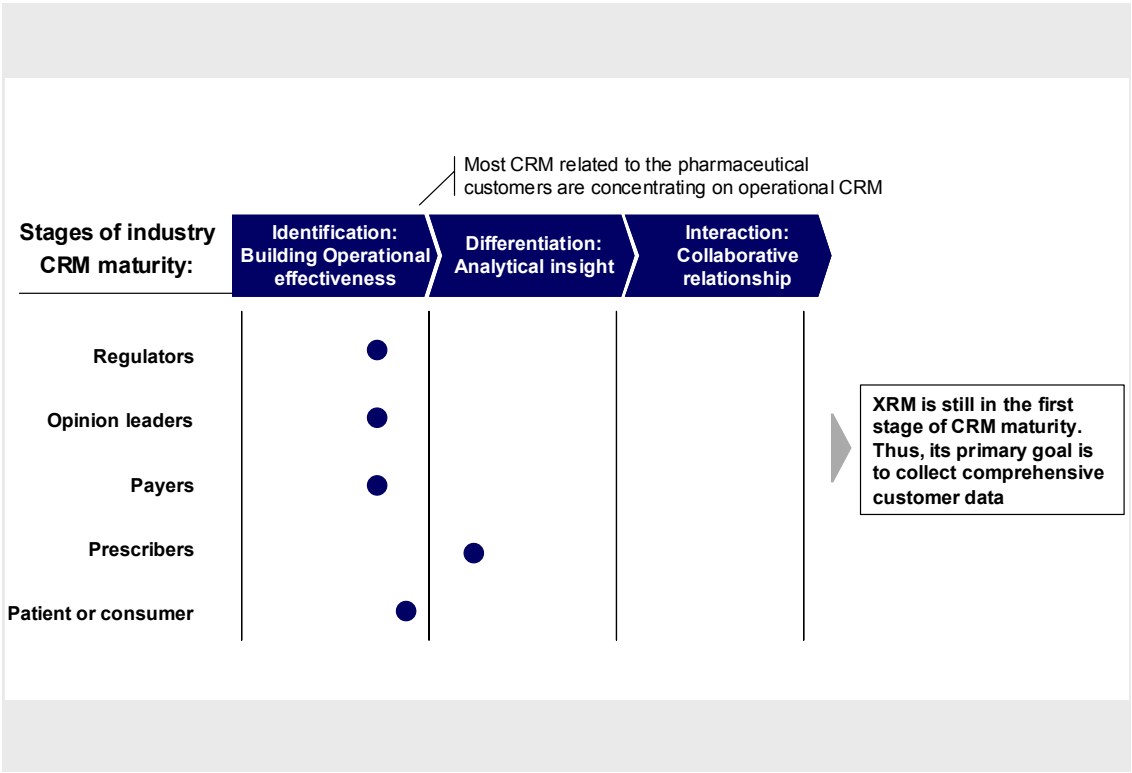

Figure 4.10. Hypothesis III.

A study by CGEY and INSEAD (2002) has already investigated this maturity stage, however, an in-depth analysis of the entire CRM system integrating all the customers' needs to be conducted. The CRM maturity stage should be adjusted by the measure of customer integration.

The pharmaceutical product has various forms depending on the targeted disease, as the involvement of the end-consumer differs whether it is a long-term or short-term relationship, understandable or complex and urgent one.

H IV: The integrated CRM approach is disease-type dependent

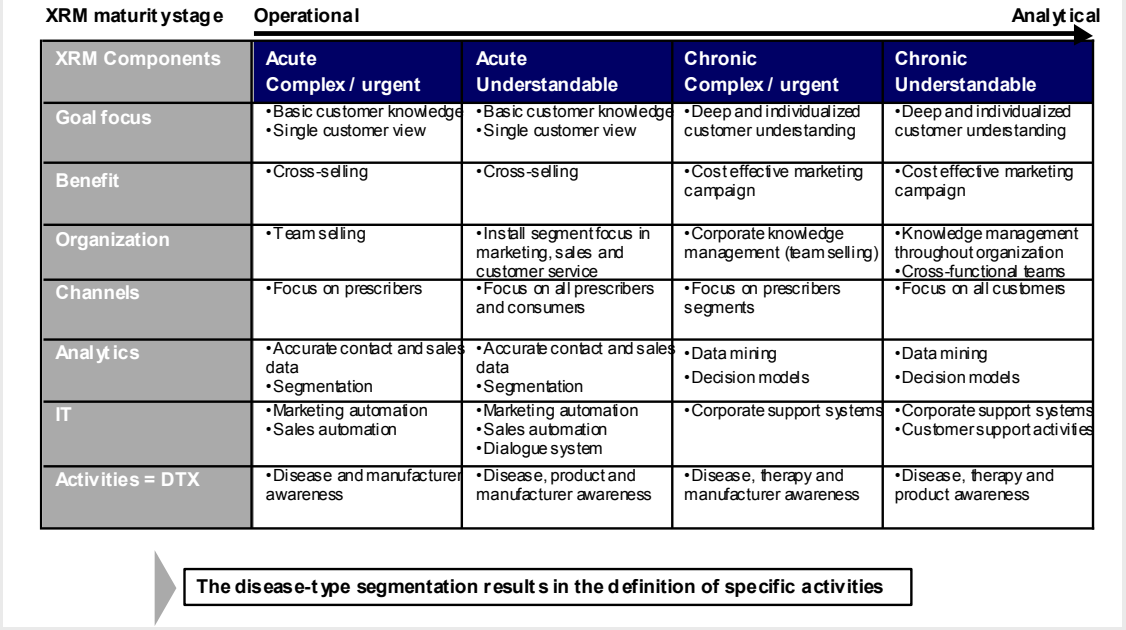

Figure 4.11. Hypothesis IV.

There are three sub-hypotheses to be discussed to validate the fourth hypothesis.

- An integrated customer relationship management is less developed for acute diseases than for chronic diseases as the nature of chronic diseases implies a close follow-up of the patient through a long period of time. Information has already been retrieved from the end-consumer and is in the analysis process, as has been the cooperation with prescribers and opinion leaders. The collection and acquisition of data retrieval is already well in place in companies focusing on chronic diseases and processes and models are being developed to analyze this information thoroughly and efficiently. Thus chronic-disease-focused organizations are entering the analytical maturity phase of its customer relationship management strategy, whereas the pharmaceutical companies concentrating on acute conditions are more at an operational phase striving to implement the systems for data collection.

- Pharmaceutical XRM targets primarily prescribers for complex and urgent conditions since they are most of the time the sole decision makers. The DTX strategy is therefore intensively turned towards manufacturer awareness for the rest of the customers. They will perceive a product positively from a known manufacturer even though they possess little knowledge of the product. On the contrary, for a condition easily understandable at different levels, product awareness is the most straightforward focus of communication measures.

- The last issue is the necessity of image transfer for acute conditions from one product to another from the same manufacturer, as acute conditions only binds the end-consumer to the product for a very limited period of time.

These three issues support the fact that an XRM strategy is different for the four defined positioning of the pharmaceutical company according to the disease targeted by its products.

5 Directions for Further Research

The hypotheses resulting from this literature analysis have to be further validated by empirical work investigating every aspect implicated in their foundations. The study should include pharmaceutical companies' current practices and how far integrated customer relationship management is reality and applicable in the different disease contexts. This would reveal further necessity to include players, processes and positioning into the marketing mix. The evolution of the customer integration can therewith be drawn in parallel with the CIA level of each case. The actual maturity stage of XRM should be exactly determined and therewith the validation of the course of action on which to focus to ensure the success of the pharmaceutical innovations.

A next step is to take personalized medicine or pharmacogenetics into consideration increasingly incorporating the advances in information technology for predictive and diagnostic medicine and for treatment delivery. The customers´ role will be reshuffled and require a tighter collaboration between the different parties. In addition pharmaceutical, biotechnology and medical devices business units will have to be developed and applied hand-in-hand while the current boundaries are becoming increasingly thinner. Deeper knowledge of the end-consumer will be beneficial to develop genomic solutions feeding into the one solution concept involving the various pharmaceutical customers. This knowledge will also allow for more precise and targeted solutions, therefore increasing the success rate of every innovation (Pirmohamed and Lewis 2004, 294). With XRM the basic foundations are laid for the traditional focus of healthcare from therapeutic areas to switch to managing the complete wellness and illness of particular genetic subgroups.

6 Summary of Contributions

Several significant research issues were resolved resulting in a practical approach applicable in the context of the marketing of pharmaceutical innovations. This dissertation offers the following contributions:

- The need to adapt the current marketing approach to the particularities of pharmaceutical innovations has been demonstrated and defined in view of the pharmaceutical market description and the challenges the industry is facing.
- An approach to explicitly model pharmaceutical marketing into an integrated customer relationship management XRM was defined to influence positively the success of pharmaceutical innovation.
- Scenarios with a detailed course of action to take according to a positioning depending on the type of disease were conducted and developed.
- This analysis rendered the design of a practical marketing direction applicable for pharmaceutical innovations that can be adapted and tailored to every situation.
- Hypotheses to be validated through further empirical work were identified.

The limitation of this work is the fact that is relies on current literature generally not steming directly from the industry but from scientific sources. Moreover, there are little objective studies in this field. An adaptation factor might be necessary to provide a more comprehensive view of the subject.

Another issue arising is the need to incorporate cultural issues as they differ from one country to another. There are disparities in mentalities between the United States and Europe, and within Europe, and the application of the American based-model to other cultures is questionable. The levels of resistance should be further investigated to judge if the barriers foreseen are easily broken.

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